The Use of Mindfulness-Based Cognitive Therapy for Patients with Inflammatory Bowel Disease

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Declaration

I declare that this thesis is entirely my own work and has been submitted only for the degree of PhD by Publication in the University of Stirling.

Mariyana Schoultz

Acknowledgements

Though only my name appears on the cover of this thesis, this PhD journey has been supported by few key people along the way. I owe my gratitude to all those who made this experience possible.

Firstly, I want to thank my supervisor Prof Angus Watson. Without his trust in my PhD proposal from the start, none of the fantastic PhD experiences would have happened. I have been amazingly fortunate to have a supervisor who gave me the freedom to explore on my own and the guidance when needed. I also want to thank my co-supervisor Dr Iain Atherton, who provided the right type of support and challenge in developing arguments for the publications, as well as guidance and expertise. I want to thank Dr Gill Hubbard and Dr Leah Macaden, who also provided great support by coming on board to co-author some of the publications included in this thesis.

In addition, I want to thank Dr Annetta Smith, for being the best possible Associate Head of School; Michelle Beattie, for being the best PhD buddy ever (the laughs and the cries), my faithful husband Martin for putting up with me and friends and family for always believing in me.

And lastly, I want to thank all the patients with IBD participating in the studies, all the NHS staff contributing to the process, all the colleagues making the Highland Campus a greater place and the Crohn’s and Colitis UK and RD&I NHS Highland for providing the extra funding and support for my PhD.

Abstract

Background: Inflammatory Bowel Disease (IBD) is a group of chronic gastrointestinal diseases with a relapsing nature. The two main types are Crohn's disease (CD) and ulcerative colitis (UC). Both CD and UC patients experience very similar and distressing symptoms: acute abdominal pain, vomiting, malnutrition, fever, fatigue, diarrhoea and rectal bleeding. These symptoms are disabling and have a severe impact on physical and psychosocial wellbeing. Around 30% of patients suffer from moderate to severe psychological distress and have difficulties coping with the illness even in remission. However, it appears that mental health is overlooked by clinicians who often focus on physical gastrointestinal symptoms only.

Mindfulness-Based Cognitive Therapy (MBCT) is evidence based, group psychological intervention that has been successful in reducing depression and anxiety scores in patients with depression while improving overall quality of life. However, MBCT has never been tested in the IBD population before.

PhD question: Can MBCT be used as an adjunct therapy to IBD symptom management, for improving IBD patients' general well-being and quality of life?

Aims and objectives: The overall aim of the thesis was to develop and collate the evidence for a definitive randomised controlled trial (RCT) testing the effectiveness of MBCT for patients with inflammatory bowel disease (IBD). The thesis brings together six publications. The six publications were integrated into four objectives that collectively contributed in answering the overall PhD question.

Results: The findings from the first three publications highlighted the disease-related concerns and psychological needs for patients with IBD. The findings from the last three publications highlighted how feasible it is to use MBCT in IBD and emphasised the IBD patients' perspectives about MBCT.

Conclusion: The thesis concluded that a definitive RCT of MBCT for IBD patients is both feasible and acceptable.

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Chapter 1

Introduction

The overall aim of the thesis was to develop and collate the evidence for a definitive randomised controlled trial (RCT) testing the effectiveness of Mindfulness-Based Cognitive Therapy (MBCT) for patients with inflammatory bowel disease (IBD). This aim was set to answer the PhD question: Can MBCT be used as an adjunct therapy to IBD symptom management, for improving IBD patients' general well-being and quality of life?

IBD is a lifelong condition affecting the gastrointestinal tract. The two main types are Crohn’s disease (CD) and ulcerative colitis (UC). Both conditions are characterised by periods of flair up (symptom exacerbation) and periods of remission (symptom reduction). The severely disabling and distressing symptoms include and are not limited to vomiting, bloody diarrhoea, faecal urgency, incontinence and malnutrition. It is estimated that over 28 million people worldwide and over a quarter of a million people in the UK are living with (IBD) (Lacatos 2006), with IBD incidence and prevalence of IBD rising (Molodecky et al. 2012).

With the prospect of no cure, recurrent hospital admissions and lengthy treatments with biological drugs, IBD severely affects patient’s quality of life. It is reported that around 30% of patients with IBD suffer from anxiety or depression and require psychological support (Graff et al. 2009).

MBCT is a psychological group intervention designed by Segal et al. (2012). The MBCT intervention is based on the concept that the participants of an eight week MBCT course will experience reduced negative effects from physiological factors, such as pain and psychological factors, such as anxiety and depression. MBCT is recommended by the National Institute for Health and Care Excellence (NICE) guidelines as a preferred psychological intervention in the ‘clinical management of persistent sub threshold depressive symptoms or mild, moderate or severe depression in adults (including people with a chronic physical health problem)’ (NICE 2011).

MRC Framework for the development of complex interventions

According to the Medical Research Council (MRC) guidance for the development and evaluation of complex interventions (Craig 2008), a question that is concerned with the examination of the effectiveness of a complex intervention such as MBCT, would be ideally answered by conducting a definitive multicentred RCT. However, although the literature suggested that mindfulness based interventions are effective in the management of chronic conditions, and MBCT has a good application in management of depression, there were a lot of uncertainties regarding the use of MBCT in patients with IBD. Some of the uncertainties were as follows:

- Feasibility and acceptability of conducting a RCT that uses MBCT for IBD patients;
- Recruitment and retention rates;
- Baseline for sample size power calculation;
- Acceptability of the intervention and trial procedures for patients such as recruitment and consent.

All of these uncertainties arose as a result of a scarcity of evidence on the effectiveness of MBCT in patients with IBD (MBCT has never before been examined in the IBD population). Therefore, according to the MRC guidance, before a recommendation for proceeding to a definitive RCT can be made, a significant amount of work needed to be completed. This includes feasibility and piloting work as well as collating of evidence.

Aims and objectives and list of scientific papers:

Aim of the PhD

The overall PhD aim was to develop and collate the evidence for the feasibility and acceptability of a definitive RCT testing the effectiveness of MBCT for patients with IBD.

Objectives of the PhD

To answer the overall PhD question and to explore the different aspects related to the overall aim, four separate objectives were devised. These are as follows:

Objective 1: To ascertain the role of psychological factors in IBD according to the current literature.

Objective 2: To establish the psychological needs’ gap in the current care services for patients with IBD.

Objective 3: To explore feasibility and piloting of MBCT for patients with IBD.

Objective 4: To explore participants’ perspectives and acceptability of using MBCT for patients with IBD.

Each of the objectives above has one or two papers associated with them (see Box 1 below). All of the papers collectively go beyond their original aims and provide a better rationale and understanding of the feasibility and acceptability of MBCT for patients with IBD in the context of future implementation of such an intervention as part of a holistic IBD care.

Box 1: Objectives and associated papers	
Objective 1: To ascertain the role of psychological factors in IBD according to the current literature.	**Paper 1. Schoultz,** M. "The role of psychological factors in inflammatory bowel disease." British journal of community nursing 17.8 (2012): 370.
	Paper 2. Schoultz, M., Atherton, I. M., Hubbard, G., & Watson, A. J. "Assessment of causal link between psychological factors and symptom exacerbation in inflammatory bowel disease: a protocol for systematic review of prospective cohort studies." Syst Rev 2.1 (2013): 8. [located in Appendix 1, p. 184]
Objective 2: To establish the psychological needs’ gap in the current care services for patients with IBD.	**Paper 3. Schoultz**, M., Macaden, L. & Watson, A. J.” Co-designing inflammatory bowel disease (IBD) services in Scotland: findings from a nationwide survey.” BMC Health Services Research, 16 (1), 1.& Gut abstract: Co-designing inflammatory bowel disease (IBD) services in Scotland: the patients perspective. Gut 2015;64:A237 [located in Appendix 2, p. 192]
Objective 3: To explore the feasibility and piloting of MBCT for patients with IBD.	**Paper 4. Schoultz**, M., Schoultz, M., Atherton, I. M., Hubbard, G., & Watson, A. J. "The use of mindfulness-based cognitive therapy for improving quality of life for inflammatory bowel disease patients: study protocol for a pilot randomised controlled trial with embedded process evaluation." Trials 14.1 (2013): 1-9.
	Paper 5. Schoultz, M., Atherton, I. M. & Watson, A. J. "Mindfulness-based cognitive therapy for inflammatory bowel disease patients: findings from an exploratory pilot randomised controlled trial." Trials 16.1 (2015): 379.
Objective 4: To explore participants’ perspectives and acceptability on using MBCT for patients with IBD.	**Paper 6. Schoultz,** M., Macaden, L. & Hubbard, G. “Participants’ perspectives on Mindfulness-Based Cognitive Therapy for Inflammatory Bowel Disease: A Qualitative study nested within a pilot Randomised Controlled Trial.” Pilot and Feasibility Studies 2:3 (2016).

Rationale to submitted publications and their interrelationship

This PhD thesis presents a collection of six interrelated publications (see Box 1). The six publications are connected through the overall aim to investigate the application of MBCT for patients with IBD in Scotland. Although each individual publication focuses on different aspects of the investigation, the publications collectively represent a body of evidence unique to this field of knowledge.

IBD is a lifelong condition with severely disabling and distressing symptoms that impacts on the everyday quality of life of patients (Lix et al. 2008). Faced with the realities of IBD disease management, there is a growing demand for non-pharmacological interventions and self-help tools that can improve the quality of life for patients (Bodenheimer et al. 2002; Barlow et al. 2002). With these facts in hindsight, the PhD journey started with the broad question: Can MBCT be used as an adjunct therapy to IBD symptom management in an aim to improve IBD patients' general well-being and quality of life?

The literature suggests that many IBD patients suffer from psychological distress and disease related worries (Mussel et al. 2004) and this psychological distress in IBD is more frequent than in the general population (Walker et al. 2008). Thus, stress (anxiety and depression) has been identified as one of the strongest predictors for a poor quality of life for patients with IBD (Vidal et al. 2008; Iglesias-Rey et al. 2014). Although there is no evidence to suggest that stress causes IBD, there is evidence suggesting that stress could affect disease activity and increase the risk of relapse (Jaghult et al. 2013). Accordingly, developing interventions that can help IBD patients to manage and cope with stress in a more efficient way seems to be a logical progression. Therefore, the first intended step towards answering the PhD question was to examine the literature and prepare a systematic review of psychosocial interventions in IBD.

One of the first literature searches revealed that such a review has already been published. This was the Cochrane systematic review on psychological interventions in IBD by Timmer et al. (2011). This review looked at twenty-one studies, with randomized, quasi-randomized and non-randomized controlled design of psychological interventions in children or adults with IBD with a minimum follow up time of 2 months. The review concluded that psychological therapy has no effect at 6 and 12 months for outcomes such as quality of life, emotional status/depression and relapse/disease activity for patients with IBD (Timmer et al. 2011). This was quite surprising, particularly with the evidence around stress, relapse and the risk factors in IBD mentioned above. Thus, the review findings raised a very important question: What is the role of psychological factors in IBD? Consequently, this question formed **Objective 1** and was the foundation for the first two papers presented: Paper 1 and Paper 2 (see Box 1, p12).

Papers 1 and 2 looked at the evidence and critiqued the methodology of previous studies that examined a variety of psychological factors in human and animal models of IBD and the possible causation of stress and symptom exacerbation. The evidence from more recent studies suggests that psychological factors may play a role in disease activity and overall quality of life for patients with IBD.

Taking into consideration the findings from Objective 1 and the overall PhD question, it was important to examine if IBD patients across Scotland felt that their emotional and psychological needs were addressed in the current IBD care services. This enquiry formed **Objective 2** and Paper 3 (see Box 1).

Paper 3 was a nationwide survey and among other wider aspects, looked at the IBD patients' experiences of care services across Scotland. One of the questions asked if their psychological and emotional needs were met through existing services and if not, what should change to meet their needs. The conclusion of the study was that patients with IBD asked for a more holistic approach to their care and wanted a greater involvement of psychological services to help with adaptation and living with the disease. This enquiry formed the foundation for the next objective, **Objective 3** and Papers 4 & 5, examining the feasibility and piloting of the use of MBCT for patients with IBD.

Paper 4 was a protocol for the pilot RCT and worked out the methodology according to the Medical Research Council (MRC) guidance for development and evaluation of complex interventions (Craig 2008). This was the methodology for a pilot RCT with a nested qualitative study, looking at the use of MBCT for patients with IBD. This study, incorporating 2 phases, received funding from 2 external sources: the charity Crohn's and Colitis UK and Research, Development and Innovation (RD&I), NHS Highland. Paper 5 reports the findings of the exploratory pilot RCT using MBCT for patients with IBD. The primary aim of this paper was to gather the evidence around methodology and assess the feasibility of conducting a large RCT testing the effectiveness of MBCT in patients with IBD.

In order to fully answer the overall PhD question**,** it was important to examine the perspectives and experiences of IBD patients about the acceptability on MBCT. This formed **Objective 4** and paper 6**.** Paper 6 was a qualitative study nested within the pilot RCT, reporting on the experiences and perspectives of patients with IBD that went through an 8 week MBCT program.

Thus, this thesis is presented in an alternative format. It describes the four objectives that were designed to answer the overall PhD question. Collectively, they concluded the piloting, feasibility and process evaluation phase of the complex intervention MBCT and its use in the IBD population. After Chapter 1, which is the Introduction and setting of the scene, Chapter 2-5 individually describe how each of the 4 objectives were achieved, while incorporating the associated papers within each objective. Chapter 6 concludes this thesis with discussion, summary and the limitations of the studies described and implication for future practice and research.

Theoretical framework underpinning

The primary conceptual framework for using MBCT in IBD is based on the bio-psychosocial model. Drossman (1998) applied the bio-psycho-social model to gastrointestinal diseases, a model firstly suggested by Engel about the understanding of determinants of health and disease (Engel 1981). This model presumes that biological, psychological, and social factors all contribute to the expression of disease and illness. According to the model (see Figure 1) environmental exposures and psychosocial modifiers also affect the clinical expression of the condition, and ultimately, the outcome in a reciprocal fashion (Drossman 1998, p260). Thus, a biological event such as gastrointestinal infection could cause the onset of disease symptoms in IBD and affect the bowel, the individual and the quality of life. Equally, a depression or other psychological event can affect the quality of life and clinical outcome and might activate the disease symptoms through biological effects on systemic immune and inflammatory function (Drossman 1998; Maunder 2005; Mawdsley et al. 2005).

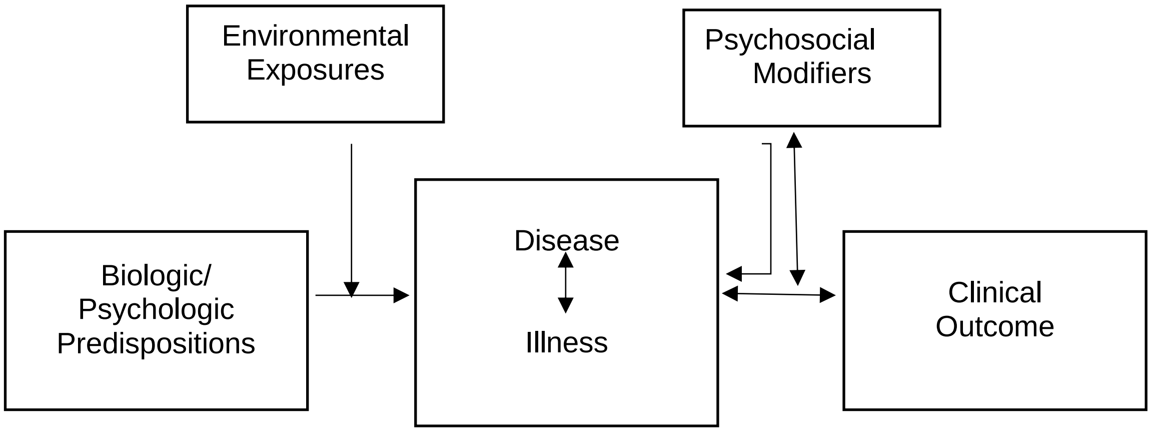


Figure 1. Schematic representation of the bio-psycho-social model. (Figure from Drossman 1998, p. 260)

This mind-body relationship is further examined by psychophysiology. The basic assumption in psychophysiology is that cognitive, emotional, behavioural and social events are mirrored in physiological processes (Hugdahl et al. 1995). Thus, all cognitive processes such as thoughts and emotions may have an effect on body processes including effects on health and illness. For example, chronic psychosocial stressors can have a measurable effect on inflammation (Hansel et al. 2010). According to the concept, any change in behaviour or attitude will make changes in physiological processes and by observing changes in physiological processes; we can learn/understand individuals' psychological status (Davidson et al. 2003). For example, there is evidence that an exposure to a stressful situation will produce a result in the cardiovascular system such as a change in heart rate (HR), vasodilation /vasoconstriction, myocardial contraction, or stroke volume (Charkoudian et al. 2009). This is because the heart is affected by both the sympathetic and parasympathetic system of the central nervous system, which means its activity is affected by arousal but also by paying attention to other stimuli (Ward et al. 2003).

As with the heart, the gastrointestinal tract is also affected by both the sympathetic and parasympathetic system of the central nervous system in what is known as the brain-gut interaction (affected by arousal or attention to stimuli) (Mayer et al. 2006). The brain-gut interaction plays a vital role in the regulation of digestive processes, as well as gut-associated immune system and regulation of the physical and emotional state of the body related to digestion (such as feeling of satiety, abdominal pain etc.).

Alteration in the gut-brain interaction may be involved in the changes of symptom activity in inflammatory bowel disease (Mayer 2000). Thus, introducing an intervention such as MBCT may have an effect on the brain-gut interaction in a way that could change the patient’s stress perceptions or/and effects of sustained life and acute stresses and change the symptom activity in these patients. Consequently, any changes in stress and stress perception, as well as symptom activity, should therefore be observed and measured accordingly.

Contribution

There is a large body of research in the area of IBD and its relation to psychological factors, quality of life, emotional well-being and psychological interventions.
However, to my knowledge, firstly, there is very little research about using mindfulness based interventions in patients with Crohn’s disease and ulcerative colitis and secondly, there is no research about the use of Mindfulness-based cognitive therapy with patients with IBD. Thus, the contribution of this PhD is significant and original to the field of knowledge about the application of MBCT in IBD.

The individual studies reported in these six papers were conducted over a period of four years (2011-2015). The studies were funded by the University of Stirling, Crohn’s and Colitis UK and RD&I NHS Highland. The six papers report on studies conducted in collaboration with Professor Angus Watson, Dr Gill Hubbard and Dr Leah Macaden all from the University of Stirling and Dr Iain Atherton from Napier University, formerly University of Stirling. Within this team, my contribution to the research studies and papers was in excess of 90%, and I was the lead grant applicant and holder, principal investigator and lead author. Further details of my contribution are provided in the individual papers.

Summary

This chapter sets the context for the submitted publications. After highlighting the overall PhD aim, the chapter outlines the main objectives and how they are addressed through the individual publications in hindsight of the MRC framework for complex interventions. It then briefly gives an overview of the publications interrelationship and rationale. After discussing the theoretical underpinning for the research, the chapter closes with a report on contribution. The key issues in the introduction are discussed in-depth in the later chapters. The later chapters also indicate how the six submitted publications have made a significant and original contribution to this particular field of knowledge.

Chapter 2

Objective 1: To ascertain the role of psychological factors in IBD according to the current literature

Chapter overview

As mentioned in the introduction, the purpose of this chapter is to discuss and investigate the role of psychological factors in IBD by examining the current literature. As part of this investigation and addressing Objective 1, two papers exploring this issue will be presented. However, the chapter will firstly provide an overview of Crohn’s Disease and ulcerative colitis, their clinical manifestations, extra-intestinal manifestations, treatment, incidence, prevalence and aetiology, as well as the burden of disease, psychological comorbidities and stress. The chapter will then present the two associated papers and their critical reflections, together with how they contribute to the overall PhD question.

Inflammatory bowel disease (IBD)

IBD is a group of relapsing chronic gastrointestinal diseases characterised by inflammation of the gut (Baumgart & Sandborn 2012; Head & Jurenka 2003). The two main types are Crohn’s Disease (CD) and ulcerative colitis (UC). Dalziel was first to describe Crohn's disease in Scotland in isolated cases in 1913 (Kyle & Stark 1980). However, Crohn’s disease was named after Burril B. Crohn, an American physician, in 1932 when he and colleagues clinically described the disease in further cases (Crohn et al. 1932). Ulcerative colitis was first described in 1859 by a British physician Sir Samuel Wilks (Wilks 1859).

Clinical Manifestations

Although the disease course for both CD and UC follows a similar pattern with periods of relapse and remission, there are differences in the clinical manifestation of the two. For example, the manifestation of CD is by patchy inflammation that can affect any part of the gastrointestinal tract, from mouth to anus, compared to UC, where the inflammation is continuous and affects only the large bowel (Hanauer 2006; Xavier & Podolsky 2007). Both CD and UC have common symptoms: vomiting, abdominal pain, diarrhoea, weight loss, anaemia and rectal bleeding. In CD, complications such as fistulas and abscesses are more common (around one third) and perianal fistulas can often lead to faecal incontinence (Lennard-Jones & Shivananda 1997; Friedman & Blumberg 2011). In UC, while in relapse, the need to urgently defecate up to 15 or more times a day and the feeling of incomplete evacuation of the bowel (tenesmus) can be common. Life threatening complications such as bowel perforation, ileus and the development of cancer can happen in both conditions (Selby 1997). Around half of UC patients might relapse in a year, with 25-35% needing surgery (removal of large bowel and formation of stoma), and up to 70-90% CD patients might need surgery, with 50% needing surgery in the first 10 years (Rampton & Shanahan 2008; Berg et al. 2002; Gardiner & Dasari 2007). Mortality of patients with CD is double that compared to the general population due to complications such as sepsis, pulmonary embolism, immunosuppressive medical treatment and complications of surgery, while mortality for patients with UC is higher compared to the general population, due to increased risk of carcinoma in patients with UC (Loftus et al. 2003; Loftus 2006; Bewtra et al. 2013).

Extra-intestinal Manifestations

Around 25-40% of both CD and UC patients can present with extra-intestinal manifestations (EIMs) (Bernstein 2010). Although any organ of the body can be affected, the most common extra GI manifestations involve the musculoskeletal and dermatologic systems, eyes, hepatobiliary and pulmonary system (Levine & Burakoff 2011). The EIMs are directly related to the inflammation in the bowel, thus, if there is inflammation, the likelihood of EIMs is increased. For some patients, EIMs can develop prior to colonic symptoms. Most EIMs respond well once the underlying bowel disease is treated, however, some diseases, such as primary sclerosing cholangitis (appears approximately in less than a third of IBD) require lifelong monitoring.

Treatment

Due to IBD being a chronic condition with no known cure, the main treatment aim is to reduce symptoms, maintain remission, decrease disease-related complications and improve the overall quality of life. There are a wide range of medical treatments for both CD and UC using either a step up (using the “mildest” form of drug therapy to treat patients first) or a ‘top down’ approach, (using biologic therapies early) aimed at inducing remission as well as maintenance treatments and preventing a relapse. These are: anti-inflammatory therapy (e.g., salicylates or corticosteroids) and immunomodulatory treatment (e.g., azathioprine or anti-tumour necrosis factor (anti-TNF preparations)) (Lichtenstein et al. 2009). Particularly in CD, the concept of deep mucosal healing is becoming increasingly supported. This treatment primarily involves anti-TNF agents and its aim is to eliminate inflammation and to increase time in remission while avoiding complications (Frøslie et al. 2007; Schnitzler et al. 2009). Several studies have shown that the elimination of inflammation can contribute towards decreased rates of surgery and hospitalization (Frøslie et al. 2007; Schnitzler et al. 2009; Baert et al. 2010; Colombel et al. 2010; Ha & Cornbluth 2010; Feagan et al. 2012). More biological therapies including biosimilar medications are reaching the formulary all the time (Jung et al. 2015; Kang et al. 2014). Although drug treatment is usually the primary option before surgery is considered, removal of the whole or parts of the colon (such as bowel resection, stricturoplasty or a temporary or permanent colostomy or ileostomy), is performed when medical therapy is unsuccessful or when there is a substantial risk of cancer development (Hwang & Madhulika 2008; Surlin et al. 2012).

Incidence and prevalence

The onset age for IBD is mainly during adolescence or young adulthood (15-30 years) with a small peak of onset in individuals at the age of 50 to 70 years old (Johnston & Logan 2008). However, because most studies define the onset age as the age of diagnosis, the actual time of onset of symptoms to time of diagnosis may vary widely between patients and healthcare systems. Approximately 240,000 people are diagnosed with IBD in the UK (IBD standards 2013) with an overall prevalence of IBD of 400 patients per 100.000 population. The prevalence for UC in the UK is higher than for CD and is 243 per 100.000

and 145 per 100.000 respectively (Rubin et al. 2000). In addition to the high prevalence of IBD in Europe, comparing to North America, Asia and the Middle East (Baumgart & Carding 2007; Molodecky et al. 2012), the incidence of IBD in the UK is on the increase, with up to a 76% increase in areas such as Scotland since the mid-1990s (Sawczenko et al. 2001; Henderson & Wilson 2012).

Aetiology of IBD

Despite intensive research, there is still no consensus on what causes UC or CD. The most common hypothesis is that the diseases are a combination of genetic predisposition and environmental factors (Blumberg & Strober 2001; Baumgart & Carding 2007). Widely proposed current aetiologies include: an inappropriate reaction to a specific infection in the intestine, subtle alterations of bacterial composition and function and overexposure to resident luminal bacterial products (Thompson-Chagoya et al. 2005). However, IBD was historically (UC in particular) considered a psychosomatic disease (Korzenik 2005). This theory was developed in the early 20th century from retrospective studies grounded in an association between ‘‘well-marked time relationship between emotional disturbance and symptoms” (Murray 1930). Since then there have been a number of studies with contradictory results regarding personality type as a predisposing factor for the development of UC (North et al. 1990; Addolorato et al. 1997; Magni et al. 1991; Moreno-Jiménez et al. 2007). This theory is now widely discredited through a number of studies where psychological predisposition to IBD is not identified, but psychological problems were found as a consequence rather than a cause of the disease (Helzer et al. 1982; Korzenik 2005).

Diet and allergy are among the environmental factors that have been considered as an aetiological factor for IBD. Historically, nutritional deficiencies were suggested to be causes of IBD (Korzenik 2005). More recently, there has been focused interest on diet as the initiating cause of IBD, including in areas such as high intake of sugar, fat and simple carbohydrates (Nahidi et al. 2014; Reif et al. 1997; Hou et al. 2011). Although high fibre and fruit intake was thought to be associated with decreased CD risk and high vegetable intake with decreased UC risk, there is no consensus about diet as a risk/protective factor for IBD.

Cigarette smoking is another environmental factor that has been widely studied as a risk factor for IBD. Smoking worsens the clinical course of CD and may exacerbate fistulas, worsen symptoms and increase the need for surgery. Smokers have a twofold risk of developing CD (Cosnes 2004; Calkins 1989). Contrary to this, smoking plays a protective role in UC and in UC insomuch that smoking is associated with less frequent symptom exacerbation (Feagan 2003). Other environmental factors have been studied, including oral contraceptives, appendectomy, vaccines, airline travel and toothpaste. There is insufficient evidence to support any of these theories (Schmidt & Stallmach 2005).

Evidence suggests that 5–22 % of UC patients have a first-degree relative with UC and CD patients have a 2–16 % chance of having a first-degree relative with CD. This suggests a genetic component to disease aetiology, particularly in CD (Baumgart & Carding 2007). Since the identification of the first gene on chromosome 16 that increases susceptibility to Crohn's disease (NOD2/CARD15) in 2001, the genetic investigation in IBD is growing (Hugot et al. 2001; Ogura et al. 2001; Cho 2002). Although there have been over 100 published IBD susceptibility loci (gene mutations), their overall contribution to developing IBD remains low, categorising IBD as a polygenic disorder (Thompson & Lees 2011).

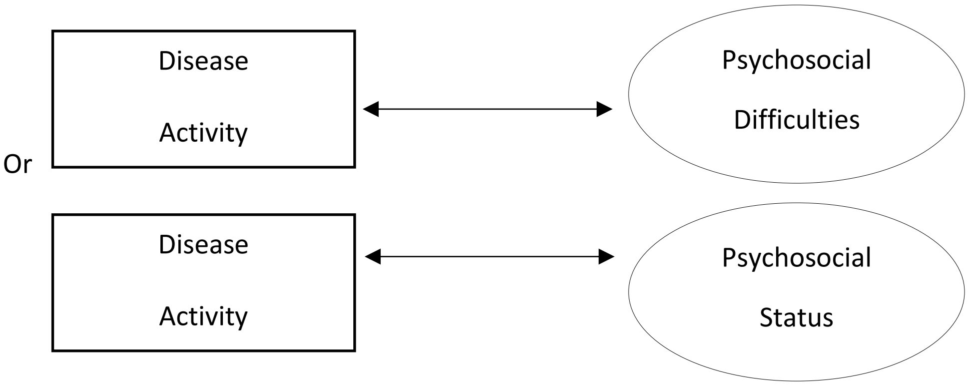
Burden of Disease/Evidence of psychological comorbidity

It is well documented that having a chronic disease leads to a greater burden of psychological stress, depression and anxiety and this is no different for IBD (Knowles & Mikocka-Walus 2014). Due to the chronic and relapsing nature of the disease, the distressing and debilitating symptoms, the fear and humiliation surrounding incontinence, feeling dirty, isolated and living in fear, the prospect of no cure and the early onset of the disease, it is evident that the disease has substantial psychosocial implications beyond the intestinal symptoms alone (Hall et al. 2005; Devlen et al. 2014). Evidence suggests that the burden is even more prevalent when the disease activity is not managed well, or when patients have active symptoms (Mikocka-Walus et al. 2007). This is reflected in the increased rates of depression, anxiety and other psychosocial comorbidities for patients with IBD and with a consequence on their ability to work and socialise (Fuller-Thomson & Sulman 2006; Netjes & Rijken 2012).

There is emerging evidence that stress and other negative psychological attributes may have an effect on the disease activity (Bonaz & Bernstein 2013). However, it is still not clear if the psychological effect is one directional, from illness leading to psychological difficulties, or if there is a two way activity between psychological status and the disease activity in a possible brain-gut interaction (see Diagram 1). This possible 'brain –gut' interaction can be understood if we look at the central nervous system. The gastrointestinal tract is affected by both the sympathetic and parasympathetic system and is also affected by arousal and attention to stimuli (Mayer et al. 2006). The brain-gut interaction plays a vital role in regulation of digestive processes, as well as gut-associated immune system and regulation of physical and emotional state of the body related to digestion (such as feeling of satiety, abdominal pain etc.). An alteration in the gut-brain interaction may be caused by sustained stressful life situations such as psychosocial circumstances or acute stress situations, such as an exam or job interview (Savignac et al. 2011; Bonaz & Bernstein 2012). The literature suggests that an alteration in the gut-brain interaction may drive changes in symptom activity in inflammatory bowel disease through the following 5 systems: (1) the autonomic nervous system, (2) the central nervous system, (3) the stress system (hypothalamic-pituitary-adrenal axis), (4) the (gastrointestinal) corticotropin-releasing factor system, and (5) the intestinal response (including the intestinal barrier, the luminal microbiota, and the intestinal immune response) (Mayer 2000; Bonaz & Bernstein 2013).

Whether the effect of psychological stress is one or two directional in the disease course, it becomes less important. It is well documented that disability and functional impairment, related with health conditions, is associated with anxiety and depression (Walker 2011; Kessler 2003) and therefore psychological stress is a great burden for patients with IBD.

Diagram 1. Possible relationship between disease activity and psychological status/difficulties



But, what is stress?

Stress as a concept, is the presence of stressful stimuli that can be external or environmental, or can be internal as a feeling, or the perception of being overwhelmed by a threatening situation (Lazarus and Folkman, 1984). To understand the experience of stress, one needs to evaluate the threat potential of the stressor and the one's capacity to cope with it (Lazarus and Folkman 1984). In the IBD context, assessing perceived stress is a way of evaluating stress and its role in heath as explored by Keefer et al (2008).

Stress as a risk factor for depression and anxiety

Stress has been identified as a risk factor for depression and anxiety. The evidence suggests that stress interacts with genetic, biological, environmental and psychological predisposing vulnerabilities, resulting in emotional distress and potentially in the onset of mental and physical health disorders such as depression and anxiety (Taylor 2010). Depression is defined as an umbrella term covering a broad range of states from feeling sad, helpless and demoralised to grief, poor self-esteem or a major depressive episode (Cooke 1980). Anxiety is defined as 'anticipation in future misfortune or danger accompanied by the feeling of dysphoria or somatic symptoms of tension' (DSM-IV). In IBD, several studies have suggested a significant association between perceived stress and anxiety and depression (Camara et al. 2009). Further studies suggest a possible association between the effect of stress, depression and anxiety in symptom exacerbation in IBD (Sajadinejad et al. 2012).

Stress and symptom exacerbation

Inflammatory bowel disease is principally thought of as a disease of the intestinal system. However, a purely gastrointestinal (GI) centric view of the illness is not sufficient to understand the full spectrum of patients' experiences and concerns (Andrews et al. 2010). As Andrews et al. (2009) remark, the gut is essential for nutrition, but it also contributes to pleasurable experiences through taste, food satisfaction, satiety and emotional, social and religious aspects of sharing meals. The inability to participate in these food/meal based community aspects because of the gut disturbances, could cause distress for the individual. Thus, for many patients with IBD, stress is a very important part of the disease experience. This is particularly evident when symptoms are active and higher perceived stress is present due to a worry about the disease and its impact on broader life activities.

As mentioned above in the aetiology section, the idea of an association or even a causal link between psychological stress and IBD symptoms is not new and the theory has been around since the 1930s (Murray 1930a). Although some of the early discussions alluded to a psychological background being of aetiological significance in UC, this author was one of the first to highlight the effect of the disease on the mental health of patients with UC and the necessity of addressing it. He suggested that mental health was often overlooked by medical professionals due to the physical symptoms being so obvious and this was where their focus often stopped (Murray 1930b). Since then, there has been a volume of literature examining the evidence concerned with the issue and although there are some contradictions in findings (Graff et al. 2009; North et al. 1990; Schwarz & Blanchard 1990; North & Alpers 1994), the weight of evidence suggests that stress and psychological factors play a role in the pathogenesis of IBD and in relapse of the illness (Searle & Bennett 2001; Mikocka-Walus et al. 2007; Maunder & Levenstein 2008; Levenstein et al. 2000; Maunder 2005).

Higher levels of distress (anxiety and depression symptoms), or perceived stress, has been reported by IBD patients with active symptoms compared to both patients in remission, or in the general population (Graff et al. 2009; Hauser et al. 2011). A high number of those with active IBD symptoms report IBD as a significant source of stress if their symptoms do not improve over time, but also report significant stress related to all other occupational and social daily activities (Bonaz & Bernstain 2013; Singh et al. 2011). This broader life stress could be a contributing factor towards re-occurrence of relapse for individuals with IBD. In view of this, there has been growing interest in examining the impact of stress, depression and anxiety on IBD symptoms. The resulting reports have been mixed.

Aim and linkage to research question

As discussed above, IBD is a chronic illness that affects around a quarter of a million people in the UK. It has physical and psychological manifestations. While debate continues about the direction of the relationship between IBD symptoms and stress, it is clear that people with IBD are likely to be caught up in a vicious circle where physical symptoms exacerbate stress and vice versa. From the patient perspective, therefore, both the physical and the psychological aspects need to be addressed. Hence, this PhD focuses on the psychological aspects of IBD and investigates if MBCT can be used as an adjunct therapy in addition to physical symptom management for improving IBD patients' general well-being and quality of life. The first step towards answering the PhD question is ascertaining the role of psychological factors in IBD through a thorough examination of the literature. This first step is very important and creates the building blocks of being able to fully understand the evidence around patients’ concerns and experiences of psychological factors and IBD disease course. The findings from this step were used as a rationale to devise the best strategy for examining the potential for MBCT to be used as an intervention in IBD symptom management and quality of life improvement. Thus, Paper 1 (embedded below) and Paper 2 (appendix 1) collectively contributed to achieving the first steps towards answering the PhD question.

Paper 1: The Role of Psychological Factors in Inflammatory Bowel Disease

Due to publisher restrictions, Paper 1 is removed from the electronic copy of the thesis http://hdl.handle.net/1893/23931

Paper 1:

Schoultz, M. (2012). The role of psychological factors in inflammatory bowel disease. British journal of community nursing, 17(8), 370. http://dx.doi.org/10.12968/bjcn.2012.17.8.370

Overview and critical reflection on Paper 1&2

The following paragraphs will give a brief critical reflection on Paper 1&2, their strengths and weaknesses but also on the whole process of shaping and refining the specific question. Although some of the issues presented in the next paragraphs have already been explored in the papers, in this chapter they will be discussed further, as the greater detail is important for the PhD question and submission, but not necessarily for the journal readership.

Methods and design

The process of writing Paper 1 was one of the key learning processes in the PhD journey that enabled me to refine the PhD question (‘if MBCT can be used as an adjunct therapy to IBD symptom management for improving IBD patients' general well-being and quality of life) and makes sense of the literature on stress and IBD. As mentioned in the introduction, the initial idea for Paper 1 was to perform a systematic review of psychological interventions in IBD. When the search revealed that such a review was already published (Timmer et al. 2011) in the first years that I started my search and PhD, it was logical that doing the same review would amount to duplication of effort and therefore was not feasible. However, the findings from the Timmer et al. (2011) review (mentioned in the introduction), raised questions around stress and symptom relapse in IBD. For example, I wanted to get to the bottom of the issue about psychological stress, to understand how it affects disease activity and patients with IBD but also how the disease itself affects the psychological status of patients. Thus, Paper 1 focused on the literature surrounding the role of psychological factors in IBD and discussed the conflicting evidence.

Although the format of Paper 1 followed the journal request to be a narrative review with relevance to clinicians, the methodology used in the literature searches followed a systematic approach. A search strategy and predetermined inclusion/exclusion criteria were devised to detect all relevant studies examining psychological factors in IBD through the databases (Medline and EMBASE via OVID, CINAHL and PsychInfo via Ebsco). This included prospective and retrospective designs as well as previous reviews from 1991 onwards. The main finding of this paper was that the evidence about the role of psychological factors in IBD is contradictory. This paper highlighted and discussed the main reasons for those contradictory findings.

The principal thoughts that polarised opinions and contributed to contradictory findings for almost a century (as mentioned in the previous section) was that researchers' approaches came from different paradigms and interpretations: either from a biomedical or biopsychosocial model perspective. The first followed the genetic and biological model in explaining causes and symptoms of IBD (Bouma & Strober 2003), while the second argued that psychological factors may play a key role in pathogenesis and symptom exacerbation in IBD (Maunder 2005). These polarised stances are not new in medicine and health. Since Aristotle and Plato, the mind and body have been separated and dualism of mind and body was the foundation for the biomedical model. This model has reduced illness to a single factor problem of biological malfunctioning for the last 300 years, thus ignoring the patient as a human being and reducing the person and their psychosocial circumstances in physico-chemical terms (Engel 1980; Knowles & Mikocka-Walus 2014). Although this model might work well for acute health problems, it is not effective in dealing with chronic conditions. Thus, with the growing incidence of chronic conditions worldwide and the works of psychotherapy in the twentieth century, the biopsychosocial model or concept of illness was born. This brought together biological, psychological and social factors as contributors to symptom relapse (Engel 1980) and enabled researchers and clinicians to understand the full spectrum of patient experiences and concerns with IBD. This model fits with the theoretical underpinning of this PhD work.

As seen in paper 1, there was evidence to support both stances, with the biopsychosocial model being more prominent in the later literature (the last millennium). However, even within reviews that used the same biopsychosocial model, looking at the same topic and published in the same year, there were contradictory findings (North et al. 1990; Schwartz & Blanchard 1990). At first, this was quite confusing, but nonetheless, I continued to review the rest of the literature. Very soon a pattern became apparent in the similarity of discrepancies between the findings. These were: inadequate methodologies, either in the original studies or in the reviews of those studies, inconsistency in defining or interpreting psychological factors, a failure to distinguish between the two types of IBD (CD and UC), lack of consistency in standardised measures of disease activity and the role of personality traits. These became the focus of discussion in paper 1.

On reflection, the writing of Paper 1 enabled me to have a better understanding of psychological stress through identifying the complexity of the issue with all of the disparities. In addition, this paper was my first publication and this contributed towards confidence building, but also skills development in terms of understanding and engaging successfully with the publication process. However, although this narrative review was a great process for the above reasons, at the time it felt that building confidence and skills development was not sufficient. I wanted to further understand the issues around psychological stress and to further examine the literature in a more systematic way with a more specific question; I wanted to find out if there is a causal link between psychological factors and IBD symptom exacerbation. I felt that this question was important, particularly in providing the rationale for using MBCT, an intervention designed to improve coping with stress and in the face of the negative findings of the Timmer et al. (2011) review (see previous chapter). Such a question would enable a better assessment of the literature, particularly prospective cohort studies that are more likely to detect an association between stress and disease activity. Thus, this is how the idea for Paper 2 came about.

Systematic reviews are seen as an essential tool for summarising evidence accurately and reliably and are therefore seen as a more rigorous scientific method compared to a narrative literature review (Tranfield et al. 2003; Liberaty et al. 2009). They are often used as a starting point for further research and they inform clinicians and researchers with the most up to date evidence in a particular field (Swingler et al. 2003). However, the value of the systematic review depends upon: what was done, what was found, and how the results were reported. While there is a clear guidance for reporting systematic reviews results, in order to allow readers to assess the strengths and weaknesses of the evidence and provide transparency of process, more recently experts are encouraging researchers to publish systematic review protocols too (Moher et al. 2009). Publishing a systematic review protocol before conducting a systematic review, provides a transparency in the process as well as helping counter publication bias by providing a permanent record of the planned review procedures (Moher et al. 2015).

In addition to the above justification, I was aware of my lack of confidence in being able to critically examine observational studies. Thus, writing the protocol for a systematic review was the perfect learning opportunity for adhering to the above guidance as well as developing my skills and confidence. Nonetheless, this process (for me personally), proved to be a lengthy and ‘painful’ one. Most of the expertise in systematic reviews that I had direct access to was in reviewing interventions and RCTs and I had to seek external experts. I also felt that the literature about systematic reviews was overwhelmed with explanations of how to conduct systematic reviews for interventions and RCTs, and there was less about systematic reviews on observational studies. However, once my confidence in performing the task improved (which was bolstered by completing the narrative review) I found the task of defining the specific aims for the systematic review more straightforward. Publishing the protocol was another confidence builder in terms of the methodology being peer reviewed by experienced systematic reviewers, and the actual publication generated a lot of interest about my research and future outcomes.

At the time of preparing the protocol for publication, the screening and selection of studies according to the identified criteria was taking place simultaneously (for full details of inclusion/exclusion see paper 2). After saving the initial searches (over 2000), the process of selection by reading abstracts and deciding if they fulfil the criteria for inclusion begun. Good practice guidance and the PRISMA 2009 checklist, lists several important steps in this process: with searching, screening and quality appraisal among the first few (Moher et al. 2009). At the same time, a second researcher, independently arranged papers according to selected criteria. Good practice suggests that two researchers independently review the screened papers and then compare outcomes (Moher et al. 2009; Higgins & Green 2011). This provides transparency and robustness of the whole process and contributes to the quality assurance of the approach.

Whilst progressing through the selection process, I came across a review dealing with a similar theme that was published in 2012 (Sajadinejad et al. 2012). Although this review was not titled as a systematic review, it was a very comprehensive paper which focussed on all of the concerns I had intended to address in the systematic review, and maybe even more. At this point I had to consult with my supervisors and co-authors as well as the literature. At the conclusion of this consultation I resolved that the purpose of my investigation was to find an answer to my question, so that I could continue to the next stage of the research. I accepted that although this was not conventional, the answer to my question came in a paper published at the same time by another author. In addition, the literature highlights that systematic reviews are time-consuming and costly to carry out, therefore duplication of effort should be avoided and avoiding unintended duplication is important in ensuring that finite research funds can be used effectively and efficiently (Davies 2012; Chang 2012; Stewart 2012). Therefore, it was decided not continue with the review, but to accept the findings of the review by Sajadinejad et al. (2012) as a sufficient rationale for the next stage of the research.

Strengths and limitations

There are numerous strengths to the first two papers, as well as limitations. In terms of the PhD process, the first two papers were confidence builders, where I developed many skills which enabled me to refine my PhD question. They also enabled me to really immerse in the topic and understand why there were some conflicting results. I also learned to look at the methodology of published literature and became able to critique and differentiate between poor and good quality research.

Contribution to the research question

Objective 1, with the two associated papers, highlighted the disease related concerns and its psychological manifestations. Despite the debates in the literature around the topic area, one of the consistent findings was that IBD has substantial psychological implications beyond intestinal symptoms. The evidence suggests that symptom exacerbation or significant perceived stress or distress is a consistent predictor for a lower quality of life (Graff et al. 2009; Guthrie at al. 2002; Zhang et al. 2013, Moradkhani et al. 2013). Thus, it highlights that a purely GI-centric view of IBD is not an adequate way of addressing the disease concerns, and attention to mental health should not be overlooked by clinicians who often focus on gastrointestinal symptoms only (Graff et al. 2009). Therefore, it advocates that mental health in IBD should be addressed and provides the rationale for examining the potential of MBCT, an intervention aimed at better coping and management of psychological stress, in IBD symptom management and quality of life improvement.

Chapter 3

Objective 2: To establish the psychological needs' gap in the current care services for patients with IBD

Chapter overview

The literature suggests that a purely GI- centric view of IBD is not sufficient to appreciate the full spectrum of the patient experiences and concerns (see chapter 2). This is because psychological stress is an important part of the disease experience for patients with IBD. However, according to the evidence, attention to mental health is still overlooked by clinicians who mainly focus on intestinal related symptoms (Graff et al. 2009). Faced with this evidence and with the PhD question in mind, it was important to find out if addressing the whole disease (physical and psychological symptoms) is part of the current standard care for patients with IBD and if IBD patients across Scotland felt that their emotional and psychological needs were adequately addressed. If this was not the case, what do patients as experts in their condition suggest?

Thus, the purpose of this chapter was to investigate if there is a psychological needs gap within the standard care for patients with IBD in Scotland. In order to do so, the chapter will firstly refer back to the literature on psychological needs in IBD, then describe and discuss current IBD care services with an emphasis on the need for holistic care. It will then discuss the unmet needs gap in the management of IBD and discuss the literature on psychological therapies as a way of addressing the psychological consequences of IBD and linkage to research question. Although paper 3 (Appendix 2) contributes to answering this chapter's objective 'If psychological needs of patients with IBD are met through their standard care', the question within paper 3 is wider than the aim of the chapter. At the end, the chapter will critically reflect on the methodology in paper 3 with reference to literature, and then explicitly discuss the contribution of objective 2 to the research question.

The literature on psychological needs in IBD

Around 1 in 250 individuals in the UK and 360 in every 100,000 individuals in Western Countries are diagnosed with IBD (Gasparetto & Guariso 2013). The impact of the disease on daily functioning and quality of life for patients is substantial, with psychological distress being a major feature. However, this high prevalence of depression and anxiety experienced by up to 60% of IBD patients, continues to be undertreated (Knowles & Mikocka-Walus 2014). Yet, the recognition and treatment of psychological comorbidities could improve the quality of life of patients with IBD and increase the overall cost-effectiveness of IBD treatment (Moser 2006).

The preliminary results of a questionnaire (ADAPT-Assessment of the Demand for Additional Psychological Treatment) that was developed to assess the subjective demand for additional psychological care in chronically ill patients, showed that a third of over 300 patients with IBD had a strong desire for additional psychological support (Miehsler et al. 2004). The findings exemplify that many patients with IBD require more than medical care. Thus, clinical attention to psychological comorbidity and quality of patient coping skills for dealing with the disease are essential components of a comprehensive and successful management approach to IBD (Moser 2006).

Overview of current IBD care and services

The majority of patients with IBD in the UK are managed in secondary care. This is because most patients with a suspected or confirmed diagnosis of IBD are referred to a gastroenterologist (IBD Standards Group 2009). However, patients often report an extended period of distressing symptoms with numerous visits to their GP before being referred to secondary care or before a diagnosis was made. This may be due to the heterogeneous nature of IBD and the variety of symptoms that patients may experience, requiring excessive examinations and investigations (Carter et al. 2004). These pose a great burden for the patient. Common concerns about the process of examination is that patients may feel embarrassed at being required to expose their ano-genital area (Knowless et al. 2014). Concerns about inadequate hygiene due to the disease symptoms or embarrassment/disgust at being required to collect stool sample or the anxiety and discomfort of having a colonoscopy is very common and contributes to the overall distress for patients (Turnbull et al. 1997; Bakun et al. 2006; Knowles & Mikocka-Walus 2014). The IBD Standards (2013) suggest developments of protocols and pathways for prompt referrals to be established locally, such as utilising faecal Calprotectin testing, which would reduce the referral and diagnosis time and hopefully distress (NICE 2013).

As discussed in Chapter 2, first line treatments include a hierarchy of drugs and/or surgical treatments. These are used to induce symptom remission or maintain remission. This process can take up to several months as some patients do not respond to the first or second type of medication (Sokol et al. 2010). This is a very difficult part of the journey for patients, as when the first few types of medications do not induce symptom remission, they can often feel hopeless and powerless about their future (Srinath et al. 2012). This is in addition to dealing with the actual disease symptoms. Although at this stage they are cared for in the medical sense, this is the point where patients often report that they struggle to adapt to the disease and the whole life adjustment that follows as a result of diagnosis. This is the point where most patients diagnosed with IBD believe they would benefit from psychological referral and input. This is also supported by the literature (Graff et al. 2009; Knowles & Mikocka-Walus 2014).

Once a ‘stable remission’ of symptoms has been achieved, patients are offered a variety of options for their further disease management. The majority of IBD patients are kept under review due to the relapsing and unpredictable nature and the need for long term cancer surveillance. Thus, being on a 12 month review warrants a rapid access back to hospital care if needed for the patient. Nonetheless, it is believed that around 20-30% of patients with mild to moderate disease may not be in secondary care follow up (BSG 2015), which creates additional distress for them. As the literature suggests, having rapid access to services is important to patients with IBD, particularly with the unpredictable nature of the disease and due to the rapid symptom exacerbation from remission for some patients (Westwood & Travis 2008). Being discharged to primary care to a GP who perhaps has little understanding of the condition, could also add stress for the patient. This is another point that patients with IBD report they would benefit from psychological referral and psychological input; to help them cope and manage the uncertainty and unpredictability of the next symptom exacerbation (Carter et al. 2004). The IBD Standards suggest that not only should pain, fatigue and urgency be addressed as very significant factors in the patients' quality of life, but psychological support for patients with IBD should be provided on a similar basis to services for patients with cancer (IBD Standards 2013).

The need for psychological support as part of holistic care in IBD

Psychological support in IBD is as important as the gastroenterological approach (Filipovic & Filipovic 2014). Thus, a holistic team approach is needed in IBD care in order to address both the significant physical and psychological impact on quality of life in IBD and the interaction of somatic and psychological symptoms. Results of a survey by the European Federation of Crohn's and Ulcerative Colitis Association's (EFCCA) (Ghosh 2007) reported that quality of life (QoL) is still not taking a central role within the care of patients with IBD, despite the large and convincing body of evidence that psychological wellbeing and quality of life is important for all people in general, particularly for those with chronic conditions such as patients with IBD (Graff et al. 2009). Therefore, it is of great importance to pay attention to the evidence while offering a model of care that enables people to receive a more holistic care (Mikocka-Walus et al. 2012). This, in particular, means acknowledging the importance of the overall quality of life and psychological status of patients with IBD. Current evidence suggests that access to psychological support for patients with IBD remains very low, with only 12% of services reporting to have access to clinical psychology through a defined referral pathway (RCP 2014).

A proposed way to improve the overall QoL and psychological status of patients is by taking a holistic approach to care, which includes a good patient –clinician relationship, appropriate patient education and timely treatment of psychological comorbidities such as depression and anxiety (Husain 2004; IBD Standards 2013). However, the appropriate and timely treatment of psychological comorbidities in IBD is not without its challenges.

Overview of current psychological interventions in IBD

Given the perceived needs of those with IBD and the recommendation for psychological support by the IBD Standards and by IBD experts (Knowles & Mikocka-Walus 2014), it is very clear that effective IBD-focused psychological interventions are needed. However, some of the evidence about interventions aimed at improving the psychological distress suffered by IBD patients report only a modest benefit for a subsection of patients with IBD Timmer (2011) and Wietersheim & Kessler (2006). In contrast, a recent review of psychotherapy for IBD shows promise in terms of reducing pain, fatigue, relapse rate and improving medication adherence (McCombie 2013). In addition, Knowles et al. (2013) points out that when psychotherapies are grouped according to the theoretical approach and skill learning strategy, their impact on psychological symptoms and quality of life in IBD, differs than when ideologically dissimilar interventions such as educational, psychodynamic and cognitive behavioural are reviewed together. For example, Knowles et al. (2013) grouped the interventions into either psychoeducation, stress management (relaxation techniques, autogenic training), psychodynamic psychotherapy (PD), cognitive behavioural therapy (CBT) or hypnosis (HYP). Reviewing all the recent psychotherapy studies in IBD in this way, Knowles et al. (2013) found that the psychotherapy interventions that fell in the category or are informed by the CBT paradigm have a greater effect on anxiety and depression, rather than on IBD symptoms or QoL. In addition, the interventions that are predominantly focused on stress management and not on coping styles and self-management skills (such as CBT), show more modest benefit for mental health symptoms and QoL when compared to the first ones. Therefore, these findings make a clear distinction between the types of psychological interventions that are more suitable or matched with the desired outcomes in IBD and represent an important rationale for exploring the use of MBCT in IBD.

Aim and linkage to research questions

In order to answer the overall PhD question (if MBCT can be used as an adjunct therapy to IBD symptom management for improving IBD patients' general well-being and quality of life), this chapter and objective 2 is expanding on the discussion in the previous chapter and objective 1 of understanding the full spectrum of patient experiences and concerns about the disease. What this objective contributes to the overall question is the understanding of the context of the current care services for patients with IBD in the UK and the lack of psychological support and input in the IBD care despite the widely recognised need for it. This chapter links the evidence for psychological needs from the literature with the evidence from the survey presented and discussed in paper 3 (Appendix 2). Both, the literature and the survey findings highlight the importance of a holistic approach to IBD care, with appropriate and timely psychological support being at the heart of it.

Overview and critical reflection on paper 3

The overall concept for this paper was to explore IBD patients' perspectives and experiences of current IBD services. This work formed part of a national strategy to improve the standards of care given to patients with IBD in Scotland. A co-design approach was adopted. Although the remit of this paper appears broader than this chapter's objective, the survey findings and process was a very effective way of assessing two important aspects relevant to the overall PhD question. Firstly, the survey was a great tool to identify any needs gaps in services, in particular the need for psychological support and input and secondly, the rationale behind co-designing and improving services with patients, is an evidence based strategy (Bate & Robert 2006) for creating a more holistic, person-centred and comprehensive care model for patients. The outcome and recommendations from this survey are important as they form the rationale behind the need for developing and testing psychological therapies appropriate for IBD.

Methods, design and theory

Faced with the evidence about the need for psychological support for patients with IBD and other anecdotal evidence, it was important to examine if the experiences described in the literature were similar for IBD patients in Scotland. Thus, in collaboration with Crohn's and Colitis UK and the Scottish Government, a cross-sectional survey was designed to examine the IBD patients' experiences and perceptions of services in Scotland.

Fundamental to answering any given research question is the need to develop an appropriate research design. The overall research question of the study in paper 3 did not fit in the positivist paradigm that focuses on theory testing, establishing causal effect or predicting and controlling variables (Polit et al. 2003). In contrast, a qualitative research method that enables a development of a theory and offers an explanation about the main concerns of patients with IBD was deemed as more appropriate.

On reflection, choosing the most appropriate methodological approach for the survey was a process of exploring and examining the different theoretical and methodological perspectives available. For example, the literature suggests that there is a range of qualitative methodological approaches that could be used to underpin the theoretical approach, such as: narrative research, phenomenology, ethnography and grounded theory. I looked at the examples of the different approaches used in different research situations in the IBD population. For example, a qualitative narrative approach was used by Dur et al. (2014) in determining concepts related to health for patients with IBD by examining the patient experience. A narrative research normally focuses on one or few individual life stories where data is gathered from (Finlay & Ballinger2006). This was not the right approach for the survey.

The phenomenology approach seeks to describe the phenomenon of an everyday 'lived' experience of a certain event as opposed to an event that is observed as an external entity (outside of the person) (Manen et al. 1990). This approach also emphasises the importance of reflexivity, or awareness of the way the researcher with its social identity and background can influence the research process. This approach has been used in a number of studies with IBD (Schneider & Fletcher 2008; Dudley-Brown 1996), but again, was not the right approach for the survey.
The ethnography approach was also not appropriate. This is because the ethnography is a systematic approach where an interpretation of the cultural phenomenon and social structures is conducted within the social groups from the viewpoint of the subject of the study, and that was not the aim of the survey. This approach has been used in IBD for describing the experiences of adolescents living with ostomies (Nicholas et al. 2008).

Although most consider grounded theory (GT) as a qualitative method, GT is actually an inductive methodology and a general method or systematic generation of theory from systematic research that can be used with both quantitative and qualitative data (Holton 2008). In other words, GT is a strategy, or set of rigorous research procedures, seeking to generate conceptual categories related to the study's topic (Glaser and Strauss 1967).

These concepts/ categories are interrelated with each other as a theory or theoretical explanation about the phenomenon being studied.

Grounded theory has been influenced by Symbolic Interactionism (Blumer 1969) where meanings are derived from social interactions that one has with other fellows and then interpreted and modified by the person that dealt with the encountered interaction. GT became a foundation for social research in the 60’s as a new way of investigation and has developed through different phases or historical moments. Denzin and Lincoln (1994: 1) specify that `qualitative research operates in a complex historical field that crosscuts five historical moments. These five moments simultaneously operate in the present'. Those phases/ moments range from traditionalism associated with the positivist paradigm (1900-1950s) to postmodernism doubting all previous paradigms (1990-present). This move towards postmodernism has resulted in GT being attacked for its positivist foundations.

The approach used in the study enabled the discovery, exploration and conceptualisation of patterns and themes that were important to the study population. It also enabled the understanding of the context and why certain themes were important to the participants. This was enabled by the ability of the qualitative approach to be a vehicle for gathering important insights into culture, practices and discourses in health and illness (Denzin 2000). Ma (2000) and Sofaer & Firminger (2005) suggest that qualitative methods are better suited to reveal and appreciate the full spectrum of the patient experiences and concerns with IBD. This method enabled participants to provide a depth of information about their experiences and perceptions of their interactions with healthcare professionals and services while using their own language.

Qualitative research is also interested in the subjective interpretation of the world with the aim of exploring and understanding peoples’ beliefs, behaviours and cultures (Mason 2002). Moreover, it has been recognised as an essential method when trying to understand the context in which individuals experience health related treatment decision making (Paley and Lilford 2011). Context is particularly important when developing complex interventions (Campbell et al. 2007), thus the understanding of the health service system, the characteristics of the population studied and how they interact with each other is fundamental information in addressing the PhD question which is about a complex intervention. Thus, adopting a qualitative design within this study allowed the exploration of patients' needs, values and experiences of current services and their views of how they could improve to cater to their needs better.

Sampling in qualitative research

Sampling in qualitative research is an equally important aspect of the research process as the research question itself (Wilmot 2005). In order to acquire valid answers, even if it were possible, it is not necessary to collect data from everyone in a studied community. Therefore, a subset of the studied population is selected (Patton 2005). The study's research objectives and the study population characteristics would determine the size of the subset. However, in qualitative studies, it is not only the size of the sample that is important, but the type of participants that can give the best insight into a researched topic (Noy 2008). In doing so, a range of sampling methods can be employed. As with the choosing of the most suitable methodological approach, different sampling methods were explored and evaluated from the literature. The most common types used in qualitative research are: purposive, convenience, snowball and theoretical sampling (Wilmot 2005).

Purposive sampling is probably one of the most common sampling strategies, where participants are grouped according to preselected criteria relevant to a particular research question (Creswell et al. 2007). According to this type, sample size may or may not be predetermined prior data collection and is often determined on the basis of theoretical saturation (when new data would not bring any additional insight into the research question) (Creswell et al. 2007).

Snowball sampling, also known as chain referral sampling, is considered as a type of purposive sampling where participants who have already been contacted, use their social networks to refer the researcher to other potential participants. This technique is often used to recruit the so called 'hidden populations' that are difficult to access in other ways (Howitt and Cramer 2005).

Convenience sampling uses the principles of selecting the most accessible participants and is the least rigorous method and may produce poor quality data that may not fully enable the exploration of the studied issue, but is the least costly in terms of time and effort (Marshall 1996).

Theoretical sampling is described as an iterative process and is an integral part in the development of theoretical concepts (Glaser and Strauss 1967). This approach is often used in GT research with the aim to develop a theory through the research process itself and as new concepts emerge from the data, a new sample is pursued (Marshall 1996).

Sampling in this study

For this study a combination of two types of sampling was used: purposive and snowball sampling. The justification behind the purposive sampling was to sample patients who have a diagnosis of IBD and receive their treatment in Scotland. The justification of the use of snowball sampling in this study, was to reach patients with IBD in rural areas that would be difficult to reach, particularly because a national database of patients with IBD is not yet available. Crohn's and Colitis UK invited all their members with IBD to participate in the survey and asked all members to invite other patients with IBD from their networks to participate. The sampling method in this study also helped to establish whether perceptions and experiences of IBD needs and services are different for people living in rural and city areas across Scotland. This is in line with Jansen (2010) who suggests that in order to represent the diversity of the studied phenomenon that covers all the relevant varieties of the studied phenomenon, a purposively selected diverse sampling should be selected.

Data collection

The method for data collection in this study was a qualitative free text survey. Many qualitative studies use semi-structured interviews or focus groups as a data collection method, which although very popular, is not without its criticism (Reichertz 2007). A survey on the other hand, as defined by Groves et al. (2004, p.4) is: "… a systematic method for gathering information from (a sample of) entities for the purpose of constructing quantitative descriptors of the attributes of the larger population of which the entities are members." Although this definition by Groves is quantitative and describes the numerical distributions of variables in the studied population, there is a qualitative way of investigating variations in a population by determining the diversity of the topic of interest in a population (Jansen 2010). Although the qualitative survey is often not described in the textbooks of qualitative research, qualitative surveys gained increased popularity in the 80s. It is thought that this was due to the limitations of questionnaire survey type, that were considered as expensive, but not sufficient for providing an in depth knowledge about the researched topic (Marsland et al. 2000). Thus, taking into account that the survey was being conducted as part of a wider project for improving services for patients with IBD, with time, cost and numbers being important parameters, free text survey was chosen as the best available data collection method.

Data analysis

Qualitative data analysis (QDA) is a range of systematic processes and procedures of understanding, explaining and interpreting the data from people and situations that are investigated. It is an iterative process that begins at the conception of a certain project and is based on an interpretative philosophy (Curry et al. 2009). The aim of the QDA is to examine the meaning and symbolic content of the data, where the researcher 'immerses oneself in the data' (Swallow et al. 2003) and concludes in a theory forming about the studied topic. The literature suggests that the process of data analysis often involves identification of themes using data and coding. While there are different approaches to analysing data such as discourse, content, conversation or framework analysis, thematic analysis has been seen as the foundation of QDA (Braun & Clarke 2006).

Thematic analysis is the process of identifying themes that arise at different stages from the data. While some argue that thematic analysis is not a method in its own right, but an approach used across other methods of analysis (Guest et al. 2011), this approach offers accessibility, theoretical flexibility and inductive qualities of GT without necessarily creating a theoretical model (Braun and Clarke 2006). Data was analysed after all data was collected from the survey.

Rigour

The coding of the data was conducted independently by another researcher and me. We independently familiarised ourselves with the data, and then generated the initial coding by creating themes from the codes. We then met to discuss the findings and extract the codes. It was at this point that my real appreciation for qualitative research grew. This was my first qualitative analysis and being of a sceptical mind, I really wanted to see how it worked in practice. Thus, when codes were compared at the first meeting, I was surprised by the similarity of our findings and how we had used similar coding independently. We also came up with almost identical themes. This was sufficient to see in practice that qualitative research and analysis is a rigorous method and allowed a depth of understanding about the topic to be assimilated. Rigour has been described as a means by which integrity and competence are demonstrated within a study (Tobin & Begley 2004). In qualitative analysis, the criteria for rigour are credibility, transferability, dependability and confirmability (Long 2000) (discussed further in chapter 6). These criteria were upheld throughout the analysis by being independently conducted by two researchers.

Ethical issues

The most pertinent ethical challenges in qualitative research stemming from the unpredictable nature of the methodology used are around informed consent, the relationship between the researcher and the participants, the ratio between risk and benefit, confidentiality and the dual role of the nurse-researcher (Houghton 2010).

There was a limitation of the study with regards to the informed consent. Although informed consent was taken, all study information including permission for consent had to be given on the first 'page' of the survey and it was not possible to provide a verbal explanation or to take verbal consent. However, as with any paper-based information sheet, the 'first page' of the survey identified who the researchers were, the reason for conducting the survey, what the survey data will be used for and anonymity of the survey. Participants had time to reflect after the information was presented and were given a choice to withdraw from the study at any point. Participants also understood that all data is anonymous and cannot be identified by anyone else but the researcher. This was ensured with allocating a participant number for each participant. An online copy of participant responses could only be accessed with a username and password. It was ensured that the printed copy of the participant responses (used in the analysis) did not contain any identifiable data.

The study was funded by Crohn’s and Colitis UK and the Scottish Government. NOS REC reviewed the study and the study received exemption from a formal ethical review.

Contribution to the research question

The conclusion of the study was that patients with IBD asked for a more holistic approach to their care and wanted a greater involvement of psychological services in their care to help with adaptation and living with IBD. Therefore, this chapter not only answered the question that there is a gap in the current IBD services for psychological input, but also provides an insight that there is a motivation and readiness amongst the IBD population for psychological therapies, a prerequisite for MBCT where part of the entry criteria for MBCT is the assessment of participants’ motivation. This was an important justification and foundation for the next question about examining the use of MBCT for patients with IBD and thereby provided the link for the next research step.

Chapter 4

Objective 3: To explore the feasibility and piloting of MBCT for patients with IBD

Chapter overview

The findings addressing Objective 2 and discussed in the previous chapter (Chapter 3), clearly suggested that patients with IBD across Scotland identify a strong need for integrating psychological and counselling help as part of their care. They highlighted that getting psychological help in the form of therapy or counselling could help with better symptom management. This need for psychological support stems from the information that many patients with IBD report to suffer from psychosocial difficulties, depression, anxiety and adjustment to living with the condition (as discussed in chapter 2). Thus, as a response to the highlighted need for psychological support in the previous chapter, the following chapter discusses and explores the use of mindfulness based cognitive therapy (MBCT), a particular psychological therapy. Before going into the description of the feasibility and piloting process of MBCT for patients with IBD, the first part of the chapter will discuss the origin of the concept of mindfulness, mindfulness theories, its use in medicine and how the mindfulness concept got incorporated into psychological interventions. The chapter will then present two papers, paper 4 and 5. This will be followed by an overview and critical reflection of both papers and their contribution to the research question.

What is mindfulness?

To discuss MBCT and its use for patients with IBD, it is important to first understand the mindfulness concept. The mindfulness concept has recently gained significantly increased attention in both clinical and experimental areas. The concept emerged from eastern spiritual traditions suggesting that mindfulness can be cultivated through regular meditation practice. The traditions suggest that through the cultivation of mindfulness, one will likely experience results in reduced suffering and an increase in positive personal qualities, such as awareness, insight, compassion, and equanimity (Goldstein 2002; Kabat-Zinn 2000).

In contemporary psychology and medicine, the mindfulness concept is taken out of the religious context and has been defined by a number of practitioners/researchers. One of the most popular definitions comes from Kabat-Zinn. He defines mindfulness as "a particular form of awareness that emerges from paying attention, on purpose, in the present moment, and nonjudgmentally to the unfolding of experience moment to moment" (Kabbat-Zinn 2003, p. 145). Kabat-Zinn was the first to incorporate mindfulness into medicine in the 70s (Kabbat-Zinn 1993). In addition, there are a few alternative definitions being used in the literature. For example, Brown and Ryan (2003) define mindfulness as the process of being attentive to what is taking place in the current moment. Bishop et al. (2004) goes on to say that mindfulness is about being present-centred, aware of all internal and external stimuli with the absence of elaborative and judgmental processes. An earlier definition by Linehan is even more descriptive. He refers to mindfulness as a series of skills including observing, describing and participating with a non-judgemental attitude, while focusing on one thing in the moment and paying attention to what is effective (Linehan 1993).

Despite the numerous definitions about mindfulness and the explosion of mindfulness research in the last decade, consensus about what exactly is the 'active' ingredient in mindfulness and what is necessary for its cultivation has not been reached. However, many researchers agree on the importance of present-centred attention in the absence of judgmental and elaborative processes (Brown & Ryan 2003). This absence of cognitive elaboration and judgment is the one that separates mindfulness from other forms of awareness such as private self-consciousness, self-awareness, and psychological mindedness (Brown & Ryan 2003; Beitel at al. 2005). The attitude and process of non-judgment and the absence of cognitive elaboration within mindfulness is believed to be the one that can interrupt the ruminative thought patterns and decrease incidence of depressive relapse, as theorised by Segal et al. (2002).

To better understand mindfulness as a construct, it can be contrasted with mindlessness. In comparison to mindfulness, mindlessness can be defined as when an individual operates much like a machine or robot; thoughts, emotions and behaviours. It means the person relies on 'programmed' routines based on similarities and associations learned in the past (Pirson et al. 2012). It is theorised that mindlessness is a state of mind often due to an over reliance on categories from past experiences and the tendency to apply previously formed attitudes to current situations. This locks the person into a repetitive, unelaborated approach to daily activities while being oblivious to novel or alternative aspects of a given situation (Langer 1992). Mindlessness is compared to more familiar concepts such as habit, functional fixedness, overlearning and automatic pilot (Langer 1992). In practice, an example of mindfulness could be eating a meal while immersing oneself into the all five senses while eating; experiencing the flavours, texture, smell, temperature or the sound made while eating the meal. In contrast, an example of mindlessness could be ‘shovelling’ handfuls of crisps into the mouth while watching TV. In the last example, many of the qualities of the food, such as smell, texture, flavour are never attended to due to engagement with another experience. While some argue that mindlessness is a necessity to get things done, at a closer inspection, the benefits of mindlessness are rarely there, due to the effect of freezing responses and preventing change (Langer 2000).

Mindfulness should also not be confused with other types of concentrative meditation that has been previously researched such as transcendental meditation (TM). Although some of the initial exercises in mindfulness include the concentration style of meditation (Kabat-Zinn 1994; Germer et al. 2013), the difference is that in TM, the awareness is focused upon a particular object, sound or so called ‘mantra’, which excludes all other aspects of the experience (Travis et al. 2010). In contrast, in mindfulness, the focus of the concentrative exercises is the practice of maintaining a clear and continuous focus as part of the self-regulation of attention (de Silva 1990; Fernandez & Goldberg 2009). Once an appropriate level of concentration is accomplished, the focus is then directed towards the immediate and ongoing stream of present experience while adopting curious, open, and accepting attitude. Because of the self-regulation of attention, Bishop et al. (2004) hypothesised that an increase in mindfulness should lead to an increase in the attentional abilities of *sustained attention*, or the ability to maintain a state of alertness over prolonged periods of time. In addition, Posner & Rothbart (1992) talk about the flexibility of attention or *switching*, where one can shift the focus of attention from one object to another. These qualities, combined with an *inhibition of secondary elaborative processing* (of thoughts, feelings, and sensations arising in response to a stimulus) (Posner 1990) and the open and *accepting attitude* towards all experiences, propose the hypothesis that mindfulness practice should lead to *less experiential avoidance* and improved *affect tolerance* and therefore lead to improvements in aspects of cognitive and emotional functioning (Bishop et al. 2004).

The non-religious adaptations of traditional mindfulness concepts and practices have been incorporated into a range of psychological interventions that conceptualize mindfulness as a set of core skills that can be learned and practiced to reduce suffering and increase well-being. One of the first of these interventions developed and applied in medicine was mindfulness-based stress reduction (MBSR), initially used with chronic pain sufferers (Kabat-Zinn 1982; Kabat-Zinn 1990). A further adaptation of MBSR with the addition of cognitive-behavioural therapy created mindfulness-based cognitive therapy (MBCT), which has been particularly successful with recurrent depression (Segal et al. 2002; NICE 2009). A further variation of the mindfulness concept has been used in other psychological therapies such as relapse prevention for substance abuse (Marlatt & Gordon 1985; Marlatt et al. 2001), dialectical behaviour therapy (DBT) (Linehan 1993a, 1993b) and acceptance and commitment therapy (ACT) (Hayes et al. 1999). The therapy of interest in this PhD enquiry is mindfulness based cognitive therapy.

What is Mindfulness Based Cognitive Therapy (MBCT)?

MBCT is an 8 week structured psychological group intervention that combines mindfulness meditation with cognitive therapy in order to alleviate suffering associated to depression, anxiety and psychosomatic concerns through becoming more aware of body sensations, thoughts and emotions (Segal et al. 2002). The program employs systematic procedures and exercises aimed at developing improved awareness of moment-to-moment experience of observable mental processes. The approach assumes that greater awareness will provide more truthful perception, reduce negative affect and improve vitality and coping with psychosocial stressors (Segal et al. 2002).

Although MBCT combines cognitive therapy with the existing MBSR (developed by Kabat-Zinn), MBCT differs from traditional cognitive therapy. In MBCT, thoughts are not being directly challenged like in cognitive therapy. Instead, the participants are taught to see their thoughts as mental events, not facts. Through distinguishing their thoughts within the framework of “thoughts are not facts” participants gradually become aware of the habitual thinking cycles. Once becoming aware of their habitual thinking patterns, participants can easily detect negative thinking patterns which may lead to depressive relapse without being caught up within them. This awareness of ones’ own thought patterns without the automatic and habitual responding allows participants to discover more skilful ways to deal with difficult thoughts and emotions (Segal et al. 2002). A full description of the MBCT curriculum is described in Chapter 5.

Conceptual models

So, how does MBCT work? Here are some of the most suggested models:

Exposure or desensitization

MBCT is derived from MBSR intervention and are both based in parts on traditional meditation practices, which often include extended periods of non-movement. While meditating, the meditator is sitting in the same position for prolonged periods of time and while a relaxed posture is usually adopted. Prolonged non-movement can lead to pain in muscles and joints. As part of mindfulness meditation practice, the instructor/facilitator often encourage students not to shift position to relieve the pain, but instead to direct the focus of attention directly on the pain sensations, while adopting a non-judgmental attitude toward these sensations. This non-judgemental attitude is further adopted towards any thoughts such as ‘this is unbearable’ and emotions such ‘anxiety or anger’ or any urges to shift position that may arise and often accompany pain. With each meditation, the meditator when experiencing pain, applies this non-judgemental attitude again and again, and with practice and time, the meditator becomes used to the experience of pain without necessarily having the emotions of anxiety or anger that would have accompanied the pain experience previously.

This principle of exposure and desensitization is used in psychology and was first developed by Mary Cover Jones for the treatment of anxiety and phobia in children and later further developed by John Wolpe in 1958 (Bernstein 2007). The core principle of exposure and the desensitization concept is for the person to be exposed (for prolonged periods) to a stimuli that can cause anxiety (pain in this case), but in a relaxed atmosphere. Being relaxed is the key. The rationale here is that you cannot have anxiety and relaxation at the same time, and therefore cultivating relaxation while in pain can bring absence of anxiety while in pain, and this may lead to desensitization and reduction to emotional responses elicited by the pain. Thus, mindfulness skill practice could lead to the ability to experience pain sensations without excessive emotional reactivity. Although pain sensations will not be reduced, the suffering and distress might be alleviated. The same principle works with anxiety and any other forms of distress caused by internal or external stimuli.

Cognitive Change

The cognitive change model explains that when the meditator applies the non-judgemental attitude, when observing pain and the anxiety related thoughts that often accompany pain, this may lead to an understanding and learning that those thoughts are ‘just thoughts’ not facts or reflections of the truth and reality (Kabat-Zinn 1990). For example feeling afraid does not necessarily mean that we are in imminent danger. With this understanding, the meditator realises that there is no need to escape or avoid situations (the fight and flight reaction). When the meditator understands and applies this principle in future practices and life situations, it becomes easier to see that thoughts are not facts and to respond to thoughts that arise from any stimuli in a way that is not going to cause further distress.

Teasdale (1999) and Teasdale et al. (2000) when describing MBCT, suggested that when the meditator notices depressive thoughts, instead of getting lost in the rumination process (process often associated with depression), due to the mindfulness skill training, the meditator can direct their attention to other aspects of the present such as breathing, walking, or environmental sounds and not allowing the rumination process to take over. Teasdale has described this perspective on one’s thoughts as a “metacognitive insight”, or cognition about cognition, where the meditator has the knowledge of when and how to apply particular knowledge for learning or problem solving. He further suggests that the practical advantage of mindfulness skills is that they encourage cognitive changes and can be practiced at any time and a mindful perspective about one's thoughts can be applied to all thoughts.

Self-management

The improved self-awareness and self-observation as a result of mindfulness training may promote the use of different coping skills. For example, Kabat-Zinn (1982) suggests that with increased awareness of pain sensation and stress responses to pain, individuals may develop and employ other coping responses that are not included in their treatment program. Teasdale (1995) further suggests that because with mindfulness training meditators become more aware of thoughts and emotions as they occur, the meditator can detect depressive thoughts and emotions at an earlier stage when it is easier to prevent relapse by using previously learned skills. Linehan (1993) points out that by learning to focus the meditator's 'mindfulness attention' on the present moment, the meditator develops a skill of controlling attention, a skill that might be useful for individuals that find it hard to complete tasks when they are distracted by worry, negative thoughts or emotions.

Acceptance

In psychotherapy, the central concept is the relationship between acceptance and change (Hayes et al. 2006). Hayes suggests that sometimes clinicians are very goal orientated and overemphasise the importance of changing all unpleasant symptoms without recognising the importance of acceptance. For example, individuals with panic attacks or pain may engage in maladaptive coping behaviours such as excessive drinking or non-prescribed drugs in order to avoid symptoms which can have negative consequences.

The concept of acceptance is particularly important for patients with IBD as it is a disease that is going to stay with the individual for the rest of their lives. Thus, acceptance is of higher importance, especially where things cannot be changed. MBCT training includes acceptance of pain, thoughts, feelings, urges, or other bodily, cognitive, and emotional phenomena, without trying to change, escape, or avoid them and can be seen as a method of teaching acceptance skills (Kabat-Zinn 1990).

Mindfulness based therapies in medicine

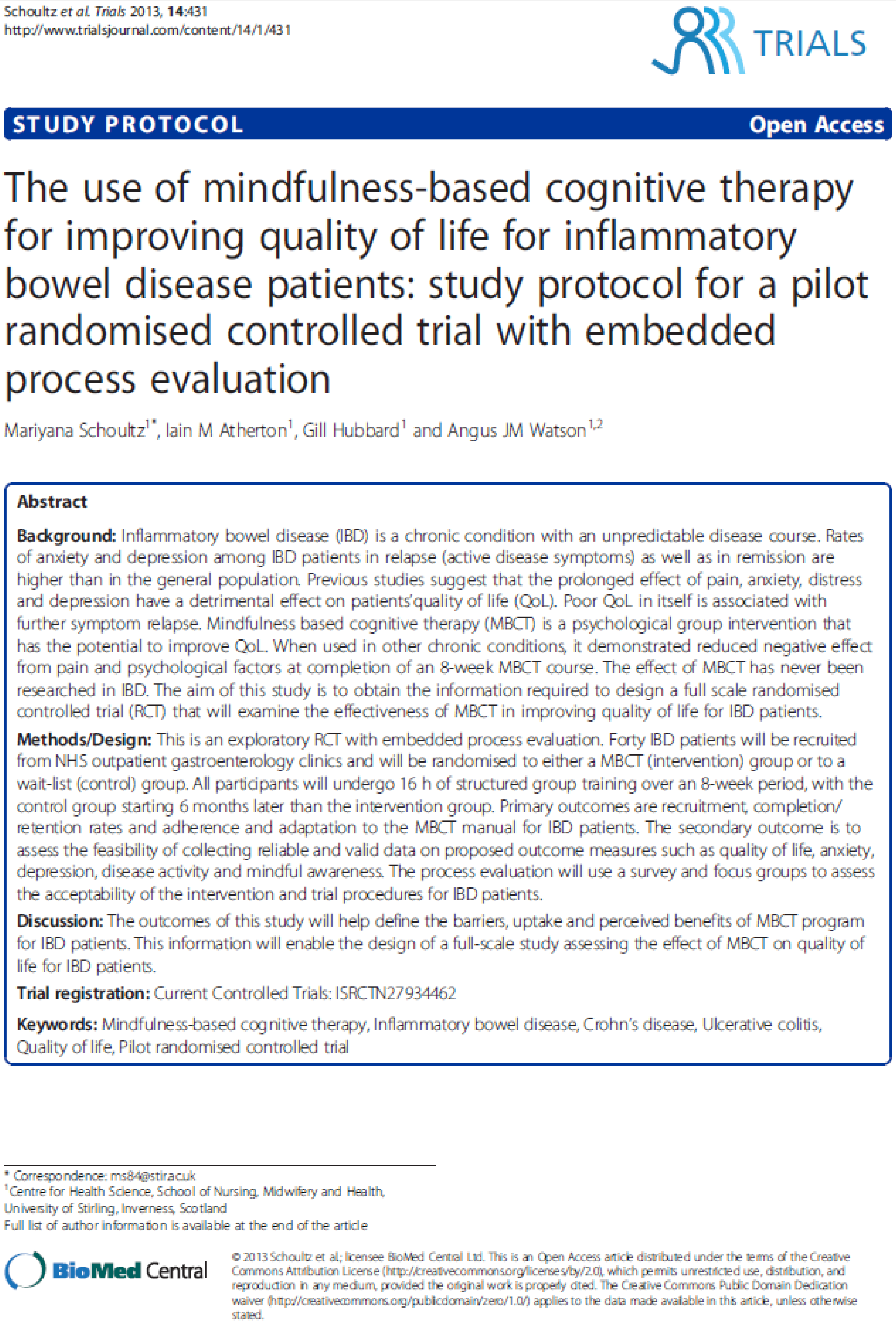
Although a definitive consensus is not reached on how mindfulness based therapies work, the list of studies researching the useful effect of mindfulness in psychology and medicine is ever growing. Previous studies have demonstrated effectiveness of MBCT for patients with depression (Kingston et al. 2007; Ma & Teasdale 2004; Teasdale et al. 2000; Williams et al. 2000). A systematic review and a meta-analysis of the effectiveness of mindfulness based interventions on anxiety, depression and psychological distress in patients with chronic pain conditions (Rosenzweig 2010) and chronic medical conditions (Bohlmeijer 2010) such as fibromyalgia, cardiac and cancer patients, have shown positive effect on anxiety, depression and psychological distress. A number of randomised controlled studies using mindfulness based therapies in other conditions have reported benefits on psychosocial problems (Zautra et al. 2008; Mularski et al. 2009; Fjorback et al. 2011; Grossman et al. 2004). Further to this, a recent prospective observational study examining the relationship between mindfulness, quality of life, depression and anxiety in UC patients, found positive associations between increasing mindfulness and reducing depression and anxiety (Jedel 2012).

While the usefulness of mindfulness based therapies has been explored in a variety of conditions as seen above, the relative effectiveness of MBCT has not been fully explored in IBD. As there is no sufficient information to use statistical techniques to measure the effectiveness of MBCT in IBD, (as mentioned in Chapter 1) the MRC guidance for complex interventions (Craig 2008) suggests designing and conducting an explorative pilot study in order to accumulate the needed knowledge. Thus, this was the purpose of aim 3 and paper 4 and 5.

Aim and linkage to research question

As mentioned in the introduction, the PhD started with a wide question ‘Can MBCT be used as an adjunct therapy to IBD symptom management for improving IBD patients' general well-being and quality of life?’ My first thoughts were that I would be examining the effectiveness of MBCT in IBD. However, after the literature searches, it was apparent that the only literature about similar psychological intervention used in IBD was about cognitive behavioural therapy (CBT). However, with CBT being an entirely different intervention, a literature gap about MBCT and IBD was discovered. Thus, according to the MRC guidelines for development and evaluation of complex interventions, feasibility and piloting work was required before investigating the effectiveness of an intervention (Craig 2008). Subsequently, this was the foundation for objective 3 and the consequent papers 4 and 5. Paper 4 is the protocol for an exploratory pilot RCT that identifies the specific objectives of a two phased trial. This paper is important in terms of peer review about methodology and external funding for the project, but also about transparency in the research process. Paper 5 reports on the feasibility and piloting work conducted, and discusses how realistic it is to have a definitive RCT that will examine the effectiveness of MBCT in IBD in the future. This paper is unique, as it is the first trial conducted exploring the use of MBCT in IBD and therefore makes a unique contribution to the field of evidence based practice.

Paper 4: The Use of MBCT for Improving Quality of Life for IBD Patients: Study Protocol



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TRIALS

STUDY PROTOCOL **Open Access**

The use of mindfulness-based cognitive therapy for improving quality of life for inflammatory bowel disease patients: study protocol for a pilot randomised controlled trial with embedded process evaluation

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Abstract

Background: Inflammatory bowel disease (IBD) is a chronic condition with an unpredictable disease course. Rates of anxiety and depression among IBD patients in relapse (active disease symptoms) as well as in remission are higher than in the general population. Previous studies suggest that the prolonged effect of pain, anxiety, distress and depression have a detrimental effect on patients'quality of life (QoL). Poor QoL in itself is associated with further symptom relapse. Mindfulness based cognitive therapy (MBCT) is a psychological group intervention that has the potential to improve QoL. When used in other chronic conditions, it demonstrated reduced negative effect from pain and psychological factors at completion of an 8-week MBCT course. The effect of MBCT has never been researched in IBD. The aim of this study is to obtain the information required to design a full scale randomised controlled trial (RCT) that will examine the effectiveness of MBCT in improving quality of life for IBD patients.

Methods/Design: This is an exploratory RCT with embedded process evaluation. Forty IBD patients will be recruited from NHS outpatient gastroenterology clinics and will be randomised to either a MBCT (intervention) group or to a wait-list (control) group. All participants will undergo 16 h of structured group training over an 8-week period, with the control group starting 6 months later than the intervention group. Primary outcomes are recruitment, completion/retention rates and adherence and adaptation to the MBCT manual for IBD patients. The secondary outcome is to assess the feasibility of collecting reliable and valid data on proposed outcome measures such as quality of life, anxiety, depression, disease activity and mindful awareness. The process evaluation will use a survey and focus groups to assess the acceptability of the intervention and trial procedures for IBD patients.

Discussion: The outcomes of this study will help define the barriers, uptake and perceived benefits of MBCT program for IBD patients. This information will enable the design of a full-scale study assessing the effect of MBCT on quality of life for IBD patients.

Trial registration: Current Controlled Trials: ISRCTN27934462

Keywords: Mindfulness-based cognitive therapy, Inflammatory bowel disease, Crohn's disease, Ulcerative colitis, Quality of life, Pilot randomised controlled trial

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Background

Inflammatory bowel disease (IBD) is a group of relapsing chronic gastrointestinal conditions characterised by inflammation of the gut [1,2]. The condition affects the normal function of the gastrointestinal system, resulting in symptoms such as bloody diarrhoea, vomiting, severe pain and malnutrition [3,4]. It affects approximately 250,000 people in the UK and 28 million worldwide with its incidence rising [5,6]. The two main types are Crohn's disease (CD) and ulcerative colitis (UC). While there is a concern about the increased risk of colorectal cancer in IBD patients [7], the main burden for patients is the relapsing course of the disease and its detrimental impact on psychosocial functioning and quality of life [8].

Anxiety, depression and quality of life in IBD

Anxiety and depression rates among IBD patients are higher than in the general population even in remission (when symptoms are settled) [9,10]. Previous studies have suggested that the prolonged effect of pain, anxiety, distress and depression have detrimental effects on quality of life (QoL) [11]. Poor QoL is further associated with symptoms relapse and additional clinical difficulties such as tissue inflammation [12,13]. Anxiety, depression and relapse thus links together in a self-perpetuating cycle with pernicious implications for those affected.

Use of medication for management of anxiety, depression and pain and its limitations

Evidence suggests that the use of antidepressants can have a positive effect on QoL and symptom management for IBD patients by reducing anxiety and depression [14-16]. This is encouraging. However, some patients using antidepressants have reported unpleasant side effects while others have reported that the antidepressants have no effect on their low mood or anxiety [17-19].

The use of painkillers for pain management also has its limitations. There are subgroups of IBD patients who irrespective of using anti-inflammatory and pain medication continue to suffer severe discomfort, again with a knock-on effect and making symptom exacerbation more likely [20].

In addition, poor medication compliance is frequently reported among IBD patients, with up to 40% of patients regularly omitting their prescribed medications [21,22]. Pharmacology is thus very limited. The search for alternative evidence-based approaches is a pressing concern.

Mindfulness based cognitive therapy

Mindfulness based cognitive therapy (MBCT) is a non-pharmacological psychological group program designed by Segal et al. [23]. The MBCT program is largely based on the mindfulness-based stress reduction (MBSR) program developed by Jon Kabat- Zinn for coping with stress and chronic illness [24]. Both programs involve teaching individuals various stress management, relaxation, self-care and self-help techniques in a systematic way over an 8-week period. In both, the core skill taught is mindfulness, which uses meditation practice to increase attention and awareness [25]. The working definition of mindfulness in the program is: 'The awareness that emerges through paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding of experience moment by moment' [26]. The main difference to the MBSR program is that MBCT has combined cognitive therapy exercises with the mindfulness skill. This combination is believed to further enable patients to increase their awareness and facilitate early recognition of any recurring unhelpful thinking patterns often associated with depressive symptoms and anxiety [23]. Hence, the National Institute for Health and Care Excellence guidelines makes a recommendation for the use of MBCT program as a psychological intervention in the 'clinical management of persistent sub threshold depressive symptoms or mild, moderate or severe depression in adults (including people with a chronic physical health problem)' [27].

Although the exact mechanism of how mindfulness-based interventions work is not yet fully understood, the evidence so far suggests that at program completion, participants would experience reduced negative effects from pain, distress, anxiety and depressive symptoms. For example, a systematic review and a meta-analysis of the effectiveness of mindfulness-based interventions on anxiety, depression and psychological distress in patients with chronic pain conditions [28] and chronic medical conditions [29] such as fibromyalgia, cardiac and cancer patients, have shown positive effect on anxiety, depression and psychological distress.

An observational study examining the relationship between mindfulness, QoL, depression and anxiety in patients with ulcerative colitis found a positive association between increasing mindfulness and reducing depression and anxiety [30]. However, MBCT and its effect on QoL has never been researched in a RCT with both Crohn's and ulcerative colitis patients.

Thus, the MBCT program may be the therapy that can provide a relief from the negative effects of a lifelong management of the disease for IBD patients.

Hypothesis

The hypothesis is that MBCT will improve QoL scores for IBD patients as well as improve anxiety and depressive symptom scores. This hypothesis is based on previous studies using mindfulness based programs in other chronic condition populations. Hence, the proposed pilot study is the first step towards testing the hypothesis in a definitive RCT and gathering the necessary knowledge to close the existing evidence gap regarding the usefulness of MBCT for IBD patients.

Aims and objectives

The overall aim of this study is to pilot the MBCT program with IBD patients in a RCT and examine the feasibility of running a large RCT testing the above hypothesis.

The specific objectives of the pilot are:

1. To determine the feasibility of conducting a large-scale RCT of group MBCT for improvement of IBD QoL.
2. To adapt the intervention manual devised by Segal et al. [31], outlining how to carry out an MBCT program for IBD patients.
3. To use data arising from differences between MBCT and control arm to inform a power calculation for sample size of a definitive RCT.
4. Estimate trial eligibility, recruitment (percentage of IBD patients who consent to the trial) and completion/retention rates (percentage of participants completing the trial).
5. To embed a process evaluation within the pilot trial to assess the acceptability of the intervention and trial procedures for IBD patients, such as:
   a. Acceptability of recruitment, randomisation and consent procedure
   b. Acceptability and feasibility of collecting reliable and valid data on primary and secondary outcomes (including follow-up at 6 months)
   c. Fidelity of intervention.
   d. Acceptability of length of intervention
   e. Appropriateness/suitability of the intervention used
   f. Barriers to attendance
   g. Expectations about intervention
   h. Perceived impact on QoL

Methods and design

Design

This exploratory trial is designed in two phases. Phase 1 is a two-arm pilot RCT (MBCT treatment *vs.* wait-list control group) with three assessments (baseline, post treatment and 6 months). Phase 1 will assess eligibility, uptake, drop-out rates and sample size calculation as well as adaptation and adherence to MBCT manual. This design is consistent with similar studies where a non-pharmacological intervention is investigated in IBD population [32-38].

Phase 2 is a process evaluation assessing the feasibility and acceptability of the intervention, primary and secondary outcomes and trial procedures as well as barriers to attendance and perceived benefits to patients. This design is in line with the Medical Research Council (MRC) framework for the development and evaluation of complex interventions to ensure that both the intervention and trial procedures are optimised and can be incorporated into routine clinical practice [39].

Setting and recruitment

The study will take place across two health board areas in the north of Scotland, an area comprising of approximately 800,000 people living across a large geographical area including urban and remote rural locations. Recruitment will focus on gastroenterology outpatient clinics.

Phase 1 - Pilot RCT

Participant selection

Less than one-third of RCTs recruit to proposed number [40]. Assessing recruitment is a key component of this study. Ensuring an effective recruitment strategy is thus important. Accordingly, the recruitment strategy devised in this study draws on best evidence [41] tailored to the specific requirements of people with IBD. Specific aspects of the recruitment strategy were developed in collaboration with all parties involved in the care of IBD patients, namely specialist IBD nurse, gastroenterology clinicians and research nurses.

Clinical staff at participating gastroenterology outpatient clinics will identify people who meet the study's inclusion criteria. They will approach consecutive patients in clinics or by sending an invitation letter with study information and research team contact details. Interested participants will then contact the researcher by telephone or email to register interest. A screening visit with the researcher will then be arranged. Informed written consent will be obtained at the first visit by a member of the research team.

Inclusion criteria

1. Be able to verbally communicate and write in English (English does not have to be their first language).
2. Able to give informed consent.
3. Age of 18 years or over (no upper limit).
4. Confirmed diagnosis of Crohn's disease or ulcerative colitis (by clinician).
5. Ability to do light exercise (for example, to lift arms above the head or bend knees) because part of the practices in the program require this movement.
6. Able to commit to attend the eight sessions (participants should consider their personal circumstances to assess if this is practical and feasible for them).
7. To be able to commit to do home practice of up to 45 minutes daily over the 8 weeks of the study (this is a core component of the program).

8. No change of antidepressants (dose or type) within the last 3 months. Any change of antidepressants within the last 3 months might interfere with the program.
9. Participants will have to be in remission of symptoms.

Exclusion criteria

Anyone not meeting the above criteria by definition will be excluded from the study. In addition, the following exclusion criteria will apply:

1. Major psychiatric illness. The treatment for a major psychiatric illness may interfere with the program.
2. Active alcohol or drug dependency. Any alcohol or drug dependency may interfere with the program.
3. Scheduled for major surgery in the next 3 months. Any scheduled surgery within the next 3 months will interfere with the program schedule.
4. Participation in a pharmacological study or psychological intervention study within the last 6 months or intention to participate in a pharmacological study during the duration of this study. Both will interfere with the program.
5. Have recently (within the last 3 months) been prescribed antidepressants. Any change of antidepressant in the last 3 months may interfere with the program.
6. With exacerbated symptoms (acute phase). Having exacerbated symptoms will make it very difficult for participants to attend the two hourly sessions or to commit to the home practice. This could cause extra unwanted stress for the patient.

Randomisation

Randomisation will be performed using a dedicated software solution after participants have given written consent and baseline data have been collected. Group allocation will be to 'MBCT group' or 'wait-list control group' in a 1:1 ratio. To ensure similarity between the groups, randomisation will take account of gender and type of disease. The randomisation will be carried out by an independent statistician.

Minimising bias

Participants will self-complete all the questionnaires. Data entry will be done by the lead researcher and independently checked by a second person. Data analysis will be done by two researchers independently and differences will be rectified by a third person.

MBCT intervention

The MBCT program used in this study will follow the manual developed by Segal et al. [31]. In brief, the manual proposes the following format for the eight group sessions:

- Welcome and introduction to the session theme
- A short opening meditation
- A discussion of at-home practice
- An introduction and practice of new exercises
- A group reflection/discussion
- A review of the next weeks' at-home practice
- A closing sitting meditation

A sample list of activities for session 1 is presented below. The manual also suggests for an additional full day of mindful practice to take place between weeks 6 and 7 (usually on a weekend). In the full day of practice participants will go through all the learned meditations one after another in silence, with the group reflection and discussion taking place at the end of the practice day. An example schedule for a day of mindful practice is presented below. Due to resource constraint, in this study, the full day of practice will be offered to participants after they have completed the 8-week course.

A sample list of activities for session 1

Theme: Awareness and automatic pilot

1. Establish the orientation of the class
2. Set ground rules regarding confidentiality and privacy
3. Ask participants to pair up and introduce themselves to each other than to the group as a whole, giving their first names and if they wish, saying what they hope to get out of the program
4. The raisin exercise
5. Feedback and discussion of the raisin exercise
6. Body scan practice-starting with short breath focus
7. Feedback and discussion of body scan
8. Home practice assignment:
    - Body scan for 6 out of 7 days
    - Mindfulness of a routine activity
    - Distribute audio files: cd's for those that not have email and session 1 participant hand-outs.
9. Discuss in pairs:
    - Timing for home practice
    - What obstacles may arise
    - How to deal with them
10. End the class with a short 2–3 minute focus on the breath.

Example schedule for a day of mindful practice [35]

9.45-10.00 Arrival
10.00-10.05 Sit in silence
10.05-10.20 Welcome, introduction, ground rules

10.20-10.50	Siting meditation: Breath, body, sounds, thoughts and choiceless awareness
10.50-11.30	Mindful stretching
11.30-12.00	Body scan
12.00-12.05	Instruction for lunchtime: bringing focus on awareness of eating, tasting, chewing, swallowing, slowing down
12.05-13.05	Lunch followed by mindful walk
13.05-13.20	Sitting meditation
13.20-13.50	Walking meditation
13.50-14.20	Mountain meditation
14.20-14.40	Mindful stretching
14.40-15.00	Silent sit or extended breathing space
15.00-15.30	Feeding back experience of day in pairs
15.50-16.30	Large group discussion and close

The program will be delivered by two experienced MBCT practitioners that have been briefed on the key concerns and difficulties that IBD patients experience as well as the nature of the disease. An experienced practitioner will have completed an 8-week MBCT course and maintained a personal practice for at least 1 year. In addition they will have facilitated at least one 8-week MBCT program.

Participants will be encouraged to do daily home practice for the duration of the program and keep a home practice diary. Participants will be provided with guided practice CDs and hand-outs with a written summary for each session and instruction for home practice. Each weekly session will be approximately 120 minutes and will be audio recorded.

Wait-list control

The control group will continue to receive their standard care and in addition will receive a leaflet entitled 'Staying well with IBD'. The leaflet is readily available to download from the Crohn's and Colitis UK website, but participants in the study will receive a printed copy [42]. After 6 months follow-up data are collected; the wait-list group will have an opportunity to attend a MBCT program if they wish.

Data collection

A screening and recruitment log will be completed by a researcher to document all patients considered for the study and subsequently included or excluded at each stage of the recruitment process with reasons given. This log will include information such as date when information was given about the study, and date of recruitment and randomisation. The data will inform the estimate for recruitment rates for a full trial and address aims 1 and 4. A full consort diagram of subject flow is presented in Figure 1.

At baseline, demographic information including age, gender, education, income and marital status will be recorded, to allow the success of randomisation to be assessed [43].

The MBCT practitioners will complete an attendance log to document the number of practice sessions attended by each participant. This log will inform the estimated attrition rates for a full trial and will address aim 3.

Semi-structured interviews with the practitioners delivering the MBCT intervention will be conducted to find out if any changes to the manual should be done to accommodate the needs of this patient group. This will address aim 2.

Outcomes and assessments

The outcomes for this study are consistent with relevant published studies assessing the use of mindfulness-based program in populations with chronic health problems [44] as well as with studies investigating the effects of non-pharmacological programs on QoL in IBD patients [35,36,45]. They include assessment of disease specific QoL, mood, mindful awareness, disease activity and demographics. All assessment tools used in the trial are validated and reliable. All outcomes will be assessed at baseline, post treatment and 6 months.

Proposed primary outcome

Quality of life All participants will be required to complete the disease specific IBD quality of life (IBDQoL) questionnaire consisting of 32 questions. The questionnaire has four domains, including bowel symptoms, systemic symptoms, emotional factors and social factors. Within the questionnaire, participants will rate their symptom experience over the previous 2 weeks. Low scores indicate more severe disease activity and/or higher emotional and social dysfunction. A relatively good correlation between the IBDQoL and a widely used measure of disease activity, the Crohn's Disease Activity Index is reported ($r = -0.67$; $P < 0.001$) [46,47].

Proposed secondary outcomes

Anxiety Anxiety will be measured by the State and Trait Anxiety Inventory (STAI) Y1 and Y2 form, consisting of 40 questions on a self-report basis. The inventory measures two types of anxiety: anxiety related to an event and anxiety level as a personal characteristic. Higher scores are positively correlated with higher levels of anxiety [48]. This tool is widely used to measure anxiety and regarded as highly reliable [13].

Depression Low mood and depression symptoms will be measured with the Beck's depression inventory (BDI-II), consisting of 21 group of statements referring to the last 2 weeks. Each answer is being scored on a scale value of 0 to 3. Higher total scores indicate more severe depressive

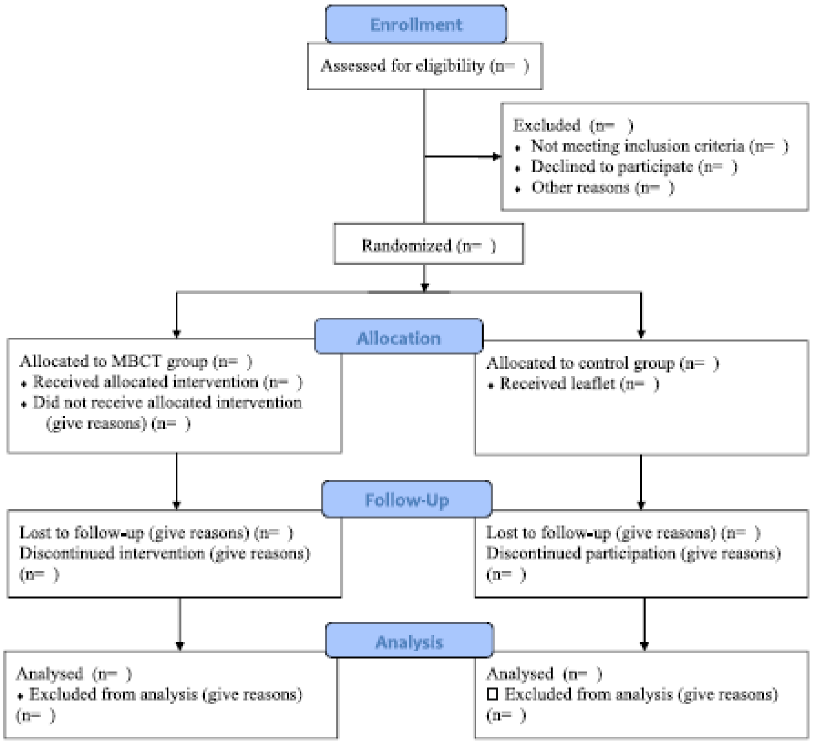

Figure 1 Consort diagram describing flow of patients through study.

symptoms. Previous studies indicate the internal consistency of the BDI-II is high [49,50].

Disease activity Disease activity will be measured with the eight-item questionnaire Crohn's Disease Activity Index (CDAI) for Crohn's patients [51,52] and six-item questionnaire Simple Clinical Colitis Activity Index (SCCAI) for ulcerative colitis patients [53]. Both tools are widely used to measure disease activity with IBD patients.

Mindful attention Mindful attention will be measured with the 15-item scale Mindful Attention Awareness Scale (MAAS). This scale consists of collection of statements about everyday experiences graded by participants, using a scale of 1 to 6 which indicates how often each experience occurs. Higher scores reflect higher levels of dispositional mindfulness. The validation of this tool has been examined in a series of studies indicating strong psychometric properties and validity [54,55].

Phase 2 - Process evaluation

To address aim 5 and examine the implementation and receipt of the intervention and trial procedures, a detailed process evaluation will be undertaken. This evaluation process will assess the acceptability of recruitment, randomisation and consent procedure for patients, acceptability and feasibility of collecting reliable and valid data on primary and secondary outcomes, fidelity of protocol, acceptability of length of intervention for patients, appropriateness/suitability of the intervention used, barriers to attendance, expectations about intervention and perceived impact on QoL.

Observations of MBCT training sessions will be undertaken by audio recording of all sessions to assess if specific components of the protocol are delivered and to use the qualitative data to assess the appropriateness of the intervention used. These data will address aim 5c.

All participants will be asked to self-complete a postal survey asking their views on research procedures such as consent and randomisation procedures and reliability of questionnaires. The MBCT group will answer further questions on expectations, acceptability, appropriateness and perceived impact of the intervention as well as the length of the program. These data will address aims 5a, 5e, 5f, 5g and 5h.

A post-intervention focus group will be facilitated to further explore the participants' views and experiences of the MBCT program and trial procedures, using the themes from the survey. The focus groups will be audio recorded. A list of topic guides for the focus group is presented below.

List of topic guides for the focus groups

Expectations

1. Did you have any expectations regarding the self-help program?
2. If yes, what were they?
3. Were your expectations met/ unmet in any way? And How?

Length and difficulty of program

4. Was the length of eight weeks for the program acceptable?
5. Did you find the program difficult to follow?
6. Please tell us which specific parts of the program you found difficult to follow.

Potential benefits

7. Do you think this program has brought any benefit to you?
8. Please tell us how you think the program benefited you.
9. Do you think you will continue to use some of the techniques you learned in the program?

Recruitment and randomisation

10. Do you think the process of recruitment was acceptable?
11. Do you think the patient information sheet was easy to understand?
12. Any suggestions to make it clearer to understand
13. Did you feel comfortable with the process of consent and randomisation?

Questionnaires

14. Was filling the questionnaires at the start and at the end of the eight weeks too much of a burden?
15. Can you please tell us what difficulties you came across with the questionnaires and perhaps any suggestions of how to overcome those difficulties

Barriers to attending

16. Were there any barriers to attending the program?
17. Can you please tell us what you think were barriers to attendance?

What did you enjoy?

18. Did you enjoy the program?
19. Which parts did you most enjoy?

Availability of MBCT program

20. Do you think this program should be made available to IBD patients through NHS?

Ethical and research and development approval

A favourable ethical opinion was obtained from NRES Committee for North of Scotland on 8th April 2013 (REC ref 13/NF/0018). NHS Highland and NHS Grampian R&D Management Approval was obtained on 9 April 2013 and 14 September 2013, respectively.

Sample size

The nature of this study is a pilot RCT. Thus, a formal sample size calculation was not performed. The determined sample size of $n = 40$ was calculated based on the estimated number of participants expected to complete the 8-week program.

This number was achieved by the following calculation. Recommendation for pilot sample size calculation is 30 [56,57]. Literature suggest that attrition rate of approximately 25% is to be reasonably expected in mindfulness intervention studies [58]. A sample size of 40 with a 25% attrition rate will give an estimated sample of 30 subjects completing the 8-week program.

The approximate number of IBD patients is 600 in NHS Highland and 1,741 at NHS Grampian. With estimated recruitment rates of IBD interventional studies ranging between 10% and 20% (234 to 468 between the two sides), a sample size of 40 is reasonably achievable.

Analysis

Audio-recorded focus groups and interviews with practitioners will be transcribed verbatim. Transcripts will be analysed thematically using the framework analysis approach [59] which is a rigorous method that allows themes to be identified (and organised) within the groups or between the groups. Hence, notable differences in experiences and perceptions can be identified.

From quantitative data we will generate the following: estimates of eligibility, recruitment and retention rates, speed of recruitment, and completion rates of study assessment tools (objectives 1 and 4); Descriptive presentations of the proposed primary and secondary outcomes will be made to inform a sample size calculation for a large-scale trial and decisions as to whether their inclusion would be informative in a future trial (objective 3).

Discussion

There is increasing evidence that mindfulness-based interventions can provide benefits to people with chronic ill health in terms of improving QoL and reducing anxiety and depressive symptoms. However, the use of these interventions in patients with both CD and UC is not researched. This paper outlines a protocol for a pilot RCT with embedded process evaluation that aims to provide data on eligibility, uptake and retention rates, barriers to recruitment and attendance and perceived benefit to IBD patients. This information is required to design a full-scale RCT assessing the effectiveness of MBCT on QoL for IBD patients.

This study is the first RCT to examine the use of MBCT in patients with IBD. The study design is a multicentred RCT and uses robust methods to evaluate feasibility and acceptability of the intervention in patients with IBD. The 6-month follow-up data will give an indication as to how long (if any) benefit from the intervention would last. The type of information that will be collected from the evaluation process will give an insight into important questions such as participants' subjective thoughts and experiences about the intervention (expectations, potential benefits, barriers to attending and availability of the program through NHS) as well as their feedback on recruitment process and procedures.

In addition, the results of this project will provide important information on integration of mindfulness-based interventions with usual medical care as well as application of MBCT for IBD.

Trial status

Recruitment commenced in May2013 and is ongoing.

Abbreviations

BDI-II: Becks depression inventory; CD: Crohn's disease; CDAI: Crohn's disease activity index; IBD: Inflammatory bowel disease; IBDQoL: Inflammatory bowel disease quality of life; MAAS: Mindful attention awareness scale;
MBCT: Mindfulness-based cognitive therapy; MBSR: Mindfulness-based stress reduction; MRC: Medical Research Council; QoL: Quality of life;
RCT: Randomised controlled trial; SCCAI: Simple clinical colitis activity index;
STAI: State and trait anxiety inventory; UC: Ulcerative colitis.

Competing interests

The authors declared that they have no competing interests.

Authors' contributions

All authors have contributed to the design of the study and the preparation of the draft manuscript. MS as chief investigator and grant holder, co-conceived the study, drafted the study protocol and study materials, applied for ethics and NHS R&D approvals, and drafted the manuscript; AJMW co-conceived the study and participated in the design of the study and study materials, statistical planning and revision of the manuscript. GH contributed to the design of the study, particularly with the conceptualisation of the theory for the process evaluation and commented on the draft manuscript. IA provided the statistical analysis plan and commented on the draft manuscript. All authors read and approved the final manuscript.

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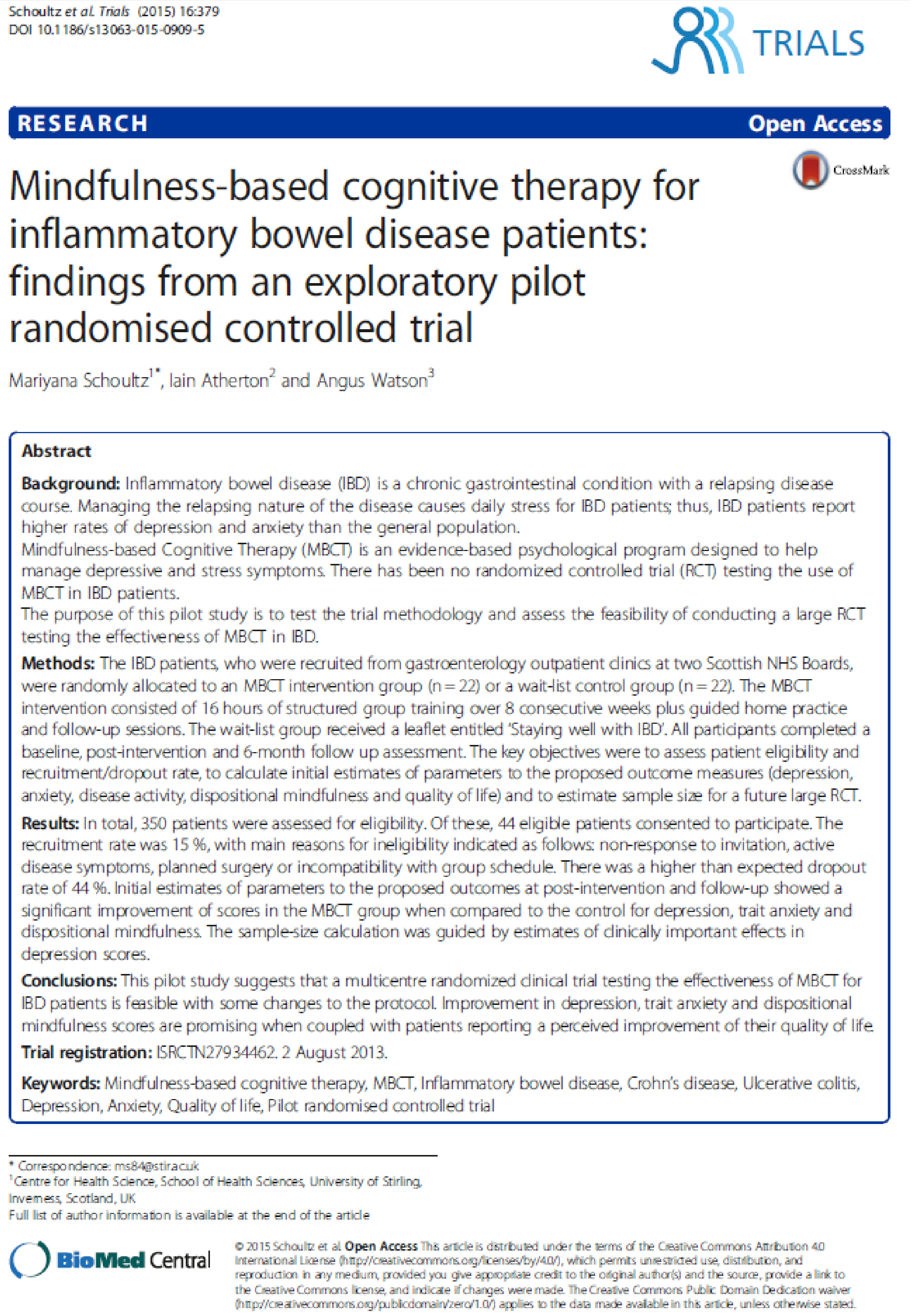

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TRIALS

RESEARCH **Open Access**

Mindfulness-based cognitive therapy for inflammatory bowel disease patients: findings from an exploratory pilot randomised controlled trial

Mariyana Schoultz[1*], Iain Atherton[2] and Angus Watson[3]

Abstract

Background: Inflammatory bowel disease (IBD) is a chronic gastrointestinal condition with a relapsing disease course. Managing the relapsing nature of the disease causes daily stress for IBD patients; thus, IBD patients report higher rates of depression and anxiety than the general population.
Mindfulness-based Cognitive Therapy (MBCT) is an evidence-based psychological program designed to help manage depressive and stress symptoms. There has been no randomized controlled trial (RCT) testing the use of MBCT in IBD patients.
The purpose of this pilot study is to test the trial methodology and assess the feasibility of conducting a large RCT testing the effectiveness of MBCT in IBD.

Methods: The IBD patients, who were recruited from gastroenterology outpatient clinics at two Scottish NHS Boards, were randomly allocated to an MBCT intervention group (n = 22) or a wait-list control group (n = 22). The MBCT intervention consisted of 16 hours of structured group training over 8 consecutive weeks plus guided home practice and follow-up sessions. The wait-list group received a leaflet entitled 'Staying well with IBD'. All participants completed a baseline, post-intervention and 6-month follow up assessment. The key objectives were to assess patient eligibility and recruitment/dropout rate, to calculate initial estimates of parameters to the proposed outcome measures (depression, anxiety, disease activity, dispositional mindfulness and quality of life) and to estimate sample size for a future large RCT.

Results: In total, 350 patients were assessed for eligibility. Of these, 44 eligible patients consented to participate. The recruitment rate was 15 %, with main reasons for ineligibility indicated as follows: non-response to invitation, active disease symptoms, planned surgery or incompatibility with group schedule. There was a higher than expected dropout rate of 44 %. Initial estimates of parameters to the proposed outcomes at post-intervention and follow-up showed a significant improvement of scores in the MBCT group when compared to the control for depression, trait anxiety and dispositional mindfulness. The sample-size calculation was guided by estimates of clinically important effects in depression scores.

Conclusions: This pilot study suggests that a multicentre randomized clinical trial testing the effectiveness of MBCT for IBD patients is feasible with some changes to the protocol. Improvement in depression, trait anxiety and dispositional mindfulness scores are promising when coupled with patients reporting a perceived improvement of their quality of life.

Trial registration: ISRCTN27934462. 2 August 2013.

Keywords: Mindfulness-based cognitive therapy, MBCT, Inflammatory bowel disease, Crohn's disease, Ulcerative colitis, Depression, Anxiety, Quality of life, Pilot randomised controlled trial

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Background

Impact of physical symptoms

Inflammatory bowel disease (IBD) is a group of idiopathic, chronic and disabling gastrointestinal conditions with a relapsing disease course. The two main types are Crohn's disease (CD) and ulcerative colitis (UC), both characterised by symptomatic periods (flare-ups) combined with less-symptomatic periods (remission) [1]. IBD symptoms are caused by inflammation of the intestinal mucosa (the lining of the gut), and the most common symptoms are bloody diarrhoea, vomiting, severe pain and malnutrition [2, 3].

Managing and learning to cope with the relapsing nature of the disease causes daily stress for IBD patients. As a result, high rates of IBD patients report anxiety and depression not only when in symptomatic periods, but even in remission [4, 5]. The prolonged effects of pain, anxiety and depression have damaging effects on psychosocial functioning and quality of life (QoL) [6]. Poor quality of life is further associated with symptom relapse [7, 8]. Thus, anxiety, depression and relapse appear to be concomitant in a self-perpetuating cycle with devastating effects for IBD patients.

Current management and limitations

Medication is the first line of treatment for patients with IBD. The therapeutic goal is to induce disease remission and keep symptoms at bay for as long as possible [9]. In addition, antidepressants are used for reducing distress, anxiety and depression [10–12]. However, the medication approach on its own is not without limitations. Firstly, it is reported that up to 40 % of IBD patients regularly omit their prescribed medications with a third of IBD patients still developing flare-ups even when complying with prescribed medication [13, 14]. Further to this, those using antidepressants often report unpleasant side effects while others report that antidepressants have no effect on their low mood or anxiety [15–17].

These limitations are a cause for concern and have prompted researchers and clinicians to look at other possible ways of symptom management and improving psychosocial functioning.

Accordingly, an alternative evidence-based therapeutic approaches focusing on stress management could have the potential to manage disease flare-ups and ultimately improve overall QoL [18–21].

Mindfulness-based cognitive therapy

Mindfulness-based cognitive therapy (MBCT) is an evidence-based psychological group program designed to help manage stress and depressive symptoms [22, 23]. The core skill taught in the program is mindfulness, which is developing a non-judgemental awareness of one's own thoughts, emotions, body sensations and their interactions. The mindfulness skill is taught via a series of meditation practices, cognitive behavioural exercises and discussions [24]. The MBCT program curriculum is structured and delivered over 8 weeks in a group setting. Through practicing the curriculum exercises in the group and at home, participants gradually develop better awareness and understanding of their individual responses to stress (psychological or physical) and learn new alternative ways to respond to stress. The evidence suggests that at program completion, participants would experience reduced negative effects from pain, distress, anxiety and depressive symptoms [25].

The clinical effectiveness of mindfulness-based therapies is evident in chronic pain conditions [26] and chronic medical conditions [27] such as fibromyalgia, cardiac and cancer patients, tinnitus and chronic fatigue syndrome [28, 29]. Mindfulness-based intervention has an anti-inflammatory effect on pro-inflammatory cytokine profiles in patients with prostate and breast cancer [30]. Systematic review and a meta-analysis of the effectiveness of mindfulness-based interventions on anxiety, depression and psychological distress in patients with chronic conditions have shown positive effects [31, 32]. Hence, the National Institute for Health and Care Excellence guidelines recommends the MBCT program as a preferred psychological therapy in the 'clinical management of persistent sub-threshold depressive symptoms or mild, moderate or severe depression in adults (including people with a chronic physical health problem)' [33].

A recent RCT suggests that mindfulness-based therapy has some benefit on IBD patients with IBS-like symptoms [34] and mindfulness-based therapy might be useful for UC patients with high stress reactivity [35]. However, MBCT and its effect on depression, anxiety and QoL have never been researched in a RCT with both Crohn's and ulcerative colitis patients.

Due to the literature gap, and in accordance with the MRC guidance for development and evaluation of complex interventions [36], the aim of this study was to pilot the mindfulness-based cognitive therapy (MBCT) program with inflammatory bowel disease (IBD) patients and to evaluate the feasibility of conducting a full-scale RCT that will test the effectiveness of MBCT for IBD patients. The specific objectives were as follows:

1. Objective one was to assess eligibility and recruitment/dropout rate.
2. Objective two was to obtain initial estimates on parameters of the proposed outcome measures (depression, anxiety, quality of life, mindfulness and disease activity).
3. Objective three was to estimate a sample size for a large scale RCT.

Methods

Design and ethics

This study was a two-centre, two-arm, exploratory pilot RCT (MBCT treatment versus wait-list control group) with three assessments (baseline, post-treatment and 6 months). The full protocol of the study reported in this paper is the phase 1 of a two-phase pilot RCT described elsewhere [37]. Phase 2 will be reported separately. There were no deviations from the previously described protocol. All pilot data were collected between April 2013 and March 2014. The study was approved by the North Research Ethics Committee for North of Scotland on 8 April 2013 (REC ref 13/NF/0018). NHS Highland and NHS Grampian R&D Management Approval was obtained on 9 April 2013 and 14 September 2013, respectively. The trial was registered on the ISRCTN register (ISRCTN27934462) on 02 August 2013.

Setting and recruitment

The study took place across two national health boards in the north of Scotland, a broad geographical area comprising urban and remote rural locations with approximate population of 800,000 people. Recruitment focused on outpatient gastroenterology clinics in the two areas.

Between May and October 2013, clinical staff at participating gastroenterology outpatient clinics scanned and identified potential participants that met the study inclusion criteria. Then, either study invitation packs were sent to patients with researchers contact details or patients seen consecutively in clinics were approached with the study information. All study information was co-designed with patients from the patient-involvement group [38]. Interested participants then registered their interest with the researcher by telephone or email. This was followed up with a screening visit with the researcher and then informed written consent was obtained. The inclusion criteria were broad enough to allow the sample to be representative of those diagnosed with IBD. Patients were excluded if they had a major psychiatric illness or alcohol dependency, were scheduled for surgery during the study period; if they were participating in other pharmacological or psychological intervention study or had a recent change of antidepressants or exacerbated symptoms. A full list of inclusion and exclusion criteria is in Additional file 1.

Randomisation

Randomisation was performed after all participants had given written consent and baseline data had been collected. Participants were randomly allocated to the intervention 'MBCT group' or 'wait-list control group' in a 1:1 ratio. To ensure similarity between the groups, randomization was stratified on two variables - disease type and sex. Random allocation was computer generated. A permuted block randomization procedure with randomly varied block sizes was used. Blinding of researchers and patients was not possible because the intervention involved attending a course. Participants were informed of the results of randomization by email or letter (depending on their preference).

Minimising bias

Bias can occur at any stage of planning, data collection, analysis or publication [39]. The following steps were taken to minimise systematic errors or bias and improve rigour: all participants self-completed all of the questionnaires, data entry was done by the lead researcher and was independently checked by a second person, and data analysis was done by two researchers independently.

MBCT intervention

The MBCT program used in this study closely followed the 8-week MBCT manual developed by Segal et al. [23]. It comprised 8 weekly face-to-face group sessions, each lasting approximately 2 hours. The sessions included facilitator instruction, group practice and instructions for home practice. In brief, the manual followed a similar layout for each session and opened with introduction to a new theme (see Additional file 2 for themes), followed by short opening meditation and discussion. The group was then introduced to a new practice/exercise, which was followed by reflection, then review and instruction for at-home practice and followed by sitting meditation. A sample list of activities for session 1 is presented in Additional file 3.

The type of practices used in the MBCT curriculum are a combination of formal exercises/meditations such as body scan, sitting and walking meditation and mindful stretching; cognitive behavioural exercises and informal practices and discussions with personal reflections of everyday life events. A sample audio file of one of the meditations is available in Additional file 4.

Part of the intervention involved home practice assignments aimed at reinforcing the in-group learned techniques and strategies. The recommended home practice was up to 45 minutes a day for 6 days a week, with guided audio CD and outlined instructions for the home practice. The hand-outs and audio CD's used for home practice are ready available from the published books respectively [23, 40].

To further reinforce the learned practices, the manual suggests that an additional full day of mindful practice take place between weeks 6 and 7 (usually on a weekend). In the full day of practice participants go through all the learned meditations one after another in silence, with the group reflection and discussion taking place at the end of the practice day. Due to resource constraint, in this study, the full day of practice was offered to participants after they have completed the 8-week course.

The program was delivered by two experienced MBCT practitioners who have been briefed on the key concerns and difficulties that IBD patients experience, as well as on the nature of the disease. Both practitioners had completed an 8-week MBCT course, maintained a personal practice and had facilitated a number of 8-week MBCT programs each over the previous five years, fulfilling the good practice guidance for teaching mindfulness-based courses [41].

Each weekly session was audio recorded except the last one due to failure of the recording device.

Wait-list control

The control group continued to receive their standard care and in addition they received a leaflet entitled 'Staying well with IBD'. The leaflet is readily available to download from the Crohn's and Colitis UK website, but participants in the study received a printed copy [42]. After the 6-month follow-up data were collected, the wait-list group had the opportunity to attend a MBCT program.

Data collection, assessments and outcomes measures

As this was an efficacy trial with the primary objective being to pilot the MBCT program with IBD patients and to assess the feasibility of the program and methodology in a definitive RCT, data were collected to assess trial feasibility [43]. Data were also collected on the proposed outcome measures to be tested in a definitive RCT.

Feasibility criteria and measures

The guidance for a good pilot study suggests setting a predetermined criterion for measuring the success of feasibility [44]. While literature suggests various figures [45, 46], the feasibility criterion for assessing success of feasibility in this study was set to at least 10% recruitment rate.

Screening and recruitment data were collected by the lead researcher on all patients considered for the study. Information was also collected on patients excluded with reasons for exclusion at each stage, date of recruitment and randomisation. A full CONSORT diagram [47] of subject flow is presented in Fig. 1 and a CONSORT checklist is available in Additional file 5.

To assess treatment compliance and to inform the estimated attrition rates for a full trial, facilitators recorded a weekly attendance log for each participant.

Baseline characteristics

Demographic data (age, sex, marital status, education and income) was obtained to assess the success of randomisation [48]. Data were also collected on participants locality (rural or urban), to assess if there is any relationship between rurality and drop-out rates.

Proposed outcomes measures

The following proposed outcomes were assessed at baseline, post intervention and at 6 months: depression, anxiety, dispositional mindfulness, disease activity and quality of life.

Depression

Low mood and depression symptoms was measured with the Beck's depression inventory (BDI-II) [49]. The BDI-II is an established self-reporting tool for screening depression, and it consists of 21 group of statements, where the participant rates each statement on a four-point scale of severity. The statements refer to the last 2 weeks. The interpretation is based on a 0 to 63 total score, with higher total scores indicating more severe depressive symptoms. Previous studies indicate high test-retest reliability as well as high internal consistency [50, 51].

Anxiety

Anxiety was measured by the State and Trait Anxiety Inventory (STAI). STAI is a widely used self-reporting tool consisting of two parts: STAI- Y1 and STAI-Y2. Both parts consist of a 20-item scale, with STAI- Y1 measuring the state or current anxiety (anxiety related to an event) and STAI-Y2 measuring the trait or chronic anxiety (anxiety level as a personal characteristic). Participants are asked to rate each individual statement on a four-point scale, depending on how well each statement is describing the participants mood. The rating options are ranging from "not at all" to "very much so". Each of the two parts of the STAI scores range between 20 and 80, with higher scores being positively correlated with higher levels of anxiety [52]. This tool is widely used to measure anxiety and regarded as highly reliable [8], but is particularly useful for IBD patients as each of the statements is focused on the cognitive symptoms of anxiety rather than mixing it with the somatic symptoms related to the disease.

Dispositional mindfulness

Dispositional mindfulness or mindful attention was measured using the Mindful Attention Awareness Scale (MAAS). This scale consists of 15 items that measure the frequency of which participants experience mindful awareness and mindful attention on a six-point Likert scale. The scale items refer to statements about everyday experiences graded by participants, using a scale of 1 to 6, which indicates how often each experience occurs. Higher scores reflect higher levels of dispositional mindfulness. The validation of this tool has been examined in a series of studies indicating strong psychometric properties and validity [53, 54].

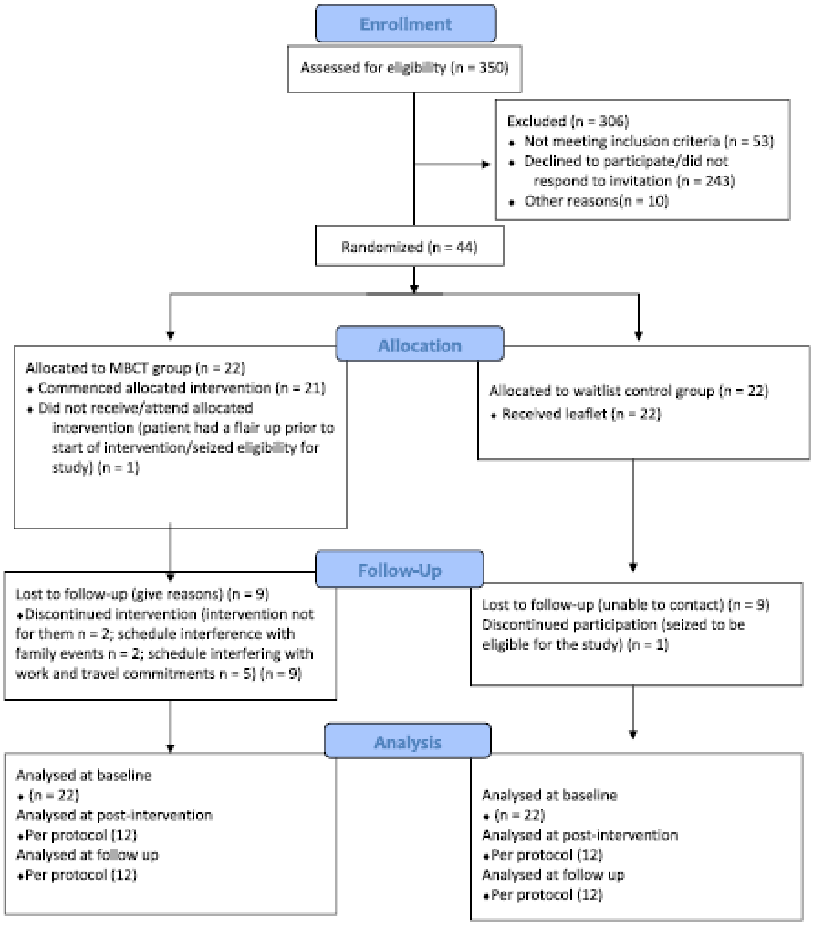

Fig. 1 Consort diagram describing flow of patients through study

Disease activity

Disease activity was assessed with an eight-item questionnaire Crohn's Disease Activity Index (CDAI) for Crohn's patients [55, 56] and six-item questionnaire Simple Clinical Colitis Activity Index (SCCAI) for ulcerative colitis patients. The CDAI has been validated prospectively and is the gold standard for the evaluation of CD disease activity [57, 58]. A decrease in the CDAI of 70 or 100 points has been defined as a CDAI-70 and CDAI-100 clinical response, respectively [59]. The SCCAI, as well as the CDAI, is a subjective disease activity index and rates overall well-being, daytime and night-time bowel movements, bowel movement urgency and rectal bleeding. SCCAI disease activity scores ≥3 correlate with active disease [60].

Quality of life

All participants were required to complete a disease-specific IBD quality of life (IBDQ) questionnaire. Although the questionnaire used in this study closely followed the validated IBDQ 32-item questionnaire that measures health-related QoL in IBD patients, the questionnaire was modified from the original version of the IBDQ. What remained were the same the four domains, including bowel symptoms, systemic symptoms, emotional factors and social factors. The only difference was that participants rated their symptom experience over the previous 2 weeks on a four-point Likert scale ranging from 0 (worse health) to 3 (best health) rather than 7-point. This was to reduce the burden of patients. Thus, scores ranged from 0 to 96 rather than 32 to 224 in the original IBDQ, and similarly, low scores indicated more severe disease activity and/or higher emotional and social dysfunction. IBDQ directly assesses the participant's view on her/his disease and a relatively good correlation between the IBDQ and a widely used measure of disease activity, the Crohn's Disease Activity Index is reported [61, 62].

Sample size

Due to the nature of this pilot study, a formal sample size calculation was not performed. The determined sample size of $n = 40$ was calculated based on the estimated number of participants expected to complete the 8-week program. Full information on how n = 40 was achieved is reported elsewhere [37].

Analysis

In line with the good practice guidance for analysis of any pilot study, the primary analysis of the study was descriptive [63, 64]. Descriptive data were calculated representing frequencies, means and standard deviations for all continuous data and n (%) for categorical data.

Further analysis was done to determine initial estimates of the parameters for the proposed outcome measures, for example, the mean and standard deviation required for sample size calculation for a future large RCT [65]. As this was an efficacy trial, the type of analysis was as per protocol [43]. For this, analysis of mixed covariance (ANOVA) statistical method was used. This method looked at the changes in outcome scores over time in the two different groups. A significance level of 5 % was chosen for proposed hypothesis testing. Data analysis was conducted using IBM SPSS version 19 software.

Results

Objective one: trial methodology

Eligibility, recruitment and dropout rates

Recruitment, intervention delivery and follow-up took place between May 2013 and March 2014. A total of 350 consecutive patients were assessed for eligibility. Study invitations were sent to 297 eligible patients and 44 consented to participate, giving a recruitment rate of 15 %. A consort diagram of patient flow is presented in Fig. 1. Although a total of 243 patients did not respond to study invitation, a recruitment target of 40 was achieved. In total, 44 participants were randomised, with 22 in each arm. Table 1 summarises reasons for discontinuing MBCT, how many sessions each of the participants who dropped-out attended and if they were from a rural or urban area. One participant randomised to the intervention arm ceased eligibility (had a flare-up) before the commencement of intervention, and one participant randomised to the wait-list control arm ceased eligibility (attended mindfulness course elsewhere while in the control) after randomisation. Data for another 18 participants were lost to follow-up (9 in each arm). In addition, 95.5 % of participants were recruited from one board only.

Table 1 Reasons for discontinuing mindfulness-based cognitive therapy (MBCT)

Reason	Number of participants (%)	Number of sessions attended	From rural area (%)
Not for them	2 (9)	1	1 (4.5)
Travel time	2 (9)	1	2 (9)
Family illness/carer	1 (4.5)	1	1 (4.5)
Work schedule interference	2 (9)	1	0 (0)
Family illness/carer	1 (4.5)	3	0
Acquired unrelated sickness	1 (4.5)	3	1 (4.5)
Seized eligibility before start of intervention	1 (4.5)	0	0 (0)
Total	10 (45)	10	5 (22.7)

Table 2 Data completion for research outcomes

	Control	MBCT	Total	Missing/Invalid
Total consented and randomised	22	22	44	n/a
Dropped out				
Prior start of MBCT	0	1	1	n/a
Prior to MBCT completion	10	9	19	n/a
Prior to 6 month follow up	0	0	0	n/a
Baseline BDI-II	22	21	43	1
Post-MBCT completion BDI-II	12	12	24	20
6-month follow-up BDI-II	12	12	24	20
Baseline STAI-Y1	21	20	41	3
Post-MBCT completion STAI-Y1	12	12	24	20
6-month follow-up STAI-Y1	12	12	24	20
Baseline STAI-Y2	22	20	42	2
Post-MBCT completion STAI-Y2	12	12	24	20
6 month follow up STAI-Y2	12	12	24	20
Baseline MAAS	22	22	44	0
Post MBCT completion MAAS	12	12	24	20
6-month follow-up MAAS	12	12	24	20
Baseline IBDQ	21	21	42	2
Post-MBCT completion IBDQ	12	12	24	20
6-month follow-up IBDQ	12	12	24	20
Baseline DA	21	22	23	1
Post-MBCT completion DA	12	12	24	20
6-month follow-up DA	12	12	24	20

Abbreviations: BDI-II Beck Depression Inventory II, *DA* Disease Activity, *IBDQ* Inflammatory Bowel Disease Questionnaire, *MAAS* Mindfulness Attention Awareness Scale, *MBCT* Mindfulness Based Cognitive Therapy, *STAI-Y1* and *Y2-State* Trait Anxiety Inventory

Protocol adherence and success of data collection strategy

Completion of data collection at each time point is summarised in Table 2. This also indicates the degree of adherence to the research protocol. A log of attendance

Table 3 Mindfulness-based cognitive therapy (MBCT) attendance log

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Sessions Missed	Sessions attended
1.						x			1	7
2.					x	x	x		3	5
3.			x		x	x		x	4	4
4.		x	x	x	x	x	x	x	7	1
5.								x	1	7
6.									0	8
7.		x	x	x	x	x	x	x	7	1
8.				x	x	x	x	x	5	3
9.									0	8
10.									0	8
11.			x		x	x	x	x	5	3
12.		x	x	x	x	x	x	x	7	1
13.							x		1	7
14.									0	8
15.									0	8
16.	x	x	x	x	x	x	x	x	8	0
17.	x		x	x	x	x	x	x	7	1
18.									0	8
19.		x	x	x	x	x	x	x	7	1
20.		x	x	x	x	x	x	x	7	1
21.		x	x	x	x	x	x	x	7	1
22.									0	8

X-missed a session

revealed that a total of 12 participants (56 %) completed at least four sessions from the intervention over the 8 weeks (Table 3). An overall of 24 participants (56 %) completed all assessments at post-intervention and 6-month follow-up.

Baseline characteristics

Table 4 shows the age, sex, income, disease type, marital status and education distribution for the 44 consented participants. An independent T-test between groups at baseline showed no significant differences between the two arms for baseline characteristics.

Objective two: initial estimates on parameters of the proposed outcome measures (depression, anxiety, dispositional mindfulness, disease activity and quality of life)

A mixed ANOVA was conducted on all dependent variables: depression, anxiety, dispositional mindfulness, disease activity and quality of life. All assumptions with regard to outliers, normal distribution, homogeneity of variances and co-variances and sphericity were tested and met. The means and standard deviation (S.D.) of all proposed outcomes for MBCT and the wait-list group over the three time points are presented in Table 5.

(BDI-II) depression

Per-protocol analysis revealed an improvement in depression scores in the MBCT group at post-intervention and follow-up. There was a statistically significant interaction between the MBCT group and time on depression scores (F(4,84) = 3,975, *P* = .027, partial η2 = .173).

(STAIY1) state anxiety

There was an improvement in state anxiety score in the intervention arm over the post-intervention and follow up period; however, the difference between the arms over time was not statistically significant (F(4,84) = 2,809, *P* = .083, partial η2 = .135).

(STAIY2) trait anxiety

When the per-protocol population was analysed, the trait anxiety scores between the two arms showed a statistically significant interaction between the MBCT group and the time on trait anxiety scores (F(4,84) = 3,286, *P* = .048, partial η2 = .147).

Table 4 Baseline characteristics

	Intervention	Control
Age (years) (n, mean (sd))	22, 48.59 (12.046)	22, 49.68 (15.370)
Sex (F (n,%), M(n,%))	16,(72.7) 6,(27.3)	18,(81.8) 4,(18.2)
Income (n, %)		
less 10K	1 (4.5)	6 (27.3)
10K-19K	7 (31.8)	6 (27.3)
20K-29K	4 (18.2)	2 (9.1)
30K-39K	4 (18.2)	4 (18.2)
40K-50K	2 (9.1)	3 (13.6)
50K+	4 (18.2)	1 (4.5)
Disease type		
CD (n, %)	9 (40.9)	12(54.5)
UC (n, %)	13(59.1)	10(45.5)
Marital status		
Single (n, %)	5 (18.2)	9 (40.9)
Married/cohabiting (n, %)	15 (68.2)	8 (36.4)
Widowed (n, %)	0 (0)	3 (13.6)
Separated/divorced (n, %)	3 (13.6)	1 (4.5)
Education (High school n, %)	9 (40.9)	9 (40.9)
(Diploma n, %)	9 (40.9)	7 (31.8)
(Degree or above n, %)	4 (18.2)	5 (27.2)

CD Crohn's Disease, *F* female, *M* male, *N* number, *SD* standard deviation, *UC* Ulcerative colitis

MAAS (dispositional mindfulness)

Dispositional mindfulness scores showed an improvement in the MBCT arm in comparison to the wait-list, with a statistically significant interaction between the MBCT group and time on dispositional mindfulness ($F(4,84) = 3,998$, $P < =.034$, partial $\eta 2 = .174$).

DA (disease activity)

Although disease activity showed improvement in the MBCT arm, there was no statistically significant interaction between the MBCT and time on Crohn's disease activity scores ($F(4,84) = 1,410$, $P = .277$, partial $\eta 2 = .168$) or between the MBCT group and time on ulcerative colitis activity scores ($F(4,84) = 2,927$, $P = .083$, partial $\eta 2 = .268$).

IBDQ (IBD quality of life)

While there was a small improvement in the IBDQ score at the 6-month follow-up, there was no statistically significant interaction between the MBCT group and time on quality of life scores ($F(4,84) = .845$, $p = .437$, partial $\eta 2 = .043$).

Objective three: sample size calculation

The sample size for a full RCT is calculated on the basis of the proposed primary hypothesis and clinically meaningful effect sizes of changes in depression scores BDI. A change of five scores in BDI is deemed to be clinically meaningful [66]. We have based our sample size estimate on the most conservative standard deviation of 11.89. To detect a mean difference in BDI score of five points at week 8 with a two-sided significance level of 5 % and power of 80 % with equal allocation to two arms would

Table 5 Means and standard deviation of proposed outcomes at baseline, post-MBCT and follow-up

Measured outcome	Condition	Baseline			Post-MBCT			6 month Follow up		
		Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N
BDI-II	MBCT	14.36	9.520	22	10.67	13.996	12	13.75	16.355	12
	Wait-list	15.57	7.291	21	14.23	10.158	12	14.17	9.173	12
STAIY1	MBCT	38.76	11.397	21	37.74	15.635	12	39.67	16.183	12
	Wait-list	37.26	10.429	20	43.67	5.806	12	45.16	9.347	12
STAIY2	MBCT	45.50	10.318	22	41.67	16.396	12	42.58	16.368	12
	Wait-list	47.45	8.666	20	47.08	6.431	12	45.92	7.354	12
MAAS	MBCT	3.6586	.7935	22	4.2758	1.0342	12	4.1450	1.1675	12
	Wait-list	3.4005	.6655	22	3.5769	.5802	12	3.5433	.7867	12
CDAI	MBCT	101.56	60.28052	3	69.0000	86.15683	3	18.6833	15.01002	3
	Wait-list	145.866	84.76086	8	101.8750	66.69212	8	139.7150	83.44660	8
SCAI	MBCT	4.3750	2.77424	8	3.8750	3.39905	8	5.5000	4.17475	8
	Wait-list	2.2500	2.62996	4	4.5000	3.0000	4	5.0000	4.39697	4
IBDQ	MBCT	34.3333	12.17922	21	31.0833	18.0225	12	34.8333	23.7863	12
	Wait-list	36.5714	14.40684	21	33.9167	15.1864	12	36.8333	12.0667	12

Depression (BDI-II); State anxiety (STAIY1); Trait anxiety (STAIY2); Dispositional mindfulness (MAAS); Crohn's disease activity index (CDAI) Ulcerative colitis activity index (SCAI); Disease specific QoL (IBDQ) require 90 patients in each arm of the trial. To consider and allow a 44 % drop-out (finding from this study), then 129 IBD patients should be recruited per arm (258 in total).

Discussion

This paper describes a pilot randomised control trial of Mindfulness-based Cognitive Therapy for IBD. The results showed that it would be feasible to conduct a full RCT. In conducting this investigation, we have identified areas of critical importance if a subsequent study of MBCT for IBD is to going to be conducted. These areas are related to recruitment and retention, data collection and trial design as well as to the intervention.

Objective one: trial methodology

Consent, recruitment and retention

Consent and baseline Recruitment for this trial was difficult, even though the recruitment target was reached. It was estimated that each individual appointment for discussing consent and making baseline assessments would last approximately 45 minutes, but in reality lasted approximately 1.5 hours. This was not due to the assessments taking longer, but due to fact that for most of the participants this was an opportunity for them to voice their difficulties, particularly the stress and anxiety related with the condition. Because much of the information was shared before actually signing the consent form, this information was not captured for analysis. In addition, tester sessions were offered to prospective participants before they made a decision to participate. This idea came from some of the prospective participants wanting to 'test drive' the intervention. Although only three signed up for the tester session, all three participants that came for a tester session decided to participate and completed all the trial assessments.

Recruitment Although the recruitment was conducted in two NHS Boards (approximately 2,341 IBD patients), 95.5 % of participants were recruited from one of the boards. A number of strategies were devised to maximise the number of patients screened for eligibility into the study. The most effective strategy of recruitment (93.2 %) was through a letter of invitation send by an IBD specialist nurse. We believe there are at least two possible explanations regarding this. Firstly, it is possible that this strategy was most effective due to the fact that there was already an established trusted relationship between the patient and the IBD nurse, and the response to the invitation to participate reflected that trust. And secondly, it could be the actual high number of letters that were sent to patients could be the reason for the good response rate. Nonetheless, this strategy was a lengthy process of going through IBD patient records and sending invitation and information packs every week for few months. To improve future recruitment, literature suggests three key areas of relevance: infrastructure, professional and public engagement with research, and methodological innovation [67]. A dedicated recruitment person working closely with the IBD nurse, using current networks such as Crohn's and Colitis UK to aid recruitment or offering incentives for prospective participants could make this process more effective. These suggestions should be considered if a full RCT is to be conducted.

Retention Both arms experienced an equally high drop-out rate of 44 %, with 33 % attending only one session in the intervention arm. If we only look at the intervention arm, the high drop-out rate suggests that the intervention may not be suitable or acceptable to all IBD patients. However, whereas seven participants (33 %) attended only one session, only two of them said the intervention was not for them. The reasons that the other five participants gave were that they realised the travel time commitment was too much (2), there was work schedule interference (2) and there was a family illness (1). Although at recruitment, the commitment required for the course was particularly highlighted, it appears that the participants either overestimated their other commitments and travel time or were overenthusiastic to start with and had a decline in motivation or had a change of circumstances by the time the intervention started. The last one is a possibility if taken into consideration that the time between recruitment and start of intervention was around 5 months for some participants [68] and should be addressed in any future trial.

If we look at the wait-list arm, the dropout rate was the same, with nine participants not responding to the two communication attempts to complete assessments after the post-intervention period or follow-up. In this arm, it is possible that the participants lacked the motivation to stay in the trial and perhaps declined participation outside of the trial setting, which could also be due to the long wait between baseline assessment and post-intervention and follow-up assessment. The other possibility is that perhaps the participants in the control were disappointed that they were not selected to be in the intervention arm, although they were offered the intervention after all data were collected. This was at least the case with the one participant that was excluded from the trial after they breached the protocol and did the intervention while in the control group. In addition, a log was kept for the wait-list arm attending the intervention after the completed assessments, and their attendance was close to 100 %, with no drop-outs. Participants in the wait-list arm remained motivated to complete all the follow-up assessments because they knew they would be eligible for the intervention after all data had been collected. In summary, while high dropout rates are a recognised occurrence in psychological intervention trials [69–71], the demand for psychological interventions in IBD is pertinent, and judging from those that attended the intervention, it appears that careful patient selection remains essential [72, 73].

Protocol adherence and success of data collection strategy

Complex psychological interventions are by definition difficult to standardise and measure, and this always should be considered [74]. Whereas a log of attendance was kept for the intervention arm in this study, it was very difficult to assess how much home practice the participants did, and home practice was a particularly vital component of the intervention. To be able to assess the time spent on home practice and truly assess the effectiveness of the intervention in the future, a measurable log of home practice might be introduced.

All data collected in the trial, including the consent form, were collected by the lead researcher. This is particularly important to support a robust methodology, especially when front line clinicians' priorities and time is constrained. However, there is a debate that involving clinicians in data collection is important, particularly in context of culture and demonstrating the concept of working together [75], and perhaps this should be considered in a future trial.

Data were collected at three time points, with the last one at 6 months. The six-month follow-up was to assess the mechanism of how feasible it is to collect follow-up data for a full RCT, thereby assessing the sustainability of any effectiveness of the intervention. Ideally, a longer follow-up, such as 12 months, would give us better information about any sustainable changes in a full RCT. Initially, the pilot considered testing the feasibility of data collection at 12 months; however, there were few points taken into consideration. The recruitment process was stretched over a few months, and judging by the dropout rate in both arms and literature [76], it could have contributed towards further drop-outs in both arms, predominantly in the wait-list arm if patients had to wait even longer to be eligible to attend MBCT after all follow-up assessments. In a future trial, this could be overcome by having a designated research person working fulltime on recruitment, which could reduce the recruitment time, thereby enable a shorter lag time between recruitment and the start of intervention.

Objective two: initial estimate on parameters of the proposed outcome measures (depression, anxiety, dispositional mindfulness, disease activity and quality of life)

With respect to the initial calculations on parameters for the proposed outcome measures for a full RCT, all outcome measures in the present study were validated and found to be reliable measures. Although this analysis has its limitations due to the small sample size and should not be generalised, it provides encouragement that MBCT has the potential to help with management of overall symptoms for IBD patients.

We measured the dependent variables (proposed outcome measures) over time in the two different groups and wanted to assess whether the dependent variables responded differently over time in the groups. Thus, a mixed ANOVA (with both between-subjects and within-subject factors) analysis was conducted. For this analysis, we looked at the group*time interaction where the group (MBCT or wait-list) was the between factor, and time (baseline, post-intervention and follow-up) was the within factor [65]. We did the analysis for each of the dependent variables: depression, anxiety, dispositional mindfulness, disease activity and quality of life. This also gave the initial estimates of the parameters to the proposed outcome measures (mean and standard deviation) required for a sample-size calculation for a future large RCT [64].

The mixed ANOVA per protocol analysis showed a statistically significant interaction between the group (MBCT and wait-list) and time (baseline, post-intervention and follow-up) on depression (BDI-II), trait anxiety (STAI-Y2) and dispositional mindfulness (MAAS) scores. This is particularly interesting as the literature suggests that high depression and anxiety are closely linked with neuroticism. In addition, the most common personality trait in IBD patients is reported to be neuroticism [77–80]. High neuroticism scores are related to reduced psychosocial wellbeing, psychological adjustment and quality of life in patients with IBD [81] or higher depression and anxiety vulnerability. Although we did not directly measure neuroticism scores, their relation to depression, state anxiety and dispositional mindfulness has been well reported.

Considering that more than 30 % of IBD patients report suffering from depression and that the preliminary analysis showed that depression scores in the MBCT group improved over time when compared to the control, these results are very promising. Further to this, MBCT had significant effect on trait anxiety, whereas the effect on state anxiety was not significant. This is particularly interesting because changes in the trait anxiety scores suggest that they are not temporary changes but they are more sustainable comparing to the state anxiety. For example, a person who has a high trait anxiety, views typical daily situation as more threatening than those with lower trait anxiety and so responds with a higher state anxiety. High trait anxiety is often linked with neuroticism and higher vulnerability to depression [82]. Reducing the trait anxiety could in return lower the vulnerability for depression. In the long run, and taking into account that IBD is a lifelong condition with distressing symptoms, the potential of MBCT to help IBD patients to respond to daily situations, as well as the disease symptoms in a less stressful way, is certainly promising. Of course, to get a better idea of how sustainable this is, a full RCT has to be conducted.

The other interesting finding was the improvement in dispositional mindfulness scores. Dispositional mindfulness has been shown to moderate the relationship between neuroticism and depressive symptoms [83]. A study suggests that neuroticism is significantly related to depression in those with low to medium levels of dispositional mindfulness but not in those with relatively high levels of mindfulness. It also suggests that increased dispositional mindfulness may act as a protective factor against the effects of negative emotional reactivity by neuroticism. This could be very important for the future tailoring of treatment based on patient characteristics which is a well-accepted approach in IBD management (for example, pharmacotherapy).

Disease activity, state anxiety and quality of life, showed improvement over a period of time, but statistical significance was not detected. This could be due to the small numbers, particularly with the disease activity, where the subgroup of CD and UC were very small to compare between the two arms. The biggest surprise is that quality of life change was very small and, in fact, did not mimic the change in depression scores or trait anxiety, as had been expected. One of the possible explanations is that the sample was too small to detect any significance. The second reason could be that the questionnaire used was an adapted version of the validated IBDQ questionnaire and was not sensitive enough to detect any real changes. What is also very interesting is that in both arms, MBCT and the wait-list, there was a reduction in the quality of life scores at post-intervention, and then increase of scores at the 6-month follow-up. It is unclear whether any external factors contributed to this or to the coincidental worsening in the quality of life for both arms at post-intervention, with improvement at the 6-month follow-up.

Objective three: sample-size calculation

We estimated a sample-size calculation for a future trial based on the dropout rate of this trial. However, we should consider that the estimate from this study is only an indication to what the 'true' dropout rate is, and perhaps, the consideration of estimates from other trials with similar type of intervention for this patient group should be not dismissed.

Conclusions

We completed an exploratory pilot RCT despite challenges in recruitment. Based on the study findings and the experience of conducting the pilot trial, we would recommend a definitive multicentre trial with 129 participants in each arm. Whereas the recommendations for consent, randomisation and data collection are to be conducted by a dedicated research team, recruitment should be in collaboration with clinical staff, particularly IBD specialist nurses, to maximise recruitment. Although dropout rates were higher than expected, a future trial could minimise this by decreasing the time lag between recruitment and start of intervention. Short tester sessions could be offered to all potential participants to help with appropriate patient selection and improving retention. Retention rates were the same in both arms, which suggests that randomisation was successful. A measurable log of home practice should be introduced to better assess protocol adherence and intervention compliance and therefore determine the 'true' effectiveness of the intervention. Information on medication or dosage changes during the study period should be collected to assess if it affects outcomes. The improvement in depression, trait anxiety and dispositional mindfulness scores in the intervention arm at post-intervention and follow-up suggest that MBCT holds a potential to improve overall symptom management and quality of life for IBD patients.

Additional files

Additional file 1: Inclusion and exclusion criteria. (DOCX 19 kb)

Additional file 2: Weekly session themes. (DOCX 15 kb)

Additional file 3: A sample list of activities for session 1. (DOCX 13 kb)

Additional file 4: Three-minute breathing space Audio. (ZIP 2972 kb)

Additional file 5: CONSORT check list. (DOC 217 kb)

Abbreviations

BDHI: Becks Depression Inventory; CD: Crohn's disease; CDAI: Crohn's Disease Activity Index; IBD: inflammatory bowel disease; IBDQ: Inflammatory Bowel Disease Quality of Life; MAAS: Mindful Attention Awareness Scale; MBCT: Mindfulness-based Cognitive Therapy; MRC: Medical Research Council; QoL: Quality of Life; RCT: randomised controlled trial; SCCAI: Simple Clinical Colitis Activity Index; STAI: State and Trait Anxiety Inventory; UC: ulcerative colitis.

Competing interests

The authors declared that they have no competing interests.

Authors' contributions

All authors have contributed to the design of the study and the preparation of the draft manuscript. MS as chief investigator and grant holder, co-conceived the study, drafted the study protocol and study materials, applied for ethics and NHS R&D approvals, and drafted the manuscript; AJMW co-conceived the study and participated in the design of the study and study materials, statistical planning and revision of the manuscript. IA provided the statistical analysis plan and commented on the draft manuscript. All authors read and approved the final manuscript.

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Overview and Critical Reflection of paper 4&5

The next few paragraphs critically reflect on the methods and methodologies used to evaluate the feasibility of MBCT. As paper 4 and 5 are interlinked, with paper 4 being the protocol for the study reported in paper 5, the critical reflection will be done collectively for both papers. Although full details of the strengths and weaknesses are provided in both papers, the following paragraphs expand on these in more depth. In addition, some of the reflections presented here are relevant to the PhD submission, but not necessarily to the journal readership.

Methods and design

Writing the protocol for the pilot RCT (Paper 4), was a very constructive exercise as it enabled a process of decision making and settlement on the trial methodology. Being a new researcher and learning rapidly, it often happens that ideas and decisions about designs and methodology will change, particularly when reading new information about interventions, RCTs or even after talking to different researchers. For example, the initial ideas about how many arms the trial should have were different to what was decided later in the protocol. This was a result of different suggestions in the literature. There is considerable evidence suggesting that using the simplest design when designing a RCT could be the best solution (Hutchison & Styles 2010). This meant going for a design of two parallel arms: one active arm and one control arm. Many trials designed this way have been published and have been able to answer the proposed questions (Schulz et al. 2010). However, in psychosocial interventions, researchers often use a third arm to compare the tested intervention with another similar intervention. This similar intervention can be either sham, or an intervention that is comparable (Dincer & Linde 2003).

At the early stage this was confusing as I wanted to use the best possible methodology for answering the PhD question. Thus, it was first considered to have a trial with three arms, an active intervention comparable to MBCT in terms of it being a group intervention with

8-10 weekly face to face sessions and daily home practice. This meant that suitably experienced facilitators for this intervention, as well as for the MBCT, were needed. It also meant recruiting more participants, which could make the recruitment time longer. Thus, a three arm design would have costed more in terms of money and time.

Being able to weigh the pros and cons between the two proposed designs and make a decision was facilitated by another process. I was applying for external funding for the project from the Crohn's and Colitis UK charity. While preparing the funding application, I looked extensively at the RCT literature, learning and understanding the different designs. This was the turning point of the design decision. The literature is very clear that a third arm is useful when looking at examining the effectiveness of an intervention (Armijo-Olivo 2009). However, I was not. I was preparing the foundation for such a trial. The focus of my PhD aim was to explore the feasibility of an RCT using MBCT for IBD and piloting the intervention with patients with IBD. Consequently, the literature provided the evidence and the confidence about choosing the right design for the research question. In addition, the process of applying for external funding for the project encouraged the decision making about the trial design and the writing of Paper 4. The process of writing Paper 4 not only enabled me to choose the right methodology, but more importantly, enabled the fine tuning of the question through the learning of being able to distinguish between efficacy and effectiveness trials. It also enabled me to secure external funding from Crohn's and Colitis UK and NHS Highland RD&I, both involved extensive processes of peer review (see Appendix 9).

Another challenging aspect about the design was the length of follow up. The initial decision of six months follow up was challenged at the NOS Ethics committee (see Ethics approval in appendices 1, 2 & 3 for full details). The committee suggested a longer follow up of 12 months. The evidence suggests that a longer follow up is particularly desired if the trial is an effectiveness trial (Armijo-Olivo 2009). However, this being an exploratory pilot RCT, it made sense to keep to a shorter follow up in order to assess the dropout rate at follow-up. In addition, because the control arm was a wait-list control, meaning the participants would have waited for over 12 months from recruitment to have an opportunity to go through the MBCT program. Waiting for such a long period might have increased dropout rates.

Strengths and limitations

Protocol

Having the protocol written and then submitted for publication was one of the strengths regarding the methodology. Although it was a lengthy process, the benefits outweighed the initial burden. It was a great opportunity for an early researcher to learn and develop, particularly with the feedback gained from the peer review process. Furthermore, having a definite protocol gave clarity to the whole execution of the trial, reduced ambiguity and provided transparency about the whole process, as suggested by the literature (Moher et al. 2015). However, the protocol was not without its limitations. For example, the current protocol did not have a way of measuring compliance of home practice, although some of the participants would have verbally said in the group. Devising a way to measure how long each participants is spending on home practice, could really give a better idea if there is a correlation between time practiced at home and benefit or perceived benefit of the intervention, and thus could give a ‘true’ value of the effectiveness of the intervention in future.

Wait-list control

Having a wait-list control rather than just a control arm gave strength to the design. This possibly kept the wait-list arm participants motivated to complete all of the follow up assessments. The literature suggest that the control arm participants can lose motivation to complete follow up assessments, as they may perceive they are not getting anything from the process (Kinser & Robins 2013). Although most participants take part in research studies for altruistic reasons with an understanding that the research they participate in may not directly benefit them, having a wait-list control means adding value or valuing their input even further, with the opportunity of attending the intervention at the end as a prize.

Participants and recruitment

A strength in the recruitment process for this trial was that the recruitment target was reached. The literature suggests that many randomised controlled trials do not meet their recruitment targets (Treweek 2013). The consequences of a poor recruitment could prolong study duration, cost more, could also affect the intended precise statistical analysis and in the worst case, could be the reason for stopping the trial. The recruitment process for this trial had two strategies. Both strategies used the NHS as sites for recruitment and using gastroenterology clinicians to invite potential participants into the trial. Although the recruitment was successful, this was a very lengthy recruitment process which required a lot of time and commitment from everyone involved. An additional strategy could have improved recruitment in terms of shortening the recruitment time (around 5 months in this trial). The literature suggests three key areas of relevance for improving recruitment: infrastructure, professional and public engagement with research and methodological innovation (Bower et al. 2014). Using current networks such as Crohn’s and Colitis UK to aid recruitment or offering incentives (for example a voucher) for prospective participants could make this process more effective.

Data collection

Data was collected at three time points: baseline, post intervention and follow up. A range of data collection methods were employed in the process of examining the use of the intervention. An overview is presented in the table below:

Table 1 Data collection points

Data collection methods	Baseline	Post intervention	Follow up
Consent interviews	X		
Demographic Data	X		
Questionnaires:			
Depression: BDI-II	X	X	X
Anxiety: STAI Y1 & STAI Y2	X	X	X
Disease specific quality of life: IBDQ	X	X	X
Disease activity for Crohn’s disease: CDAI	X	X	X
Disease activity for ulcerative colitis:	X	X	X
SCCAI	X	X	X
Mindful attention: MAAS			
Survey questionnaire		X	
Focus groups		X	

The consent interview together with filling in the questionnaires at baseline was estimated to last around 45 minutes. However, in reality some of the consent interviews lasted approximately two or three times the estimated time. This came as a surprise, because as mentioned in Paper 5, many of the potential participants had the need to discuss depression, anxiety and stress related to adapting to living with the disease. Many of the potential participants provided detailed accounts of their difficulties dating from before the diagnosis and onwards. The strength of this interview was that potential participants clearly identified once again the need for psychological help. This was a great confidence builder for me as an early researcher. The limitation was that I did not anticipate a richness of information provided at this point, particularly before signing the consent form for participation. Thus, this information was not captured. Therefore, in a future trial, there should be a way of capturing the information with perhaps a separate consent form for that initial discussion.

Demographic data was collected at baseline for gender, age, marital status, education, diagnosis and income. At the time of writing the protocol, this information appeared to be sufficient in order to assess if randomisation was successful between the two arms. On reflection and after the trial was commenced and completed, an idea about additional information on length of diagnosis, medical and surgical treatment as well as hospital admissions might have provided better information for specific analysis. Nonetheless, this can be carried forward in a future definitive RCT.

Validated questionnaires on depression, anxiety, disease specific quality of life and disease activity were collected at three time points (See table 1 above). There was a long debate about the best questionnaires capturing the above information and consensus was reached through examining the literature and discussions about which questionnaires are most effective without bringing extra burden to the participants. More details about each questionnaire are provided in paper 4 and 5. The survey questionnaire and focus groups will be discussed in the following chapter (Chapter 5), as they are closely related to the next objective.

Data analysis

In line with the good practice guidance for analysis of any pilot study, the primary analysis of the study was descriptive (Lancaster 2004). Descriptive data was calculated representing frequencies, means and standard deviations for all continuous data and n (%) for categorical data.

As mentioned in paper 5, additional analysis was conducted to determine initial estimates of the parameters to the proposed outcome measures e.g. mean and standard deviation which are required for sample size calculation for a future large RCT. The type of analysis conducted was per protocol (PP). Pragmatically, intention to treat (ITT) analysis is considered as the 'gold standard' for analysing the results of clinical trials (Armijo-Olivo 2009). However, for this type of analysis there are two key aspects to be fulfilled: a full set of data, where all patients providing data are followed, irrespectively of any protocol deviation and the type of trial is examining the effectiveness of an intervention. Thus far, this trial like many other trials had to deal with non-compliance and drop-outs and was an efficacy trial. Therefore, ITT analysis was not suitable and a different type of analysis was deemed as more appropriate. This was a per protocol (PP) analysis, which deals with patients who have completed all of the assessments according to the full protocol as planned and had near perfect compliance (Armijo-Olivo 2009). This analysis is also called ‘compliers only’, due to only counting those assigned to the intervention that actually received, complied and completed the treatment. For this, the analysis of mixed covariance (ANOVA) statistical method was used. This method looked at the changes in outcome scores over time in the two different groups. This method was chosen as the most relevant to the question proposed.

Ethical review

Ethical review and approval was received by the University of Stirling Ethics Committee, North Research Ethics Committee for North of Scotland on 8 April 2013 (REC ref 13/NF/0018). NHS Highland and NHS Grampian R&D Management Approval was obtained on 9 April 2013 and 14 September 2013 respectively. See appendices 1-8 for full details of submission.

Contribution to the research question

The specific objective of this chapter was to explore the feasibility and piloting issues of using MBCT for patients with IBD as a third objective in answering the overall PhD question. Both associated papers: the protocol (paper 4) and results from the pilot RCT (paper 5) provided all of the necessary processes and evidence about MBCT, an intervention aimed at better management of psychological stress, that it is feasible to use MBCT in the IBD population. In addition, the preliminary findings suggest that using MBCT for patients with IBD has the potential to be beneficial in reducing psychological stress.

Chapter 5

Objective 4: To explore participants' perspectives and acceptability on using MBCT for patients with IBD.

Chapter overview

The purpose of this chapter is to examine how acceptable the MBCT intervention is for patients with IBD while assessing their perspectives and experiences of going through an eight week MBCT program. This complements the previous chapter's objective; the examination of feasibility and piloting issues related to using MBCT with IBD patients in the pilot RCT. While objective 3 was an essential objective that contributed to answering the overall PhD question (particularly the preliminary analysis in paper 5, suggesting that MBCT could be potentially useful in improving depression and anxiety scores, as well as dispositional mindfulness), it did not actually communicate the whole story about MBCT for patients with IBD. For example, it did not provide the depth of information about participants' experiences of the intervention, including how the intervention affected them individually or as a group and what were the perceived benefits or barriers from the intervention. Consequently, the purpose of this chapter is to directly address these issues. Before presenting paper 6 and its critical reflection and contribution to the overall question, this chapter will provide a full description of the MBCT curriculums' content and delivery used in the study. It will then carry on the review of the evidence base for MBCT with a focus on qualitative studies exploring MBCT.

Description of the MBCT curriculum

The next section describes the MBCT curriculum used in this study, with an overview on the structure, content and methods of delivery.

The MBCT structure

The MBCT structure contained the following components: an individual pre-course session; eight weekly sessions; guided home practice and a day of guided mindfulness practice in silence.

An individual pre-course session: this session lasted anything between 30 minutes to an hour. It was led by a mindfulness facilitator and its purpose was to assess the motivation and suitability of the participant for the course, as well as orientation of the potential participant to the course. This session had a strong emphasis on the commitment required for the home practice and was an opportunity for the participants to hear about the background of MBCT with a view of how it might benefit them. For the facilitator, this session was an opportunity to learn about the factors associated with the onset of difficulties for the potential participant and through dialogue determine if the course would likely to be of benefit to the participant at that given time (Segal et al. 2002).

The eight weekly sessions: was face to face guided sessions over eight consecutive weeks lasting approximately 2 hours each. The sessions included facilitator instruction, group practice and instructions for home practice. In brief, the layout for each session was an introduction to a new theme, followed by a short opening meditation and discussion. The group was then introduced to a new practice/exercise, which was followed by reflection, then review and instruction for at-home practice and followed by sitting meditation. A full schedule of the weekly sessions (agendas) are available in Appendix 10.

Guided home practice: Participants were given instruction at the end of each weekly session for the home practice. The home practice was up to 45 minutes a day for 6 days a week, guided by an audio CD and outlined instructions for the home practice. This was the most important part of the course, as it was aimed at reinforcing the in-group learned techniques and strategies. The home practice activities were scheduled in a structured way and were a combination of formal and informal practices. The home practice reflections were discussed in depth in the weekly group practice.

A day of guided mindfulness practice in silence: This was normally scheduled during the sixth week of the MBCT program, but due to resource limitations, it was scheduled after the eight week course, in this case. The day offered the participants to immerse themselves into a day of mindfulness practice. This was enabled by the continuity of practising the learned meditations one after another in silence, with the group reflection and discussion taking place at the end of the practice day. Kabat-Zinn (1990) suggests that participants often come to a significant understanding about themselves on the day of silent practice.

The MBCT content

The MBCT content was divided into the following components: formal mindfulness meditation practices; informal mindfulness meditation practices; inquiry or reflection and discussion between facilitator and participants and didactic elements.

Formal mindfulness meditation practice

There were also a few further components that constituted the formal mindfulness meditation practice: a)body scan, b)mindful movement, c) sitting meditation, d)3 minute breathing space.

a) Body scan

The body scan meditation is the first formal meditation practice in the course. Kabat-Zinn (1990, p77) describes it as '*… lying on your back and moving your mind through the different regions of your body'.* The purpose of this practice is to enable the participant to connect to their body and pay detailed attention to the sensations that arise in the body, regardless of those sensations being pleasant or unpleasant or regardless of being distracted by thoughts about something else (Segal et al. 2002a). This practice is an effective technique for developing two core mindfulness skills simultaneously: concentration or focused attention and flexibility of attention. Developing these skills is an important foundation for the whole program, as it enables the participant to improve self-regulation of their emotions and redirects their attention to present body sensations rather than relying on thought-based processing of difficulties or emotions.

b) Mindful movement

Segal et al. (2002a, p.180) describe the mindful movement as 'meditation in motion' where ' *The focus is on maintaining moment-to-moment awareness of the sensations accompanying our movements, letting go of any thoughts or feelings about the sensations themselves'*. This practice is introduced in week three of the course. The practice of mindful movement acts as a bridge between formal practice and life's daily activities.

One of the mindful movement practices is mindful walking, where the participants focus on the complex activity of walking, one step at a time and where participants explore walking at different speeds while observing different body sensations that arise as a result. This exercise enables the participants to anchor to the present moment through the sensations arising in the body as a result of walking without the goal of getting anywhere in particular (Segal et al. 2002a).

The core of the other mindful movement practice is drawn from Hatha Yoga, Qi-Gong or Tai Chi, depending on the confidence and practice experience of the facilitator. This practice uses more stretching and gentle exercise types of movement, with invitation to move close to the boundaries of what feels possible for the body in each moment of movement. Kabat-Zinn (1990, p98) refers to it as a practice '… *to be where we already are and discover where that is'*, as with all other mindful practices. This can be particularly meaningful for people working with chronic illness or physical difficulties, as it enables them to develop a moment by moment openness and responsiveness to their experience, rather than staying fixed in their preconceptions about what is possible in any moment (Kabat-Zinn 1990).

The mindful movement practice also offers an experience of working with one's own limitations, boundaries and intense sensations, in an accepting and present-centred way. This offers the participants an alternative point of experience. Thus, this opportunity to develop an ability to relate to one's whole experience, with acceptance and awareness, is the core skill of mindfulness practice. This learned core skill, through experience, can enable participants to gain curiosity, openness and a sense of what is possible within their emotional and cognitive experiences as well.

c) Sitting meditation

The sitting meditation is where participants are guided into adopting an erect and alert but relaxed posture. They are then invited to systematically bring their awareness to different aspects of their experience usually starting with their awareness of breathing and other bodily sensations. Other experiences explored during the sitting meditation include awareness of sounds, to the process of seeing, to feelings, to thoughts and 'choiceless' awareness. The last activity is where participants do not focus on any particular experience (i.e. sounds or breath), but allow for their awareness to follow any experiences as they unfold, depending on which experience is predominant at that moment. Similar to body scan, sitting meditation is a technique which further develops two core mindfulness skills: concentration or focused attention and flexibility of attention and developing awareness about where the mind wanders to. Segal et al. (2002a, p168) describe the sitting meditation as '… t*he aim is not really to prevent the mind wandering but to become more intimate with how one's mind behaves'.* In other words, this practice offers an opportunity to observe the interaction between the mind and the body by noticing when the body follows where the mind moves to. The practice offers an alternative way of bringing awareness gently back to where it was initially intended, instead of the body jumping to where the mind decides to go next, (Kabat-Zinn 1990). This is particularly important when the mind is faced with habitual ways of dealing with boredom, likes and dislikes.

d) The 3 minute breathing space

This meditation is a 'concentrated mini version' of longer formal meditations and the purpose is to enable practical application of the formal practice into daily situations. Although the meditation is dubbed as a '3 minute breathing space', its length can be adapted as needed, as long as the three main steps of the exercise are followed. The three steps are usually described as the three parts of an hour glass clock, with the wider part on top assigned to step one, the narrow part to step two and the wide part at the bottom as step three. These are:

1st Stepping out of automatic pilot while recognising and acknowledging the current experience in body sensations, thoughts and feelings. This means taking stock of how we are in our body, thoughts or feelings at a given moment.
2nd Bringing the attention to breathing. This involves narrowing the focus of attention to the rhythmical physical sensation of breathing.
3rd Using the awareness of the breath and the body as an anchor. This step is about expanding the attention from breathing to all the experiences as they are happening.

The application of the 3 minute breathing space in daily life is developed in a structured way between weeks three and seven, starting with using it three times a day in predetermined times, through to seeing it as a ‘first step’ for coping with certain difficult situations or before taking actions. The aim is that the exercise is used as a way of reconnecting with the expanded awareness (of body sensations, thoughts and feelings), rather than getting lost in anxious thoughts and with an openness to alternative actions appropriate to the present moment (rather than going into a default anxious thinking) (Segal et al. 2002a). For example, a person anticipating that a particular important meeting will be stressful and overwhelming as they go into it can have a different outcome if they use the 3 minute breathing space exercise. Using the technique would allow the person to recognise their anxiety and then refocus their attention to the breathing. This would allow the person to be open to a different action rather than getting stressed and overwhelmed before going to the meeting.

The informal mindfulness meditation practice or ‘mindfulness in everyday life’

This part of the course content has two main components: a) deliberate awareness of routine activities and b) awareness of pleasant and unpleasant events.

- **a)** Deliberate awareness of routine activities: these include all daily activities such as eating, walking, brushing teeth, washing, driving etc. Participants are encouraged to bring deliberate awareness to these routine activities from week one and to reflect on their routine activity observations.
- **b)** Awareness of pleasant, unpleasant and neutral events: at week three, four and five, participants are asked to fill in a daily reflection dairy: with a focus on pleasant events in week three, unpleasant events in week four and neutral events

in week five. This a continuation from the formal practice applied in daily life as a way of cultivating greater awareness of how the participants classify their daily experiences according to the three categories above and according to their mood and thoughts (Segal et al. 2002a).

The inquiry, or reflection, and discussion between facilitator and participants is largely dedicated to the participants' experiences and observations of the formal and informal practices in the group and at home. The purpose of this component is to develop self-regulatory capacity and skills through exploration of the patterns of thinking, obstacles and difficulties that arise in the practices.

Didactic elements is where participants are given contextual information about applying the practices to particular difficulties that the group is working with, such as depression, anxiety, gastrointestinal problems etc. Although the curriculum of the program is established, the facilitator responds to the unique needs of the group.

Method of delivery

The structure in which the practices were delivered has been carefully designed to enable the participants to cultivate their practice in a systematic way. Although the curriculum has been previously established, (Segal et al. 2012) the facilitator is responsive to the groups' particular aspects of experience, and might expand certain aspects of the practices to fit the groups needs in order to encourage participants to open up to alternative options of thinking or acting.

Evidence base from qualitative studies exploring MBCT

The previous chapter looked at the evidence base for MBCT, primarily in RCTs, which showed great potential for using MBCT in a variety of conditions, starting from depression and anxiety, to patients with Parkinson's, cancer and IBD. However, although the previous chapter also looked at the conceptual models of how mindfulness works, there is currently very little evidence about the mechanism of MBCT and how it works, why MBCT is useful for patients and who it is useful for (Coelho et al. 2013). Thus, the literature suggests that a development of a broader theoretical understanding of the psychosocial mechanisms of MBCT is needed (Allen et al. 2009). One of the ways this could be done is by exploring and understanding the subjective experiences of those receiving MBCT. In doing so, qualitative studies, some of them embedded or nested within RCTs exploring MBCT, have emerged (Finucane and Mercer 2006; Mason and Hargreaves 2001; Ma and Teasdale 2004; Smith at al. 2007; Allen et al. 2009; Williams et al. 2011). Qualitative studies are particularly appropriate for studying a phenomenon or topic that is new and needs to be defined and understood better (Malterud 2001; Denzin et al. 2005). The qualitative approach builds a platform for explanatory processes that are important on theoretical grounds (Bendassolli 2013). MBCT is an experiential program or phenomenon, where participants are trained to become more aware of how they experience their thoughts, feelings and body sensations. Thus, it makes sense that through the qualitative approach, the richness and quality of those experiences can be better captured. The next few paragraphs will review some of the findings and evidence from qualitative studies of MBCT in various conditions, highlighting their strengths and limitations, and as a background and comparison to the qualitative study described in paper 6.

MBCT in depression

Soon after MBCT was developed for depression, in order to add to the quantitative evidence base for MBCT, participants' accounts of MBCT were explored using the qualitative approach in a few key studies. For example, Mason and Hargreaves (2001) used a sample of seven and a grounded theory approach, to explore the participants' accounts of MBCT for depression. The findings suggested that the participants valued the cultivation of the mindfulness skills and the attitude of acceptance and living in the moment. One of the limitations of this study was that it was not well adapted to examining the long term effects of MBCT, due to more than half of the participants being interviewed immediately after the completion of the program, without having the opportunity to practice their skills as part of the relapse prevention.

Another study by Ma et al. (2002) used a larger sample of 41 participants and an interpretative phenomenological analysis approach to examine the participants' accounts of MBCT for depression after 12 months of program completion. The limitation of this study was that the interview questions were limiting participants' reflections in 'predefined dimensions' such as 'usefulness' and 'difficulty'.

A mixed methods approach was used by Finucane and Mercer (2006). They interviewed 13 participants with depression, 3 months after they completed an eight week MBCT program. A limitation of the study was similar to the first one above, where the timing of interviews would have limited the breadth of findings with regards to long term effectiveness of MBCT.

MBCT In physical health chronic conditions

After MBCT became established as a recommended therapy for recurrent depression (NICE 2009), it has been explored in other chronic conditions. For example Griffiths et al. (2009) used a small sample of six participants that were diagnosed with cardiac conditions and in need of cardiac rehabilitation, to explore their experience of MBCT. They used an interpretative phenomenological analysis approach to explore how the participants experienced the intervention as well as its overall impact on their lives, in a bid to understand the psychological mechanism of cultivating mindfulness. The findings suggested that not only did the participants perceive benefits in terms of developing increased awareness regarding thoughts and feelings, but it also improved an understanding of their cardiac problems and the impact of stress on the body.

Fitzpatrick et al. (2010) used a sample of twelve participants with Parkinson's disease (PD) to explore the experience of participating in an 8 week MBCT course. He used an interpretative phenomenological analysis approach and concluded that the participants particularly found the group support very useful in addition to the experience of mindfulness meditation itself. In addition, they suggest that MBCT could contribute to various changes in patterns of coping with PD and has the potential to address the extremely distressing psychological needs of people with PD.

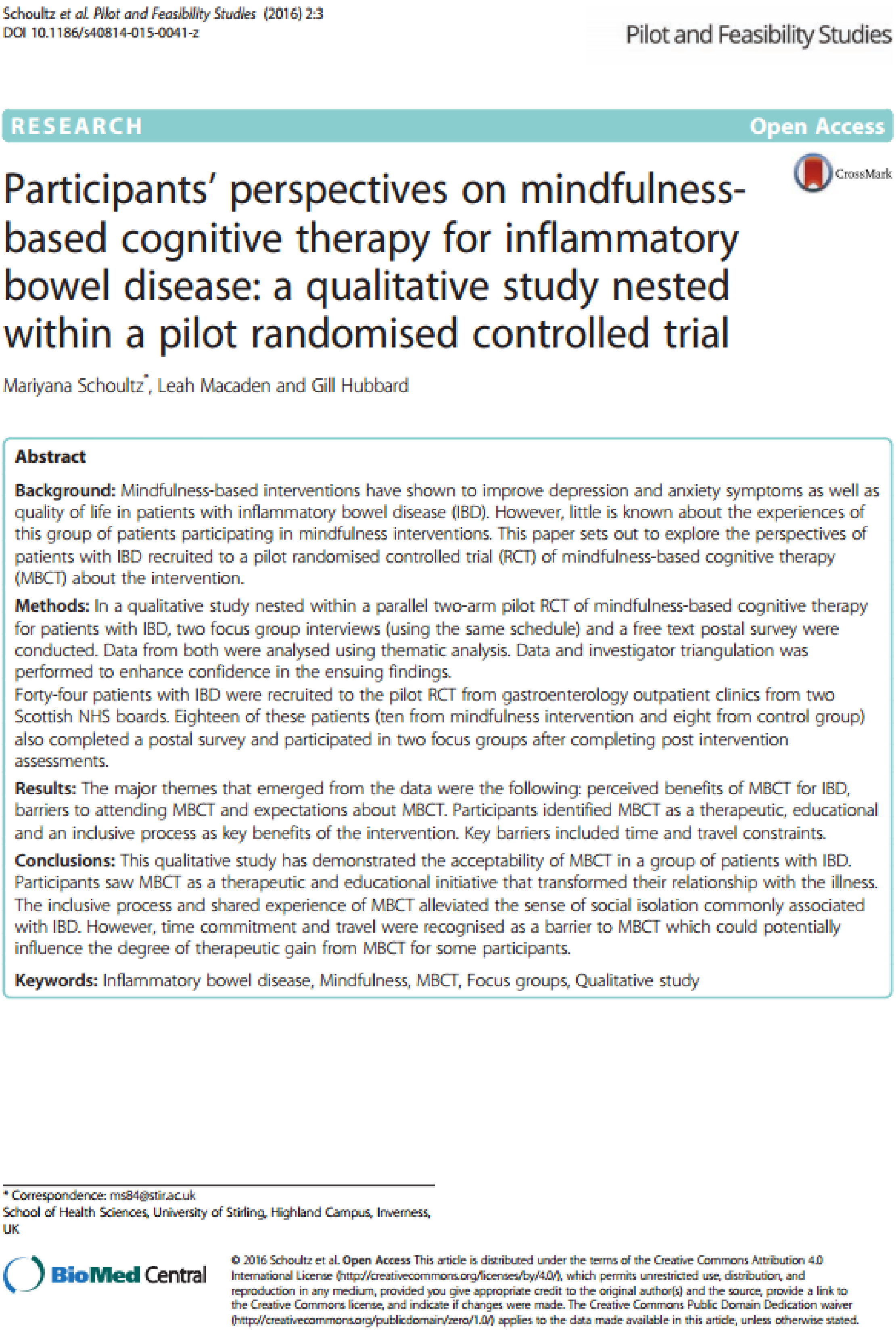
Moore & Martin (2014) used seventeen chronic pain participants who participated in a MBCT group within a public hospital pain unit, between 8 and 50 months previously, to do a qualitative study. They used a thematic analysis approach to identify themes and explored the perceived benefits from MBCT after completion of the program. Although the sample included participants with different lengths of follow up to the program, the study did not clarify if there was a difference in perceptions and applicability of the program depending on how long ago the participants attended the MBCT program. However, it brought new questions about ‘booster groups’ or follow up groups’ where participants could continue practicing the learned MBCT skills.

While participants’ accounts of MBCT have been explored in depression and other chronic physical conditions, participants’ accounts of MBCT have never been explored in IBD. Thus, this was the purpose of this chapter and paper 6.

Aim and linkage to research question

In order to be able to answer the PhD question, (Can MBCT be used as an adjunct therapy to IBD symptom management for improving IBD patients' general well-being and quality of life?) getting evidence from only the quantitative data was not sufficient. As mentioned in the previous chapters, the MRC guidelines for development and evaluation of complex interventions suggests that feasibility and piloting work is required before investigating the effectiveness of an intervention (Craig 2008). Additional work on acceptability and evaluation of the intervention is also necessary to fully inform the development of a definitive RCT. Thus, paper 6 describes a qualitative study nested within the pilot RCT, reporting on the acceptability of MBCT for patients with IBD. This study is unique, and makes an original contribution to the field of knowledge, as it is the first study to examine the accounts of patients with IBD going through an MBCT program. In addition, the findings from the study add to the knowledge base from the previous objectives required for the development of a definitive RCT and therefore the answering of the PhD question.

Paper 6: Participants' perspectives on Mindfulness-Based Cognitive Therapy for Inflammatory Bowel Disease: A Qualitative study nested within a pilot Randomised Controlled Trial



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Pilot and Feasibility Studies

RESEARCH Open Access

Participants' perspectives on mindfulness-based cognitive therapy for inflammatory bowel disease: a qualitative study nested within a pilot randomised controlled trial

Mariyana Schoultz*, Leah Macaden and Gill Hubbard

Abstract

Background: Mindfulness-based interventions have shown to improve depression and anxiety symptoms as well as quality of life in patients with inflammatory bowel disease (IBD). However, little is known about the experiences of this group of patients participating in mindfulness interventions. This paper sets out to explore the perspectives of patients with IBD recruited to a pilot randomised controlled trial (RCT) of mindfulness-based cognitive therapy (MBCT) about the intervention.

Methods: In a qualitative study nested within a parallel two-arm pilot RCT of mindfulness-based cognitive therapy for patients with IBD, two focus group interviews (using the same schedule) and a free text postal survey were conducted. Data from both were analysed using thematic analysis. Data and investigator triangulation was performed to enhance confidence in the ensuing findings.
Forty-four patients with IBD were recruited to the pilot RCT from gastroenterology outpatient clinics from two Scottish NHS boards. Eighteen of these patients (ten from mindfulness intervention and eight from control group) also completed a postal survey and participated in two focus groups after completing post intervention assessments.

Results: The major themes that emerged from the data were the following: perceived benefits of MBCT for IBD, barriers to attending MBCT and expectations about MBCT. Participants identified MBCT as a therapeutic, educational and an inclusive process as key benefits of the intervention. Key barriers included time and travel constraints.

Conclusions: This qualitative study has demonstrated the acceptability of MBCT in a group of patients with IBD. Participants saw MBCT as a therapeutic and educational initiative that transformed their relationship with the illness. The inclusive process and shared experience of MBCT alleviated the sense of social isolation commonly associated with IBD. However, time commitment and travel were recognised as a barrier to MBCT which could potentially influence the degree of therapeutic gain from MBCT for some participants.

Keywords: Inflammatory bowel disease, Mindfulness, MBCT, Focus groups, Qualitative study

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Background

Inflammatory bowel disease (IBD) is a group of chronic gastrointestinal diseases with relapsing nature. The disease affects around 250,000 patients in the UK and around 28 million people worldwide [1, 2]. The two main types are Crohn's disease (CD) and ulcerative colitis (UC) [3]. IBD incidence and prevalence are increasing with future prevalence likely to be considerably greater than at present [4]. To date, there is no cure for the disease and the main focus is on maintaining remission and keeping relapse at bay, managed primarily by medications [5]. In addition, patients with IBD are at increased risk of surgery and other complications.

The symptoms experienced by both CD and UC are very similar and very distressing. They include and are not exclusive to acute abdominal pain and gut spasms, vomiting, malnutrition, fever, fatigue, diarrhoea and rectal bleeding. These symptoms are potentially disabling and can cause severe impact on both physical and psychosocial wellbeing [6]. In fact, around 30 % of these patients suffer from moderate to severe psychological distress and have difficulties in coping with their illness [7, 8]. This distress is not only because they have to deal with the symptoms described above, but because they often experience fear and humiliation as a result of faecal incontinence, which has a profound effect on family, work, social life and identity [9–11]. In addition, they have to deal with the sense of loss of control, feeling 'dirty and smelly' and feeling they are unable to fulfil their potential at work and in sexual relationships [12, 13]. Moreover, the steroidal treatments can often induce side effects such as weight gain and mood swings [14], which might require treatment with antidepressants. Consequently, the proportion of anxiety and depression among these patients is not related to the disease severity, but to their level of perceived stress [15, 16].

There is a considerable body of research investigating the relationship between perceived stress and mindfulness. A number of studies have reported a negative correlation between perceived stress and mindfulness [17–19]. Mindfulness or mindful awareness is the core skill taught in mindfulness-based interventions such as mindfulness-based stress reduction (MBSR) and mindfulness-based cognitive therapy (MBCT). MBCT combines cognitive therapy with MBSR (a programme developed by Jon Kabat-Zinn initially for patient with chronic medical conditions) [20]. MBCT is an 8-week, facilitator-led, group-based psychological intervention. In addition to the 2-h weekly group sessions, there is a guided home practice component for up to 45 min a day. Within the 8 weeks, participants practice a series of mindfulness meditation, cognitive behavioural therapy and stretching exercises within the group and at home [21]. During the programme, participants become more aware of their body sensations, thoughts and emotions and their interrelatedness [21]. This process of cultivating awareness enables participants to explore the change (shift) in their perception and learn how to recognise certain maladaptive thinking patterns and behaviours and replace them with more helpful ones [22]. The National Institute for Health and Care Excellence (NICE) guidance recommends MBCT as a preferred psychological therapy for recurrent depression and chronic worry [23].

Previous studies have demonstrated effectiveness of MBCT for patients with depression and anxiety [24], chronic pain [25], fibromyalgia [26] and chronic fatigue syndrome [27]. In addition, there is an encouraging early evidence about the use of mindfulness-based interventions in either patients with CD or UC in improving depression and anxiety scores and quality of life [28, 29]. However, little is known about the perceptions of this group of patients about any perceived therapeutic benefit of mindfulness-based interventions and particularly MBCT. Thus, this embedded qualitative study is the first of its kind in its investigation and is aiming to close such an evidence gap.

This paper reports the findings from two focus groups and free text survey. This nested study together with a pilot RCT is part of a wider developmental and feasibility work for a full-scale RCT testing if MBCT can be used in IBD patient care as an adjunct therapy. This is in line with the Medical Research Council (MRC) framework for development and evaluation of complex interventions [30], which recommends that such a process evaluation, nested within a trial, can provide an insight into why an intervention works and how it can be optimised for patient benefit.

Nested design is when one methodology (for example qualitative) is placed within the framework of another (for example quantitative) [31].The pilot RCT, where this qualitative study was nested, was a parallel two-arm, exploratory pilot RCT (MBCT treatment, $n = 22$ versus wait-list control group, $n = 22$) with three assessments (baseline, post-treatment and 6-month follow-up). The full protocol of the pilot RCT and its results are reported elsewhere [32, 33].

Although the nested RCT designs across the health and social sciences are rising [34], there is still some criticism over using this design [35]. The criticism is mainly due to researchers not having sufficient and adequate guidance of how to deal with issues intrinsic to nesting qualitative methods within an RCT framework [36]. Recently, such guidance has been developed by O'Cathain et al. [37] for maximising the impact of qualitative research in feasibility and pilot randomised controlled studies (RCT). This qualitative study fits with the above guidance, and the focus groups and survey from the nested qualitative study were included as an important element of the pilot study to provide a better understanding on how acceptable the MBCT programme is for this group of patients.

Objectives

This qualitative study aimed to explore the perspectives of patients with IBD recruited to a pilot RCT of MBCT about the intervention.

Methods

The consolidated criteria for reporting qualitative research (COREQ), a 32-item checklist (see Table 1) for interviews and focus groups [38], was used to guide the structure of this paper.

Participants and setting

All patients that participated in the qualitative study had consented at baseline to participate in both parts: the pilot RCT and the qualitative study. All participants were recruited from two Scottish NHS boards covering city and rural areas in the north of Scotland. Recruitment took place at outpatient gastroenterology clinics through letter of invitation or in person while attending outpatient clinic. Potential participants were given details of the studies and invited to participate in both parts. At recruitment point, all participants had symptoms in remission. Participants were eligible to participate in the qualitative study if they had completed post intervention assessments. Invitation to the eligible participants with details about the focus groups was made by letter or telephone (depending on their preference).

Design

As mentioned above, this qualitative study was nested within a parallel two-arm pilot RCT of MBCT for patients with IBD. The pilot RCT had three assessment points: at baseline, post intervention and 6-month follow-up. All participants who completed the post intervention assessments from both arms were invited to participate in the focus groups as well as to complete a free text postal survey. Further details about the full design of the pilot RCT is published elsewhere [32, 33].

Data collection

Qualitative data was gathered through two focus groups and a postal survey involving patients with IBD participating in a pilot randomised controlled trial exploring the use of MBCT. The focus groups were audio-recorded and took place at a university campus.

Focus groups

The focus groups aimed to explore and understand the views and experiences the participating group of patients had about the 8-week MBCT intervention. Both focus groups examined potential benefits and barriers of MBCT. A facilitator familiar with the aims of the qualitative study and the pilot RCT facilitated both focus groups. Two focus groups lasting approximately 60 min each were conducted with each focus group following the same predesigned topic schedule in order to maintain the methodological consistency. The topic schedule was based on the questions used in the free text survey. A full topic schedule is presented in Additional file 1. The schedule reflected the specific acceptability questions set out in the pilot RCT protocol [32] and guided by the MRC guidance for developing and evaluating complex interventions [30] to determine how well the intervention was received by the target population [39]. In addition, a wide literature search on psychological interventions identified a range of issues related to expectations, benefits, barriers, availability and length of programme. The topic guide was piloted with volunteering colleagues. Travel expenses were reimbursed for all participants. The first focus group took place a week after the MBCT follow-up assessments were completed, consisting of $n = 11$ participants (four from the MBCT intervention arm and seven from the control arm). The second focus group took place 3 weeks later and comprised of $n = 7$ participants (six from the MBCT intervention arm one from the control arm). All participants self-selected to participate into the first or the second focus group depending on their availability and convenience and consented to the discussions being audio-recorded.

Focus groups have long been recognised as a purposeful interaction for generating data [40] and were used in this study because they created an opportunity for participants to reflect on their responses, which cannot be captured in a questionnaire [41]. In addition, using focus groups is particularly useful when investigating not only *what* participants think about a topic, but also *why* participants think in that particular way [42].

Survey

A cross-sectional postal survey was sent to all the participants following completion of post intervention assessments. The survey consisted of a series of questions including free text to give opportunity to participants to express their perceptions about their experiences of the MBCT programme. The questions used in the survey mirrored those of the focus group topic themes (see Additional file 2). Participants then sent the completed and anonymised survey (containing only study ID number) in a self-addressed prepaid envelope back to the researcher. A reminder to complete the survey was sent after 2 weeks.

Survey research is the most common method of collecting data in health and health service research,

Table 1 COREQ 32 checklist

No	Item	Guide questions/description	Response
Domain 1: Research team and reflexivity			
Personal characteristics			
1.	Interviewer/ facilitator	Which author/s conducted the interview or focus group?	Mariyana Schoultz Clinical Academic Fellow at University of Stirling PhD Candidate (conducted focus groups).
2.	Credentials	What were the researcher's credentials? e.g. PhD, MD	Leah Macaden Lecturer University of Stirling PhD.
3.	Occupation	What was their occupation at the time of the study?	Gill Hubbard Reader University of Stirling PhD.
4.	Gender	Was the researcher male or female?	All 3 researchers are female.
5.	Experience and training	What experience or training did the researcher have?	MS had a qualitative research training through the PhD and have previously conducted qualitative research. LM and GH are both qualitative researchers.
Relationship with participants			
6.	Relationship established	Was a relationship established prior to study commencement?	The participants were not acquainted to the researchers prior to the study commencements.
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	The participants knew that the intent of the evaluation was to identify benefits and barriers encountered in order to make improvements to the MBCT programme. Interviewees knew that the researchers were affiliated with University of Stirling.
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
Theoretical framework			
9.	Methodological orientation and theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	We used a thematic analysis approach (see [45]).
Participant selection			
10.	Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Participants were recruited consecutively.
11.	Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Participants were approached by mail and recruited by face-to-face.
12.	Sample size	How many participants were in the study?	18 in total.
13.	Non-participation	How many people refused to participate or dropped out? Reasons?	6 participants that were invited for the focus groups did not respond.
Setting			
14.	Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Focus groups were conducted at University Building.
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	No.
16.	Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Age, gender, level of education, income, marital status and disease type were included in Table 2 reported in Table 4 of the manuscript.
Data collection			
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Prompts and questions were provided by the author. The guides were not tested in a pilot study, but were discussed.
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?	No.
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data?	Focus groups was audio-recorded and transcribed prior to analysis.
20.	Field notes	Were field notes made during and/or after the interview or focus group?	No.
21.	Duration	What was the duration of the interviews or focus group?	Focus groups: 1 hour approx.
22.	Data saturation	Was data saturation discussed?	

Table 1 COREQ 32 checklist *(Continued)*

		Yes—data collection from participants ended when saturation was achieved.
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No. Transcripts were reviewed by researchers who listened to the audio recordings to verify their accuracy.
Domain 3: Analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	2 researchers (MS and LM).
25. Description of the coding tree	Did authors provide a description of the coding tree?	No. However, initial coding was informed by the interview guides but codes were continually refined as simultaneous data collection & analysis provided new insights. Codes were grouped into similar descriptive categories. The final themes were agreed upon by the analysis team through consensus.
26. Derivation of themes	Were themes identified in advance or derived from the data?	
27. Software	What software, if applicable, was used to manage the data?	No software was used.
28. Participant checking	Did participants provide feedback on the findings?	No.
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Yes.
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes.
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes.
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes.

designed to provide a snapshot of how things are at a specific moment [43]. It is a tool that can be used when describing attitudes, experience and behaviours [44], which fits with this study research question. The survey was used in addition to the focus groups to maximise response from participants about MBCT, particularly from those living remotely and to validate the results from the focus groups.

Analysis

Two researchers (MS, LM) analysed the data, one of whom was involved in conducting the focus groups. The focus groups were audio-recorded and transcribed verbatim. Respondent validation was undertaken during focus groups to ensure rigour with data collected. Data were analysed using a thematic analysis framework approach [45]. This approach is a rigorous method that provides a structure for qualitative data to be organised and coded and for themes to be identified. Initially, the first three phases of familiarisation with data, generating initial codes and searching for themes among codes were done independently by the two researchers for the survey and the focus groups separately. This is referred to as an investigator triangulation [46]. The researchers then met to discuss their findings for the initial analysis. All initial codes and themes were compared and any differences rectified. The researchers then extracted the core themes and went through the next three phases of reviewing themes, defining and naming themes for the survey and the focus groups. Before producing the final report of key themes and sub themes (see Table 2), triangulation of data was performed between the survey and focus groups. The data and investigator triangulation was performed to enhance confidence in the ensued findings as well as to reduce the uncertainty of interpretation [46, 47].

Table 2 Overview of themes and subthemes derived from the focus groups and survey

Main themes	Subthemes
Benefits from MBCT	MBCT as a healing/therapeutic process
	MBCT as an educational process
	MBCT as an inclusive process
Barriers for MBCT	Time
	Travel
Expectations about MBCT	Open
	Fixed

MBCT intervention

The intervention referred to in this study was MBCT, which followed the 8-week MBCT manual developed by Segal et al. [48]. This included eight 2-h weekly face-to-face group sessions. Each session included a facilitator instruction which included a new theme (see Additional file 3 for themes) and instruction for a new group practice/exercise. This was then followed by reflection of practice and then a review and instruction for home practice. Each session would normally close with sitting meditation. A sample list of activities for session 1 is presented in Additional file 4.

Home practice assignments were the other part of the MBCT intervention. The aim of the home practice is to reinforce the learning of the in-group strategies and techniques. The recommended 'dose' of home practice was up to 45 min a day, 6 days a week guided by an audio CD and outlined home practice instructions. The home practice handouts and audio files used for home practice are readily available for the published books respectively [48, 49].

Research team

Two investigators (MS and LM) were involved in data analysis, with the lead author conducting the focus groups and collecting all the data. None of the investigators were involved in providing patient care, and both investigators were employed by the University of Stirling as a clinical academic fellow and a lecturer. A third researcher (GH), employed as a reader by the university, overlooked the process. All of the researchers had previous experience of qualitative research and thematic analysis, with two of the researchers having extensive experience in thematic analysis.

Ethics

A favourable ethical approval was granted by the NRES Committee for North of Scotland on 8 April 2013 (REC ref 13/NF/0018). NHS Highland and NHS Grampian R&D Management Approval was obtained on 9 April 2013 and 14 September 2013, respectively.

Results

Characteristics of respondents

Out of the 44 patients who consented to participate in the pilot RCT, 24 of them completed follow-up assessments and were eligible to participate in the focus groups and complete the postal survey (see Additional file 5 for patient flow). Six participants declined participation in the focus groups and did not return a completed survey. Thus, this section presents the results for the 18 participants that took part in both, the focus groups and the survey. The focus group and survey participants' characteristics are shown in Table 3.

Table 3 Focus groups and survey demographic and clinical characteristics of participants

Baseline	
Age (years) (*n*, mean (sd))	18, 45 (13.86)
Sex F (*n*, (%)), M (*n*, (%))	13 (72.3), 5 (27.7)
Income (*n*, %)	
Less 10K	4 (22, 2)
10K–19K	3 (16, 6)
20K–29K	3 (16, 6)
30K–39K	5 (27, 7)
40K–50K	2 (11, 1)
50K+	1 (5, 5)
Disease type	
CD (*n*, %)	8 (44)
UC (*n*, %)	10 (66)
Marital status	
Single (*n*, %)	5 (27, 7)
Married/cohabiting (*n*, %)	11 (61, 1)
Widowed (*n*, %)	0 (0)
Separated/divorced (*n*, %)	2 (11, 1)
Education	
High school (*n*, %)	5 (27, 7)
Diploma (*n*, %)	9 (50.0)
Degree or above (*n*, %)	4 (22, 2)
Geographical area	
Rural (*n*, %)	9 (50)
Urban (*n*, %)	9 (50)

The key themes that emerged across both focus groups and the free text from the survey were the following: 'Benefits of Mindfulness-Based Cognitive Therapy for IBD', 'Barriers for Mindfulness-Based Cognitive Therapy for IBD' and 'Expectations about Mindfulness-Based Cognitive Therapy'. All of the major themes had few sub themes each (see Table 2) that were interlinked. The foundations for these themes are described separately alongside the verbatim quotes.

Benefits of mindfulness-based cognitive therapy for IBD patients

Three sub themes emerged from the above theme: (1) healing/therapeutic process, (2) educational process and (3) an inclusive process.

1) Healing/therapeutic process
   The perceived main benefits of MBCT for patients with IBD were that participants saw the MBCT intervention as a healing/therapeutic process. Participants noticed that the intervention offered alternative methods for dealing with anxiety, poor

sleep, pain and depression (Table 4, quotes 1, 2 and 3) and insight into gaining more control over the management of their symptoms (Table 4, quote 5). Being able to relax and regain control over symptoms is something that is very important for patients with IBD as dealing with pain and other daily symptoms brings on anxiety, depression and poor sleep for many of them [50]. These are normally managed by medications, which often have side effects and further issues. Being able to learn techniques that will ease the pain, help to relax, feel calmer and have a better sleep, while not having to rely on medications, is something that more than a few described as essential to therapeutic gain.

Many patients with IBD worry about how they would deal with a flair up (symptom exacerbation) if it happens and often become either anxious or depressed about it. Participants found the intervention helpful (both emotionally and on a practical level) in dealing with their worry, anxiety and depressive thoughts. They found the programme particularly useful in changing their unhelpful habitual behaviours such as spiralling downward into depressive thoughts with more helpful ones, but also providing them with a respite from their anxiety and a way of dealing with crisis (Table 4, quotes 4, 6 and 7).

Moreover, due to the nature of the disease, food or relationship with food is often a challenging aspect. These patients often cannot keep food down due to vomiting which brings a lot of fear and anxiety related to food and eating. This contributes to further malnutrition in addition to the malnutrition caused by inflammation of the gut. Thus, for some, like participant P016, restarting to enjoy eating was a significant therapeutic experience (Table 4, quote 8).

2) Educational process

Some of the participants saw the intervention as an educational process. There was a prevailing perception of learning to self-care as a result of the intervention as described by participants' quote (Table 4, quote 9). The learned techniques that facilitated self-care and coping were seen through the awareness and recognition when it was time to slow down or even stop before becoming too unwell (Table 4, quotes 10 and 11). The realisation of being able to take control of their body and relinquishing the state of 'auto pilot' transformed the relationship with self and the illness (Table 4, quote 13). For another participant, the transformation was through the learned acceptance of the illness, by timely recognition of mental and physical exhaustion (Table 4, quote 12).

Participants agreed that the applications of the skills learned through MBCT are transferrable and applicable to different everyday situations. They found that MBCT gave them the tools which can be used in different ways and be applied to everyday living while dealing with cramps, stress and other daily frustrations (Table 4, quotes 14, 5 and 15).

One noteworthy example of 'everyday' application of the mindfulness skills was described by a patient who normally struggled with using the MRI scanner (IBD patients often need scans to check changes in the bowel [51]), but using one of the techniques from the class helped the participant cope with the event better (Table 4, quote 16).

3) Inclusive process

And finally, some of the participants saw the intervention as an inclusive process that facilitated peer support and a supportive environment that resulted in general feeling of inclusion and less isolation.

Participants believed that the MBCT intervention for patients with IBD provided them with an opportunity for peer support in an inclusive and supportive environment. Their view was that the peer support ascended from shared experiences of participating together in group-based exercises, shared experience of similar diagnosis and shared experience of learning in an environment where they felt safe to express their emotions without being judged. For example, one participant identified that the sense of support in the group was of a great value for them (Table 4, quote 17). Another participant described the sense of support from the peers as being in a 'little club' where you can feel free to be yourself (Table 4, quote 18).

For many participants, not being judged and being left to be themselves in the group made them feel free and comfortable and increased their sense of inclusion and belonging (Table 4, quotes 19 and 20). Consequently, even though the MBCT programme is not a talking therapy, and some participants say very little, the programme offered an opportunity where participants could tap into support from their peers by just being there. For others, it was a confidence booster or a platform where they felt a part of an inclusive and supportive group in which they were free to express themselves and felt less isolated in their illness because of it (Table 4, quotes 21, 22 and 23).

Difficulties and barriers for mindfulness-based cognitive therapy

Although participants focused on the benefits largely in their discussion, there was a part of the discussion that

Table 4 Benefits quotes

Quote no.	Codes	Quote
MBCT as a healing/therapeutic process		
1	Easing the pain	'..it's, it's mostly painkillers that I'm on — I've hardly used any in the last eight weeks, hardly any at all, so em…' (P014)
2	Antidepressant/de-stress and pain relief	'The short meditation technique is a great way to control yourself-where anti-depressants can cause bigger issues to the user/stress, helps you to relax and ease the pain away' (P010)
3	Better sleep, sense of peace	'I feel calmer, and the brain feels less rushed, em you've just got a more inner sense of peace.. I'm, I'm not a poor sleeper, but I was a light sleeper — my quality of sleep's improved that I can sleep straight through and feel you know that I've had a good sleep' (P015)
4	An antidote for anxiety, worry and depression	'not worrying about something that's happened, or something that may, you know, and just slowing down really' (P014)
5	Stress and pain relief	'Gave me an insight on how I can relax, through breathing techniques and can do it anywhere anytime. Help in working through pain to relax through cramps, sleep. '(P001)
6	Relaxation	'helps me to deal with immediate crisis…allows me to relax for a short period.' (P008)
7	Helping with spiralling down (depression)	'I still have that urge just to go to bed, just pull the covers over my head and, not sleep necessarily, but just … curl up in a ball and just lie there…. but now I go up and I just, I go 'I'm doing meditation, I'll be half an hour,' and that'll gimme the kick in the arse that I need … really, I suppose getting me out of really spiralling downward, eh or maybe that was just habit …'(P012)
8	Help with food	'I find that food tastes differently because I'm taking time to eat it and taste it …' (P016)
Educational and transformational process		
9	Learned self-care and change of relationship with illness and self	'I think the fact that I learnt to think about me for a while and to learn to look after myself and to learn when my body is telling me to relax and give it a rest' (P002)
10	Realisation about taking charge of wellness	'I understand now that it is ok to stop for 5-10 minutes & its ok to think about me for a change. The processes involved in this programme made me realize I was quite unwell and have helped me throughout' (P013)
11	Transformed through reflection	'I realised I was doing everything at high speed and more than one thing at a time, whether it was at home or at work, I was never switching off … I could do that as I was walking to work, and even at work you know I've seen the benefit now of focusing on what I'm doing — being in the moment' (P008).
12	Learned acceptance	'as it opened my eyes to accept the illness, but also the mental and physical exhaustion that comes with it.'(P001)
13	Evaluate, change	'made me stop & evaluate my life.& realize I was able to take control of my body. No longer on auto pilot.' (P017)
14	Alternative to getting 'wound up' Can do it anywhere	'You don't have to go to class or yoga. You can actually do it anywhere at any time when you ready to do your three minute breathing you can just take that time out and that's.. ammm to allow the anger and other things that get you all wound up ..coz a lot of time I get grrrrr I get really wound up about over other things and full of frustration of whatever and… it and that has helped me over in a really difficult time. its It's kind of alternative to get wound up. Aha' (P008)
15	Stress relief tools	'Help me deal with stress, gave me the tools.' (P003)
16	Everyday application	'Now I don't really like closed spaces, and how tight is it inside that blinking MRI thing?..And when they slid me inside I was just about to squeeze that wee thing and shout 'get me out of here!' And you remember on the course we did that — near the end of the course — we did that meditation where we were thinking about being a mountain?..well I used the visualisation technique in that MRI scanner, I started to breath, started to, just try and calm myself down; and I was in that thing for an hour and fifteen minutes with no problems at all' (P015)
Process of inclusion with emotional support		
17	Supported, not judged	I felt very supported and not judged for feeling emotional and not having to explain myself
18	Belonging	'It's almost like…little club …its like a everyone gets to know everybody and you didn't feel … you know the barriers were coming away and everybody was…. I felt …more freely talking..'(P013)
19	Belonging	'Being part of a group of fellow sufferers was positive…non-judgemental' (P017)
20	Non-judgemental environment	'But that's what it was all about, allowing us to be, 'cause I know I was emotional one night and I went away and I was quite relieved when I came back and nobody sort of said "are you all right?," and I, you know I felt that it, it was comfortable to be like that.. I'll come back and go

Table 4 Benefits quotes *(Continued)*

		with this and be supported, and that's what it's been like; nobody's judging or … and that's so important …' (P013)
21	Not alone	'To know you are not alone is a boost to moral in itself' (P008)
22	Isolation	'IBD can feel very alone and isolated' (P004)
23	Share experiences with others	'It was reassuring to meet others in a similar situation where you can share experiences which very often turn out to be very similar to your own.' (P001)

explored barriers that they faced in accessing or attending the MBCT programme. Within this theme, the largest focus was on 'time' and management of time. While for some participants it was difficult to allocate the time for attending the class after work, for others it was the time required to do the home practice component (homework) of the programme. 'Homework' was a component of the programme where participants were encouraged to reinforce the MBCT skills through regular practice. Some of the participants recognised their difficulty in juggling work and family life together with the programme and identified that as a barrier (Table 5, quote 1). Others struggled managing to find time for homework and they recognised the effort it takes to fully participate in the programme (Table 5, quotes 2 and 3).

Table 5 Difficulties and barriers quotes

Quote no.	Quote
Time as a barrier	
1	'It was quite difficult having it from 5.30 to 7.30 because that's when most people will eat especially when you are coming straight from work ..and It's difficult to get time off off work for doing something like this but erm…' (P003)
2	'..but the homework was hard, .. hard to find the time sometimes … but I do, I really enjoy the support …' (P017)
3	'Finding the time to do the homeworks sort from week three and onwards.it got quite(pause).. week three and four was quite intense erm..' (P003)
4	'It was difficult to fit in all the homework' (P007)
5	'yea…some talking..just..(laugh) but also felt coz…I also felt …erm…its taking ,we were having to find time for ourselves. And….erm…' (P008)
6	'I think for most folk the time constraints to do meditation were the big issue weren't they?' So I can see where some people are coming from when they say they find doing the meditations difficult if you're busy, but, it's literally a case o' trying to find time, isn't it?' (P015)
7	'I didn't get that much time to do it at home, not as much… but I just didn't have the time and personally I don't feel I was committed enough to it as I should have been' (P007)
8	'I found you do have to fully embrace its concepts and the time you invest is well rewarded' (P008)
9	'once you realise how to prioritise your day, setting aside time to do the homework practices was straightstrait forward.' (P014)
Distance as a barrier	
10	'Distance…some.., I don't come from that far but others come from I bit further and going home this time of year for the next one with the weather and things.' (P008)

In contrast to the benefits of MBCT where participants recognised that slowing down and finding time for oneself is an integral part of staying well, they also recognised that the key aspect of the programme of finding time was quite difficult. While some participants viewed time as a barrier, there were others who recognised this barrier but worked towards making time for MBCT practice (Table 5, quotes 4 and 5). Other participants recognised that to get the full benefit of the programme, they somehow had 'to shift' the way they perceive time and create or find the time in the day to do the home practice (Table 5, quote 6).

While in discussion about time as a barrier to MBCT and home practice, one participant notably acknowledged a key point that perhaps others did not recognise, and that is the personal commitment to make time (Table 5, quote 7).

When talking about time as a barrier, some participants recognised that finding time for practice was related to the attitudes towards committing time for the practice. They talked about time as an investment into wellbeing, that can be very rewarding and about learning to prioritise daily activities in order to create time for home practice (Table 5, quotes 8 and 9).

In addition to the time barrier, travel and distance were difficulties recognised by some. While there were a number of participants that lived rurally, only a small number of participants (two) acknowledged the travel and distance as a barrier to attending the programme. One participant recognised that it could be difficult to travel a distance for some, especially in the winter periods (Table 5, quote 10).

Expectations about mindfulness-based cognitive therapy

Literature suggests that clarifying patients' expectations is associated with engagement and health outcome [52]. When participants were asked what their expectations about MBCT were, there were a range of responses. More so, the type of expectations participants had about the MBCT programme seemed to determine their insight and engagement into the programme, and therefore influence their perception about benefits or barriers with MBCT. When looking at the participants responses about expectations, their responses were either very open with very little expectations or very specific and fixed ones. For example, many participants talked about the importance of being open minded before the programme and the willingness (attitude) to go into it with no fixed expectations, such as curing the illness (Table 6, quotes 1, 3, 4 and 5). One participant described how their expectation changed during the programme, from worrying that the programme will be 'airy-fairy' to being pleasantly surprised at the outcome (Table 6, quote 2).

On the other hand, there were participants that described their expectations related to the MBCT programme as more specific and fixed. For example, few were hoping that the programme would help them understand their condition, how the body works and how that affects them (Table 6, quotes 6 and 7). Another participant described her expectations about the programme as being a 'cure' for the condition and provide overall improvement of the condition and lifestyle (Table 6, quote 8). While another participant talked about his specific expectation about the content of the programme, which remained unchanged at the end of the programme (Table 6, quote 9).

Discussion

The study set out to explore participants' perceptions of mindfulness-based cognitive therapy for patients with IBD recruited to a pilot RCT. It is important to acknowledge that the study used a standard curriculum of MBCT programme [32] which brought a variety of participants' experiences and perceptions.

Table 6 Expectations about MBCT

Quote no.	Quote
Flexible (open minded)	
1	'Came with an open mind to see how far this could be taken, if it would make me feel better…and I found it great, it was good' (P015)
2	'I worried it was going to be hippy, airy fairy, but was pleasantly surprised' (P003)
3	'No expectations, open mind' (P001)
4	'I didn't expect to cure my illness, had an open mind and was pretty good.' (P016)
5	'It was important to come with an open mind and be willing to go into it.' (P002)
Fixed (specific)	
6	'…to understanding the condition and effects it has on me' (P013)
7	'…Alternative therapy to drugs, hoping to understand more of how my body works' (P012)
8	'My ulcerative colitis would improve. Lifestyle would improve.' (P008)
9	'Expected to talk more about depression…I prefer to be in a group and talk about how I feel.' (P007)

The sub themes of therapeutic and educational process were at the heart of the benefits theme. Participants described their personal experience of the programme as a therapeutic and an educational initiative that has enabled them to transform their relationship with the illness and being empowered to take control over their symptom management. This transformative effect of mindfulness on attitudes and perceptions is documented in different clinical and nonclinical populations before [53, 54] and is a result of learning the key skill of being mindful. Thus, learning to respond mindfully to changing life situations and loss has enabled the participants to see stressful events such as their condition, rather than as defining characteristics of their identity. This is particularly noteworthy for patients with IBD, because some of their symptoms such as faecal incontinence and lack of bowel control could lead to loss of self-worth and exacerbate further stress and depression [55, 56]. In addition, through the programme, participants learned that some of their previous habitual responses to stress and symptoms were not always helpful, and therefore, they attained skills that enabled them to change those patterns into more helpful ones. This fits with a proposed mechanism of mindfulness where participants are able to see things from a completely different perspective as a result of the 'shift' in perception that happens in the meditation practice [22]. Both the versatile nature of the skills and their transferability into everyday situations acquired through MBCT were viewed as critical benefits by the participants to continue the use of mindfulness.

The shared experience/peer support sub theme has been previously highlighted in IBD and mindfulness literature. Sharing a similar diagnosis can often create a sense of community for the participants, which could alleviate the sense of social isolation commonly experienced by many patients with chronic conditions, including patients with IBD [57–60]. This is particularly important for patients with IBD, as their condition is hidden and they often appear well to others. However, it was very clear in this study that while the shared diagnosis benefit might have attracted participants to partake in the study, the experience of learning together to manage their symptoms in a non-pharmacological way and in a non-judgmental and supportive environment added to the benefit of peer support role and their motivation to stay in the programme. The participants themselves described the importance and value of the group experience as an aid to the therapeutic process and gain. The process of participants sharing their experience of the meditation journey as well as the process of group cohesion growth noted here is been seen in groups of other supportive expressive therapies in IBD and mindfulness-based therapies in other chronic conditions patients [61, 62]. This is particularly interesting since the format of the programme is mainly experiential rather than sharing and talking.

The largest participant focus in the barrier theme was on time or management of time, particularly with home practice. The other barriers identified were travel and distance. It was noted that there was a contrast between the benefits where participants acknowledged the necessity of finding time to listen to the body and its needs through practice; participants also reported that finding time for practice for some of them was very difficult. What is striking that one of the participants clearly pointed out that the attitude of commitment was an integral part in finding or creating time for practice. This attitude of commitment is at the core of the mindfulness practice teaching itself. According to Jon Kabat-Zin, attitudes involve intention and intention sets the stage for the mindfulness practice. Thus, the attitude is described as "the soil in which you will be cultivating your ability to calm your mind and to relax your body, to concentrate and to see more clearly" [20]. Closely connected to the attitude topic is the theme of expectations. Patient expectations in a healthcare setting are a set of beliefs concerned with the treatment/intervention and the outcomes of the treatment [63]. Expectations about interventions have been seen to be associated with engagement and health outcome [52] and therefore influence the perception about benefits or barriers of the intervention. Open and more positive expectations have been linked to better outcomes [64]. This is linked to the mechanisms involved in producing the placebo effect or patients' belief about outcome can be a powerful predictor of actual outcome or benefit of the intervention [64]. Patient expectation measures should be incorporated into future trials.

Strengths and limitations

Qualitative analysis of participants' perceptions and experiences of MBCT for IBD provided within a pilot RCT is novel and has not been explored before. This study was nested within a parallel two-arm pilot RCT examining the use of MBCT for patients with IBD. The data was obtained from participants with a wide range of age, education and social background and geographical area.

The findings from this qualitative study are consistent with and supplement the quantitative data findings from the pilot RCT [33] which showed that depression and anxiety improved at post intervention and 6-month follow-up from baseline in the intervention arm. The findings of this study extend the findings of the pilot in few ways. First, the perceived benefits of the MBCT intervention that participants experienced and discussed in the qualitative study supplements and warrants the recommendation of the pilot RCT for a future full scale RCT exploring the effectiveness of MBCT in IBD. Second, the findings about barriers about the MBCT intervention should be considered in the recruitment process for a full RCT and might be able to ameliorate the higher than expected drop-out rate from the pilot RCT. And last, the findings from the qualitative study about participants' expectations should be regarded in a future full RCT: patient expectations should be explored and patient expectations measures should be incorporated into such a trial at baseline and follow-ups. This could improve treatment recommendations for effective methods of fostering positive expectations that can ultimately improve health outcomes.

A limitation is that the study had a small sample. As with any qualitative study, the findings of the study cannot be generalised beyond this group of participants, who are unique in their characteristics. However, although the attained benefits of practice and recognised barriers of MBCT for these participants may not be replicated by every patient with IBD, they are certainly possible. The clinical implications of the findings suggest that MBCT could be an acceptable and beneficial intervention for people with IBD and could help them cope better with the disease and symptom management.

Findings also suggest that this intervention may not be appropriate for everybody. Participants' reports about their initial expectations of the MBCT programme suggest those to be highly important in influencing their experience of the programme and ultimately the therapeutic gain. Participants with fixed expectations and attitudes may need individual support at the start to fully gain the benefits of the programme and should be considered at a point of recruitment.

Because researchers are not immune to their own assumptions about stress, depression and meditation, participants' own words and phrases were used to allow the reader to make their own judgments about the trustworthiness of the analysis.

Conclusions

The findings from this study have provided evidence around patient experiences using MBCT in IBD which has not been explored before. The analysis has given an insight into what is important for patients with IBD after diagnosis and when considering psychological therapies. Participants described their personal experience of MBCT as a therapeutic and an educational initiative which has enabled them to transform their relationship with the illness. As a result, many felt empowered with regaining sense of control over their body and symptom management. In addition, the inclusive process and shared experience of MBCT have alleviated the sense of social isolation commonly associated with IBD.

However, time commitment and distance were recognised as a barrier to MBCT and it could potentially influence the degree of therapeutic gain from MBCT for some participants. This study has implications for policymakers and providers of care for patients with IBD. Providers of care may wish to consider offering an 8-week MBCT programme to patients with IBD to help with symptoms of depression and anxiety.

To conclude, this qualitative study has demonstrated the acceptability of MBCT in a group of patients with IBD. Together with the pilot RCT where this study was nested, both findings form a knowledge base for a future full-scale RCT investigating the effectiveness of MBCT in IBD. This trial is novel in its investigation and will hopefully encourage more research to address the psychological needs of patients with IBD and the use of MBCT.

Additional files

Additional file 1: Topic guide schedule for the facilitator with preamble. (DOC 24 kb)

Additional file 2: Free text survey questions. (DOC 20 kb)

Additional file 3: Weekly session themes. (DOC 20 kb)

Additional file 4: A sample list of activities for session 1. (DOC 20 kb)

Additional file 5: Diagram describing flow of patients through study. (DOC 32 kb)

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

MS and GH were involved in the research concept and design. MS and LM were involved in the analysis and interpretation of the findings. MS, LM and GH contributed to writing of this manuscript and fulfilled the ICMJE criteria for authorship. All authors read and approved the final manuscript.

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Overview and critical reflection on Paper 6

The next few paragraphs will critically reflect on the methods used in paper 6. The strengths and weaknesses of the methods used are provided in paper 6, nonetheless the following section will expand on these in more depth.

The overall concept for this paper was to explore the perspectives and experiences of patients with IBD recruited in a pilot RCT of MBCT regarding the intervention. The findings derived from this study together with the findings from the studies described earlier in the thesis, were to collectively and specifically collect evidence for a definitive RCT of the effectiveness of MBCT for patients with IBD. Examining and understanding the participants' perceptions and experiences of MBCT is a fundamental part of the preparation process for a future trial, particularly when this has been uncharted territory, in this patient group.

Methods

The study described in paper 6 utilised a qualitative research method, which unlike the quantitative method that seeks to enable clear and generalizable conclusions and statistical analysis, seeks insight and draws out the individual perceptions about a certain topic. This approach enabled discovery, exploration and conceptualisation of patterns and themes that arose from the participants' views and experiences of the intervention. Although the findings from this approach are specific to the researched group, findings that are derived through sound qualitative methodology should be replicable (generalizable) (Bell 2014).

However, this qualitative study did not sit in isolation. From the onset of preparing the protocol for the pilot RCT (see previous chapter 4), it was decided to embed a study using a qualitative approach to elicit the participants' perspectives of the intervention. Embedded or nested design is where one methodology (for example qualitative) is placed within the framework of another (for example quantitative) (Creswell et al. 2011). Depending on what the research question is, qualitative design can be embedded at different points of the framework of the intervention in a RCT. For example, it can be prior to the intervention, to inform strategies to best recruit individuals or develop the intervention; during the intervention, to examine the process experienced by the participants or after the intervention, to follow up and further better understand the quantitative data (Curry et al. 2009). In this case, the qualitative design was embedded within the intervention procedure in order to understand participants' experiences of the intervention.

The number of embedded or nested RCT designs across the health and social sciences are rising (Kaptchuk et al. 2009; Lipman et al. 2010). This is predominantly due to the scholars' criticism over the limitations of traditional RCTs and the benefits and usefulness of using qualitative methods in combination with RCTs (Creswell et al. 2009). However, despite the rising numbers of embedded designs, there are still criticisms and concerns that need to be considered when applying this type of design. Some scholars note that qualitative methods within quantitative intervention studies are not well planned, or the embedded procedures are not well conceptualized (Song et al. 2010; Creswell and Zhang 2009). Others argue that the researchers using mixed method approaches are often guided by a post-positivist framework and therefore do not fully utilise the insights that are gained through using qualitative approaches. This is believed to be due to the tendency to undervalue these insights but also, due to the fact that RCT design parameters can limit the qualitative data collection and analysis (Giddings 2006). Thus, Plano et al. (2013) debate that these limitations are due to researchers not having sufficient and adequate guidance about dealing with issues intrinsic to embedding interpretive qualitative methods within an RCT framework. A recent guide by O'Cathain et al. (2015) has been developed to maximise the impact of qualitative research in feasibility studies for RCTs and aims to enable researchers to consider the full range of contributions that qualitative research can make in relation to the RCT.

The biggest argument in the literature is that embedded designs are seen as having an unequal priority of the comparative importance between the quantitative and qualitative components in addressing the research questions (Plano et al. 2013). It is believed that researchers choose the embedded type of design when the research questions they want to answer are categorized into primary and secondary. The secondary questions are often seen as having less importance or priority when addressing a related, but different question to the primary question, with a view to enhance the interpretation of the larger design. Greene (2007) goes further to say that the embedded method has less priority and being located in a larger design is not only constrained, but often seen or described as supplementary, subservient and supportive. Further criticism by Morse and Niehaus (2009) states that an embedded design does not make sense, particularly if the findings from the qualitative study will be ignored, submerged and make no contribution to the result. Thus, Plano et al. (2013) make a suggestion that the secondary research question from the qualitative method is embedded in the context of the primary research question. Thus, when the qualitative study described in paper 6 was designed, the above was considered. For example, the aims and objectives of the study reported in paper 6 were built directly onto the aims and objectives of the primary questions in paper 4 (as seen in the previous chapter). Similarly, taking into account the criticism of Morse and Niehaus (2009), the findings of this study are reported separately as planned from the onset.

Collection of the evidence

As mentioned above, a large portion of the literature about embedding focuses on the constraints of the design and the methods used. In addition to all limitations that all study designs experience, (i.e. resources, ethical considerations, and the researchers' assumptions) a sticking point for the embedded design are the assumptions and requirements associated with the primary RCT design. This comes from the high level of internal validity needing to be achieved in order for cause –effect claims to be made. Thus, the 'typical' qualitative and quantitative approaches were considered in each major design decision: sampling, data sources, data collection procedures and relationship between researchers and participants. Thus, the sample for the embedded study was small, data collection was as per protocol and qualitative data was collected through audio recording of focus groups and postal free text survey. The qualitative data analysis was kept distant from the participants in order to adhere to the parameters of the pilot RCT.

Focus groups and surveys

As with any other research decision making, selecting the most appropriate method for data collection goes through a series of questions and factors for consideration. The literature suggests that when seeking a complete response, interviews and focus groups are most likely to provide the depth of information needed when compared to a survey (Adams & Cox 2008). From a distance, focus groups and interviews seem to provide the same outcome, in that both are intensively moderated, focused qualitative methodologies. However, there are differences. Although interviews can obtain a greater depth of information, the focus groups can get more done in a shorter time. In addition, a focus group simulates a real-world dynamics, and it is an appropriate method when trying to gain multiple perspectives in an interactive group setting, (Stewart & Shamdasani 2014) such as in this study. Furthermore, focus groups allow for participants to brainstorm, where participants' comments feed off of each other's comments, allowing the group to really 'dig deep' into an issue (Silverman 2000). While some will argue that interviews are superior to focus groups (Heary & Hennessy 2006), considering the mentioned benefits of focus groups and the logistics, focus groups were chosen over individual interviews.

There were a few benefits that the focus groups provided: firstly an opportunity for the participants to interact with each other (similarly to the interaction while attending the MBCT intervention) and secondly, it provided an opportunity for the control group to learn about the experiences of the participants. In order to validate the results from the focus groups, a decision was made to obtain data from multiple data source, which led to creating the free text survey using the same topic guides as the focus groups.

Survey research is a common method of collecting data in health and health service research, designed to provide a snapshot of how things are at a specific moment (Denscombe 2014). It is a tool that can be used when describing attitudes, experiences and behaviours (Kelley et al. 2003), fitting with this study's' research question, in a non-intimidating environment. The survey was used, in addition to the focus groups, to maximize responses from participants about MBCT, particularly from those living remotely and to validate the results from the focus groups.

Contribution to the research question

The specific objective in this chapter was to explore the participants'' accounts of MBCT for IBD as the fourth and last objective necessary for answering the overall PhD question. The findings from paper 6 suggest that, although MBCT might not be for every patient with IBD, participants described their personal experience of MBCT as a therapeutic and an educational initiative which has enabled them to transform their relationship with the illness. In addition to the preliminary findings from the quantitative data in the previous chapter, it confirms that MBCT for patients with IBD has the potential to be beneficial in reducing psychological stress.

Chapter 6

Discussion and conclusion

Chapter overview

With the IBD incidence and prevalence on the increase (Molodecki 2012) and the high percentage of IBD patients suffering from moderate to severe psychological distress (Graff et al. 2009), there has been an emerging need to minimise the psychosocial impact of IBD. Previous use of psychotherapies and antidepressants in IBD had mixed results: were suboptimal, did not have sufficient benefit for patients or had side effects. There has been very little research to date on whether MBCT, an evidence based therapy successful in recurrent depression, could minimise the psychosocial impact of IBD.

The overall aim of this thesis was to provide understanding if MBCT can be used as an adjunct therapy to IBD symptom management for improving IBD patients' general well-being and quality of life? This was done through the development of evidence for feasibility and acceptability of a definitive RCT testing the effectiveness of MBCT for patients with IBD. The thesis achieved its aim through the four objectives. The first two objectives highlighted the disease-related concerns and psychological needs for patients with IBD. The second two objectives highlighted the feasibility and acceptability of using MBCT as an approach in holistic IBD patient care and symptom management. Collectively, the four objectives demonstrated that a definitive RCT of MBCT in IBD is feasible and acceptable to patients and the submitted papers have added to the body of knowledge related to using MBCT for patients with IBD.

This chapter therefore summarises why using MBCT for IBD; the key findings of each of the individual objectives, discusses how the findings fit the overall aim, while recognising the strengths, weaknesses and limitations of the studies described, individually and collectively. The chapter then discusses how the recommendations from the research fit into the wider body of evidence in this field and concludes with implications and recommendations for future research.

Why MBCT for IBD

As mentioned in the previous chapters, it is clear that managing and learning to cope with the relapsing nature of IBD causes daily stress for patients. As a result, high rates of patients with IBD (around 30%) report psychological comorbidities (anxiety and depression), higher than other chronic conditions (Graff et al. 2009; Knowles et al. 2013). The prolonged effects of anxiety, depression and pain have damaging effect on psychosocial functioning and QoL (Faust et al. 2012). Poor quality of life is further associated with symptom relapse (Levenstein 2004; Simrén et al 2002). Thus anxiety, depression and relapse appear to be concomitant in self-perpetuating cycle for patients with IBD.

Some propose that treating psychological co-morbidities with antidepressants may help to manage the disease better and improve quality of life (Filipovic & Filipovic 2014; Taylor et al. 2011). However there is limited evidence suggesting that using antidepressants are effective in reducing IBD related distress, depression and anxiety (Mikocka-Walus et al 2006; Mikocka-Walus et al 2007). There is also evidence to suggest that antidepressants have side effects and that around 40% of IBD patients regularly omit their medications (Andersohn et al. 2009; Jackson et al. 2010).

Previous studies have found that IBD patients expressed a greater need for a psychological support compared to other chronic condition patients, suggesting that a third of IBD patients' psychotherapy needs are not met (Miehsler 2008; McCombie et al. 2013).

Given the high prevalence of psychological comorbidities, the growing evidence for the negative effect psychological distress has on symptom exacerbation and the perceived need for psychological support by patients with IBD, it is clear that an effective evidence based psychotherapeutic approach is needed.

However, determining which patients will respond to a specific psychotherapy is complex. To date, there have been a number of psychological interventions aimed at reducing distress in IBD. Their focus has been varied. For example some have focused on psychoeducation (Bregenzer 2005; Jäghult 2007); others on stress management (Larsson et al. 2003; Garcia-Vega & Fernandez-Rodriguez 2004); psychodynamic (PD) psychotherapy (Deter 2007); cognitive behavioural therapy (CBT) (Diaz et al 2007; Kaneko 2009), or hypnosis (Emami et al. 2009; Keefer at al. 2007).

The variable psychotherapeutic foci are understandable due to the variable requirements of the individual IBD patients who may benefit from psychotherapy and the variable stressors that they may have. These interventions have had inconsistent effect on symptoms such as depression, anxiety, distress, QoL or disease symptoms and course. A review by Goodhand et al (2009) concluded that IBD patients are most likely to benefit from psychotherapy if it is individualised, holistic and targets psychological symptoms as well as individual life stressors and is CBT based. This was contradicted by a later review (Timmer at al. 2011) where the authors concluded that there was no evidence for efficacy of psychotherapy in adults, but there is in adolescents. A further review by Knowles at al. (2013) concluded that psychotherapy informed by CBT seem to have a positive effect on IBD related anxiety and depression rather than on the physical symptoms of IBD or QoL. In contrast, hypnosis has been seen as beneficial for physical symptoms and QoL.

Given the conclusions of the two reviews suggesting that CBT focused psychotherapy will be most beneficial for those IBD patients that require psychotherapy; MBCT sits well within this paradigm. The MBCT approach contains CBT elements that the MBSR approach lacks. Therefore, that strengthens the justification for choosing MBCT over MBSR for IBD patients. In addition, the curriculum for MBCT, allows individualisation and adaptation to the participants' needs/stressors and fits with the recommendations by Goodhand et al (2009). Furthermore, the rationale for choosing MBCT over regular CBT is due to the rest of the principles and extra activities that MBCT offers in addition to the CBT approach. For example, CBT is an analytical or 'thinking' therapy where cognition is used to understand the negative thought processes. Although CBT takes note of the body reaction to stress and negative thoughts, the main focus is to 'push out' the negative thoughts. MBCT on the other hand uses mindfulness, a wider approach of experiencing the present moment. The tools used in MBCT are different to CBT, and often integrate the attention and awareness through noticing how the body feels thought the different exercises (focused breathing, body scan and sitting meditation). Thus, although MBCT still requires a lot of work through recognising the thought patterns, MBCT is more 'body based' and experiential than CBT.

Like CBT, the goal of MBCT is to develop consistent awareness of your thoughts and reactions to them, which will help the person notice when they are becoming triggered by negative thoughts. MBCT teaches the best ways to notice these triggers and to manage the stress and anxiety by not only the ongoing awareness, but by acceptance of the present moment. Thus, in MBCT instead of pushing the thoughts the person have out of consciousness; it promotes accepting the thoughts without judgement while allowing them to drift away from the minds without attaching to much meaning to it. Thus, this principle of non-judgement and of acceptance typical for MBCT is particularly important for patients with IBD, especially with things that cannot be changed such as having the disease, which is going to stay with the individual for the rest of their lives.

The improved self-awareness and self-observation as a result of mindfulness training may promote the use of different coping skills that can be used for disease related stressor as well as wider life stressors. For example, Kabat-Zinn (1982) suggests that with increased awareness of pain sensation and stress responses to pain, individuals may develop and employ other coping responses that are not included in their treatment program. Therefore, theoretically, MBCT fits with the recommendations of Goodhand et al (2009) & Knowles at al. (2013) for a possibly suitable psychotherapy for patients with IBD. The developmental work undertaken within this thesis looked at the practical application of this psychotherapy with IBD patients, while looking at areas of usefulness as well as areas that need further development.

Summary of key findings and contribution to literature

Chapter 1 outlined the objectives of this thesis with four specific research questions which the subsequent papers endeavoured to address. This section summarises the main findings of each of the objectives and discusses their contribution to the literature.

Collectively, the findings of the studies described in the four objectives revealed that IBD has substantial psychological implications beyond the intestinal symptoms and that the purely gastrointestinal centric view of the illness is not a representative of the IBD patient experience and concerns. Instead, depression, anxiety and stress negatively affect the quality of life of patients and their ability to work and socialise. The results also revealed that attention to the psychological needs for patients with IBD is often overlooked by clinicians and healthcare systems in Scotland and the nationwide survey suggested that patients with IBD in Scotland have a strong desire for additional psychological support. The perceived needs of IBD patients, together with the recommendations for psychological support by IBD standards and IBD experts, justified the need for development and testing of focused psychological interventions such as MBCT. The findings suggest that MBCT has the potential to provide the needed psychological support for patients with IBD. Depression, trait anxiety and dispositional mindfulness improved in the intervention group at post intervention and follow up. Although these findings cannot be generalised, together with the feasibility findings of the pilot, they suggest that a definitive RCT testing the effectiveness of MBCT in IBD is feasible. Also in support of a further trial are the findings from the qualitative study. This study was nested within the pilot RCT and explored the IBD participants' perspectives and experiences of the MBCT intervention. The findings demonstrated the acceptability of MBCT for IBD, with participants describing their personal experience of MBCT as a therapeutic and educational initiative that enabled them to transform their relationship with the illness.

Overall, the studies presented in this thesis allow the researcher to draw three main conclusions. Firstly, patients with IBD across Scotland identified a psychological needs gap in the current IBD care and a strong desire for psychological help. Secondly, an eight week, facilitator- led MBCT program has the potential to produce a positive effect on the psychosocial wellbeing of patients with IBD. Lastly, an eight week MBCT program is feasible, adhered to and received positively (accepted) by the participating patients with IBD. The significant and original contribution of this work in the field of MBCT as an adjunct therapy for patients with IBD is discussed in detail through the findings of the individual objectives below.

Objective 1: The role of psychological factors in IBD according to the current literature.

In retrospect, the narrative review of the role of psychological factors in IBD (Paper 1) and the systematic review protocol (Paper 2), contributed indirectly to my understanding of how feasible it is to use MBCT for patients with IBD. These two papers, which addressed objective 1, provided a better understanding of the magnitude that psychological factors and psychological status have on the overall wellbeing and quality of life for patients with IBD, regardless of the directional influence of these psychological factors. They also provided the evidence and rationale for the design (explained in detail below) of the pilot RCT and its specific objectives, in order to fully explore the potential of using MBCT for IBD.

As discussed in chapter 2, in both papers (Paper 1 and 2), there has been a lengthy debate about the associations between psychological comorbidities and disease activity. The process of reviewing and making sense of the literature and the reasons for the lengthy debate actually served as a rationale in the designing process of the pilot/feasibility work that followed the review.

For example, as discussed in paper 1, conceptually it has been difficult to define psychological factors. Even the terminology used to describe or define psychological factors varies historically. The term ‘psychological factors’ is often used as an umbrella term, including a variety of psychosocial events that could cause pathopsychological changes within the individual (Keefer 2008); ranging from specific psychiatric disorders such as depression and anxiety, to stressful life events, daily stress and perceived stress. Therefore, as North and Alpers (1994) pointed out, due to the heterogeneity of ‘events’ that constitute psychological factors, the review of the topic becomes like comparing apples, mangos and pears. Bearing in mind this heterogeneity of ‘events’, there is also heterogeneity in the measurement of these psychological factors, which becomes another issue. As the literature pointed out, the range of tools used to measure the different psychological factors varied from a ‘psychological stress diary’ (Greene et al. 1994) through ‘Holmes recent life changes’ (Mardini et al. 2004) to ‘Beck depression inventory’, making the review of the topic even more complex. However, the detailed examination of this issue provided the rationale for choosing to measure the most relevant psychological factors (depression and anxiety) and use the most appropriate measurement tools (BDI, STAI Y1 & Y2) for the pilot RCT.

Secondly, other complexities contributing to the lack of consensus in the literature were due to the studies not explicitly distinguishing between CD and UC when examining psychological factors (North and Alpers 1994; Britton et al. 2003). In other words, some studies have assumed that the relationship between psychological-physical symptoms is the same in both conditions, which could be misleading if we consider the evidence that some clinically similar conditions such as UC and CD can differ physiologically at molecular level (Shanahan 1997; Vermeire et al. 2006) and therefore have a different psychological-physical symptom relationship. This finding prompted the decision for having an even distribution of patients with CD and UC in both arms of the RCT and allowing any definitive RCT to consider a separate analysis for both conditions.

Thirdly, the inconsistency in standardised tools to measure disease activity for both conditions created a comparability issue. For example, some of the tools for measuring disease activity use only patient recall data for scoring (such as Harvey Bradshaw Index for CD and Simple Clinical Colitis Activity Index –SCCAI for UC) while others (such as Crohn's' Disease Activity Index –CDAI for CD) uses a biochemical test for scoring. The major criticism of these scoring systems is the recall bias associated with the tool that does not use biochemical testing (Maunder & Levenstein 2008). Thus, this finding provided the rationale for choosing the disease activity tools (CDAI and SCCAI) that are not only most reliable for both CD and UC, but also provide least burden for the patients.

Fourthly, the evidence suggested that psychological factors might be more important or not important at all for certain personality types (Boye et al. 2008). For example, some researchers believe that the personality traits can modify the relationship between stress and immunological reaction to it (Thornton and Andersen 2006). Some patients also believe that their own personality is a major contributor to the development of their disease (Roberson et al. 1989). This provided the rationale for using STAI Y1 and Y2 (State/Trait Anxiety Inventory, fully described in paper 4 &5), which considers the trait personality when measuring anxiety, without actually overburdening the patients with an extra separate tool.

Finally, the direction of causality between psychological factors and disease activity has been debated for a very long time, due to studies being unable to detangle whether stress causes symptoms or symptoms cause stress. In relation to the overall PhD question, reviewing this issue provided the necessary understanding that regardless of which direction the causality goes, both paradigms highlight the key issue: that patients with IBD experience an extra burden of depression, anxiety and stress that needs addressing. Thus, this finding on its own is a strong rationale to trial MBCT, a psychological intervention designed for addressing depression and anxiety, which has never been examined or utilised in the IBD population.

Consequently, objective 1 and papers 1 and 2 collectively made an important contribution to the overall PhD work. Traditionally, a systematic review of psychological therapies in IBD would have been conducted to guide the design of a pilot RCT. However, objective 1, provided the evidence and rationale in an alternative way, suggesting that reviewing RCTs of psychological therapies in IBD alone would have not been sufficient to understand the complexity of the issue of psychological factors in IBD; or the understanding of the important part psychological stress plays in the disease experience for patients with IBD. In line with the guidance for development and evaluation of complex interventions (MRC 2000; Campbell et al. 2007; MRC 2008), paper 1 and 2 therefore identified a need for adopting a broader and more inclusive approach to gathering evidence for addressing psychological needs in IBD.

Objective 2: The psychological needs' gap in the current care services for patients with IBD

The findings from objective 2 and Paper 3 also made a significant contribution to the knowledge base in the field of psychological aspects and needs of IBD. They emphasized the participants' concerns about the impact of IBD on their quality of life and highlighted the need for a more holistic approach to IBD care that includes psychological and counselling services, at least at the point of diagnosis. The identification of the psychological needs gap provided a direct justification for the preliminary testing of MBCT as a potential psychological intervention to address those needs.

As discussed in chapter 3, these findings explored the perspectives and experiences of over 700 IBD patients across Scotland about the current IBD services. The survey was carried out as part of a co-design process for improving IBD care and was conducted by the national charity, Crohn’s and Colitis UK. Participants described their needs as being much wider than medical and biological and the findings provided further evidence that psychological stress is a notable part of the disease experience and has an impact on their overall quality of life. For example, participants described the effects of living with IBD on their mental and emotional health as being worse than a terminal illness. This is due to the nature of the disease that often causes patients to be ridden with fear about the next flair up and can often cause fear fixation for patients (Knowles & Mikocka-Walus 2014). Prolonged exposure to this fixated state of fear could cause chronic anxiety in patients (DSM-5 APA 2013). In addition, the prolonged emotional exhaustion from the relapsing nature of the disease, the extra-gastrointestinal manifestations and side effects from medication often causes depression in patients (Levine & Burakoff 2011). Thus, to cope mentally with this, many participants in the survey reported taking antidepressants.

The findings from the survey are consistent with the literature. Depressive symptoms have been reported to be greater at times of increased disease activity, or may precede a relapse of disease activity (Porcelli 1994; Mittermaier et al. 2004; Faust et al. 2012). Thus, emotional support plays a key part in the quality of life for patients with IBD. As Drossman et al. (1991), De Boer (1998) and Miehsler et al. (2008) suggest, this is reflected in how patients with IBD use healthcare. For example, patients often attend outpatient clinics, not just with medical issues, but because of psychological factors, which are often unrecognized. This can result in the request of unnecessary investigations and prescriptions instead of psychological interventions. Altogether, these unmet psychological needs cause a major increase in the use of services (Miehsler et al. 2008). Accordingly, providing psychological interventions for patients with IBD in order to fulfil their emotional and psychological support needs, will not only improve the quality of life for patients, but has the potential to lessen the burden of health services in general.

Participants also described that psychological stress affects all aspects of social and family life and sometimes leads to social constraint or isolation. This may be due to the IBD patients being unable to take part in simple social activities, such as going to town or for a meal. This is consistent with the literature, which suggests that IBD patients have higher levels of social constraint compared with healthy controls (Lix et al. 2008). In addition, research in other chronic conditions has revealed that increased social constraint is associated with greater psychological distress and poorer quality of life (Cordova et al. 2001; Zakowski et al. 2004). Thus, providing psychological support through psychological therapy, such as MBCT, can have a twofold benefit for patients: firstly, the intervention has the potential to help patients deal with the psychological stress related to the disease and secondly, it can provide a social venue and support for discussing stressors and other traumatic events where patients feel unsupported or constrained by their own social networks.

Perhaps the most significant contribution of objective 2 findings, is the readiness for psychological therapies in IBD as articulated by the participants. This is particularly important, because so far, controlled trials of psychological interventions in IBD failed to demonstrate a convincing benefit (as seen by the Cochrane review by Timmer et al. (2011) (details in chapter 1). With a large body of evidence suggesting that the effect of psychotherapy is dependent on a patient's motivation to undergo psychotherapy (Schneider et al. 1999; Ryan et al. 2010), it appears that these findings provide a valuable insight about the motivation of patients with IBD in Scotland. Thus, this paper not only provides the evidence around the psychological needs gap in the current IBD services, but also provides an insight about the motivation and readiness amongst patients with IBD for psychological therapies, which is a prerequisite for MBCT (part of the entry criteria for MBCT is the assessment of participants' motivation, see objective 4).

Objective 3: Feasibility and piloting the use of mindfulness based cognitive therapy for patients with IBD.

Following on from paper 3, the findings from paper 4 and 5 provided the direct findings necessary for answering the overall PhD question. As discussed in chapter 4, the study described in papers 4 and 5 was the first to: pilot the MBCT program in the IBD population and to evaluate the feasibility of conducting a definitive RCT. Thus, the key findings concerned with the trial mechanisms, testing of the proposed outcome measures and sample size have provided a valuable insight into how a definitive RCT may be conducted.

As there was no previous study examining MBCT in the IBD population, objective 3 aimed to explore the factors associated with recruitment of IBD patients. It was unknown whether a sufficient number of patients with IBD would be interested to participate in such a trial that requires a long commitment (8 weekly group meetings and daily home practice).

Although recruitment for the trial was lengthy and difficult, the recruitment target was reached and surpassed, validating the approach used. In addition, many of the potential participants welcomed the recruitment process, as for some, this was a first opportunity to discuss at length their psychological distress. Unfortunately, this information was not captured in the trial due to participants sharing most of the information before the consent form was signed. Future trial should ask for permission to capture such data, as that would provide a further understanding of the psychological impact of IBD and the daily issues IBD patients have as a result.

The findings around recruitment are also significant in the field of clinical RCTs. Only less than a third of RCTs achieve their target recruitment and more than half of RCTs have to extend the recruitment period. In addition, some studies close prematurely due to poor recruitment (Treweek et al. 2013; McDonald et al. 2006; Watson & Torgerson 2006).

Expanding to the findings about recruitment, are the findings related to retention, or drop-out rate of participants. The drop-out rate of the pilot was higher than predicted, when compared to similar studies using MBCT in other conditions (Rimes & Wingrove 2013). However, it is interesting that the dropout rate of 44% was equal in both arms. As described in chapter 4, the higher dropout rates could be linked with the longer recruitment period and drop of motivation in the wait-list control arm (details in paper 5). With the intervention group, however, there is a possibility that a better retention of patients could have been achieved with an enhanced participant commitment and motivation assessment at the start (see chapter 5 for pre-MBCT entry assessment) and improved management of expectations about what is involved in the intervention. These findings are consistent with studies of mindfulness based therapies in other chronic conditions, suggesting that careful patient selection remains essential (Ljótsson et al. 2010; Kearney et al. 2012; Gaylord et al. 2011). In other words, the findings highlight that if more time and effort in the process of recruitment and consent process are invested, it could have a positive effect on retention rates.

In summary, although the improvement in the preliminary outcomes (depression, anxiety, dispositional mindfulness, disease activity and quality of life) from the pilot cannot be generalised, they provided encouragement that MBCT has the potential to help with the management of the psychological impact of the disease. Other studies have confirmed that MBCT can also be a very cost effective way of psychological support for patients when compared to antidepressants (Kuyken et al. 2015). This supports the need for further investigation of MBCT in the IBD population in a definitive RCT, in order to determine any effectiveness that can be generalised. In addition, patients with IBD are increasingly seeking out psychological support, which was demonstrated by their interest to participate in the study. Having access to appropriate psychological support can build the self-efficacy for making lifestyle changes (Bandura 1986). This highlights the need for accessibility of such an intervention to patients, which should be investigated in a future trial.

The last but not least finding of this study is the sample size calculation for a future RCT. No other study has calculated this due to the very limited research in this field, making this information of particular value. Although an estimate of 129 participants in one arm was reached considering the dropout rate of this trial (44%), literature suggests consideration of estimates from other trials with similar type of intervention for this patient group not to be dismissed (Armijo-Olivo 2009).

The overall finding of objective 3 about feasibility and piloting of MBCT for patients with IBD postulates that a definitive RCT is possible and MBCT has the potential to provide the needed psychological support for patients with IBD, which provides vital contribution to the research in this field.

Objective 4: Participants' perspectives and acceptability on using mindfulness based cognitive therapy for patients with IBD.

Objective 4 found that patients with IBD that participated in the eight week MBCT program deemed MBCT as an acceptable intervention for them. With paper 5, it could be argued that Paper 6, which described the findings from the qualitative study nested within the pilot RCT, makes the most significant contribution to answering the PhD question, and makes an original contribution to the knowledge in the field. This was the first qualitative study of IBD participants' perceptions and experiences of MBCT to be published in the literature.

As discussed in paper 6, the analysis has given an insight into why participants considered MBCT as an acceptable intervention for them. The findings indicated what is important to the IBD population after diagnosis and when considering psychological therapies.

Firstly, participants described their personal experience of MBCT as a therapeutic and an educational initiative which has enabled them to transform their relationship with the illness. For example, the skills they attained through the eight week MBCT program, enabled them to change their previous habitual responses to stress and symptoms from unhelpful to helpful. As a result, many felt empowered by regaining a sense of control over their body and symptom management. A transformative effect of mindfulness on attitudes and perceptions through shifts in perception, has been previously documented in different clinical and nonclinical populations (Shapiro et al. 2006; Cordova & Andrykowski 2003; Schure et al. 2008).

Secondly, the inclusive nature of the process and the shared experience of undergoing MBCT may have alleviated some of the sense of social isolation commonly associated with IBD. This is supported by other published work which suggests that sharing a similar diagnosis can often create a sense of community for the participants. This could alleviate the sense of social isolation commonly experienced by many patients with chronic conditions, including patients with IBD (Sparacino 1984; Drossman & Ringel 2000; Friedmann et al. 2006; Kiebles et al. 2010).

Thirdly, the findings about participants' expectations about MBCT provided an insight into how expectations can influence the perceptions about benefits or barriers of the intervention. This is supported by the literature and suggest that patients' expectations are associated with engagement and health outcome (Mondloch et al. 2001). It appeared that the type of expectations participants had about MBCT seemed to determine their insight and engagement into the programme, and therefore influence their perception about benefits or barriers with MBCT. Open and more positive expectations are often linked to better outcomes, due to the mechanisms involved in producing the placebo effect or patients' belief about outcome (Goossens et al. 2005). Therefore, in light of this finding, a definitive RCT should consider expectations as a powerful predictor of actual outcome or benefit of the intervention, and should therefore incorporate a patient expectation measure. Thus, the overall finding of objective 4 was that despite the barriers of time and distance for some of the participants, MBCT is an acceptable intervention for patients with IBD.

Methodological considerations

The collection of studies can be described as a piece of health services research using pragmatic approach. The thesis therefore describes a combination of quantitative and qualitative approaches or a multiple method approach (see box 2 below). Using a multiple method approach allowed for a more comprehensive depiction of the investigated phenomenon compared to either approach alone (Creswell 2013). The approach contributed to the strength of this thesis.

Box 2. Study design and methods used for objectives 1-4

Objective	Study Design	Data collection methods	Method of analysis
1	Literature review	Online database search	Descriptive
2	Qualitative cross-sectional study	Online survey with open ended questions	Thematic analysis
3	Pilot Randomized controlled study with intervention and wait-list controls	Questionnaires, three data collection points	Descriptive quantitative and mixed ANOVA
4	Qualitative cross sectional study	Focus groups, open ended question survey	Thematic analysis

This section will discuss the strengths and limitations of the designs used to address the different objectives individually and collectively.

Objective 1: The role of psychological factors in IBD according to the current literature

Methodological strengths and limitations

The approach to answering objective 1 could be criticised in several ways. Firstly, the literature review was not systematic. Secondly, the systematic review protocol was not followed through with an actual review and thirdly, no systematic review of RCTs was conducted for this objective. However, my approach had many strengths. Firstly, the narrative review used a systematic approach. Using a systematic approach in reviews contributed towards the rigour of the review (Whittemore & Knafl 2005).

Secondly, it reviewed different types of literature (such as observational studies). The limitation of reviewing only one type, as initially planned, would have not enabled a deeper understanding of the issues around the role of psychological factors in IBD. For example, if observational studies were excluded and only RCTs were reviewed, I would not have detected and fully appreciated the important findings related to psychological stress and IBD. The issue with a systematic review of only RCTs is related to the methodology and inadequate intervention description within the RCTs included in the review and to an extent, the inappropriateness of categorising a number of educational or other interventions as psychological interventions. Therefore, the initial idea of reviewing only RCT to answer the question would have been a limitation.

Thirdly, the strength of the approach used in objective 1 was that it provided the fundamental steps for designing the pilot RCT. Both papers identified that there is a two directional influence of psychological stress on IBD and its impact on quality of life is significant. This work, therefore, created a rationale to examine the utility of MBCT in IBD to improve psychological stress. Furthermore, the detailed investigation of the IBD literature, supported the decision making of using the most relevant and most appropriate measure tools for psychological factors and disease activity in the pilot RCT.

Finally, it taught me that the research process is not a straight forward one. On the contrary, it is a very iterative process that requires a lot of flexibility, evaluation and clarification of the aims, particularly when faced with new evidence that might change the direction of the enquiry (Marshall & Green 2004).

Objective 2: The psychological needs gap in the current care services for patients with IBD

Methodological strengths and limitations

The qualitative design used in this study allowed the participants to express their perceptions and experiences of using IBD services within NHS in Scotland and talk freely about their disease related concerns and needs. While some of the strengths about the study lie within the key aim to co-design IBD services in the NHS in Scotland with service users, as well as the diverse and large sample of patients plus the systematic method of data analysis, there are areas of limitations and these should be considered when interpreting the findings.

One of the limitations was related to not having an opportunity to provide oral explanation about the study or take oral consent, due to all study information being provided on the first 'page' of the survey. However, this is not uncommon for surveys. Every step was taken to provide information to the potential participants that identified the researchers and the reason for the survey, as well as assuring potential participants about anonymity of the survey.

Although qualitative research is not aiming to be representative and although the sample contained a diverse group of participants in terms of age, sex, socio-economic status, and length of diagnosis, all participants that responded to the survey did so through the web links. This means that we could not observe the opinions and experiences of services by patients with IBD that have no access to internet.

A methodological issue in qualitative research is the researchers' own assumptions and pre-understanding of the issue, which could affect objectivity. To reduce this subjective bias that could affect objectivity, qualitative studies are often judged on the basis of trustworthiness and rigour (Creswell 2013). The rigour of this study was upheld throughout the analysis by being independently conducted by two researchers. The rigour of sampling was ensured through purposive selection using both intensity sampling (experts in the subject – people living with IBD) and maximum variation sampling (diverse sample) to make the data "information rich" (Patton 2005)

Objective 3: To explore feasibility and piloting of MBCT for patients with IBD

Methodological strengths and limitations

Although the findings of the pilot RCT present some interesting results about the use of MBCT among patients with IBD, it is important to acknowledge some of their limitations.

The study described in objective 3 used prospective quantitative design (RCT) with questionnaires as outcomes measures at three data collection points. While RCT design is often treated as a gold standard among experimental methods (particularly in clinical trials) (Moher 2010), self-reported measures (the questionnaires used) are often seen as a limitation. For example, self-reported measures may result in participants giving socially desirable answers. Social desirability bias is a well-documented phenomenon and refers to the propensity of research participants to give socially desirable responses rather than accurate ones (Paulhus 2002, Robinson et al. 2013). This may be particularly relevant when participants report sensitive topics such as depression, anxiety, disease activity, where the individuals may feel they are judged on their behaviour.

Self-reported measures are also subject to recall bias as patients may not always be able to remember events that occurred several weeks, months or years ago. Some evidence suggests that around 20% of events details are irretrievable after one year (Bradburn et al. 1987). This of course could threaten the internal validity of a study (Hassan 2005). In order to minimise the bias that could arise from the recall period, all questionnaires in the study were asking participants to recall events not longer than 2 weeks ago.

Not everyone diagnosed with IBD and eligible for participation within the Scottish health boards was invited to the study. This was due to the limited resources and time available for recruitment. In addition, not everyone that was invited to the study responded. The external validity of the study relies on the assumption that the study participants are representative of the population from which they are recruited. Thus, bias can be introduced by non-response and attrition. The response rate was 15% for the pilot trial. Unfortunately, no information was available on non-responders. It could be speculated that the non-responders were less interested in the topic of MBCT or too busy to take part in the study.

The attrition rate was higher than expected in both arms. It appears that the higher dropout rate could be connected to the long recruitment time, causing participants to lose motivation. Perhaps employing an additional recruitment strategy such as involving networks like Crohn's and Colitis UK could have enabled reaching more potential participants in a shorter time, and therefore reduced the dropout rates, particularly in the waitlist group. The type of analysis used to detect change in variables over time, required for the participants to have full data at all three data collection points on at least one variables. Thus, as described in paper 5, those that remained in the study until the last data collection point were subsequently included in the analyses. This has therefore introduced bias, as those who dropped out of the study and were not included in the analysis.

The inability to blind participants and research staff to the intervention allocation due to the nature of the study was another limitation. Although randomized double blind placebo control studies are considered to be the gold standard as they provide the strongest possible evidence for causation, the inclusion of waitlist control group was important in order to compare the differences between MBCT groups and leaflet only. While having a placebo control would allow participants, investigators and study staff to be blinded, due to resource constrain, this was not possible to do.

A further limitation is the relatively small sample size. Nonetheless, it should be noted that considering the limited resources and the aim of the pilot/feasibility study to provide information about future definitive RCT, the sample size was acceptable. A development of a nationwide, multidisciplinary team in collaboration with existing Crohn's and Colitis UK network, could allow data collection from more centres and would therefore improve the sample size and the overall research design.

Information about the length of diagnosis and current medication at the three assessment points were not collected, which could be interpreted as another limitation. It should be noted that due to the many questionnaires used at the three assessment points, the main rationale was not to overburden participants with even more questionnaires. A future definitive RCT should consider the use of smart technology for collecting any additional data without overburdening participants.

With home practice being such a key component of the MBCT programme, objective measure of home practice could have given a better idea of correlation between practice time at home and improvement in scores. Thus, this could be deemed as another limitation of the study, or a learning point that a future study should design a method of objective measure of home practice without overburdening participants with more forms.

Objective 4: Participants' perspectives and acceptability on using mindfulness based cognitive therapy for patients with IBD

Methodological strengths and limitations

The study described in Objectives 4 used a qualitative design. This design allowed the participants to express their perceptions and experiences about the eight week MBCT program and how the program fitted with their needs. As with the findings of the pilot RCT, the findings of the embedded qualitative study present a case for the usefulness of MBCT among patients with IBD. Nonetheless, it is also important to consider the limitations when interpreting the results. The following are in addition to those identified in paper 6.

It can be debated that one of the limitations of the embedded qualitative study could be the small sample size. Literature suggests that sample sizes for qualitative research in feasibility studies can be small (between 5 and 20) (Mhurchu et al. 2009 & Mittal et al. 2009). In addition, O'Cathain et al. (2015) and Faulkner (2003) suggest that having 10 participants can possibly be sufficient to identify a minimum of 80% of problems when testing usability of technology and having 20 participants can apparently identify 95% of problems. Considering this suggestion, it will appear that the sample size of 18 in the study would be sufficient. However, further limitations lie with the diversity of sampling and the sample.

The diversity of sampling in qualitative research is not related to the sample being representative, but is about including a diverse range of patients to allow for identifying a wider range of issues that the receivers of the intervention might have. In this study, the sample was diverse in some aspects and included participants at various points from diagnosis, with different treatments, different ages and both sexes. However, most of the participants were well educated and had a higher income. Getting a wider and more diverse sample could have possibly been achieved by having another focus group with the participants from the waitlist control group after they experienced the MBCT intervention.

Further limitations to this study lies with the self-selected bias as well as the focus groups sample (containing a mixture of participants from both arms, intervention and wait-list control). The self-selection bias relates to the possibility that the self-selected participants could have been more motivated or been better informed than the general population or the rest of the participants in the pilot RCT. In relation to the focus group sample containing participants from both arms, the rationale for this was to get data to answer the questions not only about the intervention, but also on the trial procedures as part of the feasibility process. As noted in the literature, the priority of the questions changes throughout the feasibility study (O'Cathain et al. 2015). Thus, paper 6 focused on the participants' experience of the intervention, without using the data that was covering the broader issues related to mechanism of the pilot procedures. Nonetheless, there is the potential bias that this could have influenced the group dynamic of the focus group and therefore potentially influenced the participants' responses.

Qualitative studies are often judged on the basis of trustworthiness, which concerns credibility, transferability, dependability and confirmability (Creswell 2013).

Credibility is the criteria of internal validity, seeking to ensure the study measures what was actually intended to be measured (Shenton 2004). One of the strategies employed to ensure credibility was triangulation. For this study, two data collection methods were utilised (survey and focus groups) to achieve a higher degree of validity and reliability and to overcome the deficiencies of the single methods. In addition, the first author (MS) was involved in the recruitment and consent procedure of participants, but was not involved in their care.

Transferability is the degree to which the qualitative research findings can be generalized or transferred to other contexts or settings. While there is a debate if generalizability is possible at all, due to the findings in qualitative studies being specific to a small number of particular environments and individuals, it was ensured that there was sufficient contextual information and description of MBCT and IBD. This was to allow the readers to have an appropriate understanding of it and thereby enable them to compare this with similar research.

Dependability is an issue of reliability, which means if the research work was repeated, in the same context, with the same methods and with the same participants, similar results should be obtained. This again is debatable, as technically you cannot measure the same thing twice. As by definition, if you are measuring twice, you are measuring two different things (Trochim 2006). However, we took the approach of reporting the processes within the study in detail, which should enable a future researcher to repeat the work, but also to allow the reader to assess the extent to which appropriate research practices have been followed.

Although in qualitative research there is a tendency to assume that the researcher brings a unique perspective to the study, confirmability refers to the degree to which the researcher is objective. To ensure confirmability, both researchers checked and rechecked the data from the study. The authors, independently, read and analysed all the text. Consensus was achieved with discussion if there was any disagreement in the analysis and interpretation of the themes.

Potential impact of personal bias and belief in MBCT

When discussing the limitations about the individual studies described in the thesis, it is important to also mention the potential impact of personal bias about MBCT from the point of clinical perspective and experience. Being a mindfulness practitioner and teacher, I have been involved in facilitating MBCT groups for a number of years with a variety of patients suffering from depression, anxiety and chronic conditions. Seeing the improvement in depression and anxiety scores and the reported perceived benefit of MBCT by patients in clinical practice, I could see how my personal experience could have influenced the decision making related to study design, analysis, and study recommendations. For example, there is a possibility that the study recruited to target due to my close involvement in the recruitment process. There is also a possibility that the participants committed to participate in the study due to my enthusiasm about MBCT in the initial interview. This is of course debatable and perhaps a further study elsewhere could show if this aspect is replicable.

There is a further possibility that my subjective belief in MBCT could have influenced the analysis or study recommendations. Due to the subjective nature of qualitative research, this is very likely. However, many steps was taken to reduce bias in design and analysis. For example, for the pilot study, the design was peer reviewed at different stages by different internal and external colleagues. The statistical analysis and report were independently checked by an experienced external statistician and the journal peer reviewers. The qualitative data analysis was done independently by two researchers and then checked by a third and then peer reviewed by the journal. Nonetheless, the direction the research has taken could have been influenced by my clinical experience and therefore is a potential bias.

Implications and future directions

The findings of this thesis have considerable implications for the development and testing of psychological/ behavioural interventions as adjunct therapies in the holistic care of patients with IBD. Although there have been other psychotherapies in IBD (psychodynamic therapy, cognitive behavioural therapy, systemic therapy or relaxation techniques and patient education programs) with mixed results, they were either not appropriate for implementing on a larger scale, or did not have sufficient benefit for patients (Abbass et al. 2009; Mickocka-Walus et al. 2010; Garcia- Vega et al. 2004; Bregenzer et al. 2005; Jaghult et al. 2007). For example, a stress management program in

IBD was successful in reducing tiredness, constipation and abdominal pain at post treatment in the intervention group (Garcia- Vega et al. 2004). However, this study did not measure depression and anxiety and therefore it is not clear how it affected mood.

Although there is a suggestion that perhaps IBD is less amenable to change via psychological interventions comparing to other chronic conditions (chronic pain, chronic fatigue syndrome, and diabetes) (McCombie 2013), antidepressants therapies show that they can have effect on mood and possibly disease activity (Mikocka-Walus et al. 2006; Mikocka-Walus et al. 2007; Esmaeili et al. 2008). In addition, there have not been many psychological/behavioural interventions for IBD in the UK that have included mindfulness, despite the consistent evidence that psychological stress exacerbates IBD (Goodhand et al. 2009) and despite MBCT being a recommended therapy for reducing stress and depression (NICE 2010).

In response to the above need, the findings of this thesis have generated implications that are encouraging for patients with IBD as well as healthcare practitioners and researchers. This is because they indicate that an eight week instructor led group-based MBCT intervention for patients with IBD (with potential to reduce depression and anxiety) is feasible, adhered to and received positively amongst patients with IBD.

The results from the collection of studies in the thesis came about during a time when Crohn’s and Colitis UK and the Scottish Government have been working on a series of projects to improve services for patients with IBD. The findings from objective 2 (nationwide survey) highlighted the IBD patients’ need for psychosocial support. This suggests that health care staff should become more observant and vigilant of the psychosocial wellbeing of patients with IBD, especially patients in relapse and possibly offer psychosocial distress screening as part of routine care. Thereby, this would enable early detection of any psychosocial issues and adequate referral of patients to appropriate psychological support. This is in line with the bio-psycho-social model suggested for the management of chronic diseases in the late 1970s by Engel (1980) which was further utilised by Drossman (1998) for an understanding of patients’ experience and behaviour related to gastrointestinal symptoms and IBD. In addition, this highlights the need for healthcare professionals involved in the care of patients with IBD to be appropriately trained to acknowledge the psychological needs of IBD patients. Furthermore, it highlights a clear need to identify ways of incorporating psychological care into the IBD care pathway, as supported by the IBD standards of care (IBD Standards 2013).

The findings from objective 3 and 4 informed the developmental work for a definitive RCT in a number of ways. The analysis of the pilot RCT showed encouraging improvement in psychosocial symptoms (depression and anxiety) as well as mindfulness awareness for the intervention group. These findings on their own are very promising, and in line with the theory about correlation of mindfulness and depression and anxiety (Barnhofer et al. 2011). The findings support the theory of the clinical application of mindfulness as a trainable skill (Baer et al. 2006) that can protect against the negative effects of emotional vulnerabilities such as stress (Giluk 2009).

These findings, when coupled with those (from objective 4) about participants' perceptions of the intervention as beneficial and acceptable, suggests that MBCT could be used towards psychological support for patients with IBD. The findings also suggest that further investigation of MBCT in IBD, on a larger scale is needed and warranted. Any future study of MBCT should include a 12 month follow up, to allow researchers to investigate the long term effects of MBCT.

Further research investigating the 'dose' depended relationship between MBCT home practice and psychological symptoms and disease activity is also needed. This could be achieved by introducing a method of monitoring home practice without adding extra burden to participants. Similarly, there is a need for more studies to investigate the 'dose' of MBCT home practice that is required to detect improvements in objectively assessed psychological symptoms and disease activity. The pilot RCT described here is the first of its kind. Consequently, further research is required in order to provide healthcare staff with more accurate recommendations about the role of MBCT in improving overall quality of life for patients with IBD.

Conclusions

The collection of studies in this thesis, document the developmental work and justification towards a definitive RCT investigating the effectiveness of MBCT in IBD population. The steps of this developmental work were guided by the MRC framework for the development of complex interventions. Objective 1 and 2 collectively provided enough evidence and cemented the rationale for investigating the feasibility and acceptability of MBCT in IBD, a psychological intervention aimed to improve depression, anxiety and stress. This is evident from the literature advising that regardless of which direction psychological factors influence disease activity in patients with IBD, the bottom line is that around 30% of patients with IBD require psychological input. Supporting this need for psychological input were the findings from the nationwide survey in Scotland, confirming a strong desire among the IBD population for psychological support as part of their care. Objective 3 and 4 collectively provided sufficient evidence about feasibility, adherence and acceptance of an eight week group based MBCT intervention among patients with IBD. This is evident by the recruitment and feasibility findings, but also by the promising findings of the pilot RCT reporting significant improvement in in measures of depression, trait anxiety and dispositional mindfulness in the intervention arm when compared to control arm. Furthermore, the findings about the participants' perceptions of the MBCT intervention as beneficial are evidence about the acceptability of the intervention for patients with IBD.

The collection of studies within the thesis makes an original contribution towards the body of knowledge in the field of IBD and MBCT. The nationwide survey as part of objective 2 is the first of its kind in Scotland exploring the psychological gap within IBD service. The pilot RCT as part of objective 3 is a first of its kind piloting and exploring the use of MBCT for both Crohn's and colitis patients. The qualitative study as part of objective 4 is the first of its kind to explore the perceptions and experiences of the participating IBD patients in an eight week MBCT intervention. The strengths, weaknesses and limitations of each of the individual studies are acknowledged at each stage. The collection of studies concludes that a definitive RCT of MBCT for patients with IBD is feasible and acceptable.

Chapter 7

Dissemination

Journal standing, journal choice and reception of submitted papers

Paper 1. "The role of psychological factors in inflammatory bowel disease (Schoultz 2012)
This paper was published in the British journal of community nursing (BJCN). BJCN is the only peer-reviewed professional journal for community nursing in the UK. This journal promotes excellence in clinical practice with an emphasis on sharing of innovation and expertise in clinical, professional and policy developments. This journal was targeted because of the professional audience-community nurses, who are involved in the care of patients with IBD; however, they might not be aware of the evidence on relationship and implication of psychological factors in disease activity and overall wellbeing for patients with IBD. Strategically, it was a great journal for the authors' first publication, where the author learned the mechanism of peer review process and publishing. This journal has a citation index of 0.25 (as at August 2012). (Licence for reprint available in Appendix 11)

The aim of paper 1 was to discuss and inform clinical practice and future research, therefore a journal easily accessible to nurses was an advantage. Although the journal does not have a very high impact, it is perceived as a credible source of evidence among nurses. Because this paper was the first publication for the author, it was also seen as a great starting point and confidence builder for writing for publication. As at August 2012, Paper 1 has received 7 citations, mainly international ones such as Sweden, Greece and China.

Paper 2. Assessment of causal link between psychological factors and symptom exacerbation in inflammatory bowel disease: a protocol for systematic review of prospective cohort studies (Schoultz et al. 2013a)
The paper 2 was published in the Systematic reviews journal (Syst Rev). This was the target journal for the publication due to the paper being a protocol for a systematic review, and Syst Rev is a journal that promotes the attitude of transparency in research by encouraging authors to publish all aspects of the design, conduct and reporting of

systematic reviews. The journal is also open access, which allows a wider access to the publications and therefore better chance of citations and impact of the publications.

The aim of paper 2 was to discuss the evidence and methodology of publications reporting on psychological factors in IBD and devise a protocol for such a review that will systematically examine the evidence. Although the journal does not have an impact factor yet, due to being a fairly new journal, this journal is perceived as very credible for publications related to systematic reviews. As at January 2013, the paper has been highly accessed and falls in the category of mostly viewed articles on BioMed Central. In addition, the paper has received 9 citations, mainly international ones such as Italy, Canada, Spain and China.

Paper 3: Co-Designing Inflammatory Bowel Disease (IBD) Services in Scotland: Findings from a nationwide survey (Schoultz et al. 2016b) BMC Health Services Research. 16(1),1
Paper 3 was presented as a poster presentation at the Digestive Diseases Week DDW in London 2015. The abstract selection process for the conference was peer reviewed and the abstract was published in Gut (see appendix 2). The journal Gut aims to publish original articles related to gastroenterology describing novel mechanisms of disease or new management strategies, both diagnostic and therapeutic, that might impact on clinical practice in the field. The impact factor of Gut is 14.66.
A full paper 3 was published in BMC Health Services Research. The aim of paper 3 was to explore the IBD patients' experiences of current services and make a recommendation for future IBD service development. This was closely related to the target journal, as the aim of the journal is to provide debates and research on improving quality of healthcare, and is aimed at academics, clinicians, healthcare managers and policy makers. The impact factor of the journal is 1.77.

Paper 4: The use of mindfulness-based cognitive therapy for improving quality of life for inflammatory bowel disease patients: study protocol for a pilot randomised controlled trial with embedded process evaluation (Schoultz et al. 2013b) Trials 14(1), pp.1-9
This paper was published in Trials, which is an established, interdisciplinary, open access, peer-reviewed and online journal focusing on all aspects of the performance and findings of randomised controlled trials in health. This journal was targeted due to its credibility

for reporting randomised controlled trials and due to its open access, making the publication freely and permanently accessible online after publication and therefore increasing chances of citations. Paper 4 describes the protocol and methodology of a two phased RCT exploring the use of mindfulness based cognitive therapy in IBD. Publishing the protocol in the journal improves outcome reporting by providing a record of the intended method. Although the main intervention in the RCT is MBCT, mindfulness journal was not considered at this stage due to mindfulness journals being classed as a niche. The research team felt that a more interdisciplinary journal with a good standing will reach a wider audience including gastroenterology clinicians and researchers as well as mindfulness practitioners and researchers. This reinforced Trials as a first choice journal.

At time of publication, the impact factor was 2.12. To date (January 2016), this paper has received 8 citations, from international researchers (Germany and America). The paper has also received 'highly accessed' status and falls in the category of mostly viewed articles on BioMed Central.

Paper 5: Mindfulness-Based Cognitive Therapy for inflammatory bowel disease patients: the findings from an exploratory pilot randomised controlled trial (Schoultz et al. 2015) Trials, 16(1), p.379.

This paper was published in Trials as well as the previous paper. In addition to what was mentioned above about the journal, further rationale for publishing in the same journal is that having the protocol and results in the same journal makes it easy for the reader to access both. Likewise, this can also allow for readers to easily critically assess the outcome in light of the original study aims. Because the paper was published at time of writing of the thesis, only 4 citations are available at present.

Paper 5 was also presented at two international conferences: ISQua (International Society for Quality in Health Care) in Rio de Janeiro 2014 (oral presentation) and UEG (United European Gastroenterology) Vienna 2014 (poster presentation).

Paper 6: Participants' perspectives on Mindfulness-Based Cognitive Therapy for Inflammatory Bowel Disease: A Qualitative study nested within a pilot Randomised Controlled Trial (Schoultz et al. 2016)

This paper was published in Pilot and Feasibility Studies, but this was not the first choice journal. Paper 6, which is a qualitative study, highlighted the experience and perspectives of patients with IBD using MBCT, while discussing acceptability and barriers to its use. This is an original paper as it is the first to report on this topic. The first choice was BMJ open (Impact factor 2.271), but disappointingly the submitted manuscript was returned without reaching peer review. This is due to the journal's policy of not publishing papers using data from RCTs that have been retrospectively registered. The paper was then submitted to Trials. Trials said this paper will not be relevant to the journal readership and again did not reach peer review. However, they did suggest that Pilot and Feasibility Studies Journal might be more suitable. Thus, the paper was submitted to this journal and accepted for publication. Pilot and Feasibility Studies is an open access, peer-reviewed, online journal publishing articles related to all aspects of the design, conduct and reporting of pilot and feasibility studies in biomedicine, with intention to future clinical trials. The journal is new and does not have impact factor, but it is part of the reputable BMC group.

I am a sole author for the first paper. The rest of the papers were co-authored with a team of co-authors. Within this team and for each paper my contribution was in excess of 90%. This meant, as a lead author I drafted each paper and the co-authors had an opportunity to comment before the paper was submitted to the respective journals. In addition, I was the lead grant applicant and holder and principal investigator.

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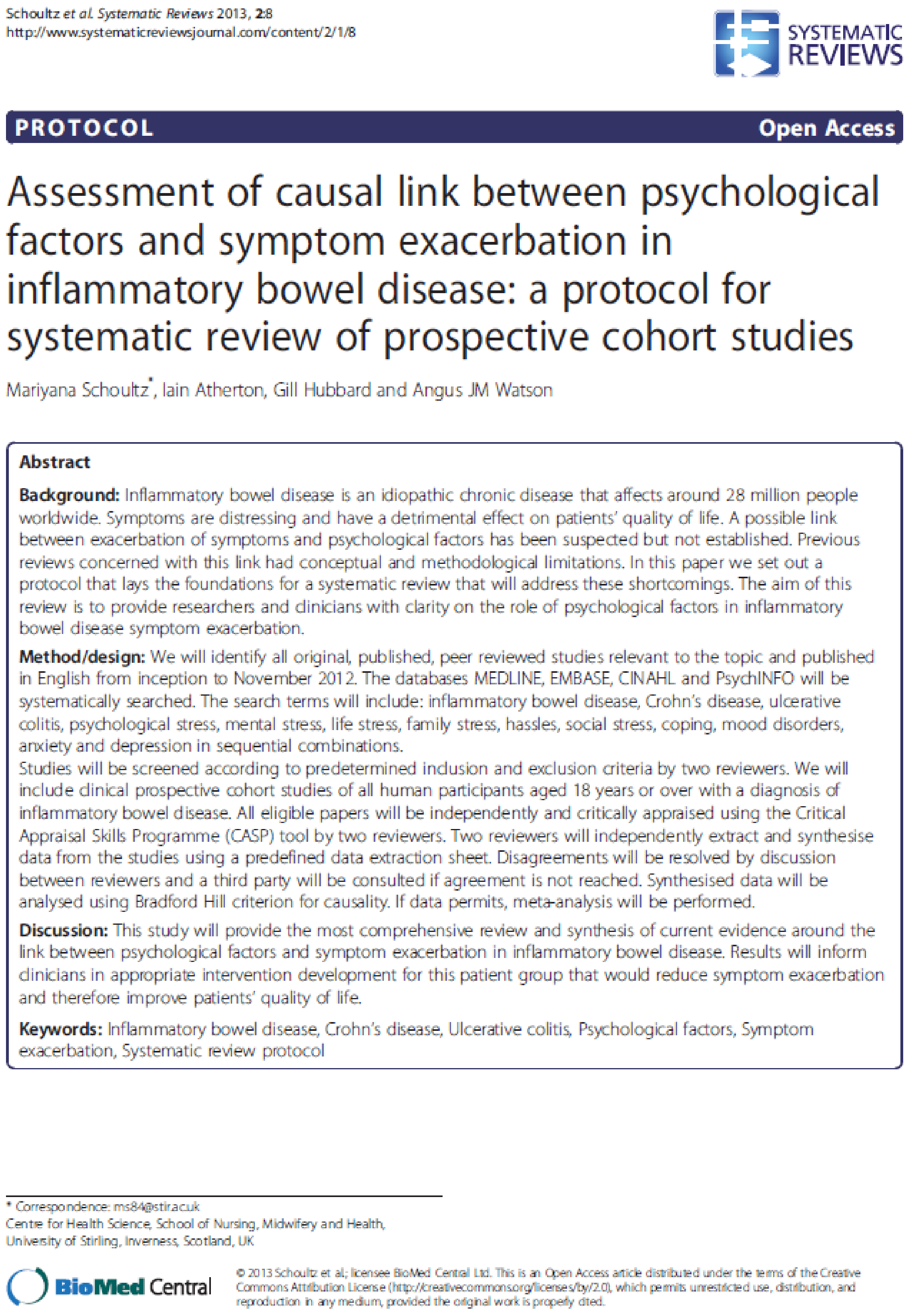
Appendices

Appendix 1: Paper 2: Assessment of Causal Link Between Psychological Factors and Symptom Exacerbation in Inflammatory Bowel Disease: A protocol



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SYSTEMATIC REVIEWS

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Assessment of causal link between psychological factors and symptom exacerbation in inflammatory bowel disease: a protocol for systematic review of prospective cohort studies

Mariyana Schoultz*, Iain Atherton, Gill Hubbard and Angus JM Watson

Abstract

Background: Inflammatory bowel disease is an idiopathic chronic disease that affects around 28 million people worldwide. Symptoms are distressing and have a detrimental effect on patients' quality of life. A possible link between exacerbation of symptoms and psychological factors has been suspected but not established. Previous reviews concerned with this link had conceptual and methodological limitations. In this paper we set out a protocol that lays the foundations for a systematic review that will address these shortcomings. The aim of this review is to provide researchers and clinicians with clarity on the role of psychological factors in inflammatory bowel disease symptom exacerbation.

Method/design: We will identify all original, published, peer reviewed studies relevant to the topic and published in English from inception to November 2012. The databases MEDLINE, EMBASE, CINAHL and PsychINFO will be systematically searched. The search terms will include: inflammatory bowel disease, Crohn's disease, ulcerative colitis, psychological stress, mental stress, life stress, family stress, hassles, social stress, coping, mood disorders, anxiety and depression in sequential combinations.

Studies will be screened according to predetermined inclusion and exclusion criteria by two reviewers. We will include clinical prospective cohort studies of all human participants aged 18 years or over with a diagnosis of inflammatory bowel disease. All eligible papers will be independently and critically appraised using the Critical Appraisal Skills Programme (CASP) tool by two reviewers. Two reviewers will independently extract and synthesise data from the studies using a predefined data extraction sheet. Disagreements will be resolved by discussion between reviewers and a third party will be consulted if agreement is not reached. Synthesised data will be analysed using Bradford Hill criterion for causality. If data permits, meta-analysis will be performed.

Discussion: This study will provide the most comprehensive review and synthesis of current evidence around the link between psychological factors and symptom exacerbation in inflammatory bowel disease. Results will inform clinicians in appropriate intervention development for this patient group that would reduce symptom exacerbation and therefore improve patients' quality of life.

Keywords: Inflammatory bowel disease, Crohn's disease, Ulcerative colitis, Psychological factors, Symptom exacerbation, Systematic review protocol

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Background

Inflammatory bowel disease (IBD) is an idiopathic chronic disease that affects around 250,000 patients in the United Kingdom and around 28 million people worldwide [1,2]. IBD incidence is increasing with future prevalence likely to be considerably greater than at present [3]. With no imminent prospects of cure, the need for effective symptom management is becoming ever more pressing. Part of the development of such interventions to relieve symptoms requires a better understanding as to what actually triggers those symptoms.

IBD encompasses various different conditions, with the main two types being Crohn's disease (CD) and ulcerative colitis (UC). Both conditions are characterized by chronic inflammation of the gastrointestinal tract. Clinically, they are often considered together given their similar aetiology and symptoms, but they differ in terms of which part of the digestive tract they affect and in the nature of the inflammation that they cause [4].

The symptoms experienced by this group of patients are often distressing. They include abdominal pain, bloody diarrhoea, nutritional failure and weight loss. However, they are not limited to the gastrointestinal tract only and can also cause ocular, musculoskeletal and skin pathologies [5]. All can occur intermittently, with periods of remission and exacerbation being experienced throughout the patient's life. The impact of these IBD symptoms can adversely affect patients' quality of life, affecting them psychologically, socially, educationally and vocationally [6].

Evidence suggests that a high proportion of IBD patients suffer from anxiety and depression, a percentage that is more than double when compared to healthy population [7]. This observed high anxiety and depression comorbidity in IBD patients have led many researchers and clinicians to believe that there could be a causal relationship between anxiety, depression (psychological factors in general) and IBD symptoms, even more so when other chronic diseases have established such links [8-10].

The idea about possible causality between psychological factors and IBD symptoms is not new and firstly emerged in the 1930s [11]. Since, there have been a number of reviews examining the evidence concerned with the issue, and to date, their conclusions remain somewhat contradictory [12-20]. Some have concluded that psychological factors contribute to exacerbations of symptoms [15,17] while others have refuted it [14]. More recent reviews, however, are leaning towards psychological factors having an impact on IBD symptomology, but they remain controversial and unclear [12,18-20].

This lack of clarity has brought a lot of confusion [21], particularly when empirical evidence from animal studies is suggesting potentially causal mechanisms between depression and inflammation [22,23]; and around 74% of IBD patients seem to believe that psychological factors such as anxiety and depression contribute towards symptom exacerbation [24].

This potentially causal mechanism between depression and inflammation and the patient's belief are noteworthy influences when considering why the previous reviews have arrived at contradictory findings. Methodological weaknesses of the reviews themselves and weaknesses of the studies on which they were based on are just some of the possibilities explored by previous researchers [25] as well as the conceptual limitations [16]. Both methodological and conceptual limitations have stemmed from the complexity of the disease, the difficulty in defining psychological factors and their relationship with symptom exacerbation. All of them need a careful consideration when planning and determining the objectives of a systematic review such as this one. A summary of those identified potential limitations and recommendations are as follows:

1. The aggregation problem: some studies have assumed the psychological-physical symptom relationship to be the same for both UC and CD [19,26,27];
2. Disease activity measures: different measures of disease activity have varying levels of validity and reliability. Contrasting findings may thus have resulted depending on which tools were used [12,25];
3. Definition and measurement of psychological factors: psychological factors are complex and encompass a range of aspects and degrees of severity which could each have different implications for disease symptoms [17,25]. Similarly, utilising different tools may lead to apparently contradictory findings [28];
4. Direction of causality: studies available to previous systematic reviews have been unable to disentangle whether stress causes symptoms or symptoms cause stress, which more recent studies may have addressed [17];
5. A moderation affect: psychological factors may be an important factor for some personality types but less so, or even not at all, for others [29]. Study participants will have had different degrees of coping skills with implications for the relationship between psychological factors and disease activity. Those with more effective ability to cope will potentially have been less at risk of experiencing exacerbation of symptoms [30,31].

Previous reviews

Systematic reviews provide robust and comprehensive overviews of research findings within a specified topic area. The aim of systematic reviews, unlike the non-systematic approach of literature reviews and overviews, is to minimise bias and offer reproducibility while using scientific and transparent approach [32]. The approach is achieved by following transparent, systematic and robust procedures.

A number of previous reviews concerned with the role of psychological factors and symptom exacerbation have not followed a systematic approach [12,18]. These papers were limited because only a single database was searched and potentially important studies were missed. This limitation might have resulted in the authors arriving at misleading conclusions. Others did not provide a clear description of their methods [19,20], denying other researchers the opportunity to make judgments on their scientific robustness [12,13,18].

Some reviews have treated IBD as a single entity [17] while others analysed specifically UC patients [14] or CD patients [15]. We highlighted earlier that IBD consists of two different diseases. For most purposes they are so similar that aggregating them together makes sense [33]. However, it has been shown that patients with clinically similar disease might vary physiologically, at a molecular level [34,35], which makes its just possible that the relationship between the psychological and physical symptomology differs in individual patients. If this were the case, then the constituent conditions should be disaggregated for analytical purposes where psychological influences are being considered. The subtlety different focuses may be a reason why the papers arrived at differing conclusions and why a review is required that distinguishes between UC and CD.

Justification

Among the criticism about methodological and conceptual limitations, there are recommendations of previous robust reviews that should not be ignored [14-17]. However, the most recent of these is now more than a decade old, a period of time during which many more studies are likely to have been carried out. Hence, that makes a clear justification for this review to fill such a literature gap.

Causality

Simply reporting an association between psychological factors and symptom exacerbation in IBD is not sufficient to establish causality. To prevent misleadingly causal associations, the epidemiologist Bradford Hill proposed a number of viewpoints later used as criteria that should be considered before declaring a causal relationship truly exists [36]. To date, no systematic review examining causality between psychological factors and symptom exacerbation in IBD has explicitly applied the Bradford Hill criteria to assess the evidence supporting a potentially causal association between the two.

Hence, in this paper we set out a protocol that lays the foundations for such a systematic review that will apply the Bradford Hill criteria for causality while bypassing the limitations noted from previous studies. The outcome of this review will provide clinicians with a clear foundation on which they might be able to develop therapies that reduce the likelihood of symptom exacerbation and therefore improve patient quality of life.

Study aim and objectives

The aim of this study is to provide researchers and clinicians with clarity on the role of psychological factors in IBD symptom exacerbation. In doing so, we will conduct a systematic review that will synthesise available evidence from prospective cohort studies that are reporting on causal associations between psychological factors and symptom exacerbation in IBD and on which we will apply the Bradford Hill criteria for causality. Guided by the recommendations from previous reviews outlined in the background section, the specific objectives that will help us attain our aim are:

1. To determine whether there is a causal relationship between minor stressors and exacerbation of symptoms in IBD patients and if any causality differ between UC and CD patients;
2. Whether there is a causal relationship between life events and exacerbation of symptoms in IBD patients and if any causality differ between UC and CD patients;
3. Whether there is a causal relationship between personality type/trait and exacerbation of symptoms in IBD patients and if any causality differ between UC and CD patients.

To address the above specific objectives we will firstly identify and then examine studies concerned with the relationship between minor stressors and symptom relapse, life events and symptom relapse, and personality and symptom relapse in all IBD population. We will then synthesise and evaluate data against Bradford Hill criteria for causality and do meta-analysis if deemed appropriate.

Method/design

Study method

To ensure the methodology of this systematic review is robust, we will follow the 27 checklist of PRISMA statement and the guidance outlined by the Centre for Reviews and Dissemination (CRD) [37,38]. Following this guidance would ensure the methodological limitations of previous reviews outlined in the background section will be avoided.

Criteria for considering studies for this review

Inclusion and exclusion criteria

To be included in the review, the papers will have to meet the following set criteria relating to study type, population of interest, risk factors studied, outcome measures and language restrictions:

Study types We will only utilise prospective cohort studies that report on causal association between psychological factors and symptom relapse in IBD patients. Thus, data obtained from long-term cohort studies is of considerably higher quality to those obtained from retrospective/cross-sectional studies and retrospective cohort studies [39]. Using prospective cohort study data for the systematic review will help observe the risk factors for symptom relapse in IBD patients. Cohort studies involve observation of the individuals (over a period of time), and collection of data at regular intervals, which reduces recall error.

Cross-sectional studies are not able to ascertain the direction of effect and thus will not be included in this review. Previous reviews have acknowledged that using studies with retrospective design to answer this question could have contributed to the contradictory findings and introduced recall bias [25]. Thus we will limit our review to prospective cohort studies only.

Population of interest We will include studies with all patients aged 18 years or older with diagnosis of Crohn's disease or ulcerative colitis. Studies using mixed sample of both diagnosis will also be included. We will not use any studies using mixed sample of children and adults. While symptom presentation and therapeutic presentation could be similar between adults and children, significant differences are noted between the two populations [40].

Risk factors/exposure Psychological variable specifications.

We will include studies reporting on psychological factors where they are clearly defined and the measurement tools used are clearly identified. As mentioned in the background section, psychological factors can be many and varied and often different studies will measure different psychological factors. For example, unspecified 'stress' will not be considered as valid psychological factor since is too vague and difficult to be accurately measured, but 'daily stress' or 'perceived stress' will be considered as valid. A sample list of clearly identified psychological factors is presented in the list below (the list is not definitive).

A sample list of Psychological factors

Anxiety
Depression
Depressive mood
Major life events/bereavement/separation
Daily events
Social stress/support
Life stress
Work/employment stress
Family stress/support
Coping
Personality
Financial stress
Satisfaction/quality of life

Types of outcome measures reported by studies Disease activity and symptom relapse/exacerbation specifications

Studies reporting on disease activity and explicitly giving details on tools used to measure disease activity/symptom relapse will be included in this review. Similar to the psychological variable factors, disease activity and symptom relapse/exacerbation have to be clearly defined and measured. To be included in the review, studies will have to give details on tools used for disease activity measurement (for example, simple clinical colitis activity index -SCCAI), and details on frequency of relapses, exacerbations of symptoms and change of symptoms.

Language and geographical area limitations Only studies published in English will be included in the review. Due to funding constraints, we are unable to translate studies published in other languages at this stage. There will be no geographical limitation for the included studies.

Search strategy for identification of studies

We will follow the guidance outlined by CRD [38] in the search and selection of studies for the review to ensure robustness. Two reviewers will independently attempt to identify all studies relevant to the review while using a pre-set screening checklist presented in Table 1. We will only include those studies that meet all criteria. The following four methods will be used to identify studies:

Electronic searches The database Medline will be searched via Ovid and PubMed, EMBASE via Ovid and CINAHL and PsychInfo via Ebsco will be searched for

Table 1 Screening check list for inclusion to review

Title			
	Yes	No	Unsure
Human			
English language			
Prospective cohort study			
Reporting on psychological factors in IBD, UC or CD and disease symptoms			
Psychological variables (exposure) defined			
Disease activity and symptom exacerbation measures clearly defined			

relevant articles published in English from commencement of databases to November 2012. The CRD guidance does not specify what constitutes a sufficient number of databases searched for a review as that number can vary from topic to topic [38]. Pragmatically, Medline and EMBASE might reveal most of relevant studies, however, the use of more specialised databases in addition might bring studies that are relevant to the systematic review and not included in the previous two [41].

We will use subject term services of the different databases. The following search terms and their MeSH (medical subject heading) equivalents will be used: inflammatory bowel disease, Crohn's disease, ulcerative colitis, psychological stress, mental stress, life stress, family stress, hassles, social stress, coping, perceived stress, mood disorders, anxiety, depression, personality . These terms will be used in various combinations and wildcards will be used to pick up variant terminology. As per CRD guidance [38], a sample search strategy for Medline is presented in the list below.

Search strategy for MEDLINE

1. Inflammatory Bowel Diseases/
2. Crohn's Disease/
3. Colitis, Ulcerative/
4. Stress, Psychological/
5. mental stress.mp.
6. life stress.mp.
7. family stress.mp.
8. hassles.mp.
9. social stress.mp.
10. coping.mp.
11. perceived stress.mp.
12. mood disorders.mp. or Mood Disorders/
13. Anxiety/
14. Depression/
15. 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14
16. 1 or 2 or 3
17. 15 and 16

Reference lists We will manually check the reference list of all the studies included and identified by the above search strategy to identify relevant studies that have not been detected with the database searches. These studies will be assessed against the inclusion criteria and included if appropriate. We will also check the reference list of any previous reviews on psychological factors in inflammatory bowel disease for papers suitable for inclusion in our review.

Citations databases We will check Citations Google Scholar, Citations Web of Science and Citations Scopus for papers that have cited the Searle and Bennett [17] review to identify further papers that could be relevant and eligible for the review but that have not been identified using the search strategy identified above. We believe that this review is a key paper for the period up to 2001 and this paper would be referenced in more recent studies.

Grey literature We will include unpublished material as part of our search given that not all relevant material will have been published. CRD recommends looking at databases such as NTIS (National Technical Information Service) and HMIC (Health Management Information Consortium) for grey literature which may reveal unpublished papers relevant to our review. We will also

Table 2 Data extraction sheet

General information	
	Researcher's name
	Date of data extraction
	Author
	Article title
	Citation
	Type of publication (for example, journal article, conference abstract)
	Country of origin
Study characteristics	Aim/objectives of the study
	Study design
	Study inclusion and exclusion criteria
	Recruitment procedures used (for example, details of randomisation, blinding)
	Unit of allocation (for example, participant, GP practice, and so on)
Participant characteristic	Age
	Gender
	Ethnicity
	Socioeconomic status
	Disease characteristics
	Co-morbidities
	Number of participants
Setting of the study	
Outcome/results	
	Whether all outcomes were defined and reported
	Measurement tool or method used
	Unit of measurement (if appropriate)
	Length of follow-up, number and/or times of follow-up
	Type of analysis used in study (for example, intention to treat, per protocol
Conclusion as per authors	

Table 3 Grouping of studies data for analysis

Studies reporting on following psychological factors	Studies reporting on symptom exacerbation in these patient groups	Studies reporting on symptom exacerbation in these patient groups	Studies reporting on symptom exacerbation in these patient groups
Minor stressors	UC patients	CD patients	Mixed CD and UC
Major life events	UC patients	CD patients	Mixed CD and UC
Personality	UC patients	CD patients	Mixed CD and UC

attempt to contact authors and experts in the field for any relevant materials rough the British society of gastroenterologists (BSG) or the World Gastroenterology Organisation (WGO). An updated search will be conducted immediately prior to data synthesis.

Data collection and management

Screening and selection of studies All retrieved studies identified by the search strategy will be downloaded onto RefWorks and duplicates will be removed. Two reviewers will work independently. They will read title and abstract of all papers sourced to determine suitability for inclusion into the study based on the predetermined eligibility criteria (see Table 1). Discrepancies and disagreements regarding eligibility will be resolved by discussion. All papers meeting the eligibility criteria will be included for quality assessment in this systematic review. We will record reasons for exclusion of any papers excluded in quality assessment stage.

Authors will be contacted in order to clarify missing data or unclear information.

Data extraction and management The two reviewers will independently extract data using a predesigned data extraction form (see Table 2). The extracted data will be grouped in general information, study characteristics, participant characteristics, setting and intervention and outcome/result data as per CRD guidance for systematic reviews [38]. Any discrepancies in extracted data will be discussed by two authors, and if consensus is not reached, a third party will be consulted. In case of incomplete data, authors will be contacted for clarification.

Assessment of risk of biases and methodological quality Methodological rigour can vary from study to study and certain flaws in design or study conduct can

Table 4 Bradford Hill criteria for assessing causation in cohort studies and interpretations to be used in this review

Criterion no.	Bradford Hill Criteria [36]	Interpretations for this review
1. Strength of the association	The stronger the association between a risk factor and outcome, the more likely the relationship is to be causal	*For strength of association we will use odds ratio which will be graded as 1, 2, 3, 4 with 4 being strong association, 3 being moderate, 2 being weak association and 1 protective [46]
2. Consistency of findings	Have the same findings been observed among different populations, in different study designs and different times?	Findings of associations between psychological factors and symptom exacerbation have been established in other populations
3. Specificity of the association	When a single assumed cause produces a specific effect outcome	This is not going to be evaluated because single exposure to psychological factors and outcome of symptom relapse does not preclude a causal relationship
4. Temporal sequence of association	Exposure must precede outcome	Analyses will be restricted to prospective cohort studies, a design that ensures exposure will precede outcome
5. Biological gradient	Changes in disease rates should be associated with changes in exposure (dose–response)	Changes in disease (symptom) activity should correspond to changes in exposure (length or intensity of exposure to psychological factors or degree of stress experienced)
6. Biological plausibility	Presence of a potential biological mechanism of causality	Exposure selected in this review meets the criteria for plausibility of scientific credible mechanism for causality [15,17]
7. Coherence	Does the relationship agree with the current knowledge of the natural history/biology of the disease?	Current evidence needs to support an association between psychological factors and symptom relapse
8. Experiment	Does the removal of the exposure alter the frequency of the outcome?	There are experimental studies supporting the plausibility of causal relationship between psychological factors and symptom exacerbation [47]

result into bias which could influence the end result or conclusion of a study. This is particularly important for observational studies as they are often seen as at greater risk for bias.

The first step of assessing any potential bias within the eligible studies is by evaluating their methodological quality. For such evaluation the Critical Appraisal Skills Programme (CASP) tool for cohort studies will be used [42]. The CASP tool uses a systematic approach to appraise three broad areas for consideration: study validity, an evaluation of methodological quality and presentation of results and an assessment of external validity [42]. There are 12 specific questions in total assessing the following: study validity, risk of bias in recruitment, exposure, outcome measurement, confounding factors, reporting of results and the transferability of findings. Each of the questions can be answered with 'yes', 'no' or 'can't tell' and each study can have a maximum score of 12.

Two reviewers will independently use the CASP tool for cohort studies and record each quality assessment. The scores will be used to grade the methodological quality of each study assessed. Discussion of unresolved disagreements regarding quality assessment with a third person will further ensure methodological rigour.

Data presentation As per CRD [38], summary of extracted data from included studies will be presented in tabular form as part of the review.

Data synthesis, subgroup analysis and investigation of heterogeneity We will combine data in groups by psychological factor (minor stressors, major life events and personality) with each containing three subgroups for UC, CD and mixed sample of IBD in order to address each of the aims of the systematic review (see Table 3). We will then apply the Bradford Hill criteria for causal relationship [36].

The Bradford Hill criteria are widely used to evaluate systematically whether a causal link between an exposure of interest and a health outcome exists. These criteria are often used by epidemiologists to test a causal hypothesis [43-45]. Table 4 is summarising the Bradford hill criteria for assessing causation in cohort studies together with interpretations of each criterion that will be used in this review. In addition to the Bradford Hill analysis, we will consider performing meta-analysis if appropriate. As recommended by CRD [38] and if studies characteristics are homogeneous enough, we will group studies and perform meta-analysis of the pooled data. All meta-analyses would be performed using subgroup analysis by type of disease and by type of psychological factors.

Discussion

There is still a debate and controversy about the influence of psychological factors in symptomology in IBD. In times when the prevalence of IBD is increasing worldwide [3,48] it is important to tackle this issue. Symptom relapse in IBD patients is often associated with worsening of quality of life [29,49]. Thus, it is important that service providers and IBD clinicians are provided with clear evidence about the relationship between psychological factors and symptom exacerbation in order to develop and implement appropriate therapies and services. Consequently, new therapies may help improve the quality of life for IBD patients by reducing factors that cause symptom exacerbation.

Systematic review status

The systematic review is currently in the phase of screening and selection of studies. We expect completion by December 2013. PROSPERO registration number: CRD42012003143.

Abbreviations

CD: Crohn's disease; IBD: Inflammatory bowel disease; SCCAI: Simple clinical colitis activity index; UC: Ulcerative colitis.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

MS is the lead researcher of this project. All authors contributed significantly to the design, methodology, writing and revision of the protocol. All authors read and approved the final manuscript.

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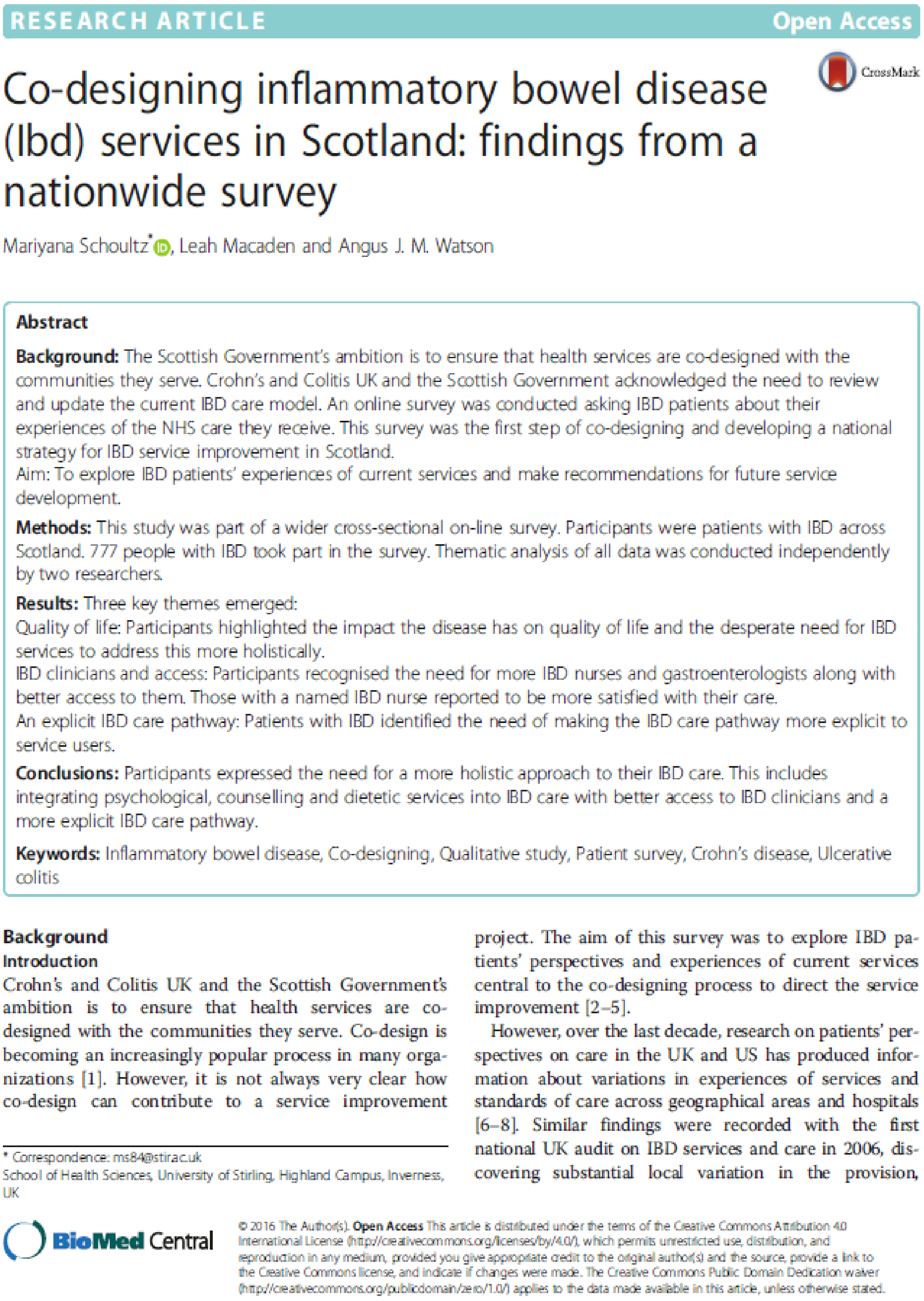
Appendix 2: Paper 3: Co-designing inflammatory bowel disease (IBD) services in Scotland: Findings from a nationwide survey (accepted for publication) & Gut abstract: Co-designing inflammatory bowel disease (IBD) services in Scotland: the patients' perspective



RESEARCH ARTICLE Open Access

Co-designing inflammatory bowel disease (Ibd) services in Scotland: findings from a nationwide survey

Mariyana Schoultz*, Leah Macaden and Angus J. M. Watson

Abstract

Background: The Scottish Government's ambition is to ensure that health services are co-designed with the communities they serve. Crohn's and Colitis UK and the Scottish Government acknowledged the need to review and update the current IBD care model. An online survey was conducted asking IBD patients about their experiences of the NHS care they receive. This survey was the first step of co-designing and developing a national strategy for IBD service improvement in Scotland.
Aim: To explore IBD patients' experiences of current services and make recommendations for future service development.

Methods: This study was part of a wider cross-sectional on-line survey. Participants were patients with IBD across Scotland. 777 people with IBD took part in the survey. Thematic analysis of all data was conducted independently by two researchers.

Results: Three key themes emerged:
Quality of life: Participants highlighted the impact the disease has on quality of life and the desperate need for IBD services to address this more holistically.
IBD clinicians and access: Participants recognised the need for more IBD nurses and gastroenterologists along with better access to them. Those with a named IBD nurse reported to be more satisfied with their care.
An explicit IBD care pathway: Patients with IBD identified the need of making the IBD care pathway more explicit to service users.

Conclusions: Participants expressed the need for a more holistic approach to their IBD care. This includes integrating psychological, counselling and dietetic services into IBD care with better access to IBD clinicians and a more explicit IBD care pathway.

Keywords: Inflammatory bowel disease, Co-designing, Qualitative study, Patient survey, Crohn's disease, Ulcerative colitis

Background

Introduction

Crohn's and Colitis UK and the Scottish Government's ambition is to ensure that health services are co-designed with the communities they serve. Co-design is becoming an increasingly popular process in many organizations [1]. However, it is not always very clear how co-design can contribute to a service improvement project. The aim of this survey was to explore IBD patients' perspectives and experiences of current services central to the co-designing process to direct the service improvement [2–5].

However, over the last decade, research on patients' perspectives on care in the UK and US has produced information about variations in experiences of services and standards of care across geographical areas and hospitals [6–8]. Similar findings were recorded with the first national UK audit on IBD services and care in 2006, discovering substantial local variation in the provision,

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organization and clinical quality of services with aspects of care not meeting clinical guidelines [9]. The findings prompted a UK-wide strategy to improve services and care for patients who have Ulcerative Colitis or Crohn's Disease. The strategy produced collaboration between patients and professionals, defining the minimum standards for patient-centered and high quality IBD services in 2009. The update of this strategy in 2013 suggests that significant improvements were made in IBD care and service delivery; however it also identified deficits in certain aspects of provision across the board [10]. Acknowledging this report, Crohn's and Colitis UK and the Scottish Government recognised the need to review and update the current IBD care model in Scotland to a model that fully reflects the range of needs of patients with IBD.

Inflammatory bowel disease

IBD is a group of chronic gastrointestinal diseases with relapsing nature and unpredictable disease course. The disease affects around 28 million people worldwide and around 250,000 patients in the UK [11, 12]. The incidence of IBD in the UK is on the increase, with up to a 76 % increase in Scotland since the mid-1990s, making Scotland the highest UK region with an incidence of 0.65 per 10.000 per year ([13, 14].

Although IBD is principally thought to be a disease of the intestinal system, a purely gastrointestinal (GI) centric view of the illness is no longer sufficient [15]. The complexity of IBD is becoming well recognized. In addition to the multiple challenges in the disease management caused by the nature of the disease (incurable, unpredictable symptoms and severity), medication side effects and surgery; the psychological stress and burden from the disease is an important part of the disease experience for patients with IBD [16, 17]. This is evident throughout the literature in the proportion of IBD patients experiencing depression and anxiety [16, 18]. In return, higher depression and anxiety in IBD patients have been linked to further exacerbation of symptoms [19], recurrent hospital admission, non-compliance and poor quality of life [20, 21]. Thus, addressing the disease management of IBD in a more holistic way that acknowledges the psychological burden of the disease, should be reflected in the IBD services.

Models of integrated IBD care in other countries

Previous attempts to integrate IBD care in a holistic way have been seen in a number of countries as described by Mikocka-Walus [22]. For example in Adelaide (Australia) an IBD service model of care has been developed based on the recommendation of the British IBD Standards [9]. The model involves collaboration between all specialists involved in the care (gastroenterologists, IBD nurses and clinical/health psychologists as a core specialists and surgeons and dieticians as resources available), as well as number of services led by IBD nurses [22]. Similar patient focused models of IBD services based on multidisciplinary integration of activities is seen in Italy at Istituto Clinico Humanitas in Milan, Netherlands at the Erasmus Medical Centre and Canada at the IBD clinic at Winnipeg [22]. However, although the above examples use a holistic approach to care for IBD patients, those models are not a representative of common organisation and practice of services in the respective countries.

Crohn's and colitis UK

Crohn's and Colitis UK is a charity organisation founded in 1979 dedicated to improve lives of people affected by Crohn's disease and ulcerative colitis. The 28,000 members include not only patients, but their families, health professionals and others who support the work for improving quality of life and clinical care for people with Crohn's disease, ulcerative colitis and other IBD diseases.

This paper reports the findings from the free text data of an online survey about the perceptions and experiences of service users of the current IBD services across Scotland. The study was part of a wider survey and the first of its kind in Scotland.

Aim

To explore IBD patients' perspectives and experiences of current IBD services and make recommendations for future service development.

Method

The consolidated criteria for reporting qualitative research (COREQ) was used to guide the structure of this paper.

Study design

This qualitative study was part of a wider national online survey on patient perspectives and experiences with current IBD services across the NHS in Scotland. The cross-sectional survey was made available between March and May 2014. Open invitations to take part in the survey were placed on the website of Crohn's and Colitis UK, Crohn's and Colitis UK Newsletter and an online survey link was distributed by Crohn's and Colitis UK members using social networks such as Facebook and Twitter.

Participants and setting

The survey was organised and administered by Crohn's and Colitis UK in collaboration with the Scottish Government as the first step of a pilot project for co-designing IBD services in a bid to improve standards of care for IBD in Scotland. Participants in the study were patients across Scotland with a diagnosis of IBD. Participants recruited fulfilled both of the inclusion criteria: 1) to have a diagnosis of Crohn's disease or ulcerative colitis and 2) to receive their treatment in Scotland (see Additional file 1 for full survey). Any respondent who did not meet the above criteria was excluded from the survey analysis. There is an understanding that online surveys do not require separate consent form, however the introduction paragraph accompanying the survey link as well as the introductory paragraph of the survey, conveyed the information about the purpose and anonymity of the study and consent was obtained by virtue of completion of the study. Research Governance at NRES (National Research Ethics Service) Committee for North of Scotland reviewed and exempted the study from a formal ethical review.

Questionnaire

The on-line questionnaire was developed and designed by patients with IBD and members of Crohn's and Colitis UK using Survey Monkey. Survey Monkey is a web-based, flexible and secure survey development tool [23]. The survey had 22 questions in total and took no more than 10 min to answer (see Additional file 1). However, only the findings from the three open ended questions, (see research questions) are presented in this paper. All open responses were reviewed in detail to identify common themes.

Research questions

1. Please tell us two things which you think are good about your NHS care?
2. Please tell us two things which you think would improve your NHS care?
3. Anything else you would like to tell us about living with IBD?

Analysis

Two researchers (MS, LM) independently coded the data to minimize subjectivity. All data were analysed using a thematic analysis framework approach [24]. This method is a rigorous approach consisting of 6 phases that provides structure for qualitative data to be organised, coded and themes to be identified. Both researcher read all data twice in order to become familiarized with it. After familiarization with data, generating initial codes and searching for themes among codes independently, researchers met to discuss their findings and extract the core themes. Then, researchers reviewed, defined and named the themes before producing the final report of key themes and sub themes (see Table 1). A report on the findings was presented to Crohn's and Colitis UK members and discussed with them.

Rigour

Qualitative studies are often judged on the basis of trustworthiness and rigour [25]. Rigour has been described as a means by which integrity and competence are demonstrated within a study [26]. These criteria were upheld throughout the analysis by being independently conducted by two researchers. Researcher met at three points (after the third, fifth and sixth step) to discuss findings and rectify any differences. Rigour with sampling was ensured through purposive selection using both intensity sampling (experts in the subject—people living with IBD) and maximum variation sampling (diverse sample) to make the data "information rich" [27].

Table 1 Themes and subthemes

Themes	Subthemes
Quality of life	a. Impact on emotional/mental health b. Impact on physical health c. Impact on social health d. Impact on occupational health
IBD clinicians and better access	–
Clear IBD care pathway	a. Access to psychological and dietician services b. More advice and practical support on living with IBD c. Better education for GPs and A&E staff d. Availability of IBD care facilities

Results

Demographics

Out of the 777 participants that responded to the survey, 10 (1.29 %) were excluded from the analysis as they did not meet the eligibility criteria of receiving treatment in Scotland. Table 2 includes the demographic data and clinical characteristics of participants in the sample (note that not all participants answered all demographic questions).

Key themes

Three major themes emerged at the final point of analysis: quality of life, access to IBD clinicians and the need for an explicit IBD care pathway. The themes occurred across all of the three questions. Further to the main themes, separate areas or sub themes unfolded (see Table 1).

Quality of life

Survey data suggested that some of the participants were concerned about the impact of IBD on their quality of life. Four categories or domains of quality of life were identified in the coding process. The categories that were consistently identified by the participants as being associated with quality of life, were: emotional/mental, physical, social and occupational health. The foundations for these sub themes are described separately alongside the verbatim quotes. Some of the quotes illustrate more than one sub theme simultaneously. See Fig. 1 for interconnectedness between the subthemes in this theme.

a. Impact on emotional/mental health

Table 2 Baseline demographics and clinical characteristics of participants

Baseline	
Answering the 1^{st} question (*n*,%)	610 (78.50)
Answering the 2^{nd}question (*n*,%)	600 (77.22)
Answering the 3^{rd} question (*n*,%)	419 (53.92)
Age (years) (*n*, %)	
Under 16	37 (4.85)
16–65	671 (88.06)
Over 65	54 (7.09)
Sex	
F (*n*, %)	406 (66.56)
M (*n*, %)	204 (33.44)
Last flair up (*n*, %)	
Less than 6 months ago	367 (50.62)
6–12 months ago	124 (17.10)
1–2 years ago	107 (14.76)
2–4 years ago	70 (9.66)
More than 4 years ago	57 (7.86)
Length of diagnosis (*n*, %)	
Less than a year	17 (2.33)
1–5 years	265 (36.35)
5–10 years	181 (24.82)
10–20 years	142 (19.47)
Over 20 years	124 (17.00)

Participants described that living with IBD affects their emotional and mental health in a way that some consider it to be worse than a terminal illness (Table 3, quotes 1 & 2). Some participants described that the emotional impact for them is so great, that is affecting their confidence and sense of self (Table 3, quote 3). Others describe that the disease has left them feeling embarrassed and isolated with very little energy to form or keep up relationships (Table 3, quotes 4, 5, 6 &7). Participants described experiencing depression and anxiety that often followed exacerbation of symptoms, and therefore a identifying a need for acknowledgement and support for that aspect of the disease (Table 3, quotes 8, 9 & 10).

b. Impact on physical health

In addition to the mental health, participants identified the effects of constant tiredness, fatigue and pain (often present even in remission) on their physical health as a key area that needed to be addressed by practitioners. The quotes 1, 2, 3 & 4 (Table 4) demonstrate the participants' experience of the physical effect the disease has on quality of life that they feel is underestimated.

c. Impact on social health

The quotes in this section describe the patients' experiences of the impact that the disease has on every aspect of social and family life, leading to social isolation in some instances. Simple social activities that most people take for granted, such as going to

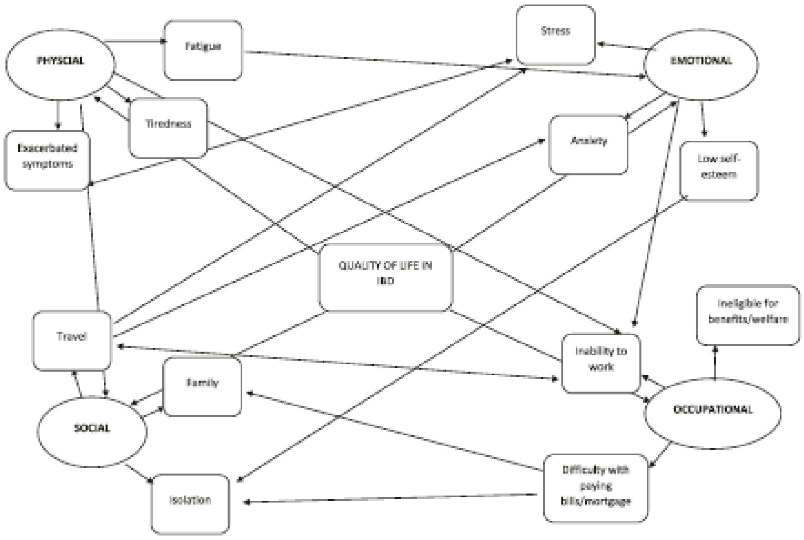

Fig. 1 Thematic map showing interconnectedness between subthemes. The thematic map is showing how Quality of life is closely interconnected and affected by the physical, social, emotional and occupational health. In addition, it shows how for example physical symptoms (fatigue, tiredness & exacerbated symptoms) can have effect on specific aspects of social, occupational and emotional health and vice versa

Table 3 Quality of life: Impact on emotional/mental health

Quote no.	Quote
Quality of life:	Impact on physical health
1.	"The extreme tiredness is very hard to cope with."(P315)
2.	"Feel tired even when asymptomatic. This affects my working ability and it would be very helpful to receive some sort of financial help like a tax credit or small benefit so I could always work 4 days a week without struggling."(P412)
3.	"The fatigue that is debilitating and under estimated." (P61)
4.	"My life has went on hold since diagnosis. Either because of pain or fatigue I have been unable to go on holiday, and worse still, my work has been hugely affected with long absences…"(P169)
Quality of life:	Impact on social health
5.	"Can be difficult when out for day and have to join queue for toilet-if use disable one can get dagger looks from other people who are me judging me as they don't realise what it is like as I do not look any different ." (P5)
6.	"I have lost 3 years of an important stage in my life to Crohn's and it has affected my friendships, my family and my education. "(P50)
7.	"Also feel quite fed up about having IBD because of travelling issues and being anxious about needing the toilet and having access to a toilet. The fear never goes away and you are always on the alert for where the nearest toilet is even if you hardly ever have to go urgently. "(P136)
Quality of life:	Impact on occupational health
8.	"It's very difficult and I worry a lot about not being able to work and pay my mortgage. Was refused benefit when I was off for around 6 months the last time." (P41)
9.	"It isn't easy. Struggling more with working as I get older and coping with IBD." (P102)
10.	"It is a constant struggle to get any welfare when not able to work. I have worked since I was 16 and paid my way but never there when I need it adding to stress levels" (P168)

Table 4 Quality of life: impact on physical, social and occupation health

Quote no.	Quote
Quality of life: Impact on emotional/mental health	
1.	".at least cancer has the decency of killing you after torture. Not build you up and attack again…Also on antidepressants…" (P1)
2.	"it takes over your life….always have constant fear of what's next." (P148)
3.	".impact on confidence is greatly affected." (P8)
4.	"This illness is so debilitating and embarrassing…" (P131)
5.	"people don't realise just how low you can get when having a flare up…it just drains you emotionally." (P95)
6.	"its been horrendously isolating….has precluded me from contemplating seeking a partner." (P139)
7.	"its horrible and upsetting and makes life a lot more difficult for the sufferer and sufferer' family." (P40)
8.	"More could be done on the counselling side of things too, depression and anxiety can follow a flare up." (P36)
9.	"I find stress makes me flare up and feel that the nurses and GP's seem to be disregarding the help people need emotionally." (P86)
10.	"Fatigue, stress and anxiety all make the condition worse and are brought about by it but no strategies are ever offered by NHS staff." (P155)

town, or for a meal, can often be very stressful events due to not having access to disabled toilets (Table 4, quotes 5, 6 & 7). Participants wished for more support to be given to deal with these issues.

d. Impact on occupational health

The impact the condition has on occupation is particularly interlinked with the other domains of quality of life. Participants identified that coping with the disease and all the side effects, makes work very difficult for them (Table 4, quote 9). They also expressed the need for better help with benefits and welfare when unable to work (Table 4, quote 8). Some felt that the impact on occupational health presents a great cause for further distress (Table 4, quotes 9 & 10).

IBD clinicians and better access

An important issue that participants highlighted was the need for more IBD nurses and gastroenterologists, together with improved access to them (Table 5, quote 3, 5, 8 & 9). Approximately one third of the participants agreed that having a named IBD nurse is one of the best things about their care (Table 5, quote 4, 6, 7). When asked about the part of the care that patients were happy about, participants described that nursing and consultant care were

Table 5 IBD clinicians and access

Quote no.	Quote
IBD Clinicians	
1.	"Quicker access to medical help over the weekend, my inflammatory flare ups always happen over the weekend. NHS 24 is hopeless over the weekend "(P78)
2.	"That they don't only support your physical disease but the emotional scars it leaves. That between the GI ward and IBD nurse it just feels like one big family. "(P78b)
3.	"More frequent gastroenterology visits with gastroenterologist or IBD nurse. Surely an IBD nurse for every sufferer in Scotland is achievable."(P213)
4.	"IBD nurses are amazing people and having a named nurse to call when things go wrong is an amazing resource that is seriously undervalued." (P58)
5.	I wasn't referred to the IBD nurse until I first went to hospital on the mainland. I live in a very remote area and knowing that this resource was available would have been very useful when I was first diagnosed. (P359)
6.	But having a nurse specialist is of great support and keeps things monitored much more closely (P89)
7.	Easier access to IBD and stoma nurse. (P64)
8.	More staff/nurses! The current ones are overworked and underpaid. (P85)

the parts of the service that they were happy about (Table 5, quote 2), but having better access to nurses and the gastroenterology team would improve the care for many (Table 5, quote 1 & 8).

Some participants described that a particular improvement to services would be an access to an IBD nurse or consultant over the weekend. They highlighted that it is difficult to cope with exacerbated symptoms over the weekend if they are not able to access a knowledgeable healthcare professional (Table 5, quote 1).

A more explicit IBD care pathway

Participants are looking for a more consistent and explicit care pathway that they can navigate with ease. For example, a participant expressed dissatisfaction with the care due to the poor coordination between departments which resulted in the patient staying at the bottom of their waitlists. In addition, the perception of the patient is that the different departments were working in isolation within their own deadlines, without working in a holistic person centered way (Table 6, quote 1).

Other participants felt are left not knowing who to contact for advice when sick and have a flair up, without getting conflicting advice (Table 6, quote 2); or feel that are getting 'lost' in the system (Table 6, quote 3). According to the participants' answers and suggestions towards service improvements in the IBD pathway, four main areas were identified:

a. Access to psychological and dietician services:
   Participants repeatedly described the need for availability and access to psychological and dietician services as part of the IBD care pathway (Table 6, quotes 4 & 5 and Table 3, quote 8). This would enable many diagnosed with IBD to cope better with a condition and symptoms that are a taboo.
b. Better information and practical support on living with IBD:
   This sub theme identifies the need for a more holistic approach to the condition, where all symptoms, including the extra-gastrointestinal ones are addressed early on. Quotes 6, 7 & 8 (Table 6) describe the need for advice and support being available to patients with IBD as part of the care package.
c. Better education for GPs and A&E staff:
   Patients with IBD felt that health professionals have to be better educated about the condition. Participates often felt they had to 'fight' with clinical staff because of their lack of knowledge on IBD and often felt like they are on opposite 'teams'. In addition, they recognised that it is very difficult or impossible to be an advocate for the disease and their care particularly at critical times, when their symptoms are exacerbated. Quote 9 in Table 6 comprehensively captures what other participants also described.
d. Availability and coordination of IBD care facilities and services:
   Another area highlighted by patients was the availability of their own toilet on the ward, not having to share a room with others and the poor quality of hygiene in hospitals (Table 6, quote 10). In addition: quicker appointments, quicker diagnosis, regular follow up and at least, an annual review of care and local IBD facilities for patients living in the remote areas was among the other key areas identified by the participants in need of improvement (Table 6, quote 11).

Table 6 An explicit IBD care pathway

A more explicit IBD care pathway	
1.	"…but I kept being put back to day one in waiting lists in the next department, and felt there was a real lack of co-ordination between different departments in the hospital for outpatients, and was regularly made to feel that every department worked in isolation and only interested in their own deadlines…So I would improve the NHS by making different departments working together more rather than in tunnel vision. "(P145)
2.	"I have never seen the IBD nurse. I would like to know if he is available to me. Not sure who to ask." (P234)
Access to psychological and dietician services	
3.	"I think more psychological help should be available, especially for people diagnosed as children, teenagers or young adults as it impacts your whole life and is still a taboo subject so it's difficult to talk about it" (P179)
4.	"A review by a dietician who is knowledgeable about IBD and allergic reactions of gut to chemicals"(P20)
Better information and practical support on living with IBD	
5.	"..more advice on how to live with IBD."(P67)
6.	"Starter information pack giving new sufferers advice about lifestyle and diet." (P170)
7.	"NHS care would also be improved by holistic approach that tackled non bowel symptoms such as fatigue." (P213)
Better education for GPs and A&E staff	
8.	"There needs to be more belief in what patients are saying to health professionals about our symptoms and pain. I have felt on so many occasions that I'm not being believed. It minimises my pain and agony which affects my belief and trust in myself and my doctors too… It also makes me feel like I need to be on top of my game all the time, fighting and advocating for myself and the correct treatment. Sometimes I feel like its 'them vs me' when we should all be working for the same end goal at getting me better. This can be even more exhausting on top of the disease itself." (P135)
Availability and coordination of IBD care facilities and services	
9.	"When in hospital I think putting u in a ward with a shared toilet is a bit hard."(P184)
10.	"I have had very little follow up care after being diagnosed in 2012. My referral has been lost twice and I am still not under the care of a gastroenterologist or on any medication despite my diagnosis! (P768)

Discussion

The primary aim of this survey was to explore IBD patients' experiences of current services and make recommendations for future service development. The strength of this study lies in: the key aim to co-design IBD services in the NHS in Scotland; the diverse sample of patients (making it a cross sectional representation of patients with IBD in comparison to other similar studies [28–30]) and the systematic method of data analysis. To the authors' knowledge, this is the first study to qualitatively explore the IBD patients' experiences and perspectives about their NHS IBD care in Scotland using a cross-sectional analysis. The findings have given a clear insight into what is important to patients with IBD.

Participants expressed that while living with IBD, their needs are wider than just being medical or biological. Coping with the extra-gastrointestinal manifestations, side effects from medications and particularly the distress from the relapsing nature of the condition was something that participants found challenging when not supported adequately. They also acknowledged that exacerbation of symptoms often caused extra stress associated with travel to and from work. This in addition to the tiredness, fatigue and pain, made working full time very difficult. The participants also reported that the disabling impact of IBD was not always recognised by the employers and the public in general and therefore suggested that strategies needed to be put in place to raise awareness on the disabling nature of IBD.

The data reflects that the participants perceived that the disease had wider effect on their quality of life (inclusive of mental/emotional, physical, social and occupational health). This highlighted the need for a more holistic approach to their care, which includes psychological, counselling and dietician services at least at the point of diagnosis. This is supported by evidence from the literature that emotional and dietary support plays a key part in the quality of life for patients with IBD and should be met accordingly [31–35].

In addition, they suggested practical advice and strategies on how to live with IBD as soon as diagnosed. For example, one of the main symptoms, poor bowel control, is a major concern for patients with IBD, because it limits their personal, working and social lives in complex ways; thus practical advice at diagnosis would be invaluable for better quality of life [36]. This is also in line with evidence from recent literature that highlights the limitation of a purely GI-centric view of IBD [37], advocating the need for a biopsychosocial model in gastroenterology particularly for chronic GI conditions [38].

Participants were most satisfied with their care when had good access to IBD clinicians and IBD patients with a named IBD nurse reported higher satisfaction. In contrast, some service users were not aware of such a specialist role, and many participants described that improved access to an IBD clinician (IBD nurse and gastroenterologist) would be an advantage when having exacerbated symptoms. In fact, previous studies suggest that hospital visits were reduced and remission increased among patients with IBD when IBD specialist nurse was involved in their care management [39, 40].

And finally, participants described that one of the difficulties with their care was not having a clear IBD care pathway. They felt that there were gaps in communication across different departments and as a result, their care was not well coordinated which resulted in waiting for appointments with specialists for months or have even been referred to the wrong place. The relapsing nature of the disease can have a restrictive effect on many aspects of daily life for patients. Thus, the services for these patients should not only be comprehensive but also easily accessible and well-coordinated. This requires integration and coordination of different health care sectors, medical and non-medical professionals, social and health care facilities and funding agencies [41]. In return, integrated care with a clear pathway for patients could play a significant role in determining health-related quality of life for IBD patients [22, 42].

Thus, findings that illustrate the patients' perspective about the care received, are worth considering by clinicians, researchers and policy makers aiming at improving the standards of care for patients with IBD. This study has provided strong evidence from patients' perspectives that a purely GI-centric view of IBD is no longer an adequate way of addressing the disease concerns and attention to mental and social health should not be overlooked by healthcare providers who often tend to focus only on gastrointestinal symptoms [16]. Thus, the patients' accounts from the study make a stronger case for adopting the biopsychosocial model in IBD care. Although the biopsychosocial model is not new in gastroenterology and IBD care and has been applied in various degrees in different countries as mentioned before, nonetheless is still rare even more so on a national scale.

This model identifies the need for specialists from different disciplines to work together in a holistic and coordinated way. This means that the various specialists (services/teams/clinicians) communicate regularly, have a collective referral system and work together to offer integrated treatment to patients. In return, this would lessen the confusion not only among patients, but also among healthcare providers when giving advice or making referrals. This in addition, could prevent patients being 'lost' in the system and allow an early engagement with services when needed before escalating to emergency admissions. Patients also require easy treatment access to IBD specialists such as IBD nurses. Patients expressed a greater satisfaction with their care when they consulted

IBD nurses. Evidence also suggests that having IBD nurses with extended roles results in improvement in health outcomes and saving in healthcare costs [22].

Limitations

A limitation of this study was that all study information had to be given on the first 'page' of the survey and it was not possible to provide an oral explanation or to take oral consent. However, as with paper-based information sheet, the 'first page' of the survey identified who the researcher was, reason for conducting the survey, what the survey data will be used for and anonymity of the survey [43].

Another limitation is that the experiences of the respondents may not be representative of all IBD service users in Scotland as not everyone with IBD responded to the survey. Patients with IBD that do not have access to the media that was used to distribute the survey were not able to participate. However, in qualitative studies, the strength lies with the richness of data, which was received from those that participated, providing invaluable feedback about the current IBD services.

Conclusions

In conclusion, this study described the personal experiences of IBD services by the users who identified key areas for improvement. Although these findings do not represent the views of all patients with IBD in Scotland, the findings give a clear insight into some practical recommendations for treatment providers, service managers and policy makers to enhance the IBD standard of care. These findings also provide information for service planners and policy makers on the importance and value of co design both for designing and restructuring of services that are relevant for service users.

Additional files

Additional file 1: Full Scotland IBD questionnaire. Description of data: Supplementary Material 1: This is the full IBD survey questionnaire that was used across Scotland to collect the qualitative (reported in this manuscript) and quantitative data (not reported in this manuscript). (PDF 188 kb)

Abbreviations

A&E-Accident and Emergency; IBD-Inflammatory Bowel Disease; NHS-National Health Service; NRES-National Research Ethics Service; UK-United Kingdom

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Availability of data and materials

After a discussion with the Head of Crohn's & Colitis UK and its members, it was decided that due to the data containing identifiable information about certain clinical areas and staff, it would breach the anonymity of the survey.

Authors' contributions

MS and LM contributed to data analysis and interpretation. All authors (MS, LM & AW) were involved in drafting the manuscript and revising it. All authors have given final approval of the version to be published.

Competing interests

The author(s) declare that they have no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

Research Governance at NRES (National Research Ethics Service) Committee for North of Scotland reviewed and exempted the study from a formal ethical review. There is an understanding that online surveys do not require separate consent form, however the introduction paragraph accompanying the survey link as well as the introductory paragraph of the survey, conveyed the information about the purpose and anonymity of the study and consent was obtained by virtue of completion of the study.

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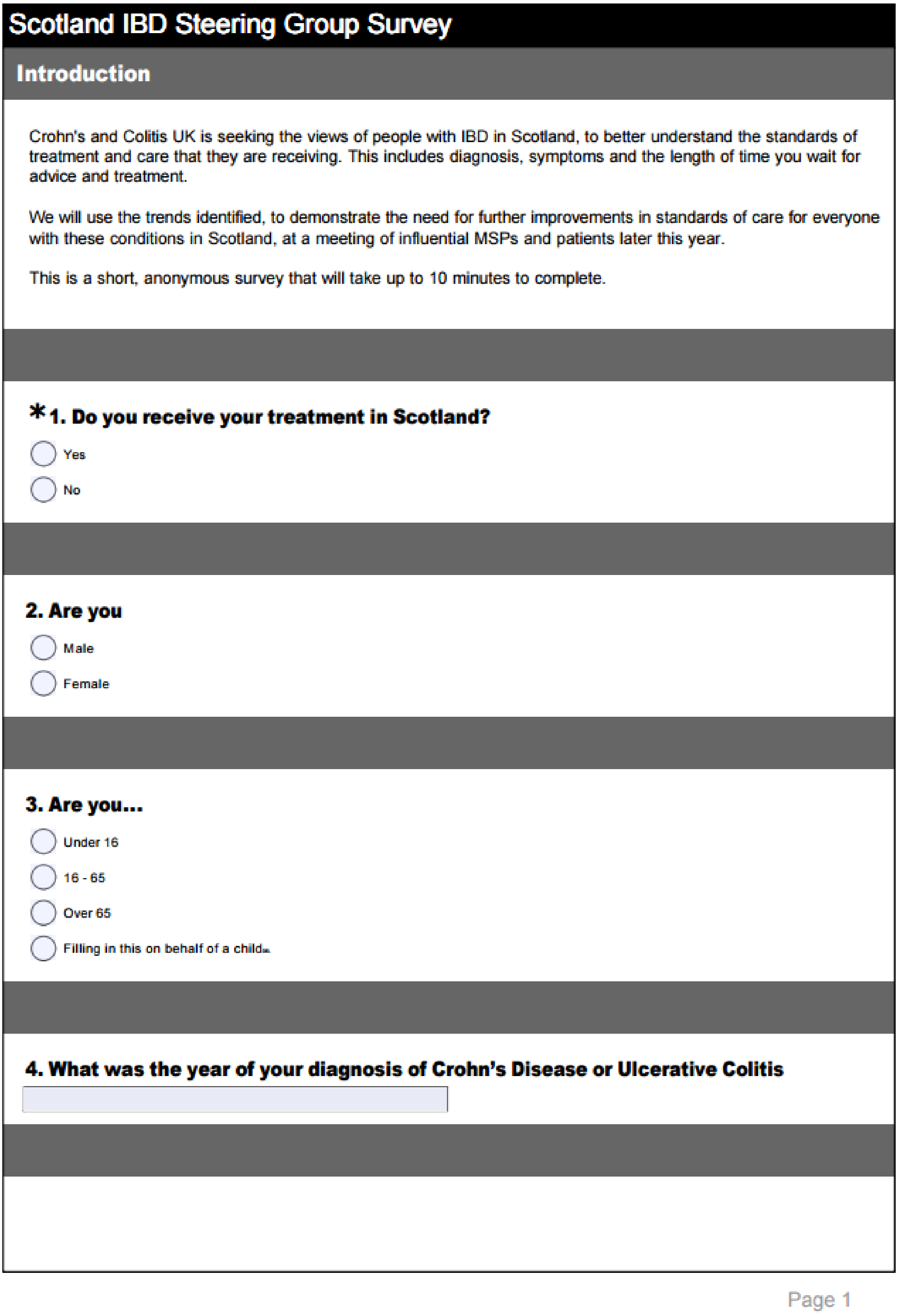


Scotland IBD Steering Group Survey

Introduction

Crohn's and Colitis UK is seeking the views of people with IBD in Scotland, to better understand the standards of treatment and care that they are receiving. This includes diagnosis, symptoms and the length of time you wait for advice and treatment.

We will use the trends identified, to demonstrate the need for further improvements in standards of care for everyone with these conditions in Scotland, at a meeting of influential MSPs and patients later this year.

This is a short, anonymous survey that will take up to 10 minutes to complete.

***1. Do you receive your treatment in Scotland?**

○ Yes
○ No

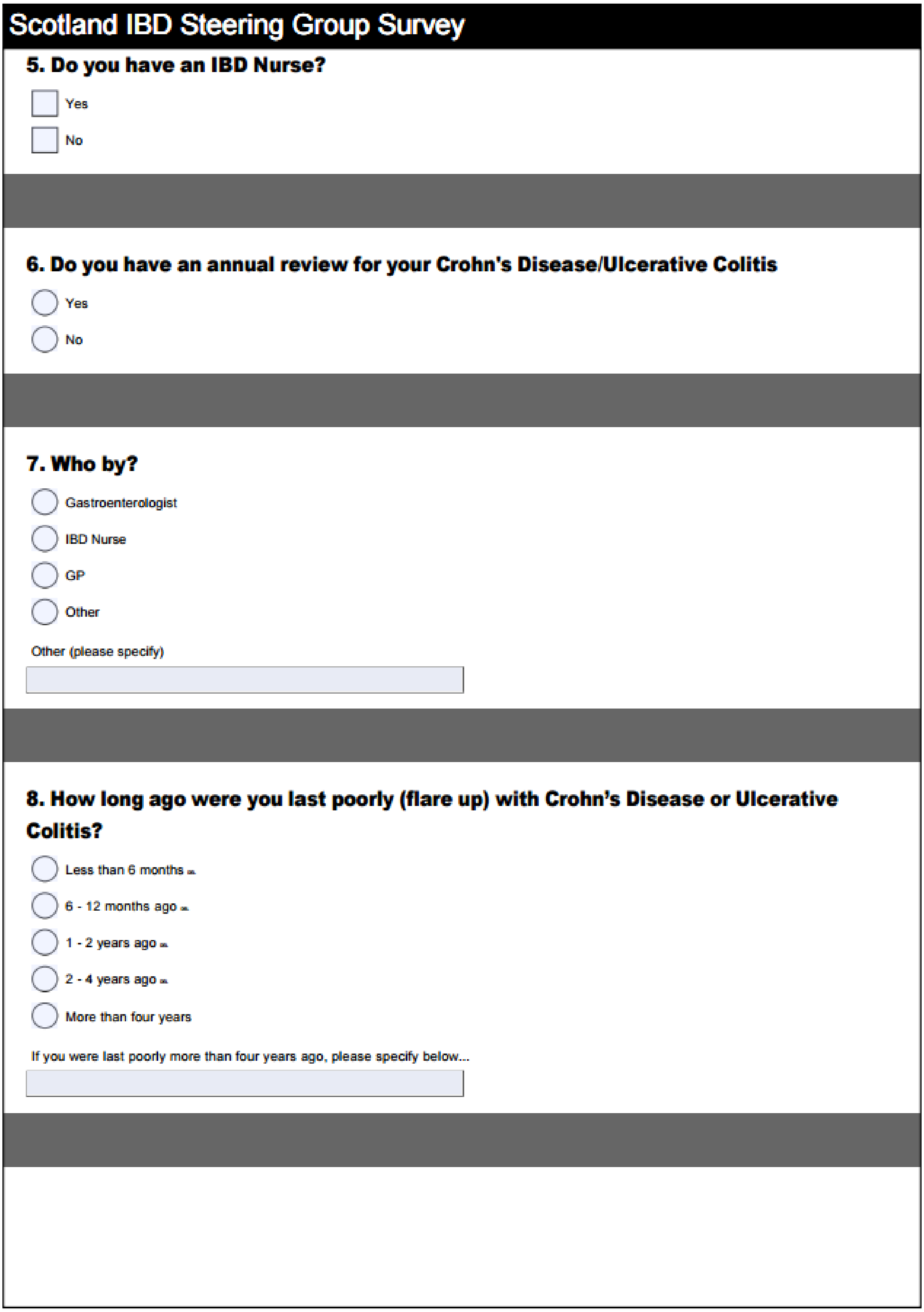
2. Are you

○ Male
○ Female

3. Are you...

○ Under 16
○ 16 - 65
○ Over 65
○ Filling in this on behalf of a child

4. What was the year of your diagnosis of Crohn's Disease or Ulcerative Colitis



Scotland IBD Steering Group Survey

5. Do you have an IBD Nurse?

☐ Yes
☐ No

6. Do you have an annual review for your Crohn's Disease/Ulcerative Colitis

○ Yes
○ No

7. Who by?

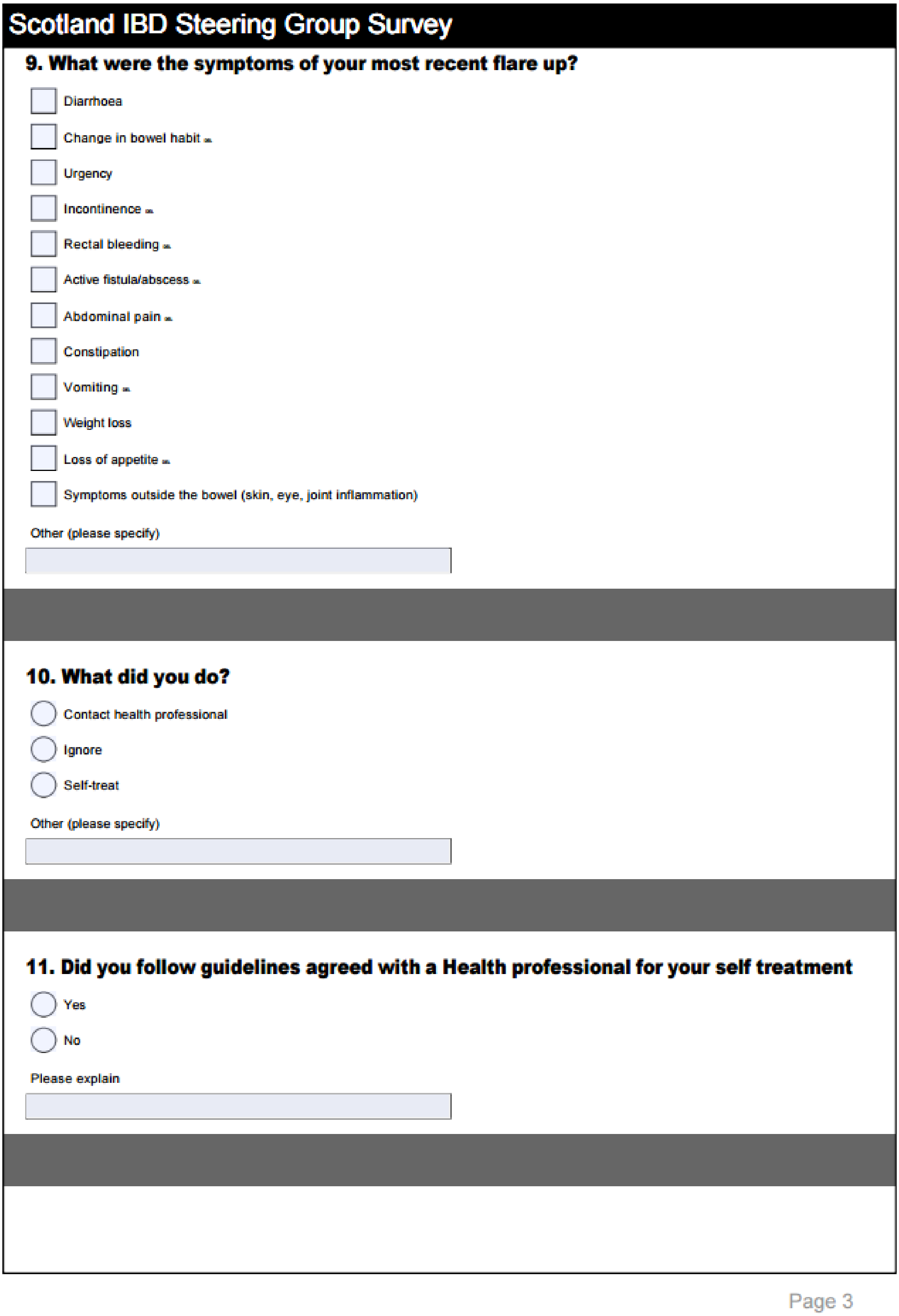
○ Gastroenterologist
○ IBD Nurse
○ GP
○ Other

Other (please specify)

8. How long ago were you last poorly (flare up) with Crohn's Disease or Ulcerative Colitis?

○ Less than 6 months
○ 6 - 12 months ago
○ 1 - 2 years ago
○ 2 - 4 years ago
○ More than four years

If you were last poorly more than four years ago, please specify below...



Scotland IBD Steering Group Survey

9. What were the symptoms of your most recent flare up?

☐ Diarrhoea
☐ Change in bowel habit
☐ Urgency
☐ Incontinence
☐ Rectal bleeding
☐ Active fistula/abscess
☐ Abdominal pain
☐ Constipation
☐ Vomiting
☐ Weight loss
☐ Loss of appetite
☐ Symptoms outside the bowel (skin, eye, joint inflammation)

Other (please specify)

10. What did you do?

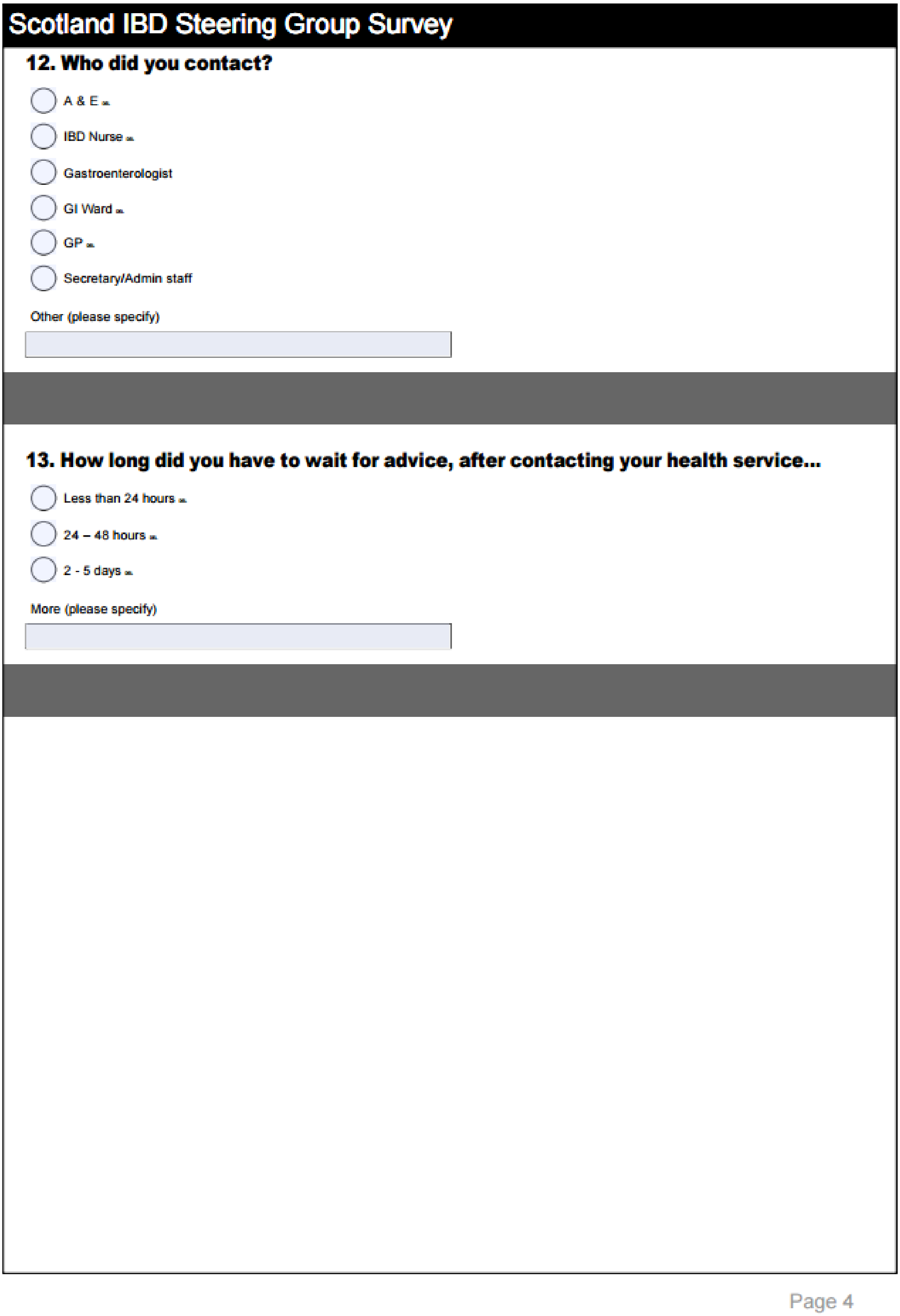
○ Contact health professional
○ Ignore
○ Self-treat

Other (please specify)

11. Did you follow guidelines agreed with a Health professional for your self treatment

○ Yes
○ No

Please explain



Scotland IBD Steering Group Survey

12. Who did you contact?

○ A & E
○ IBD Nurse
○ Gastroenterologist
○ GI Ward
○ GP
○ Secretary/Admin staff

Other (please specify)

13. How long did you have to wait for advice, after contacting your health service...

○ Less than 24 hours
○ 24 – 48 hours
○ 2 - 5 days

More (please specify)

Page 4

14. What action was taken

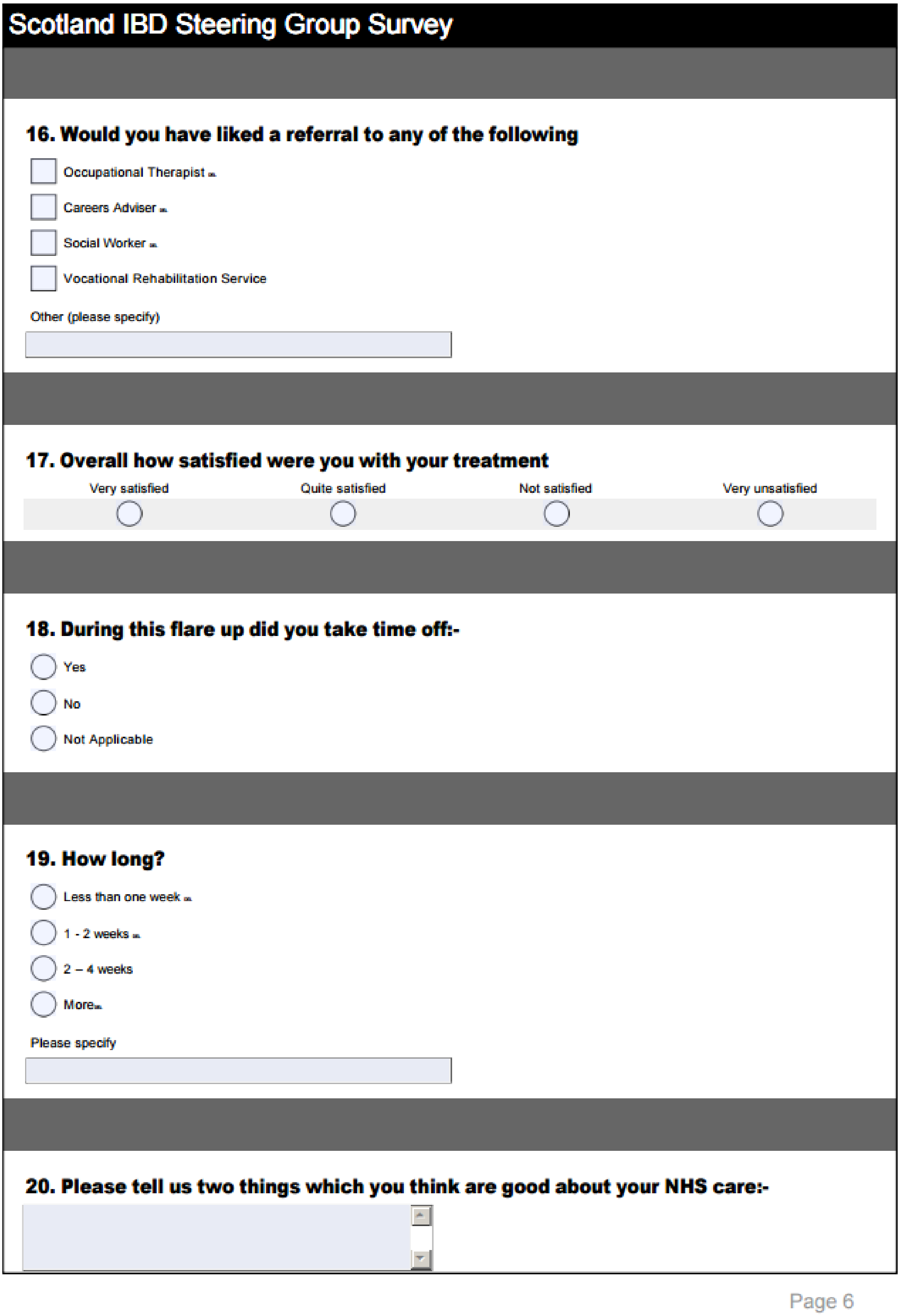
☐ No action taken
☐ Advice/information about managing my illness
☐ Old medication altered
☐ New medication begun
☐ Nutritional therapy begun
☐ Blood test
☐ Stool test
☐ Endoscopy
☐ Faecal Calprotectin test
☐ X-ray
☐ Scan
☐ Referral to a Gastroenterologist
☐ Referral to a Surgeon
☐ Referral to a Rheumatologist
☐ Referral to a Dermatologist
☐ Referral to an IBD nurse
☐ Referral to a Dietitian
☐ Referral to a Counsellor/Psychologist
☐ Admission to hospital

Other (please specify)

15. Would you have liked to have been referred to

☐ Gastroenterologist
☐ Surgeon
☐ Rheumatologist
☐ Dermatologist
☐ IBD nurse
☐ Dietitian
☐ Counsellor/Psychologist

Other (please specify)



Scotland IBD Steering Group Survey

16. Would you have liked a referral to any of the following

☐ Occupational Therapist
☐ Careers Adviser
☐ Social Worker
☐ Vocational Rehabilitation Service

Other (please specify)

17. Overall how satisfied were you with your treatment

Very satisfied	Quite satisfied	Not satisfied	Very unsatisfied
○	○	○	○

18. During this flare up did you take time off:-

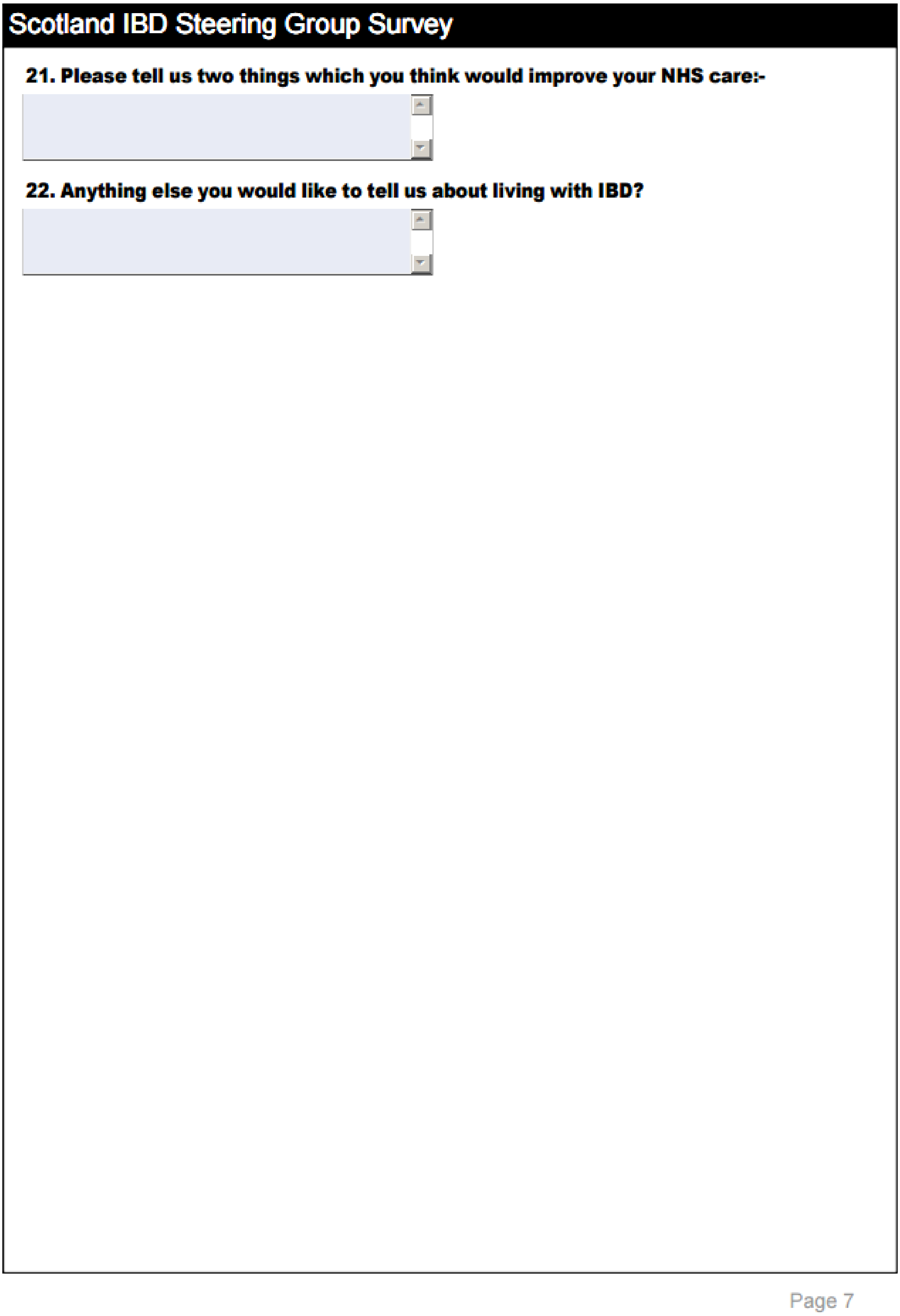
○ Yes
○ No
○ Not Applicable

19. How long?

○ Less than one week
○ 1 - 2 weeks
○ 2 – 4 weeks
○ More

Please specify

20. Please tell us two things which you think are good about your NHS care:-

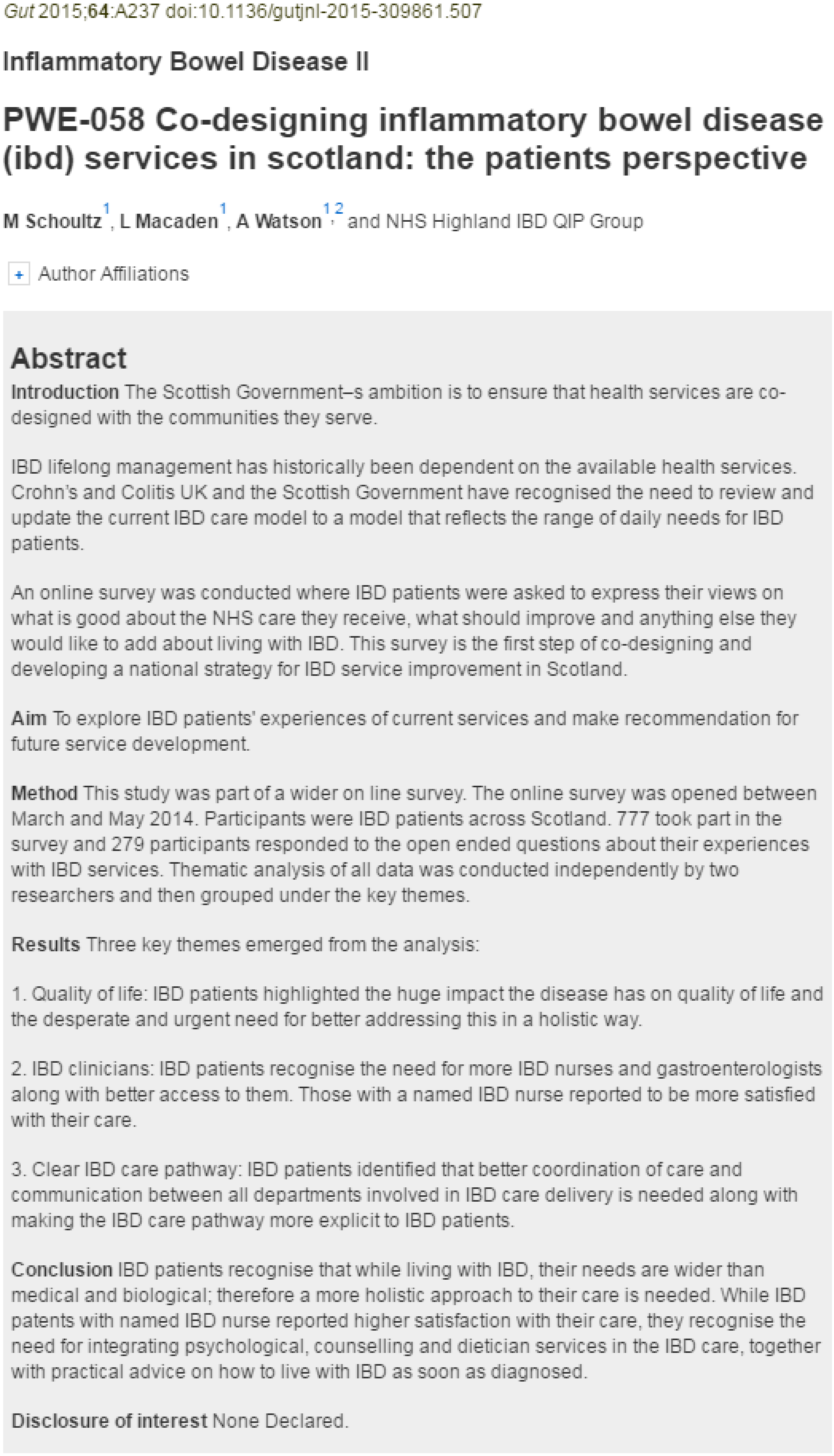


Scotland IBD Steering Group Survey

21. Please tell us two things which you think would improve your NHS care:-

22. Anything else you would like to tell us about living with IBD?

Page 7



Gut 2015;**64**:A237 doi:10.1136/gutjnl-2015-309861.507

Inflammatory Bowel Disease II

PWE-058 Co-designing inflammatory bowel disease (ibd) services in scotland: the patients perspective

M Schoultz[1], **L Macaden**[1], **A Watson**[1,2] and NHS Highland IBD QIP Group

+ Author Affiliations

Abstract

Introduction The Scottish Government–s ambition is to ensure that health services are co-designed with the communities they serve.

IBD lifelong management has historically been dependent on the available health services. Crohn's and Colitis UK and the Scottish Government have recognised the need to review and update the current IBD care model to a model that reflects the range of daily needs for IBD patients.

An online survey was conducted where IBD patients were asked to express their views on what is good about the NHS care they receive, what should improve and anything else they would like to add about living with IBD. This survey is the first step of co-designing and developing a national strategy for IBD service improvement in Scotland.

Aim To explore IBD patients' experiences of current services and make recommendation for future service development.

Method This study was part of a wider on line survey. The online survey was opened between March and May 2014. Participants were IBD patients across Scotland. 777 took part in the survey and 279 participants responded to the open ended questions about their experiences with IBD services. Thematic analysis of all data was conducted independently by two researchers and then grouped under the key themes.

Results Three key themes emerged from the analysis:

1. Quality of life: IBD patients highlighted the huge impact the disease has on quality of life and the desperate and urgent need for better addressing this in a holistic way.

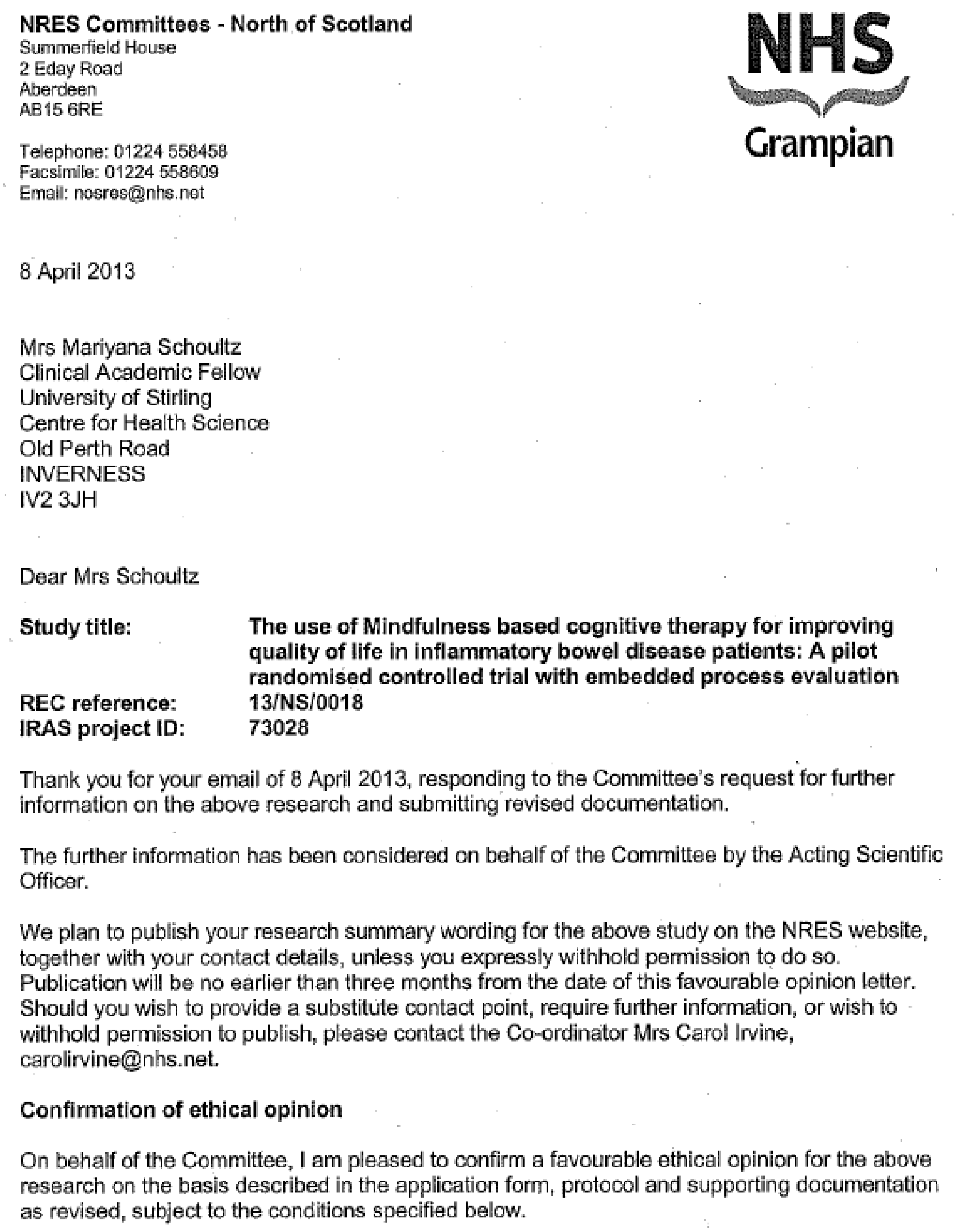
2. IBD clinicians: IBD patients recognise the need for more IBD nurses and gastroenterologists along with better access to them. Those with a named IBD nurse reported to be more satisfied with their care.

3. Clear IBD care pathway: IBD patients identified that better coordination of care and communication between all departments involved in IBD care delivery is needed along with making the IBD care pathway more explicit to IBD patients.

Conclusion IBD patients recognise that while living with IBD, their needs are wider than medical and biological; therefore a more holistic approach to their care is needed. While IBD patents with named IBD nurse reported higher satisfaction with their care, they recognise the need for integrating psychological, counselling and dietician services in the IBD care, together with practical advice on how to live with IBD as soon as diagnosed.

Disclosure of interest None Declared.

Appendix 3: Ethics application documents: NRES approval with amendments



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8 April 2013

Mrs Mariyana Schoultz
Clinical Academic Fellow
University of Stirling
Centre for Health Science
Old Perth Road
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IV2 3JH

Dear Mrs Schoultz

Study title:	**The use of Mindfulness based cognitive therapy for improving quality of life in inflammatory bowel disease patients: A pilot randomised controlled trial with embedded process evaluation**
REC reference:	**13/NS/0018**
IRAS project ID:	**73028**

Thank you for your email of 8 April 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Acting Scientific Officer.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Mrs Carol Irvine, carolirvine@nhs.net.

Confirmation of ethical opinion

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

Ethical review of research sites

NHS sites

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

Non-NHS sites

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

Conditions of the favourable opinion

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

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

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

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

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

Approved documents

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

Document	*Version*	*Date*
Covering Email		8 April 2013
Evidence of insurance or indemnity		12 February 2013
Interview Schedules/Topic Guides	1	14 February 2013
Investigator CV: Mariyana Schoultz		14 February 2013
Letter from Sponsor		12 February 2013
Letter of invitation to participant: L1	3	8 April 2013
Information for Clinicians	2	24 January 2013

Document	*Version*	*Date*
CV - Claire Byard		18 February 2013
CV - Angus Watson		18 February 2013
CV - Iain Atherton		18 February 2013
CV - Peter Wilkes		18 February 2013
Flow Diagram	1	24 January 2013
GCP Certificate of Completion - Claire Byard		4 April 2013
Participant Consent Form	2	24 January 2013
Participant Information Sheet: P2	3	26 March 2013
Protocol: P1	3	8 April 2013
Questionnaire: UK Inflammatory Bowel Disease Questionnaire	1	14 February 2013
Questionnaire: Beck's Depression Inventory	1	14 February 2013
Questionnaire: Self Evaluation Questionnaire STAI Form Y-1	1	14 February 2013
Questionnaire: Self Evaluation Questionnaire STAI Form Y-2	1	14 February 2013
Questionnaire: Crohn's Disease Activity Index (CDAI)	1	14 February 2013
Questionnaire: Simple Clinical Colitis Activity Index	1	14 February 2013
Questionnaire: Day-to-Day Experiences	1	14 February 2013
Questionnaire: SQ	1	30 November 2012
Questionnaire: Demographic Information	1	24 January 2013
REC application	73028/41612 3/1/590	14 March 2013
Referees or other scientific critique report		18 February 2013
Response to Request for Further Information		4 April 2013
Response to Request for Further Information		8 April 2013

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review.

13/NS/0018	**Please quote this number on all correspondence**

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

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

Yours sincerely

Carol Irvine

pp **Dr Alex Johnstone**
Chair

Enclosures:	"After ethical review – guidance for researchers" SL-AR2
Copy to:	Ms Carol Johnstone Ms Frances Hines, NHS Highland Research and Development Office

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Grampian

28 August 2013

Mrs Mariyana Schoultz
Clinical Academic Fellow
University of Stirling
Centre for Health Science
Old Perth Road
INVERNESS
IV2 3JH

Dear Mrs Schoultz

Study title:	**The use of Mindfulness based cognitive therapy for improving quality of life in inflammatory bowel disease patients: A pilot randomised controlled trial with embedded process evaluation**
REC reference:	**13/NS/0018**
Amendment number:	**AM01**
Amendment date:	**06 August 2013**
IRAS project ID:	**73028**

Thank you for your email of 28 August 2013, notifying the Committee of the above amendment and the omission of the Protocol.

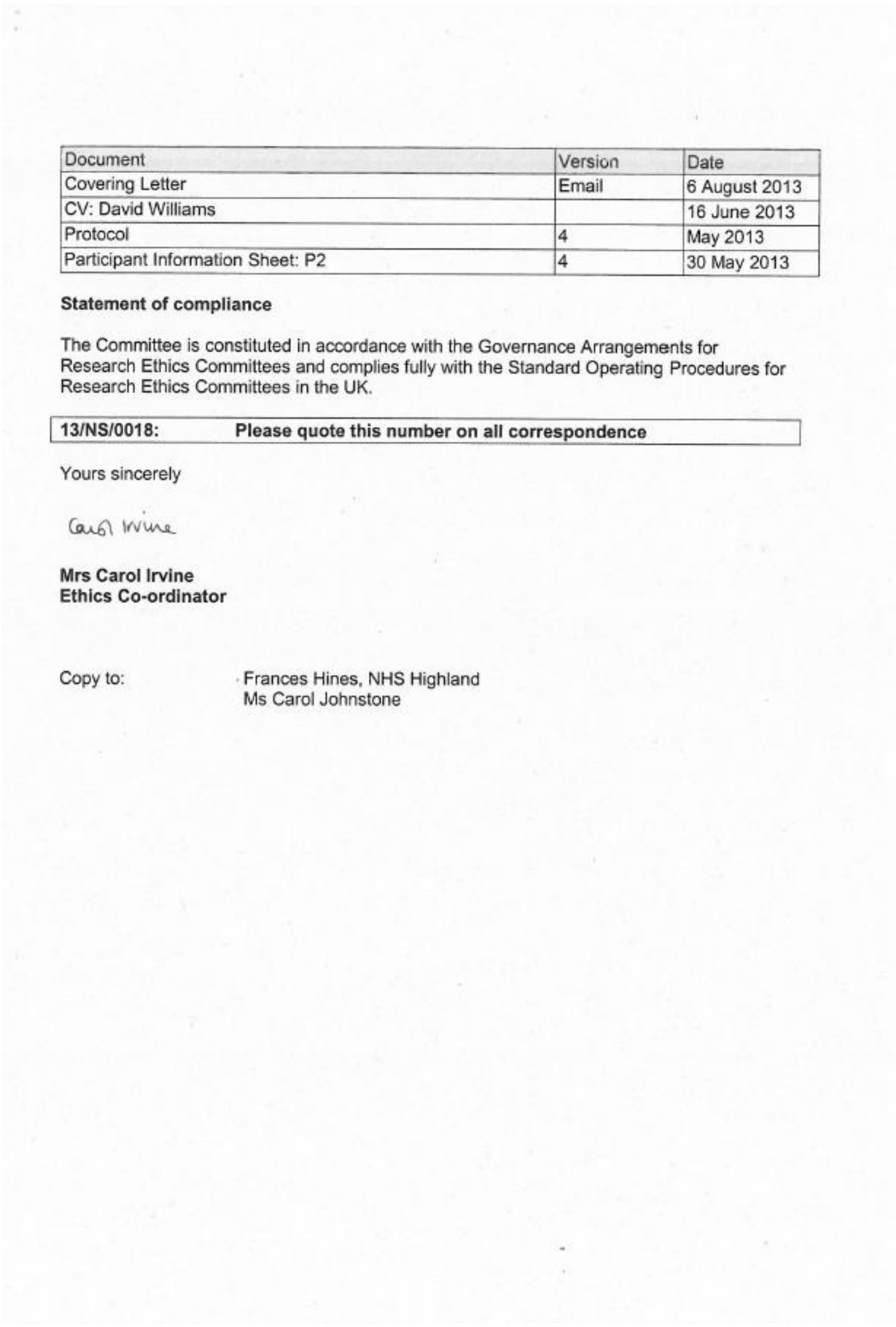
The amendment has been considered by the Ethics Co-ordinator.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	Version	Date
CV: Sheelagh Rodgers		18 July 2013
Notification of a Minor Amendment	AM01	6 August 2013
Letter from Sponsor		17 June 2013
CV: Margot Henderson		19 June 2013



Document	Version	Date
Covering Letter	Email	6 August 2013
CV: David Williams		16 June 2013
Protocol	4	May 2013
Participant Information Sheet: P2	4	30 May 2013

Statement of compliance

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

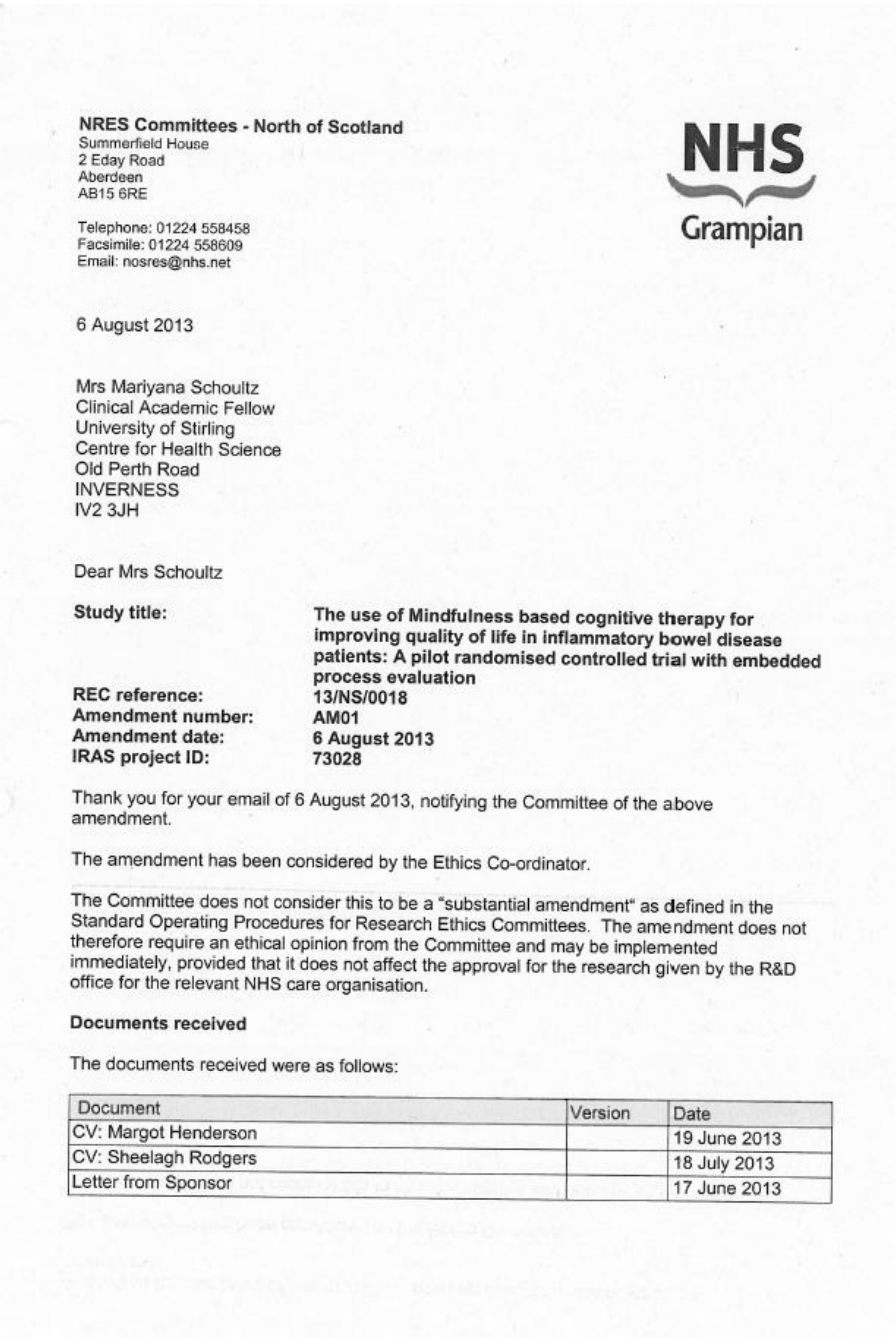
13/NS/0018:	**Please quote this number on all correspondence**

Yours sincerely

Carol Irvine

Mrs Carol Irvine
Ethics Co-ordinator

Copy to: Frances Hines, NHS Highland
Ms Carol Johnstone



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Grampian

6 August 2013

Mrs Mariyana Schoultz
Clinical Academic Fellow
University of Stirling
Centre for Health Science
Old Perth Road
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Dear Mrs Schoultz

Study title: **The use of Mindfulness based cognitive therapy for improving quality of life in inflammatory bowel disease patients: A pilot randomised controlled trial with embedded process evaluation**
REC reference: **13/NS/0018**
Amendment number: **AM01**
Amendment date: **6 August 2013**
IRAS project ID: **73028**

Thank you for your email of 6 August 2013, notifying the Committee of the above amendment.

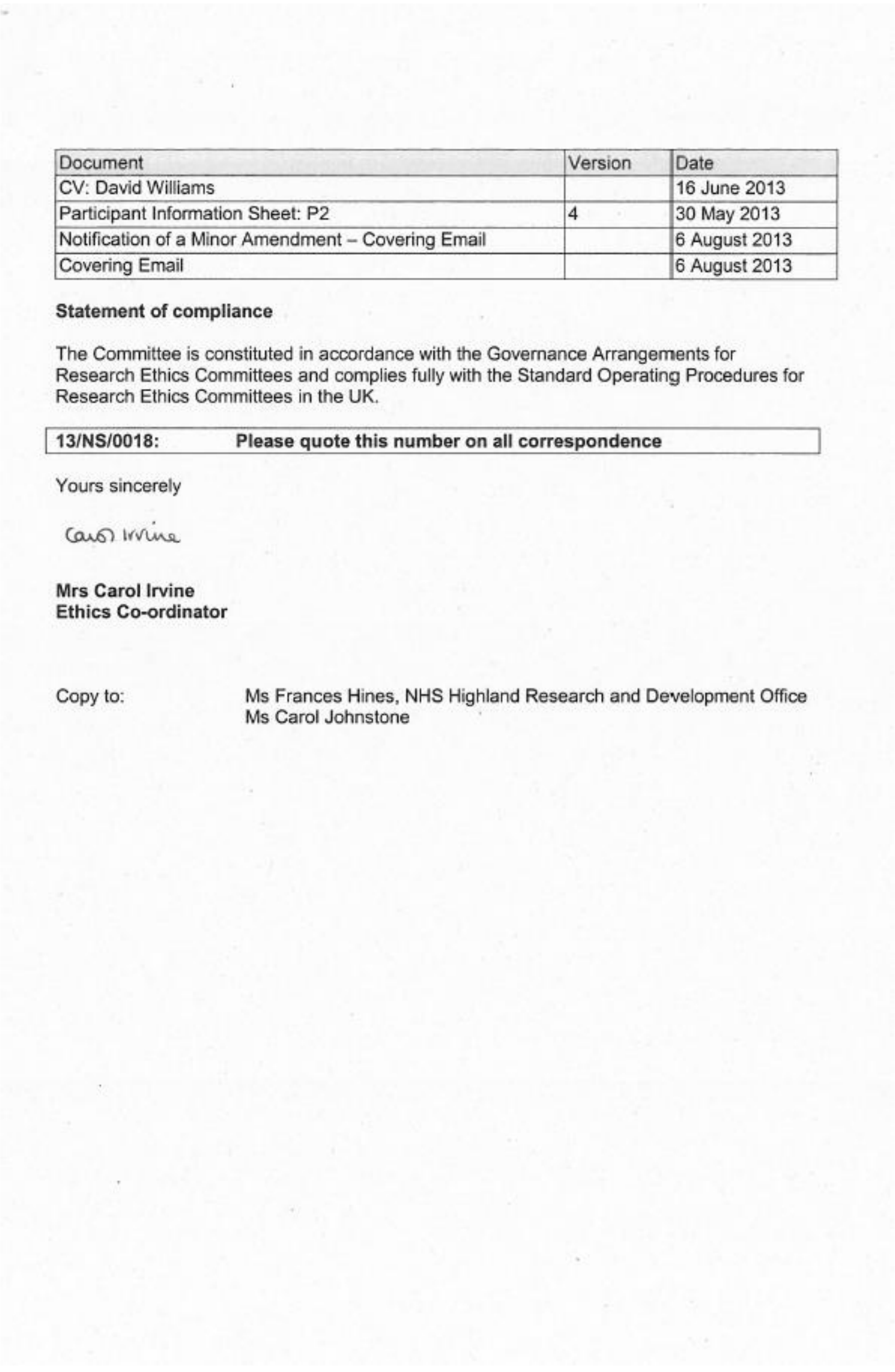
The amendment has been considered by the Ethics Co-ordinator.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	Version	Date
CV: Margot Henderson		19 June 2013
CV: Sheelagh Rodgers		18 July 2013
Letter from Sponsor		17 June 2013



Document	Version	Date
CV: David Williams		16 June 2013
Participant Information Sheet: P2	4	30 May 2013
Notification of a Minor Amendment – Covering Email		6 August 2013
Covering Email		6 August 2013

Statement of compliance

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

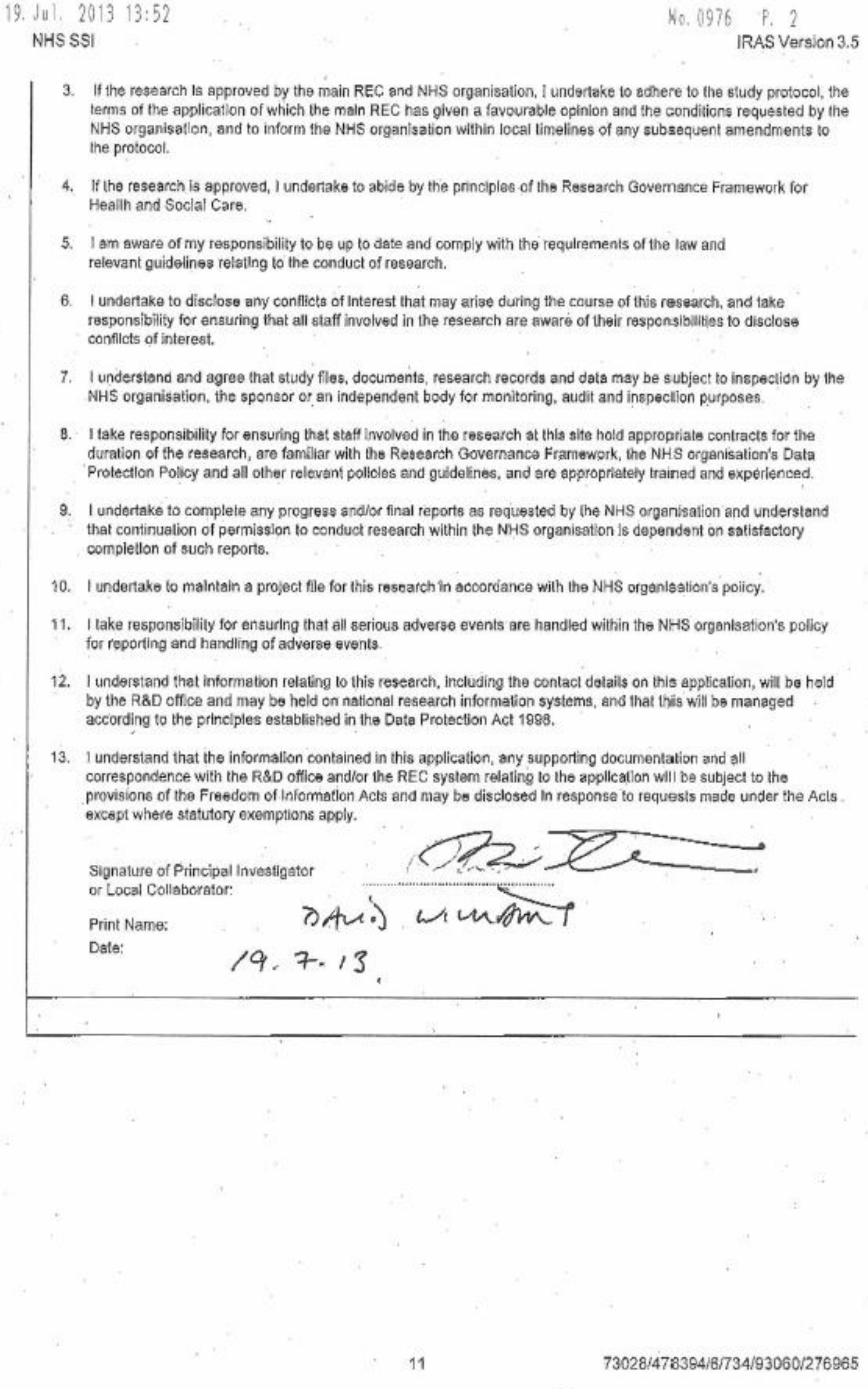
13/NS/0018: Please quote this number on all correspondence

Yours sincerely

Carol Irvine

Mrs Carol Irvine
Ethics Co-ordinator

Copy to: Ms Frances Hines, NHS Highland Research and Development Office
Ms Carol Johnstone



3. If the research is approved by the main REC and NHS organisation, I undertake to adhere to the study protocol, the terms of the application of which the main REC has given a favourable opinion and the conditions requested by the NHS organisation, and to inform the NHS organisation within local timelines of any subsequent amendments to the protocol.

4. If the research is approved, I undertake to abide by the principles of the Research Governance Framework for Health and Social Care.

5. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research.

6. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.

7. I understand and agree that study files, documents, research records and data may be subject to inspection by the NHS organisation, the sponsor or an independent body for monitoring, audit and inspection purposes.

8. I take responsibility for ensuring that staff involved in the research at this site hold appropriate contracts for the duration of the research, are familiar with the Research Governance Framework, the NHS organisation's Data Protection Policy and all other relevant policies and guidelines, and are appropriately trained and experienced.

9. I undertake to complete any progress and/or final reports as requested by the NHS organisation and understand that continuation of permission to conduct research within the NHS organisation is dependent on satisfactory completion of such reports.

10. I undertake to maintain a project file for this research in accordance with the NHS organisation's policy.

11. I take responsibility for ensuring that all serious adverse events are handled within the NHS organisation's policy for reporting and handling of adverse events.

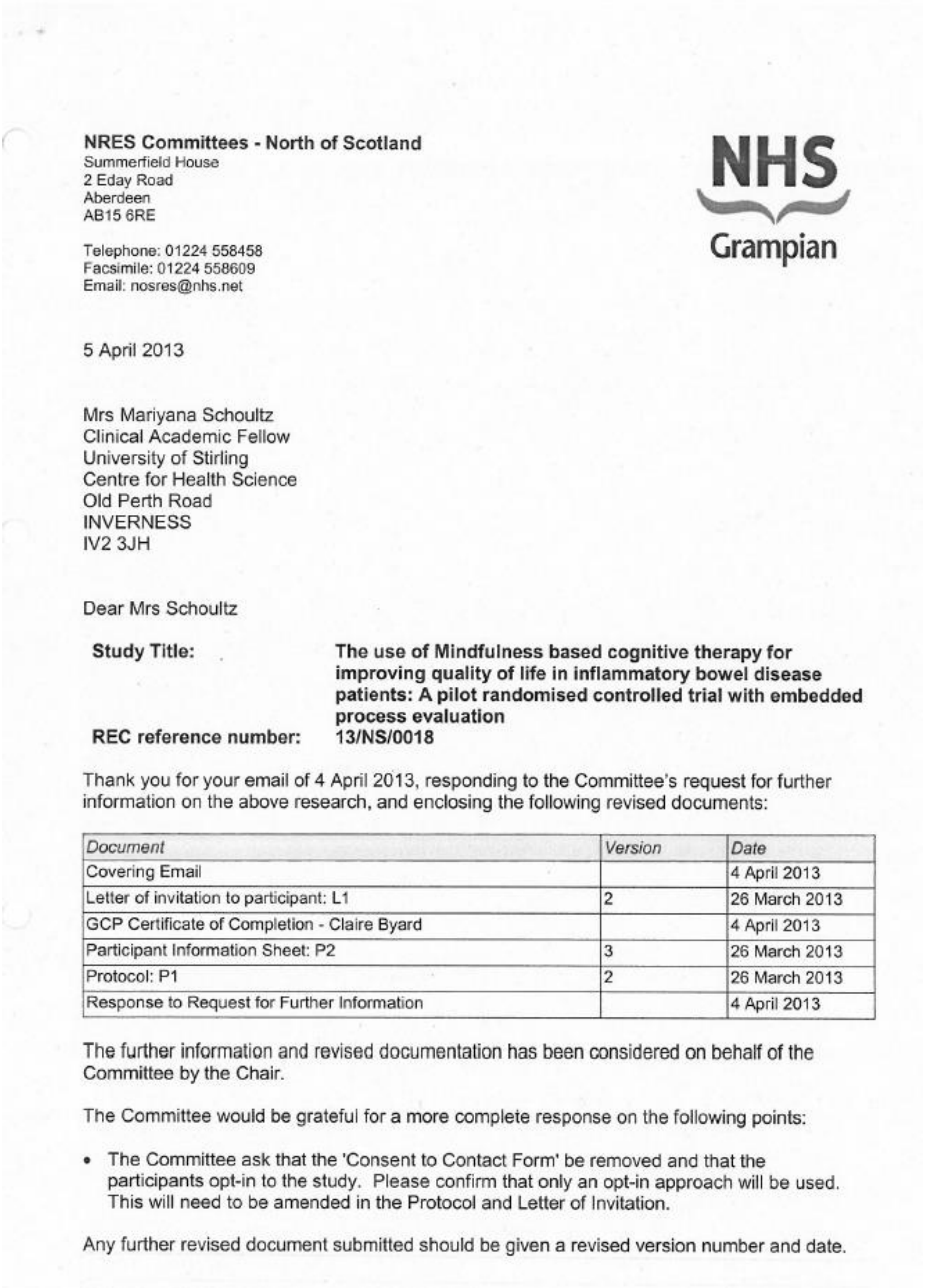
12. I understand that information relating to this research, including the contact details on this application, will be held by the R&D office and may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

13. I understand that the information contained in this application, any supporting documentation and all correspondence with the R&D office and/or the REC system relating to the application will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

Signature of Principal Investigator or Local Collaborator: ....

Print Name: DAVID WILMOT

Date: 19.7.13.



NRES Committees - North of Scotland
Summerfield House
2 Eday Road
Aberdeen
AB15 6RE

Telephone: 01224 558458
Facsimile: 01224 558609
Email: nosres@nhs.net

5 April 2013

Mrs Mariyana Schoultz
Clinical Academic Fellow
University of Stirling
Centre for Health Science
Old Perth Road
INVERNESS
IV2 3JH

Dear Mrs Schoultz

Study Title:	**The use of Mindfulness based cognitive therapy for improving quality of life in inflammatory bowel disease patients: A pilot randomised controlled trial with embedded process evaluation**
REC reference number:	**13/NS/0018**

Thank you for your email of 4 April 2013, responding to the Committee's request for further information on the above research, and enclosing the following revised documents:

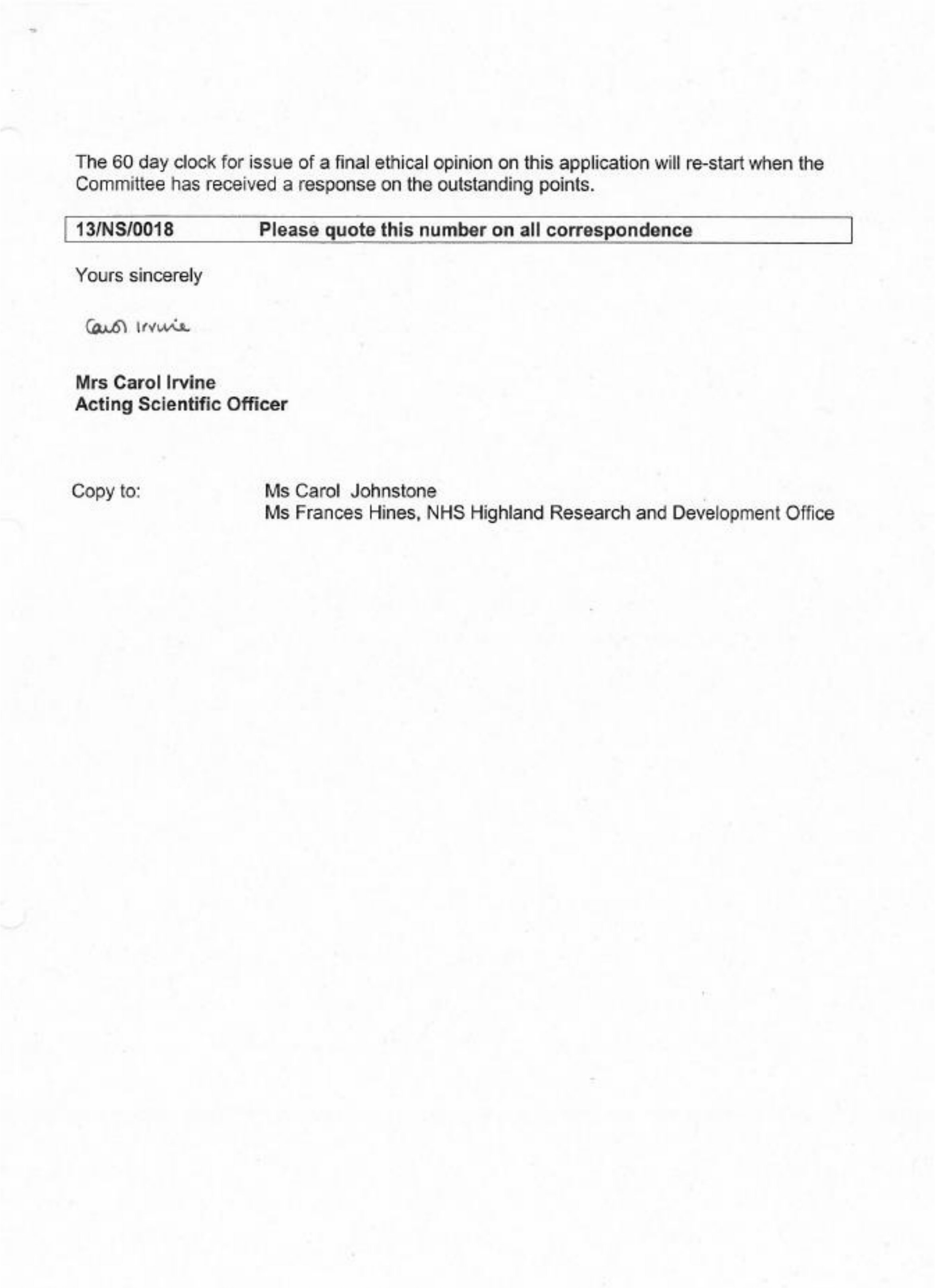
Document	*Version*	*Date*
Covering Email		4 April 2013
Letter of invitation to participant: L1	2	26 March 2013
GCP Certificate of Completion - Claire Byard		4 April 2013
Participant Information Sheet: P2	3	26 March 2013
Protocol: P1	2	26 March 2013
Response to Request for Further Information		4 April 2013

The further information and revised documentation has been considered on behalf of the Committee by the Chair.

The Committee would be grateful for a more complete response on the following points:

- The Committee ask that the 'Consent to Contact Form' be removed and that the participants opt-in to the study. Please confirm that only an opt-in approach will be used. This will need to be amended in the Protocol and Letter of Invitation.

Any further revised document submitted should be given a revised version number and date.



The 60 day clock for issue of a final ethical opinion on this application will re-start when the Committee has received a response on the outstanding points.

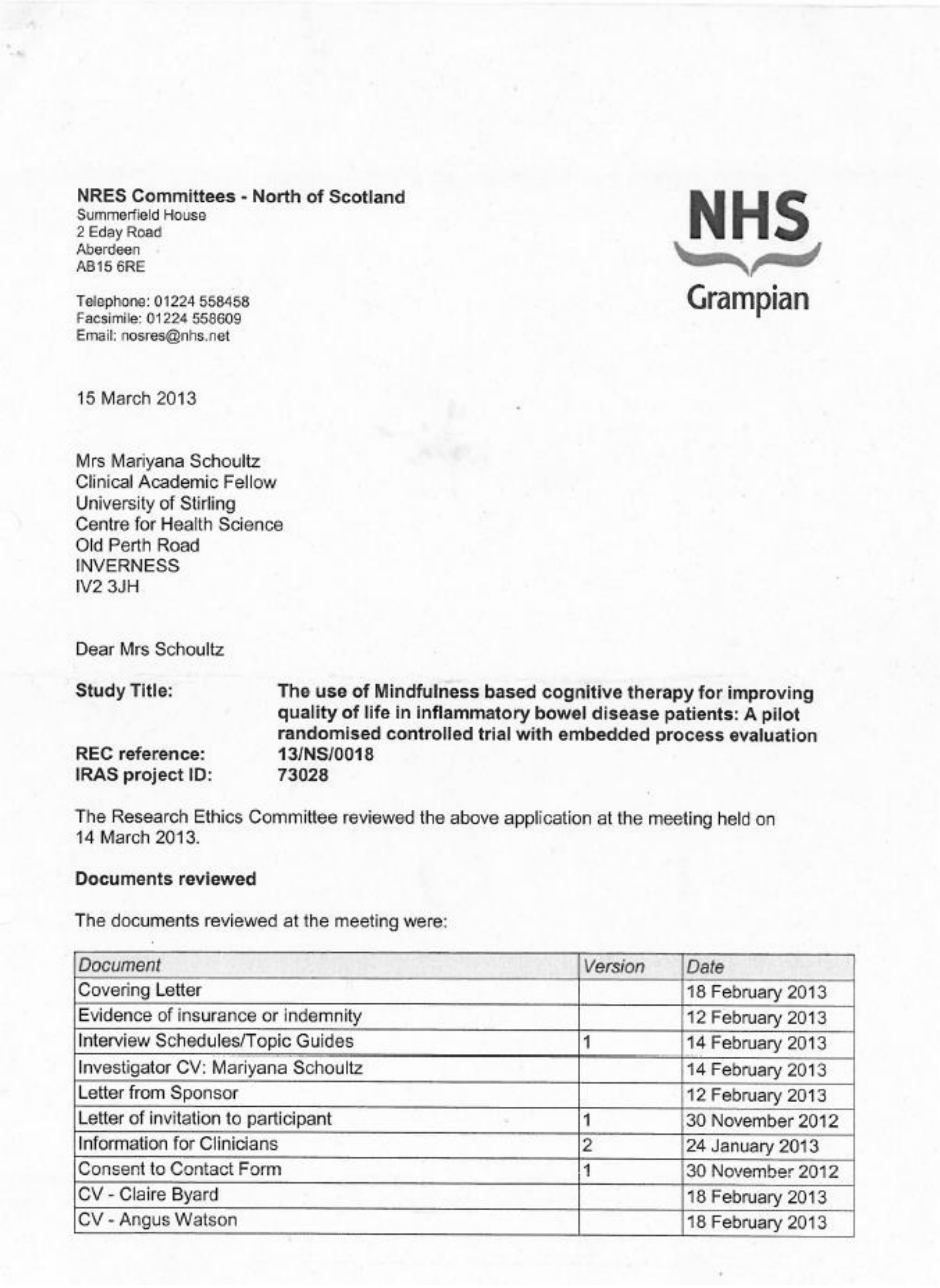
13/NS/0018	**Please quote this number on all correspondence**

Yours sincerely

Carol Irvine

Mrs Carol Irvine
Acting Scientific Officer

Copy to: Ms Carol Johnstone
Ms Frances Hines, NHS Highland Research and Development Office



NRES Committees - North of Scotland
Summerfield House
2 Eday Road
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AB15 6RE

Telephone: 01224 558458
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Email: nosres@nhs.net

15 March 2013

Mrs Mariyana Schoultz
Clinical Academic Fellow
University of Stirling
Centre for Health Science
Old Perth Road
INVERNESS
IV2 3JH

Dear Mrs Schoultz

Study Title: **The use of Mindfulness based cognitive therapy for improving quality of life in inflammatory bowel disease patients: A pilot randomised controlled trial with embedded process evaluation**
REC reference: **13/NS/0018**
IRAS project ID: **73028**

The Research Ethics Committee reviewed the above application at the meeting held on 14 March 2013.

Documents reviewed

The documents reviewed at the meeting were:

Document	*Version*	*Date*
Covering Letter		18 February 2013
Evidence of insurance or indemnity		12 February 2013
Interview Schedules/Topic Guides	1	14 February 2013
Investigator CV: Mariyana Schoultz		14 February 2013
Letter from Sponsor		12 February 2013
Letter of invitation to participant	1	30 November 2012
Information for Clinicians	2	24 January 2013
Consent to Contact Form	1	30 November 2012
CV - Claire Byard		18 February 2013
CV - Angus Watson		18 February 2013

Document	*Version*	*Date*
CV - Iain Atherton		18 February 2013
CV - Peter Wilkes		18 February 2013
Flow Diagram	1	24 January 2013
Participant Consent Form	2	24 January 2013
Participant Information Sheet	2	24 January 2013
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Questionnaire: Crohn's Disease Activity Index (CDAI)	1	14 February 2013
Questionnaire: Simple Clinical Colitis Activity Index	1	14 February 2013
Questionnaire: Day-to-Day Experiences	1	14 February 2013
Questionnaire: SQ	1	30 November 2012
Questionnaire: Demographic Information	1	24 January 2013
REC application	73028/4161 23/1/590	14 March 2013
Referees or other scientific critique report		18 February 2013

Provisional opinion

The Committee would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

It must be noted that full ethical approval for the study should not be assumed until you receive a final letter of approval.

The Committee is unable to give an ethical opinion on the basis of the information and documentation received so far. Before confirming its opinion, the Committee requests that you provide the further information set out below.

Authority to consider your response and to confirm the Committee's final opinion has been delegated to the Chair.

Further information or clarification required

Thank you for attending the meeting by video-conference and clarifying the following points:

- The Committee wondered whether the approach to deliver MBCT therapy would be standard, as it was noted that in some places, a full day session was delivered before rolling out the weekly sessions. You replied that MBCT was a standard approach and that this would be a 2 hour session over 8 weeks and would be delivered by a group facilitator. You added that participants would be encouraged to practice at home for 45 minutes a day.

- The Committee noted that Claire Byard would be carrying out the sessions and felt that Ms Byard should attend GCP Training as it was not clear from her CV whether she had any previous study experience. You replied that Claire Byard and Peter Wilkes would facilitate the sessions and felt that it would be acceptable for them to attend GCP training and would arrange for this.

- The Committee noted that a Topic Guide or Interview Schedule had not been included for the Focus Groups and Interviews. You replied that a copy had been submitted. This was the document entitled Process Evaluation Survey.

- The Committee pointed out that there were a number of spelling/typographical errors with the Letter of Invitation and Participant Information Sheet but that these would be detailed in the letter. The Committee added that audio-recording should be included in the Information Sheet and that on page 4, under the heading 'What will happen if I don't want to carry on in the study?', the word 'treatment' was not the right word. You agreed that this should be changed.

- The Committee wondered what would happen if a participant was prescribed medication during the study. You replied that as this was a pilot study it would not be affected if they started medication during the study and could remain in the study. The Committee asked if participants might have taken part in MBCT previously. You replied that this was something that had been debated but as the study was mainly looking for an effect at this stage then it would not matter. However this might need to be reconsidered.

- The Committee noted that the approach to participants would be made by the consultant and that they would be given a 'Consent to Contact' form. The Committee felt that it might be easier if participants were given the information and then they opt-in by contacting the researcher rather than completing the Consent to Contact form. You replied that both options would work.

- The Committee felt that it would take longer than 25 minutes to complete the Questionnaires and asked you to reconsider the time aspect. The Committee also pointed out that the master copy of one of the Questionnaires had been submitted and asked that the scoring sheet be removed prior to sending to the participant. You agreed to this.

- The Committee noted that 3 reminders would be sent to participants and felt that this was excessive. The Committee asked that no more than 2 reminders be sent. You agreed to this.

- The Committee wondered whether a session would run with a minimum number of participants. You replied that that was one of the things participants would be advised of, that it might be up to a month before the session started but no longer than that. The session would run with whatever numbers were available. This would also apply to the control participants.

- The Committee noted that the Questionnaire and the Topic Guide overlapped and asked if this was a deliberate approach. You replied that the idea was to think about the discussion and that the information in the Questionnaires were the key areas that were important to know.

- The Committee felt that the study could not be regarded as a randomised controlled trial as the design of the study would just show that the intervention might/might not improve quality of life. You replied that the design of the study was to see if any changes had arisen as a result of the intervention. The Committee felt that the study should include longer term follow up as changes made over a period of time would be relevant to the outcome. You replied that participants would be followed up at 6 months but would be happy to extend this to 12 months as well as this would provide more information over the long term.

As a result of the above discussion, the Committee asked for the following points to be addressed:

- Please confirm in writing that Claire Byard and Peter Wilkes will attend GCP training and forward copies of their Certificates when received.

- Please clarify the approach made to participants, taking into consideration the comments above regarding removing the 'Consent to Contact' form.

- Please confirm the time aspect involved in completing the Questionnaires.

- Please confirm in writing that only 2 reminders will be sent.

- Please provide paperwork for the 6 and 12 month follow-up.

Letter of Invitation

- In the first paragraph, please include 'A' at the start of the second sentence and change 'Cronh's' to 'Crohn's'. It may also be necessary to remove the second paragraph if the Consent to Contact option is removed.

Participant Information Sheet

- Please insert a sentence advising participants that the sessions, Focus Group discussion and interviews will be audio-recorded.

- Under the heading 'What is the purpose of the study?', first paragraph, please change 'tall' to 'toll' and in the second paragraph, change 'elevate' to 'alleviate'. The paragraph starting 'We think that now...about living with IBD' should also be removed.

- Under the heading 'What will happen if I don't want to carry on in the study?', please find a suitable replacement for 'treatment' as per the comments above.

- Under the heading 'Who has reviewed the study?', please remove the first 3 sentences and replace with 'The North of Scotland Research Ethics Committee has reviewed this study'.

If you would find it helpful to discuss any of the matters raised above or seek further clarification from a member of the Committee, you are welcome to contact Dr Alex Johnstone.

When submitting your response to the Committee, please send revised documentation where appropriate underlining or otherwise highlighting the changes you have made and giving revised version numbers and dates.

If the Committee has asked for clarification or changes to any answers given in the application form, please do not submit a revised copy of the application form; these can be addressed in a covering letter to the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 13 April 2013.

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

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

13/NS/0018	**Please quote this number on all correspondence**

Yours sincerely

Carol Irvine

pp **Dr Alex Johnstone**
Chair

Enclosures:	List of names and professions of members who were present at the meeting and those who submitted written comments.
Copy to:	Ms Carol Johnstone Ms Frances Hines, NHS Highland Research and Development Office

NRES Committees - North of Scotland (2)

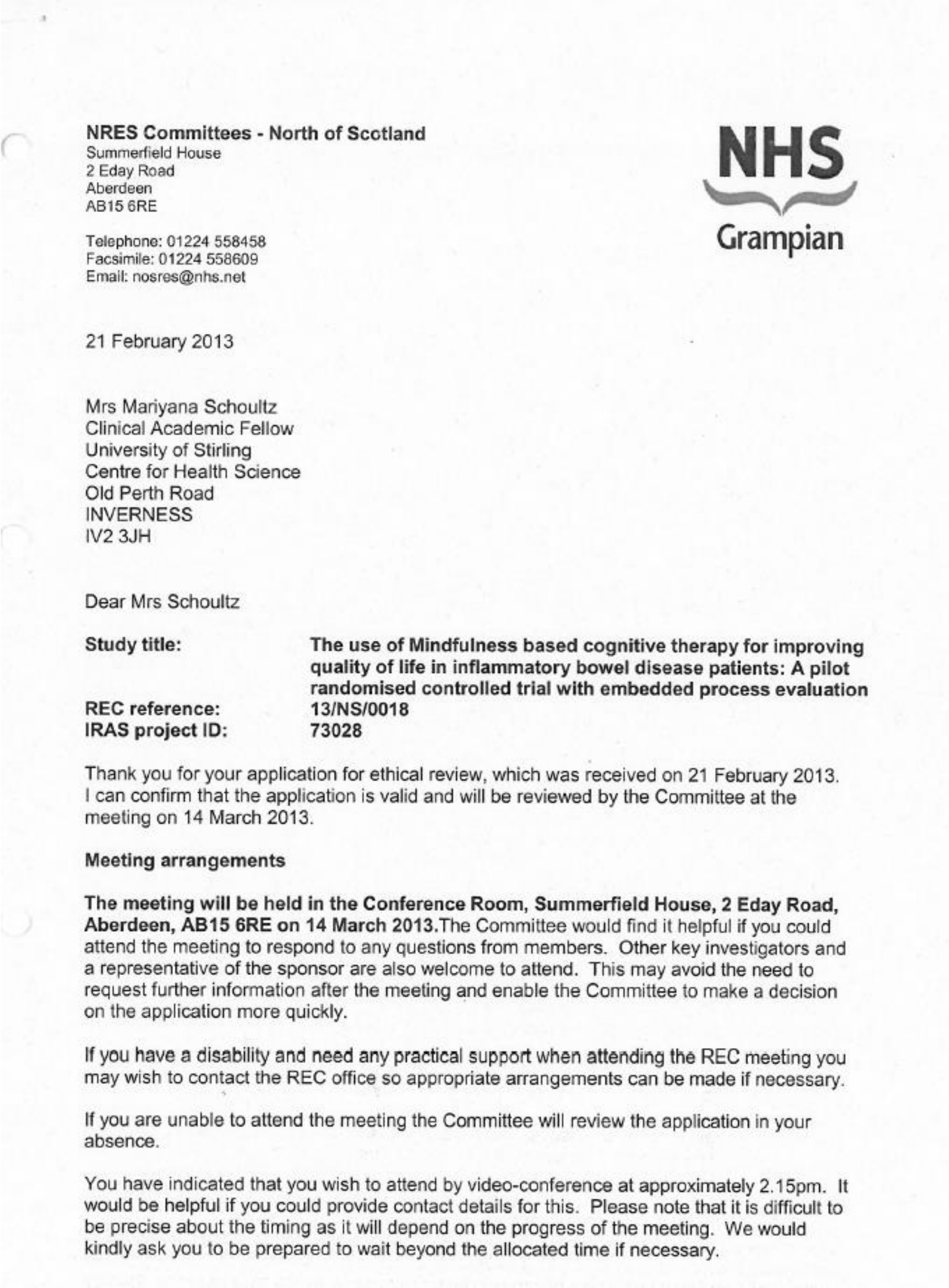
Attendance at Committee meeting on 14 March 2013

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr Stuart Bale	Lay Member - Retired HSE Manager - Shell	Yes	
Mr Russell Brinklow	Community Psychiatric Nurse	No	Written comments received
Dr Jennifer Caldwell	Senior Lecturer in Occupational Therapy	Yes	
Dr Sarah Christie	Lay Member - Reader in Law	Yes	
Mr Gary Cooper	Quality Assurance Manager	Yes	
Dr Stuart Hannabuss	Lay Member - Independent Researcher	Yes	
Dr Georgina Hold	Senior Lecturer - Gastroenterology	Yes	
Mrs Baljit Jagpal	MRI Lead Superintendent	Yes	
Dr Alex Johnstone	Chair & Senior Scientist in Human Nutrition	Yes	
Dr Petr Kalous	Consultant Neonatologist	Yes	
Dr Kirsty Kiezebrink	RCUK Research Fellow in Obesity	Yes	
Miss Rhoda MacKenzie	Senior Lecturer in Medical Education. Vascular Surgeon	No	
Professor Iain McEwan	Professor - Personal chair in Molecular & Cellular Endocrinology	Yes	
Dr Mandy Moffat	Research Fellow - Psychology	No	
Dr Jeremy Morse	Manager of Clinical Skills	Yes	
Ms Anna Maria Radwanska	Observer	No	
Mrs Sian Roughton	Intensive care Research & Follow-Up Nurse	Yes	
Dr Ruth Stephenson	Vice Chair and Consultant in Anaesthesia	No	
Mrs Fiona Watson	Lay Member - Ex Company Director	No	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Karen Gauld	Ethics Administrator
Mrs Carol Irvine	Ethics Co-ordinator



NRES Committees - North of Scotland
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Telephone: 01224 558458
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Email: nosres@nhs.net

NHS
Grampian

21 February 2013

Mrs Mariyana Schoultz
Clinical Academic Fellow
University of Stirling
Centre for Health Science
Old Perth Road
INVERNESS
IV2 3JH

Dear Mrs Schoultz

Study title: **The use of Mindfulness based cognitive therapy for improving quality of life in inflammatory bowel disease patients: A pilot randomised controlled trial with embedded process evaluation**
REC reference: **13/NS/0018**
IRAS project ID: **73028**

Thank you for your application for ethical review, which was received on 21 February 2013. I can confirm that the application is valid and will be reviewed by the Committee at the meeting on 14 March 2013.

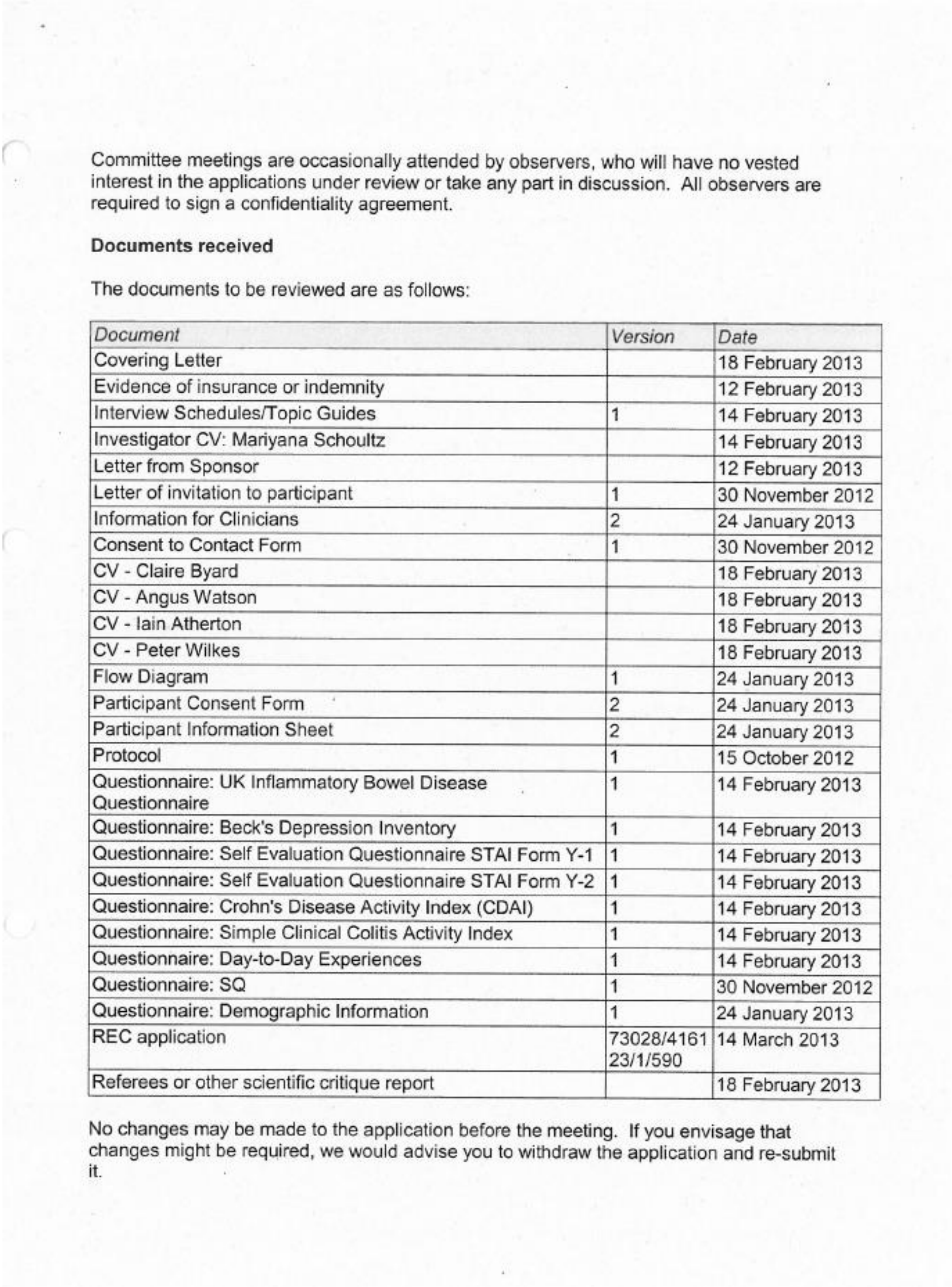
Meeting arrangements

The meeting will be held in the Conference Room, Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE on 14 March 2013. The Committee would find it helpful if you could attend the meeting to respond to any questions from members. Other key investigators and a representative of the sponsor are also welcome to attend. This may avoid the need to request further information after the meeting and enable the Committee to make a decision on the application more quickly.

If you have a disability and need any practical support when attending the REC meeting you may wish to contact the REC office so appropriate arrangements can be made if necessary.

If you are unable to attend the meeting the Committee will review the application in your absence.

You have indicated that you wish to attend by video-conference at approximately 2.15pm. It would be helpful if you could provide contact details for this. Please note that it is difficult to be precise about the timing as it will depend on the progress of the meeting. We would kindly ask you to be prepared to wait beyond the allocated time if necessary.



Committee meetings are occasionally attended by observers, who will have no vested interest in the applications under review or take any part in discussion. All observers are required to sign a confidentiality agreement.

Documents received

The documents to be reviewed are as follows:

Document	*Version*	*Date*
Covering Letter		18 February 2013
Evidence of insurance or indemnity		12 February 2013
Interview Schedules/Topic Guides	1	14 February 2013
Investigator CV: Mariyana Schoultz		14 February 2013
Letter from Sponsor		12 February 2013
Letter of invitation to participant	1	30 November 2012
Information for Clinicians	2	24 January 2013
Consent to Contact Form	1	30 November 2012
CV - Claire Byard		18 February 2013
CV - Angus Watson		18 February 2013
CV - Iain Atherton		18 February 2013
CV - Peter Wilkes		18 February 2013
Flow Diagram	1	24 January 2013
Participant Consent Form	2	24 January 2013
Participant Information Sheet	2	24 January 2013
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Questionnaire: Crohn's Disease Activity Index (CDAI)	1	14 February 2013
Questionnaire: Simple Clinical Colitis Activity Index	1	14 February 2013
Questionnaire: Day-to-Day Experiences	1	14 February 2013
Questionnaire: SQ	1	30 November 2012
Questionnaire: Demographic Information	1	24 January 2013
REC application	73028/4161 23/1/590	14 March 2013
Referees or other scientific critique report		18 February 2013

No changes may be made to the application before the meeting. If you envisage that changes might be required, we would advise you to withdraw the application and re-submit it.

Notification of the Committee's decision

You will receive written notification of the outcome of the review within 10 working days of the meeting. The Committee will issue a final ethical opinion on the application within a maximum of 60 days from 21 February 2013, excluding any time taken by you to respond fully to one request for further information or clarification after the meeting.

Site-specific assessments

NHS sites

Site-specific assessment (SSA) for any site within the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland will form part of the research governance review. The Site-Specific Information (SSI) Form for the site should be included with the application for R&D approval.

If the REC gives a favourable opinion, this will apply to any NHS/HSC site on condition that management permission is obtained from the host organisation prior to the research starting at the site.

There is no need to submit the SSI Form to the local REC.

R&D approval

You should seek approval from the R&D office for the relevant care organisation to conduct this research at a NHS site. The R&D approval process may take place at the same time as the ethical review. Final R&D approval will not be confirmed until after a favourable ethical opinion has been given.

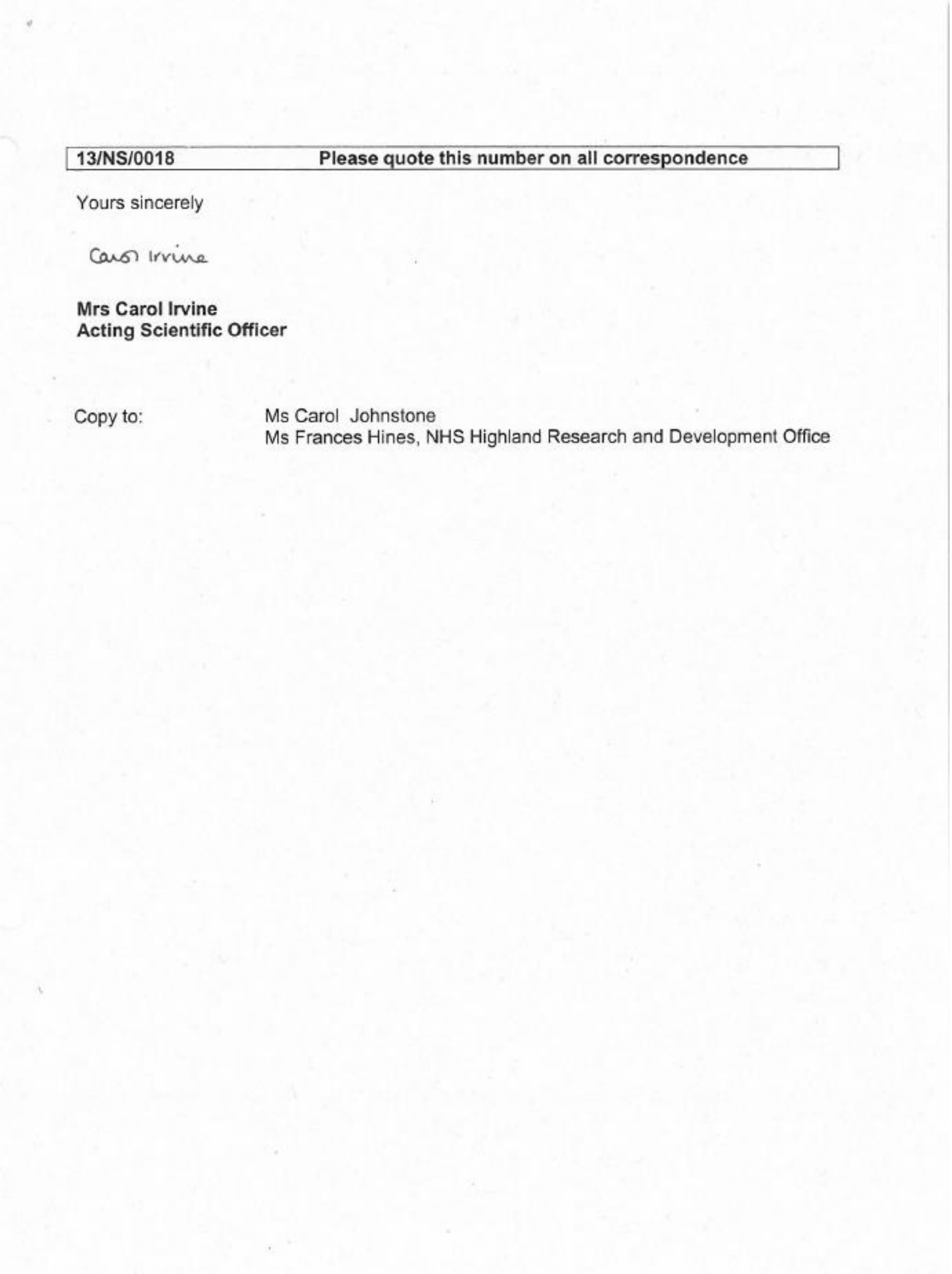
Any researchers and local research collaborators who intend to participate in this study at other NHS sites should also apply for R&D approval from the relevant care organisation. You should advise researchers and local collaborators accordingly.

For guidance on applying for R&D approval, please contact the NHS R&D office at the lead site in the first instance. Further guidance resources for planning, setting up and conducting research in the NHS are available from http://www.rdforum.nhs.uk.

Communication with other bodies

All correspondence from the REC about the application will be copied to the research sponsor [and to the R&D office for [name of care organisation at lead site]]. It will be your responsibility to ensure that other investigators, research collaborators and NHS care organisation(s) involved in the study are kept informed of the progress of the review, as necessary.

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



13/NS/0018 **Please quote this number on all correspondence**

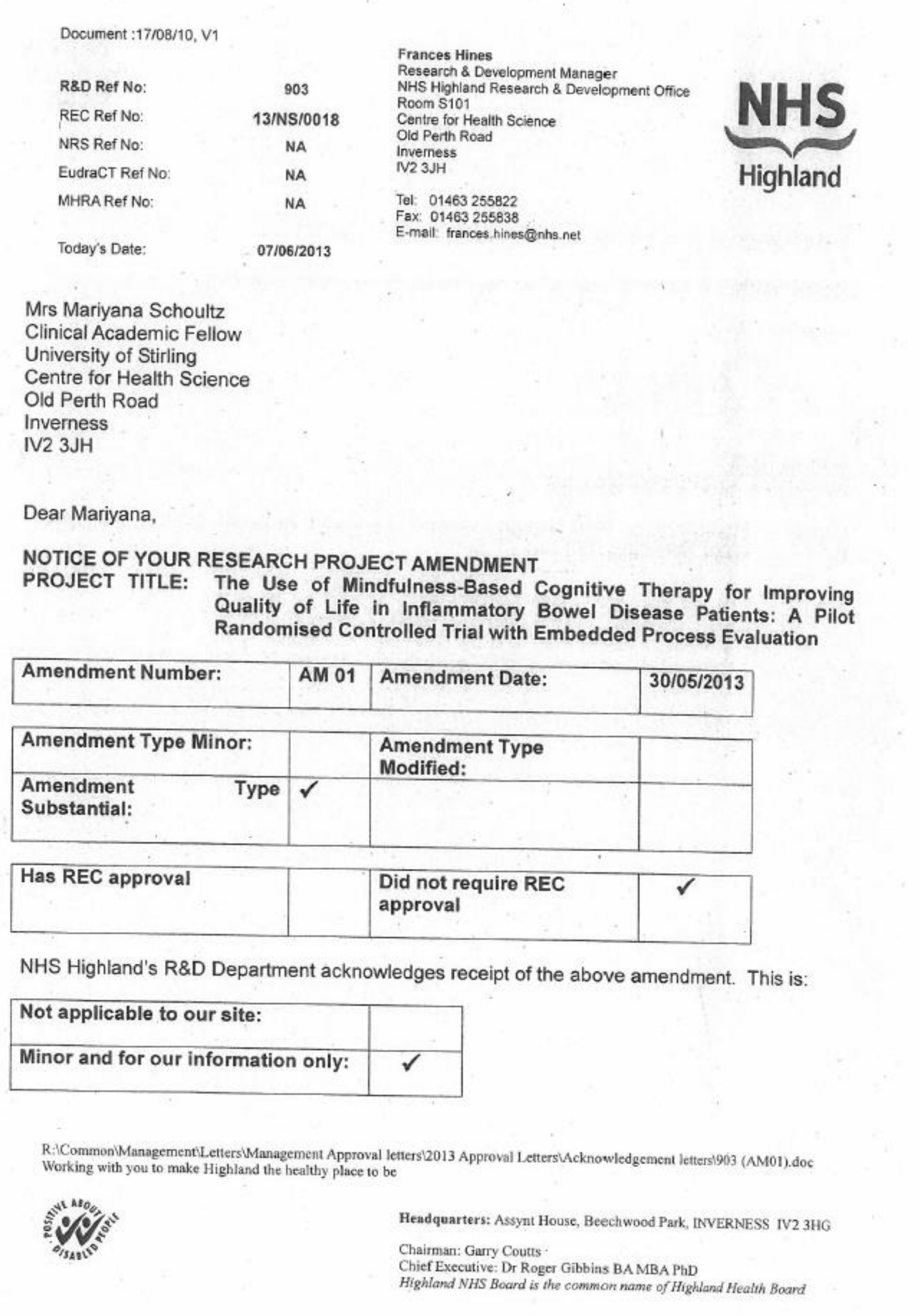
Yours sincerely

Carol Irvine

Mrs Carol Irvine
Acting Scientific Officer

Copy to: Ms Carol Johnstone
Ms Frances Hines, NHS Highland Research and Development Office

Appendix 4: R&D management approval and amendments



Document :17/08/10, V1

R&D Ref No:	903
REC Ref No:	13/NS/0018
NRS Ref No:	NA
EudraCT Ref No:	NA
MHRA Ref No:	NA
Today's Date:	07/06/2013

Frances Hines
Research & Development Manager
NHS Highland Research & Development Office
Room S101
Centre for Health Science
Old Perth Road
Inverness
IV2 3JH

Tel: 01463 255822
Fax: 01463 255838
E-mail: frances.hines@nhs.net

NHS Highland

Mrs Mariyana Schoultz
Clinical Academic Fellow
University of Stirling
Centre for Health Science
Old Perth Road
Inverness
IV2 3JH

Dear Mariyana,

NOTICE OF YOUR RESEARCH PROJECT AMENDMENT
PROJECT TITLE: The Use of Mindfulness-Based Cognitive Therapy for Improving Quality of Life in Inflammatory Bowel Disease Patients: A Pilot Randomised Controlled Trial with Embedded Process Evaluation

Amendment Number:	**AM 01**	**Amendment Date:**	**30/05/2013**

Amendment Type Minor:		**Amendment Type Modified:**	
Amendment Type Substantial:	✓		

Has REC approval		**Did not require REC approval**	✓

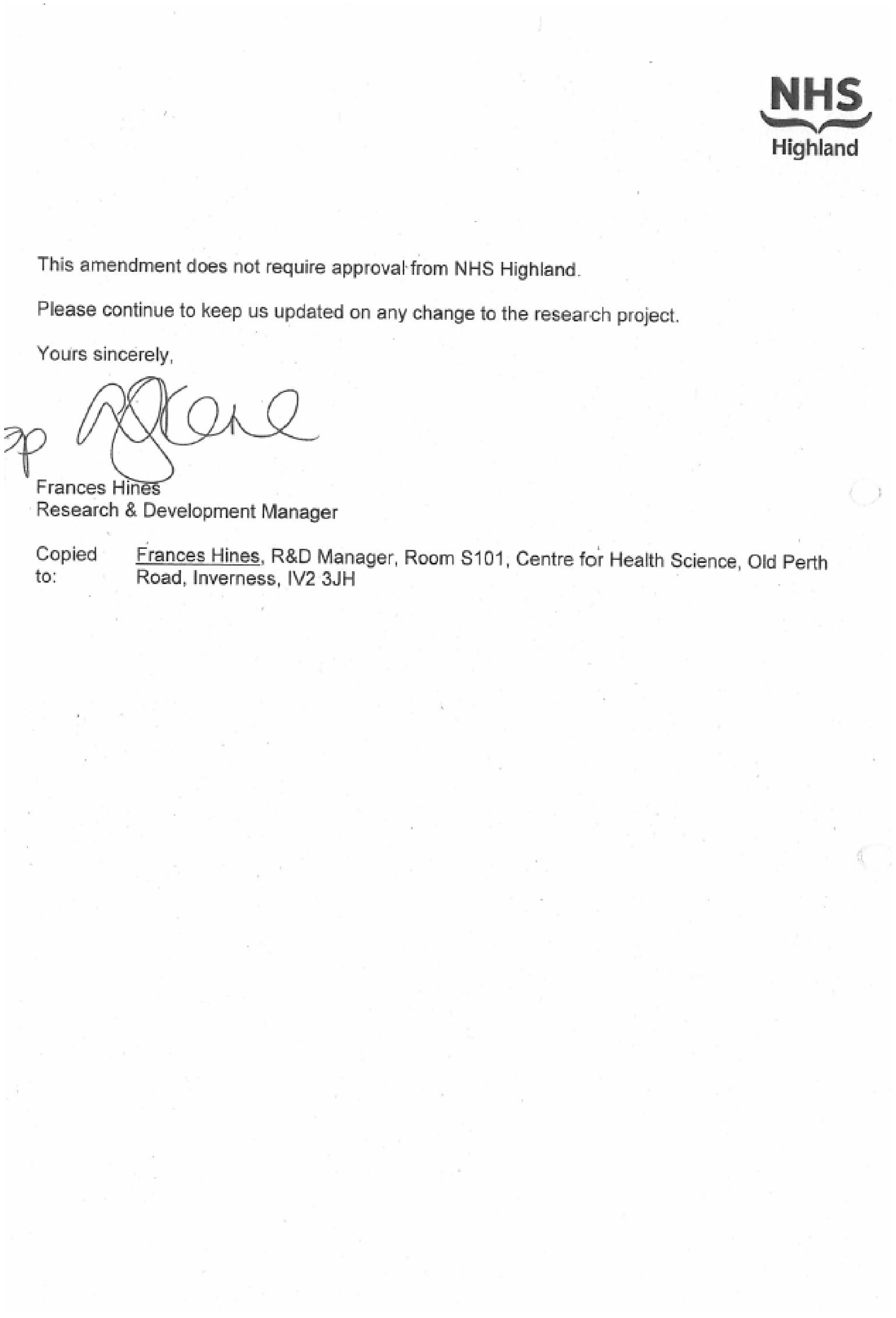
NHS Highland's R&D Department acknowledges receipt of the above amendment. This is:

Not applicable to our site:	
Minor and for our information only:	✓

R:\Common\Management\Letters\Management Approval letters\2013 Approval Letters\Acknowledgement letters\903 (AM01).doc
Working with you to make Highland the healthy place to be

Headquarters: Assynt House, Beechwood Park, INVERNESS IV2 3HG

Chairman: Garry Coutts
Chief Executive: Dr Roger Gibbins BA MBA PhD
Highland NHS Board is the common name of Highland Health Board



NHS
Highland

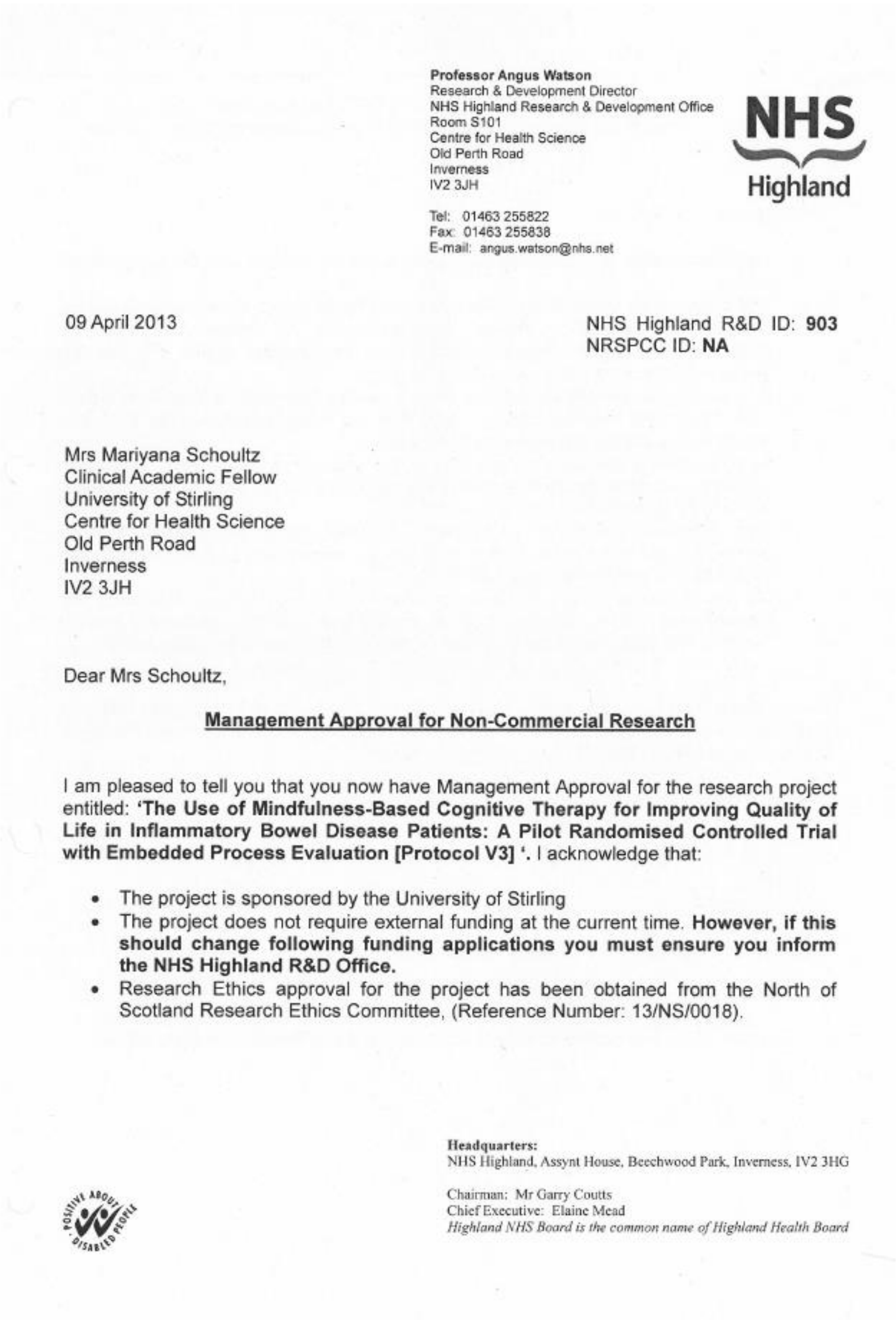
This amendment does not require approval from NHS Highland.

Please continue to keep us updated on any change to the research project.

Yours sincerely,

Frances Hines
Research & Development Manager

Copied to: Frances Hines, R&D Manager, Room S101, Centre for Health Science, Old Perth Road, Inverness, IV2 3JH



Professor Angus Watson
Research & Development Director
NHS Highland Research & Development Office
Room S101
Centre for Health Science
Old Perth Road
Inverness
IV2 3JH

Tel: 01463 255822
Fax: 01463 255838
E-mail: angus.watson@nhs.net

09 April 2013

NHS Highland R&D ID: **903**
NRSPCC ID: **NA**

Mrs Mariyana Schoultz
Clinical Academic Fellow
University of Stirling
Centre for Health Science
Old Perth Road
Inverness
IV2 3JH

Dear Mrs Schoultz,

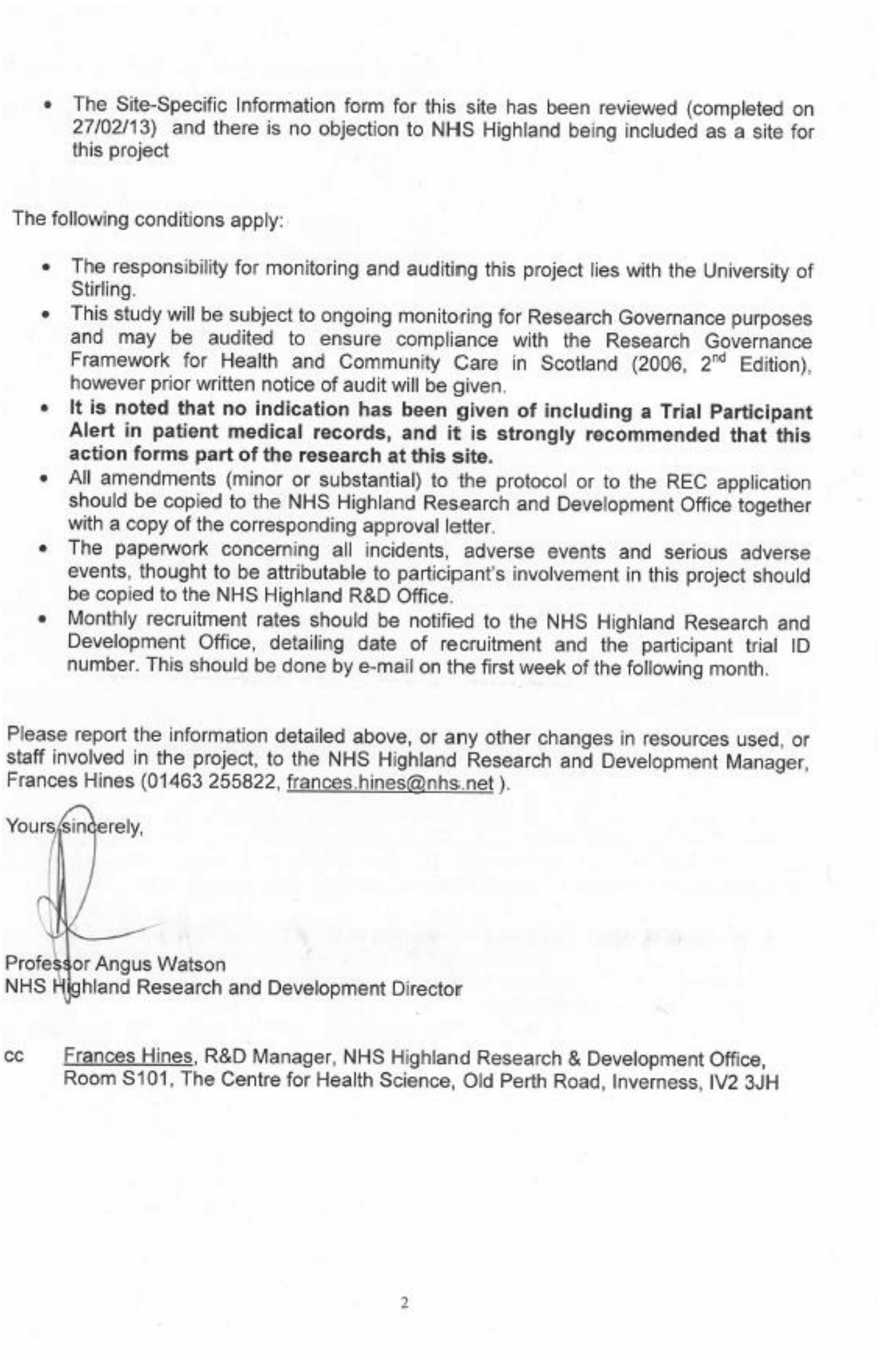
Management Approval for Non-Commercial Research

I am pleased to tell you that you now have Management Approval for the research project entitled: **'The Use of Mindfulness-Based Cognitive Therapy for Improving Quality of Life in Inflammatory Bowel Disease Patients: A Pilot Randomised Controlled Trial with Embedded Process Evaluation [Protocol V3] '.** I acknowledge that:

- The project is sponsored by the University of Stirling
- The project does not require external funding at the current time. **However, if this should change following funding applications you must ensure you inform the NHS Highland R&D Office.**
- Research Ethics approval for the project has been obtained from the North of Scotland Research Ethics Committee, (Reference Number: 13/NS/0018).

Headquarters:
NHS Highland, Assynt House, Beechwood Park, Inverness, IV2 3HG

Chairman: Mr Garry Coutts
Chief Executive: Elaine Mead
Highland NHS Board is the common name of Highland Health Board



- The Site-Specific Information form for this site has been reviewed (completed on 27/02/13) and there is no objection to NHS Highland being included as a site for this project

The following conditions apply:

- The responsibility for monitoring and auditing this project lies with the University of Stirling.
- This study will be subject to ongoing monitoring for Research Governance purposes and may be audited to ensure compliance with the Research Governance Framework for Health and Community Care in Scotland (2006, 2nd Edition), however prior written notice of audit will be given.
- **It is noted that no indication has been given of including a Trial Participant Alert in patient medical records, and it is strongly recommended that this action forms part of the research at this site.**
- All amendments (minor or substantial) to the protocol or to the REC application should be copied to the NHS Highland Research and Development Office together with a copy of the corresponding approval letter.
- The paperwork concerning all incidents, adverse events and serious adverse events, thought to be attributable to participant's involvement in this project should be copied to the NHS Highland R&D Office.
- Monthly recruitment rates should be notified to the NHS Highland Research and Development Office, detailing date of recruitment and the participant trial ID number. This should be done by e-mail on the first week of the following month.

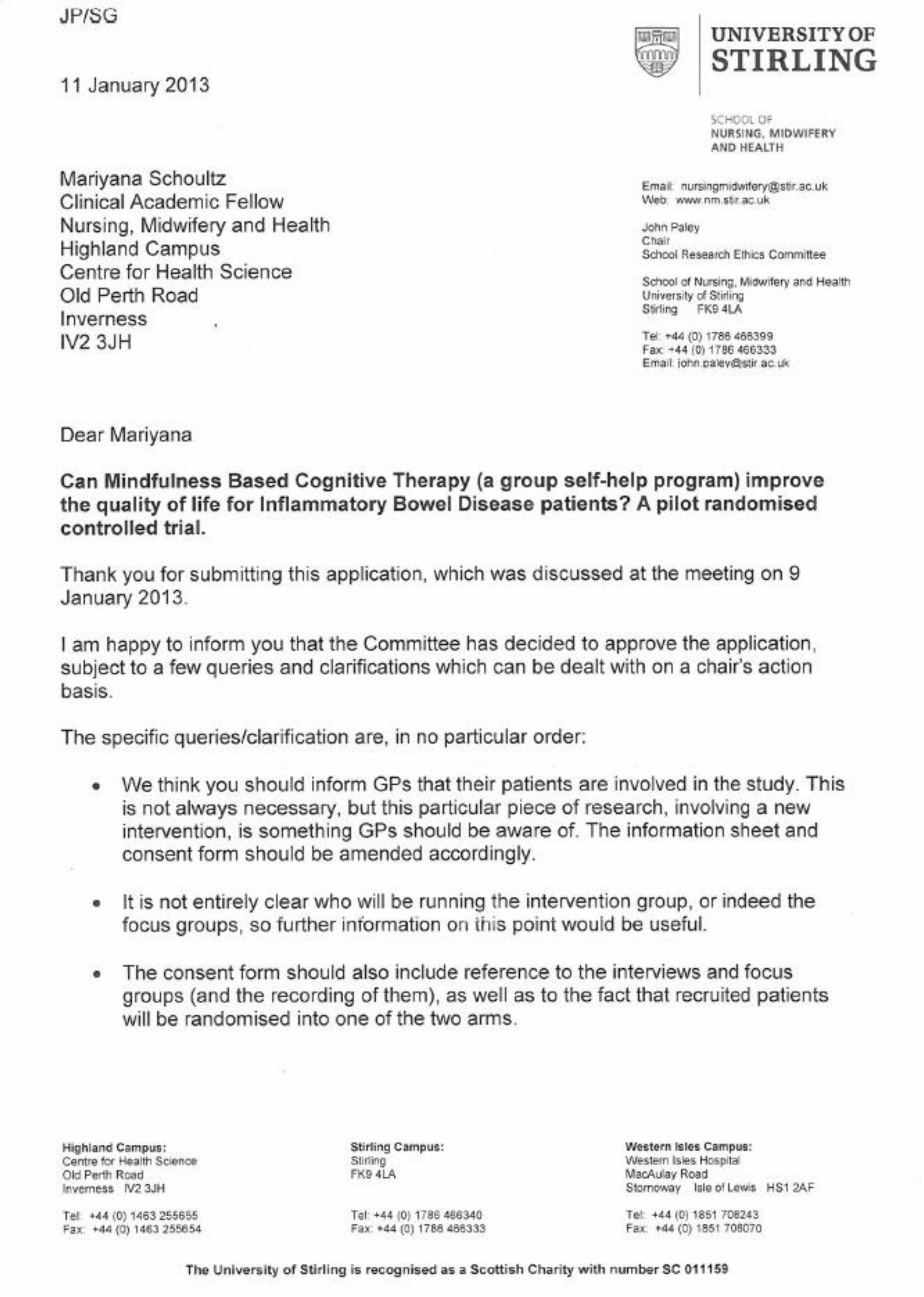
Please report the information detailed above, or any other changes in resources used, or staff involved in the project, to the NHS Highland Research and Development Manager, Frances Hines (01463 255822, frances.hines@nhs.net).

Yours sincerely,

Professor Angus Watson
NHS Highland Research and Development Director

cc Frances Hines, R&D Manager, NHS Highland Research & Development Office,
Room S101, The Centre for Health Science, Old Perth Road, Inverness, IV2 3JH

Appendix 5: University Ethics Approval



JP/SG

11 January 2013

UNIVERSITY OF STIRLING

SCHOOL OF
NURSING, MIDWIFERY
AND HEALTH

Email: nursingmidwifery@stir.ac.uk
Web: www.nm.stir.ac.uk

John Paley
Chair
School Research Ethics Committee

School of Nursing, Midwifery and Health
University of Stirling
Stirling FK9 4LA

Tel: +44 (0) 1786 466399
Fax: +44 (0) 1786 466333
Email: john.paley@stir.ac.uk

Mariyana Schoultz
Clinical Academic Fellow
Nursing, Midwifery and Health
Highland Campus
Centre for Health Science
Old Perth Road
Inverness
IV2 3JH

Dear Mariyana

Can Mindfulness Based Cognitive Therapy (a group self-help program) improve the quality of life for Inflammatory Bowel Disease patients? A pilot randomised controlled trial.

Thank you for submitting this application, which was discussed at the meeting on 9 January 2013.

I am happy to inform you that the Committee has decided to approve the application, subject to a few queries and clarifications which can be dealt with on a chair's action basis.

The specific queries/clarification are, in no particular order:

- We think you should inform GPs that their patients are involved in the study. This is not always necessary, but this particular piece of research, involving a new intervention, is something GPs should be aware of. The information sheet and consent form should be amended accordingly.
- It is not entirely clear who will be running the intervention group, or indeed the focus groups, so further information on this point would be useful.
- The consent form should also include reference to the interviews and focus groups (and the recording of them), as well as to the fact that recruited patients will be randomised into one of the two arms.

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Old Perth Road
Inverness IV2 3JH

Tel: +44 (0) 1463 255655
Fax: +44 (0) 1463 255654

Stirling Campus:
Stirling
FK9 4LA

Tel: +44 (0) 1786 466340
Fax: +44 (0) 1786 466333

Western Isles Campus:
Western Isles Hospital
MacAulay Road
Stornoway Isle of Lewis HS1 2AF

Tel: +44 (0) 1851 708243
Fax: +44 (0) 1851 706070

The University of Stirling is recognised as a Scottish Charity with number SC 011159

- Some of the inclusion criteria need to be operationalized. For example, it is not clear how 'ability to do light exercise' will be assessed, or by whom.

- Question A62 on the IRAS form probably needs a little more detail. For example, it is not clear how the qualitative data will be analysed

- There is a possibility, though perhaps a remote one, of interview and focus group participants becoming distressed, given the nature of the condition from which they suffer; so arrangements for support and/or counselling, in this eventuality, would be helpful.

- We would be grateful if you could let us have copies of the outcome measure and instruments that will be used in the study.

If you could let me have the additional information and amended passages, I will be able to let you have a chair's action decision quite quickly.

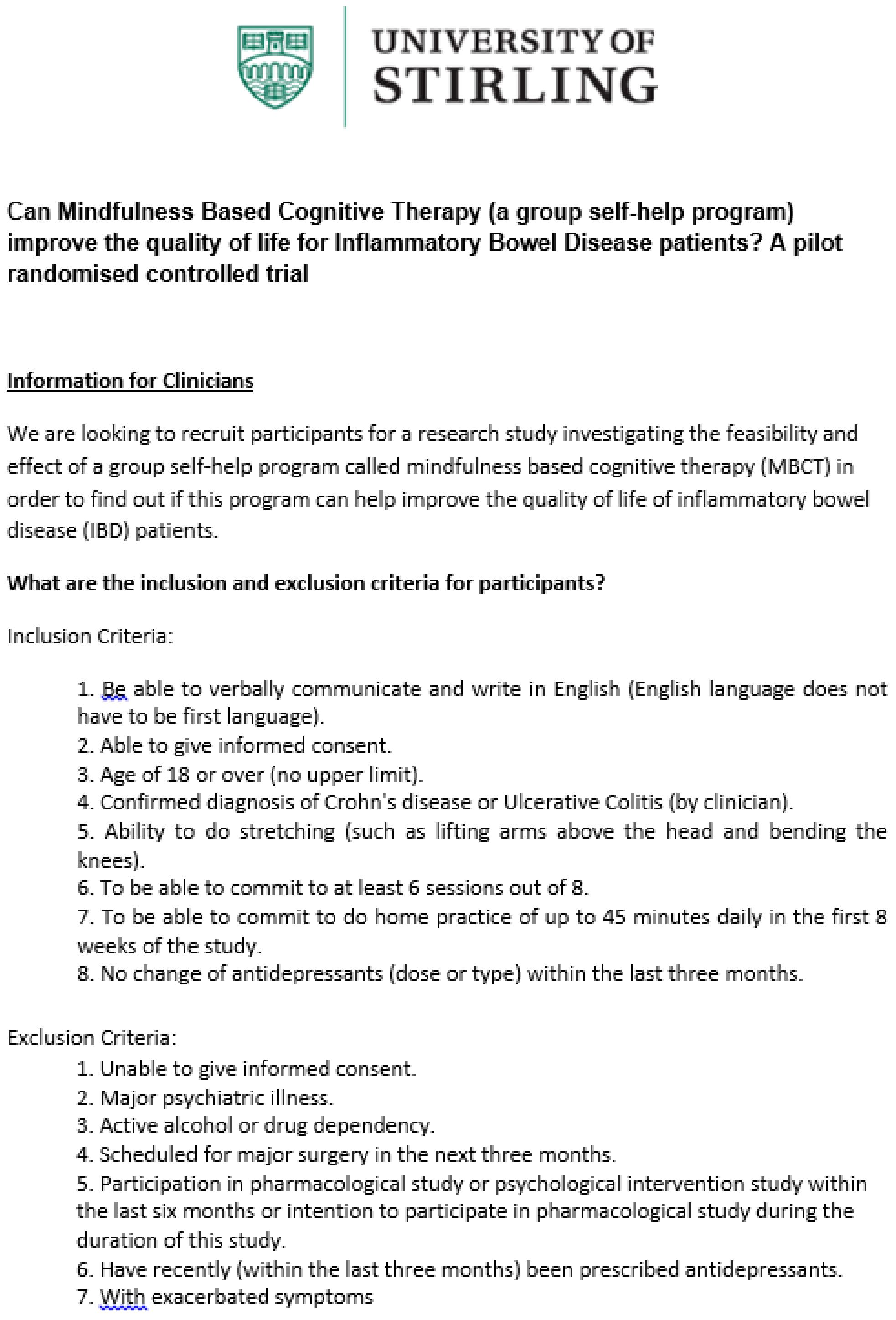
Incidentally, the final version of the protocol should be thoroughly proof-read. For example, there are a number of typos in the information sheet.

Yours sincerely

pp. Sarahjane Gilvear

John Paley
(Chair)
School of Nursing, Midwifery and Health Research Ethics Committee

Appendix 6: Patient information documents



UNIVERSITY OF STIRLING

Can Mindfulness Based Cognitive Therapy (a group self-help program) improve the quality of life for Inflammatory Bowel Disease patients? A pilot randomised controlled trial

Information for Clinicians

We are looking to recruit participants for a research study investigating the feasibility and effect of a group self-help program called mindfulness based cognitive therapy (MBCT) in order to find out if this program can help improve the quality of life of inflammatory bowel disease (IBD) patients.

What are the inclusion and exclusion criteria for participants?

Inclusion Criteria:

1. Be able to verbally communicate and write in English (English language does not have to be first language).
2. Able to give informed consent.
3. Age of 18 or over (no upper limit).
4. Confirmed diagnosis of Crohn's disease or Ulcerative Colitis (by clinician).
5. Ability to do stretching (such as lifting arms above the head and bending the knees).
6. To be able to commit to at least 6 sessions out of 8.
7. To be able to commit to do home practice of up to 45 minutes daily in the first 8 weeks of the study.
8. No change of antidepressants (dose or type) within the last three months.

Exclusion Criteria:

1. Unable to give informed consent.
2. Major psychiatric illness.
3. Active alcohol or drug dependency.
4. Scheduled for major surgery in the next three months.
5. Participation in pharmacological study or psychological intervention study within the last six months or intention to participate in pharmacological study during the duration of this study.
6. Have recently (within the last three months) been prescribed antidepressants.
7. With exacerbated symptoms

What does the study involve?

The first stage of our research will involve informing eligible patients about the current study carried out in NHS Highland. If the patients are seen in clinic, this can be done verbally and passing the participant information sheet to the interested patient. If the patients are not going to be seen in clinic in the next few months, sending a letter of invitation will be appropriate together with participant information sheet. The participant information sheet will have researcher's contact details, giving an option to the patient to contact the researcher and find out more about the study. Potential participants will be given the opportunity to meet with researcher to discuss the study before signing a consent form.

Does this study affect usual treatment?

No. The usual treatment should not be affected in any way.

How can I help?

By informing patients who meet the inclusion criteria by letter of invitation or verbally if possible, about the study. Information sheet with researcher contact details, consent form and self-addressed envelope will be enclosed with this letter.

Who is organising the research?

The Chief Investigator for this project is Mariyana Schoultz-Clinical Academic Fellow under supervision of Professor Angus Watson. The research team also include Dr Iain Atherton-Lecturer both based at University of Stirling, Centre for Health Science, Inverness. The sponsors for this research are University of Stirling. This study has been approved by the Ethics Committee of University of Stirling and North of Scotland Ethics Committee. The research is funded by NHS endowments.

Thank you for your assistance. If you would like to further discuss any aspect of this research, please contact:

Mariyana Schoultz in first instance on 01463255647/ ms84@stir.ac.uk or

Professor Angus Watson on 01463255612/ angus.watson@nhs.net.

UNIVERSITY OF STIRLING

NHS Highland

CONSENT FORM

Can Mindfulness Based Cognitive Therapy (a group self-help program) improve the quality of life for Inflammatory Bowel Disease patients? A pilot randomised controlled trial

Name of Researcher:

Please initial box

1. I confirm that I have read and understand the information sheet dated........................ (Version ....) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I agree to take part in the above study. ☐

4. I understand that my GP will be informed about my involvement in the study. ☐

5. I understand that the group self-help training and the group chat will be audio recorded. ☐

Name of Patient	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

1 copy for patient; 1 copy for researcher; 1 copy to be kept with hospital notes

24/01/2013: C1 Version 2

Mariyana Schoultz
Clinical Academic Fellow
University of Stirling, School of NMH
Centre for Health Science
Old Perth Road
Inverness
IV2 3JH
01463255647
mariyana.schoultz@stir.ac.uk

Address:

Date:

Dear Dr <Surname>

Can Mindfulness Based Cognitive Therapy (a group self-help program) improve the quality of life for Inflammatory Bowel Disease patients? A pilot randomised controlled trial

Patient Hospital number:

I write to inform you that your patient has agreed to participate in the above study.

Approval for the study has been obtained from the appropriate Ethics and Research Committees and R&D Highland management.

Please could you advise me if you have any concerns regarding your patient's involvement in the study. If so, please contact me on 01463255476 within a week of the date of this letter. If I do not hear from you by that date I will take it that you have no objections.

I would be happy to discuss the study further with you if you feel that would be necessary.

Yours sincerely

proceed

Mariyana Schoultz

Clinical Academic Fellow

UNIVERSITY OF
STIRLING

NHS
Highland

Dear XXXXXX

Re: Can Mindfulness Based Cognitive Therapy (a group self-help program) improve the quality of life for Inflammatory Bowel Disease patients? A pilot randomised controlled trial

I am contacting you to let you know about some research currently being carried out at NHS Highland. A research student from University of Stirling is working with the NHS to identify people with a confirmed diagnosis of Crohn's disease or ulcerative colitis. They are asking people to take part in a research project that is investigating the effectiveness of a group self-help program called mindfulness based cognitive therapy and to find out if this program can help improve the quality of life of inflammatory bowel disease patients and help reduce any distress associated with symptom management.

This letter is to let you know that NHS Highlands is involved in the study and to ask if you would be willing to consider taking part. Please be assured that involvement in this research is completely voluntary and whether or not you decide to take part will not affect the treatment we offer you now or in the future.

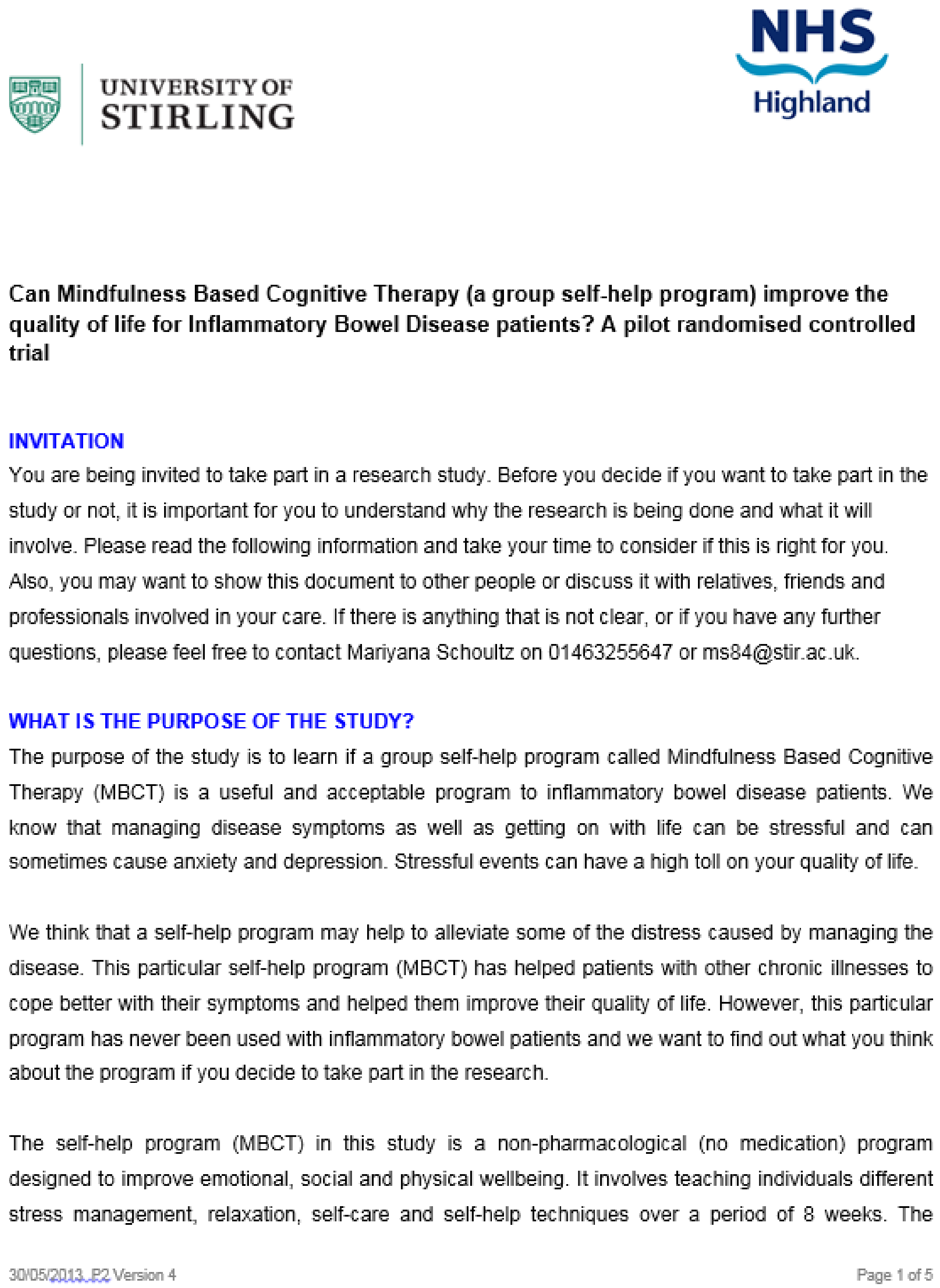
If you are interested in helping with this research, please read the attached information sheet very carefully as it gives a full description of what will be expected of each volunteer. Any study travel expenses will be reimbursed.

If you decide you want to get in touch with the researcher to find out more about the study, the researcher's contact details are provided in the information sheet. The researcher will answer any questions you might have about the research.

Kind regards,

Dr XXXXXX

08/04/2013: L1- Version 3



UNIVERSITY OF STIRLING

NHS Highland

Can Mindfulness Based Cognitive Therapy (a group self-help program) improve the quality of life for Inflammatory Bowel Disease patients? A pilot randomised controlled trial

INVITATION

You are being invited to take part in a research study. Before you decide if you want to take part in the study or not, it is important for you to understand why the research is being done and what it will involve. Please read the following information and take your time to consider if this is right for you. Also, you may want to show this document to other people or discuss it with relatives, friends and professionals involved in your care. If there is anything that is not clear, or if you have any further questions, please feel free to contact Mariyana Schoultz on 01463255647 or ms84@stir.ac.uk.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of the study is to learn if a group self-help program called Mindfulness Based Cognitive Therapy (MBCT) is a useful and acceptable program to inflammatory bowel disease patients. We know that managing disease symptoms as well as getting on with life can be stressful and can sometimes cause anxiety and depression. Stressful events can have a high toll on your quality of life.

We think that a self-help program may help to alleviate some of the distress caused by managing the disease. This particular self-help program (MBCT) has helped patients with other chronic illnesses to cope better with their symptoms and helped them improve their quality of life. However, this particular program has never been used with inflammatory bowel patients and we want to find out what you think about the program if you decide to take part in the research.

The self-help program (MBCT) in this study is a non-pharmacological (no medication) program designed to improve emotional, social and physical wellbeing. It involves teaching individuals different stress management, relaxation, self-care and self-help techniques over a period of 8 weeks. The

MBCT program is taught in a group setting. The teaching will involve using regular daily activities like sitting, walking, lying down and light stretching (for example lifting your arms above your head or bending your knees). Those daily activities will be enhanced by focusing on breathing and paying attention in a particular way.

If you decide to take part in the study, you will be involved in the study for approximately 8-12 weeks with follow up questionnaires at 6 months.

WHY HAVE I BEEN INVITED?

You have been invited to take part in this study because you have a diagnosis of either Crohn's disease or Ulcerative Colitis, you are of age 18 or over and are able to give informed consent. We are looking to recruit 40 patients from the Highlands area.

DO I HAVE TO TAKE PART?

No, it is up to you to decide if you want to take part in the study. Once you have read through all the information about the study, you will be able to ask us any questions you have that might help you to make your decision. We will then ask that you sign a consent form to show that you understand what the study is about, and what you have agreed to do.

You are free to withdraw from the study at any time without giving a reason if you decide to do so. Whether you choose to take part or not, you will continue to receive the same standard of care and your treatment will not be affected in any way.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

Sometimes we don't know which way of treating patients is best. To find out, we need to make comparisons between the different treatments. We put people into groups and give each group a different 'treatment'; the results are compared to see if one is better than the other. To ensure the groups are the same to start with, each patient is put into a group by chance (randomly) via computer. The results are then compared. We will inform you which group have the computer selected for you.

If you decide to take part in the study, you will be asked to sign a consent form. Once a consent form has been signed, you will be asked to fill in five short questionnaires which you can take home and send it back in stamped self-addressed envelopes provided. The questionnaires will be asking you questions about quality of life, daily stresses, low mood, mindfulness and disease activity specific questions.

After the eight weeks, you will be asked again to fill in the same five questionnaires to see if the self-help training has made any difference on stress, mood, quality of life etc. We will also ask you to fill in one further short questionnaire asking you what your thoughts are about the program and the whole research process. You will also be invited to come along to a group chat where you can tell us what your experience was of the program and the research process. The group sessions and the group chat will be audio recorded.

In this study we will have two groups. One group will receive the training in self-help (MBCT) and the other group will receive a leaflet 'living with IBD'. You will have 50/50 chance to be selected by a computer to be in the group that will receive the self-help training and 50/50 chance to be in the group with 'living with IBD' leaflet. When we have enough people for both groups (approximately 8-10 in each group) we will start the self-help group. We are planning to start the groups no earlier than 22nd July 2013. Patients in the group with 'living with IBD' leaflet will have an opportunity to get free training in the same self-help program after all follow up questionnaires have been completed and returned (after approximately 12 months).

WHAT DO I HAVE TO DO?

If you are selected for the self-help (MBCT) group, you will be asked to attend 8 group session (approximately 2 hours each) over a period of 8 weeks. You will be encouraged to do home practice for approximately 45 minutes for six out of seven days in the eight weeks. You will be provided with audio CD's and instruction booklets to guide you through your home practice.

If you are selected for the group receiving the leaflet 'living with IBD', you will be given the leaflet and you will be asked to read the leaflet in full within the 8 weeks.

Regardless of which group you are, you will also be asked to fill in the same five questionnaires at the start (after you have signed consent form) and the end of the eight weeks. We will ask you to fill in a further short questionnaire at the end of the eight weeks and we will invite you to come for a group chat that will last for an hour.

After 6 and 12 months from the start of the study we will ask you to complete and return the same five questionnaires (we will send you a reminder closer to the time).

WHAT IS THE PROGRAM BEING TESTED?

The self-help program being tested is called Mindfulness Based Cognitive Therapy. The program consists of eight practitioner led group sessions over eight weeks. Each session is approximately two hours long. This program has been tested and has been used in a range of physical illnesses in UK and USA. The treatment is based on Mindfulness Based Stress Reduction programme developed in Massachusetts for lower back pain twenty years ago. Since then, it has been adapted and used for distress, pain, anxiety and depression across the UK.

WHAT ARE THE SIDE EFFECTS OF TAKING PART?

There have not been any known side effects to date recorded for taking part in this program.

EXTRA SUPPORT

If you notice that you might need any additional support in the course of the self-help training, we will advise you to contact the GP to access further support. You can also contact the Breathing Space number 0800838587 free of charge if you feel you need to speak to somebody confidentially.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

We believe that going through the self-help training, you may learn different skills of how to reduce the effect of daily stress, anxiety and depression. Learning those skills may help improve your quality of life. Learning those skills may also give you a sense of empowerment and control of how you are feeling.

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

When the study stops, we will have to analyse the information that we have collected in the study. If you were allocated to the 'living with IBD' leaflet group, and if you wish, there will be an option for you to enrol for an eight week self-help training after we have collected all questionnaires. If you were allocated to the MBCT group, you will not have to do anything.

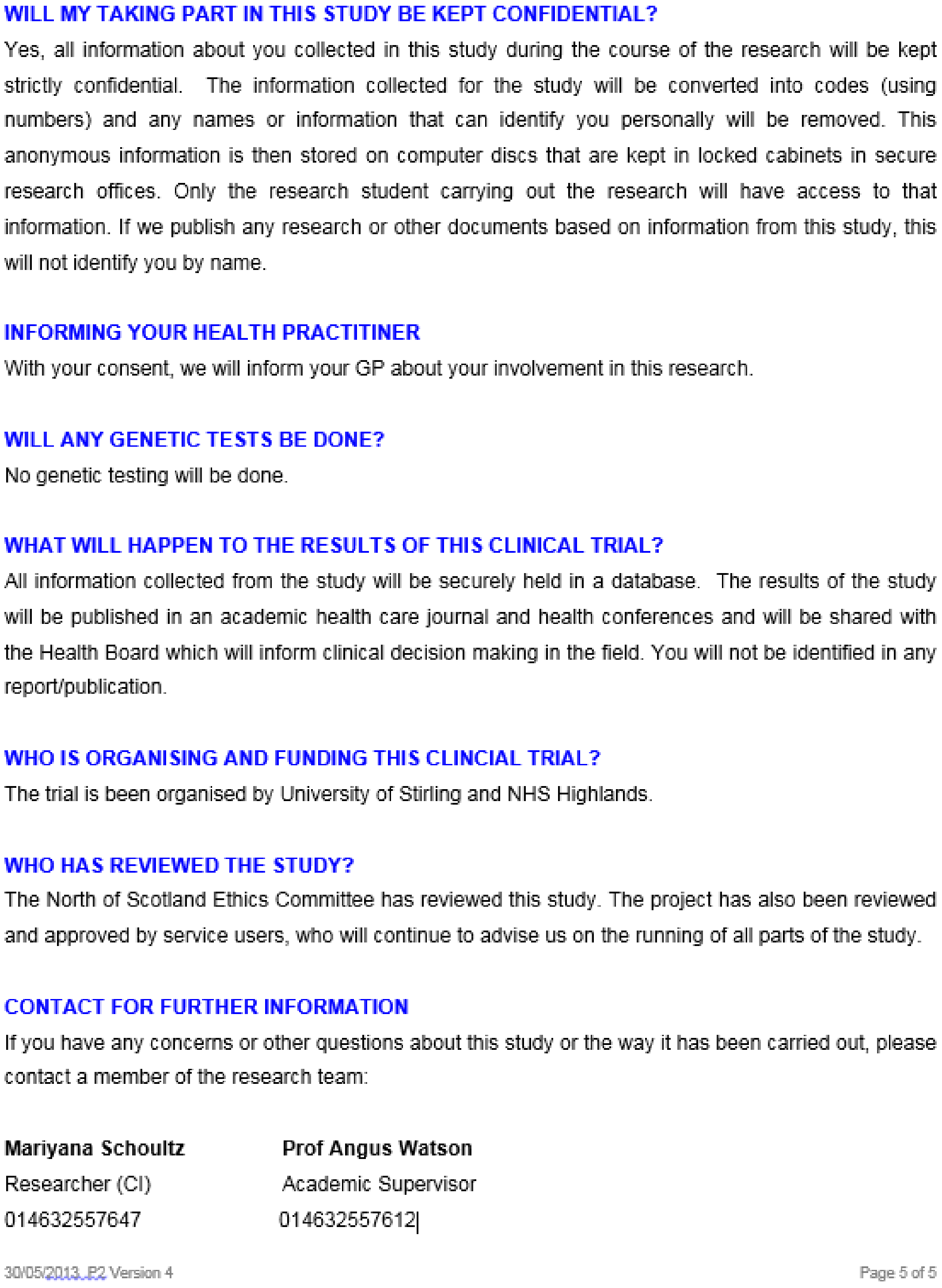
When the results are going to be published, we will send you a brief summary of the findings, if you wish.

WILL I BE PAID?

You will not receive payment for taking part in this research but if you attend the group sessions, we will cover any travel expenses related to attending those appointments.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON IN THE STUDY?

In a clinical trial, the participant may wish to withdraw entirely or may wish to withdraw from the self-help program, but be willing to continue to be followed up. You can inform us of any decision at any time. Your decision to withdraw will not affect the care you receive. If you withdraw from the study, we will use the data collected up to your withdrawal.



WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Yes, all information about you collected in this study during the course of the research will be kept strictly confidential. The information collected for the study will be converted into codes (using numbers) and any names or information that can identify you personally will be removed. This anonymous information is then stored on computer discs that are kept in locked cabinets in secure research offices. Only the research student carrying out the research will have access to that information. If we publish any research or other documents based on information from this study, this will not identify you by name.

INFORMING YOUR HEALTH PRACTITINER

With your consent, we will inform your GP about your involvement in this research.

WILL ANY GENETIC TESTS BE DONE?

No genetic testing will be done.

WHAT WILL HAPPEN TO THE RESULTS OF THIS CLINICAL TRIAL?

All information collected from the study will be securely held in a database. The results of the study will be published in an academic health care journal and health conferences and will be shared with the Health Board which will inform clinical decision making in the field. You will not be identified in any report/publication.

WHO IS ORGANISING AND FUNDING THIS CLINCIAL TRIAL?

The trial is been organised by University of Stirling and NHS Highlands.

WHO HAS REVIEWED THE STUDY?

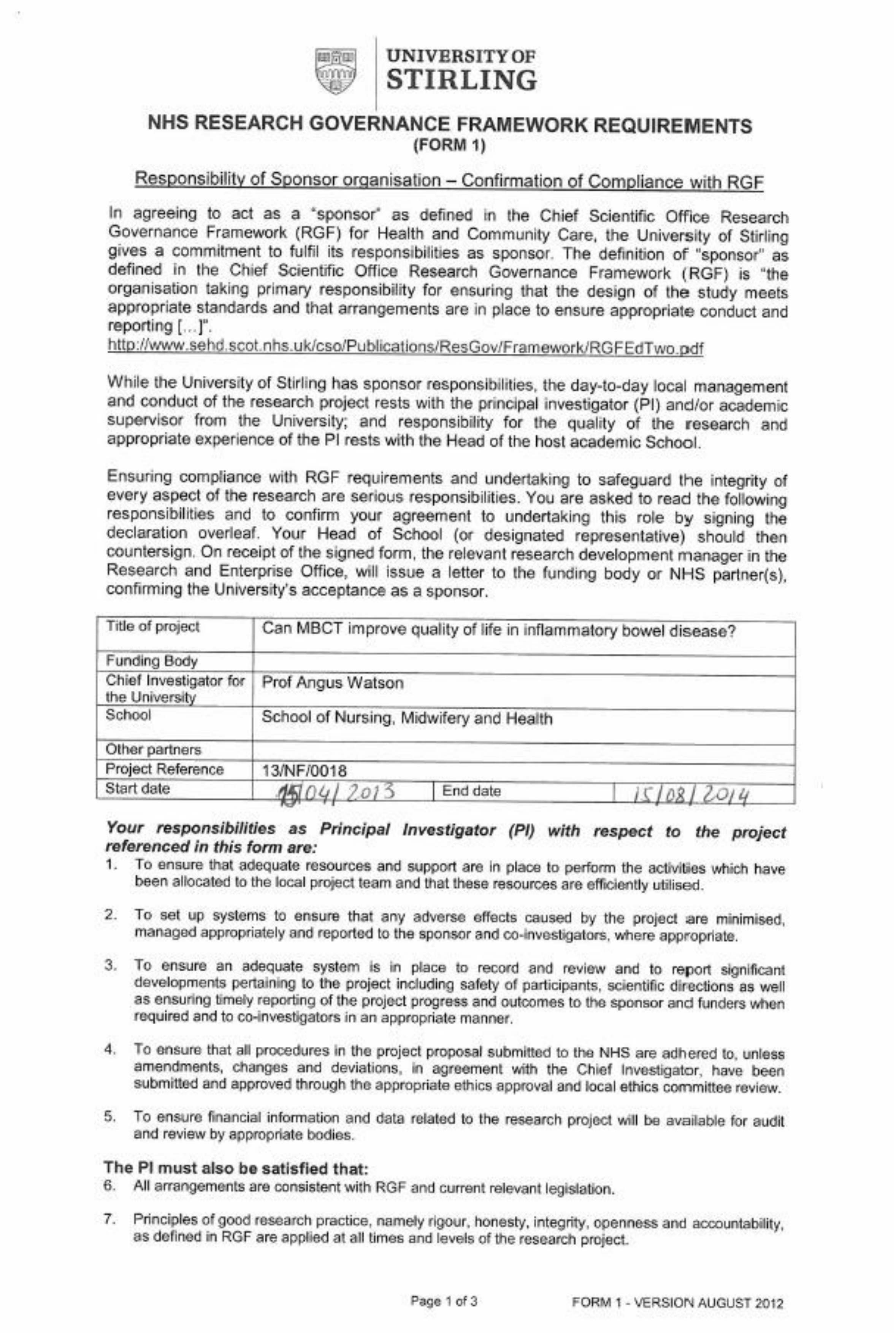
The North of Scotland Ethics Committee has reviewed this study. The project has also been reviewed and approved by service users, who will continue to advise us on the running of all parts of the study.

CONTACT FOR FURTHER INFORMATION

If you have any concerns or other questions about this study or the way it has been carried out, please contact a member of the research team:

Mariyana Schoultz	**Prof Angus Watson**
Researcher (CI)	Academic Supervisor
014632557647	014632557612

Appendix 7: Sponsor and Indemnity



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NHS RESEARCH GOVERNANCE FRAMEWORK REQUIREMENTS
(FORM 1)

Responsibility of Sponsor organisation – Confirmation of Compliance with RGF

In agreeing to act as a "sponsor" as defined in the Chief Scientific Office Research Governance Framework (RGF) for Health and Community Care, the University of Stirling gives a commitment to fulfil its responsibilities as sponsor. The definition of "sponsor" as defined in the Chief Scientific Office Research Governance Framework (RGF) is "the organisation taking primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting [...]".
http://www.sehd.scot.nhs.uk/cso/Publications/ResGov/Framework/RGFEdTwo.pdf

While the University of Stirling has sponsor responsibilities, the day-to-day local management and conduct of the research project rests with the principal investigator (PI) and/or academic supervisor from the University; and responsibility for the quality of the research and appropriate experience of the PI rests with the Head of the host academic School.

Ensuring compliance with RGF requirements and undertaking to safeguard the integrity of every aspect of the research are serious responsibilities. You are asked to read the following responsibilities and to confirm your agreement to undertaking this role by signing the declaration overleaf. Your Head of School (or designated representative) should then countersign. On receipt of the signed form, the relevant research development manager in the Research and Enterprise Office, will issue a letter to the funding body or NHS partner(s), confirming the University's acceptance as a sponsor.

Title of project	Can MBCT improve quality of life in inflammatory bowel disease?		
Funding Body			
Chief Investigator for the University	Prof Angus Watson		
School	School of Nursing, Midwifery and Health		
Other partners			
Project Reference	13/NF/0018		
Start date	15/04/2013	End date	15/08/2014

Your responsibilities as Principal Investigator (PI) with respect to the project referenced in this form are:

1. To ensure that adequate resources and support are in place to perform the activities which have been allocated to the local project team and that these resources are efficiently utilised.

2. To set up systems to ensure that any adverse effects caused by the project are minimised, managed appropriately and reported to the sponsor and co-investigators, where appropriate.

3. To ensure an adequate system is in place to record and review and to report significant developments pertaining to the project including safety of participants, scientific directions as well as ensuring timely reporting of the project progress and outcomes to the sponsor and funders when required and to co-investigators in an appropriate manner.

4. To ensure that all procedures in the project proposal submitted to the NHS are adhered to, unless amendments, changes and deviations, in agreement with the Chief Investigator, have been submitted and approved through the appropriate ethics approval and local ethics committee review.

5. To ensure financial information and data related to the research project will be available for audit and review by appropriate bodies.

The PI must also be satisfied that:

6. All arrangements are consistent with RGF and current relevant legislation.

7. Principles of good research practice, namely rigour, honesty, integrity, openness and accountability, as defined in RGF are applied at all times and levels of the research project.

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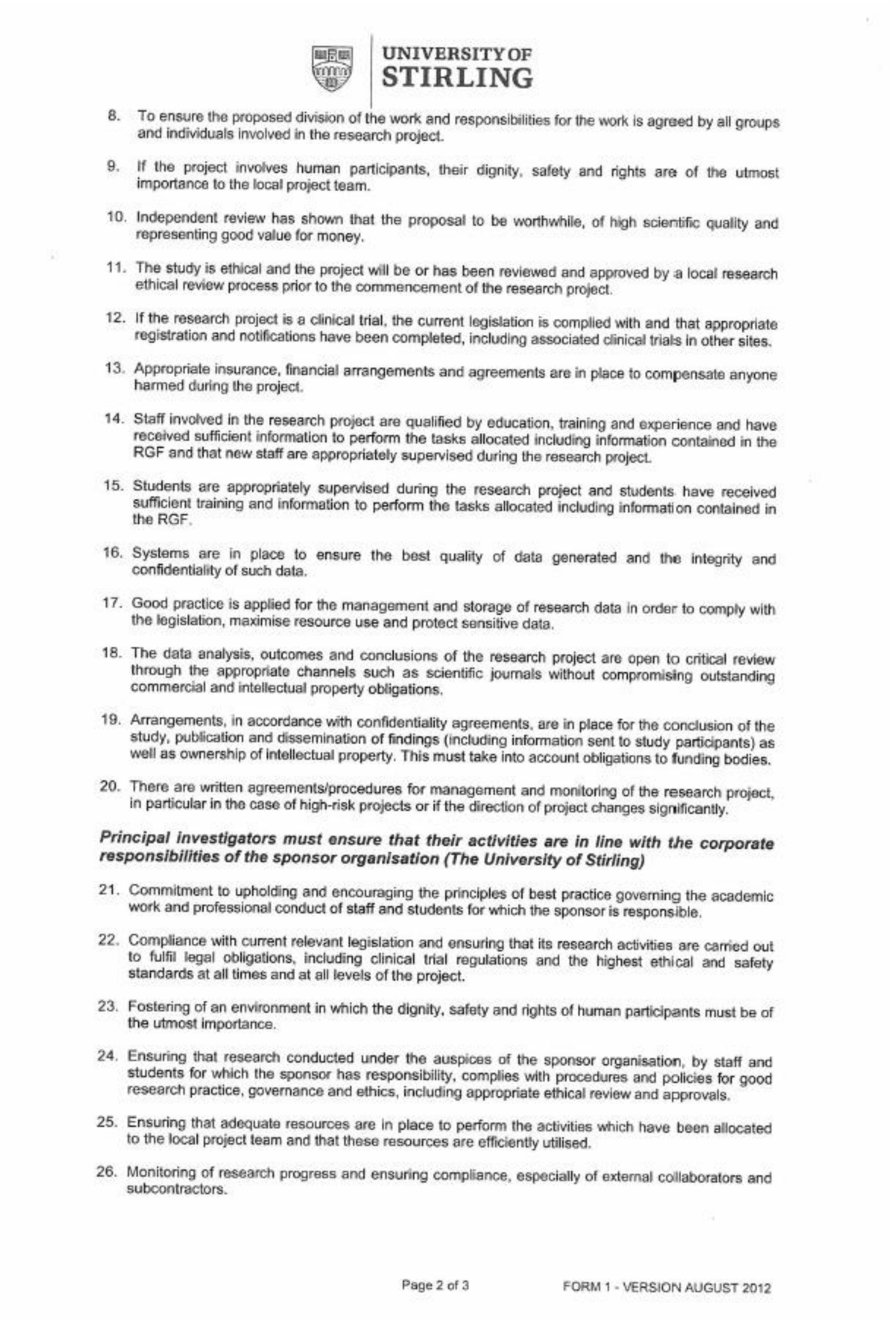


8. To ensure the proposed division of the work and responsibilities for the work is agreed by all groups and individuals involved in the research project.

9. If the project involves human participants, their dignity, safety and rights are of the utmost importance to the local project team.

10. Independent review has shown that the proposal to be worthwhile, of high scientific quality and representing good value for money.

11. The study is ethical and the project will be or has been reviewed and approved by a local research ethical review process prior to the commencement of the research project.

12. If the research project is a clinical trial, the current legislation is complied with and that appropriate registration and notifications have been completed, including associated clinical trials in other sites.

13. Appropriate insurance, financial arrangements and agreements are in place to compensate anyone harmed during the project.

14. Staff involved in the research project are qualified by education, training and experience and have received sufficient information to perform the tasks allocated including information contained in the RGF and that new staff are appropriately supervised during the research project.

15. Students are appropriately supervised during the research project and students have received sufficient training and information to perform the tasks allocated including information contained in the RGF.

16. Systems are in place to ensure the best quality of data generated and the integrity and confidentiality of such data.

17. Good practice is applied for the management and storage of research data in order to comply with the legislation, maximise resource use and protect sensitive data.

18. The data analysis, outcomes and conclusions of the research project are open to critical review through the appropriate channels such as scientific journals without compromising outstanding commercial and intellectual property obligations.

19. Arrangements, in accordance with confidentiality agreements, are in place for the conclusion of the study, publication and dissemination of findings (including information sent to study participants) as well as ownership of intellectual property. This must take into account obligations to funding bodies.

20. There are written agreements/procedures for management and monitoring of the research project, in particular in the case of high-risk projects or if the direction of project changes significantly.

Principal investigators must ensure that their activities are in line with the corporate responsibilities of the sponsor organisation (The University of Stirling)

21. Commitment to upholding and encouraging the principles of best practice governing the academic work and professional conduct of staff and students for which the sponsor is responsible.

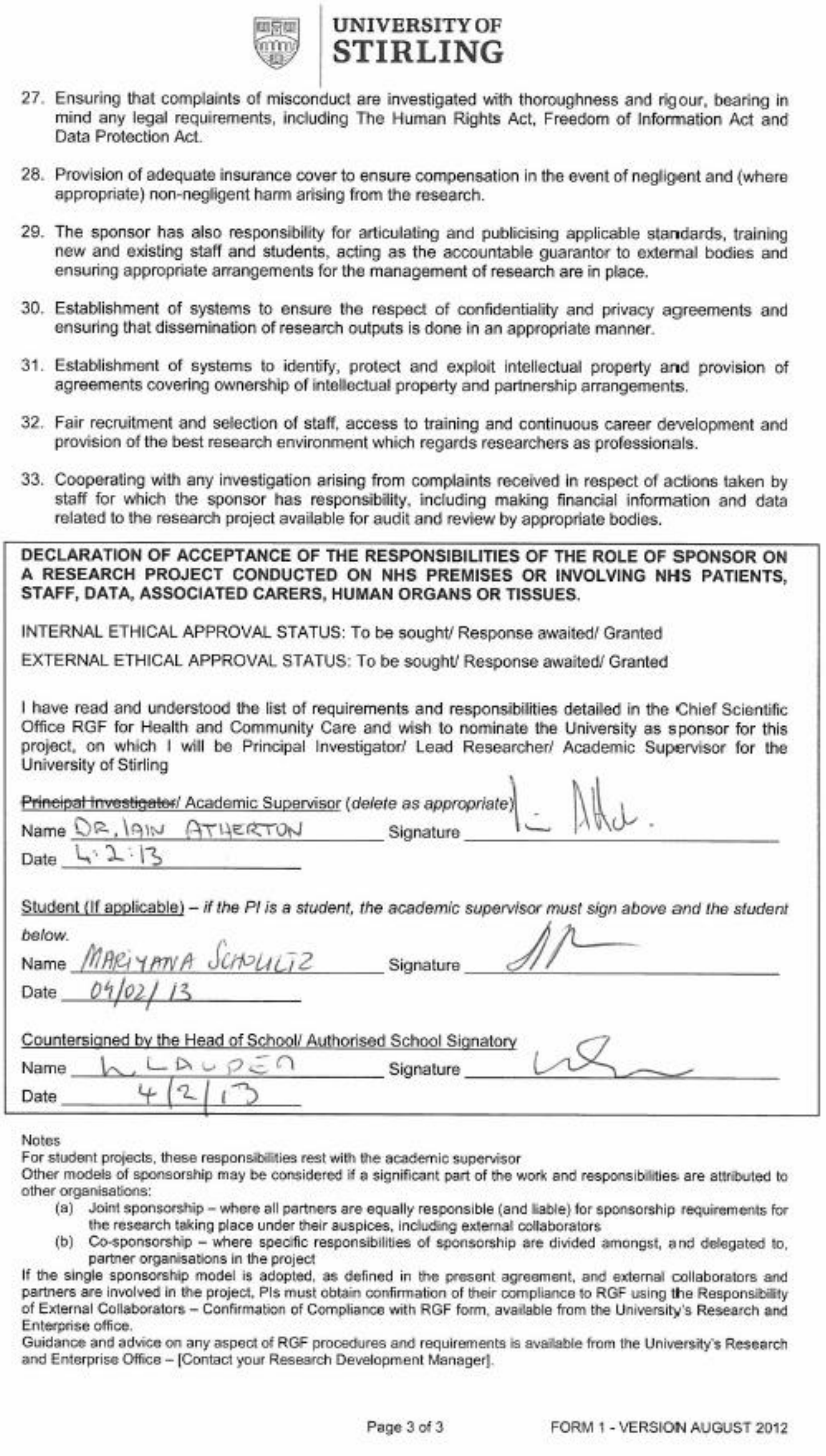
22. Compliance with current relevant legislation and ensuring that its research activities are carried out to fulfil legal obligations, including clinical trial regulations and the highest ethical and safety standards at all times and at all levels of the project.

23. Fostering of an environment in which the dignity, safety and rights of human participants must be of the utmost importance.

24. Ensuring that research conducted under the auspices of the sponsor organisation, by staff and students for which the sponsor has responsibility, complies with procedures and policies for good research practice, governance and ethics, including appropriate ethical review and approvals.

25. Ensuring that adequate resources are in place to perform the activities which have been allocated to the local project team and that these resources are efficiently utilised.

26. Monitoring of research progress and ensuring compliance, especially of external collaborators and subcontractors.



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27. Ensuring that complaints of misconduct are investigated with thoroughness and rigour, bearing in mind any legal requirements, including The Human Rights Act, Freedom of Information Act and Data Protection Act.

28. Provision of adequate insurance cover to ensure compensation in the event of negligent and (where appropriate) non-negligent harm arising from the research.

29. The sponsor has also responsibility for articulating and publicising applicable standards, training new and existing staff and students, acting as the accountable guarantor to external bodies and ensuring appropriate arrangements for the management of research are in place.

30. Establishment of systems to ensure the respect of confidentiality and privacy agreements and ensuring that dissemination of research outputs is done in an appropriate manner.

31. Establishment of systems to identify, protect and exploit intellectual property and provision of agreements covering ownership of intellectual property and partnership arrangements.

32. Fair recruitment and selection of staff, access to training and continuous career development and provision of the best research environment which regards researchers as professionals.

33. Cooperating with any investigation arising from complaints received in respect of actions taken by staff for which the sponsor has responsibility, including making financial information and data related to the research project available for audit and review by appropriate bodies.

DECLARATION OF ACCEPTANCE OF THE RESPONSIBILITIES OF THE ROLE OF SPONSOR ON A RESEARCH PROJECT CONDUCTED ON NHS PREMISES OR INVOLVING NHS PATIENTS, STAFF, DATA, ASSOCIATED CARERS, HUMAN ORGANS OR TISSUES.

INTERNAL ETHICAL APPROVAL STATUS: To be sought/ Response awaited/ Granted

EXTERNAL ETHICAL APPROVAL STATUS: To be sought/ Response awaited/ Granted

I have read and understood the list of requirements and responsibilities detailed in the Chief Scientific Office RGF for Health and Community Care and wish to nominate the University as sponsor for this project, on which I will be Principal Investigator/ Lead Researcher/ Academic Supervisor for the University of Stirling

~~Principal Investigator~~/ Academic Supervisor (*delete as appropriate*)
Name DR. IAIN ATHERTON Signature
Date 4·2·13

Student (If applicable) – *if the PI is a student, the academic supervisor must sign above and the student below.*
Name MARIYANA SCHOULTZ Signature
Date 04/02/13

Countersigned by the Head of School/ Authorised School Signatory
Name W. LAUDER Signature
Date 4/2/13

Notes
For student projects, these responsibilities rest with the academic supervisor
Other models of sponsorship may be considered if a significant part of the work and responsibilities are attributed to other organisations:
- (a) Joint sponsorship – where all partners are equally responsible (and liable) for sponsorship requirements for the research taking place under their auspices, including external collaborators
- (b) Co-sponsorship – where specific responsibilities of sponsorship are divided amongst, and delegated to, partner organisations in the project

If the single sponsorship model is adopted, as defined in the present agreement, and external collaborators and partners are involved in the project, PIs must obtain confirmation of their compliance to RGF using the Responsibility of External Collaborators – Confirmation of Compliance with RGF form, available from the University's Research and Enterprise office.
Guidance and advice on any aspect of RGF procedures and requirements is available from the University's Research and Enterprise Office – [Contact your Research Development Manager].

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Sponsor letter

UNIVERSITY OF
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STIRLING FK9 4LA SCOTLAND

Carol Johnstone
Business Development Manager
RESEARCH & ENTERPRISE OFFICE
Tel: 01786 466690
Fax: 01786 466688
E-mail: carol.johnstone@stir.ac.uk

17 June 2013

To Whom It May Concern:

Research Study: Can MBCT improve quality of life in inflammatory bowel disease

I am pleased to confirm that the University of Stirling will undertake the role of sponsor as outlined in the Research Governance Framework for Health and Community Care for the project entitled "Can MBCT improve quality of life in inflammatory bowel disease", Chief Investigator Mrs Mariyana Schoultz, School of Nursing, Midwifery and Health, University of Stirling.

The study was initially planned to be single centred but the Chief Investigator is submitting an amendment to make it multi centred to maximise recruitment and I hereby confirm that the University of Stirling is happy to proceed as sponsor on that basis.

Yours sincerely

Carol Johnstone

Carol Johnstone
Research Development Manager

UNIVERSITY OF
STIRLING

STIRLING FK9 4LA SCOTLAND

Carol Johnstone
Business Development Manager
RESEARCH & ENTERPRISE OFFICE
Tel: 01786 466690
Fax: 01786 466688
E-mail: carol.johnstone@stir.ac.uk

9 April 2013

To Whom It May Concern:

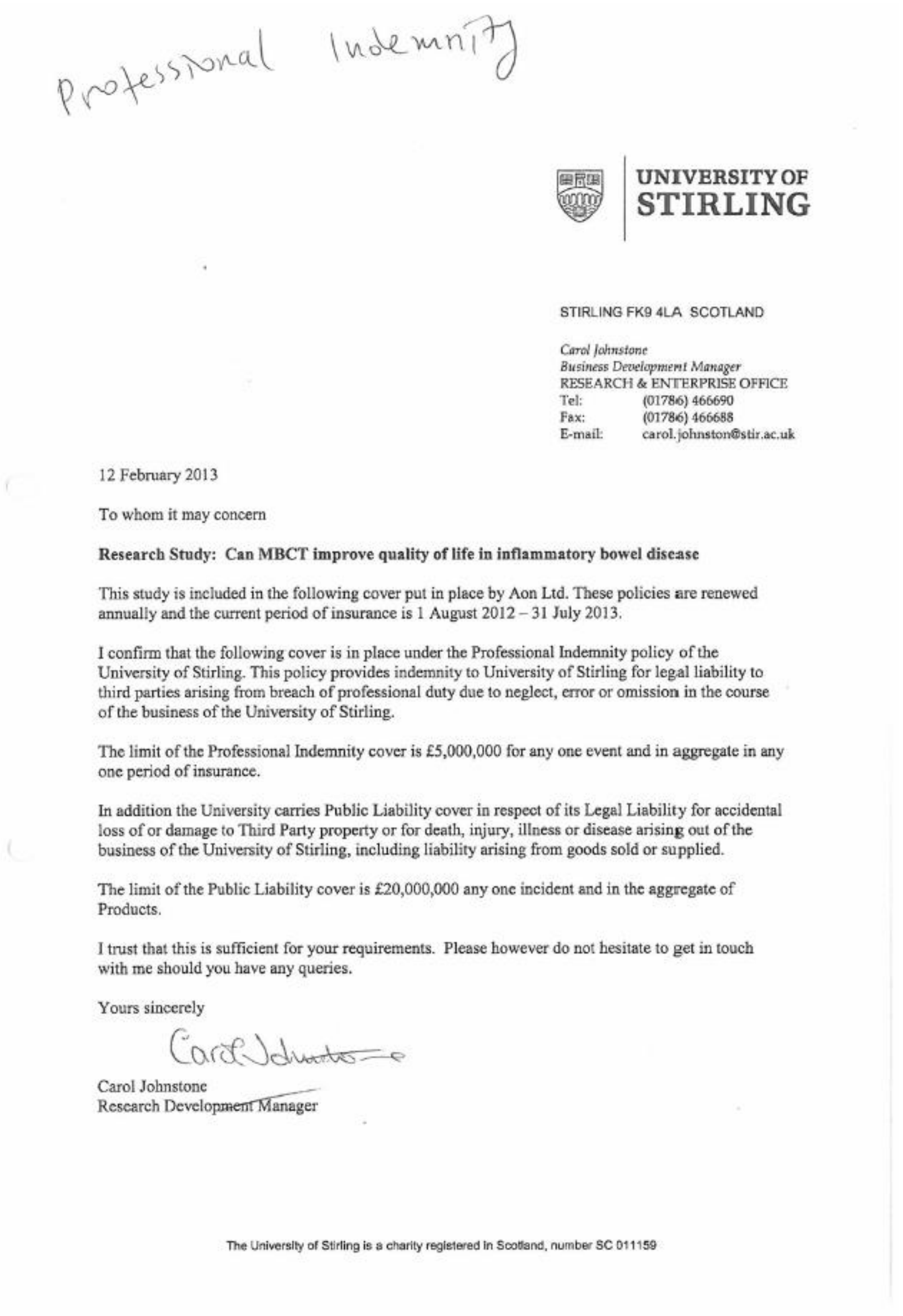
Research Study: Can MBCT improve quality of life in inflammatory bowel disease

I am pleased to confirm that the University of Stirling will undertake the role of sponsor as outlined in the Research Governance Framework for Health and Community Care for the project entitled "Can MBCT improve quality of life in inflammatory bowel disease", Chief Investigator Mrs Mariyana Schoultz, School of Nursing, Midwifery and Health, University of Stirling.

Yours sincerely

Carol Johnstone

Carol Johnstone
Research Development Manager



Professional Indemnity

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STIRLING FK9 4LA SCOTLAND

Carol Johnstone
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12 February 2013

To whom it may concern

Research Study: Can MBCT improve quality of life in inflammatory bowel disease

This study is included in the following cover put in place by Aon Ltd. These policies are renewed annually and the current period of insurance is 1 August 2012 – 31 July 2013.

I confirm that the following cover is in place under the Professional Indemnity policy of the University of Stirling. This policy provides indemnity to University of Stirling for legal liability to third parties arising from breach of professional duty due to neglect, error or omission in the course of the business of the University of Stirling.

The limit of the Professional Indemnity cover is £5,000,000 for any one event and in aggregate in any one period of insurance.

In addition the University carries Public Liability cover in respect of its Legal Liability for accidental loss of or damage to Third Party property or for death, injury, illness or disease arising out of the business of the University of Stirling, including liability arising from goods sold or supplied.

The limit of the Public Liability cover is £20,000,000 any one incident and in the aggregate of Products.

I trust that this is sufficient for your requirements. Please however do not hesitate to get in touch with me should you have any queries.

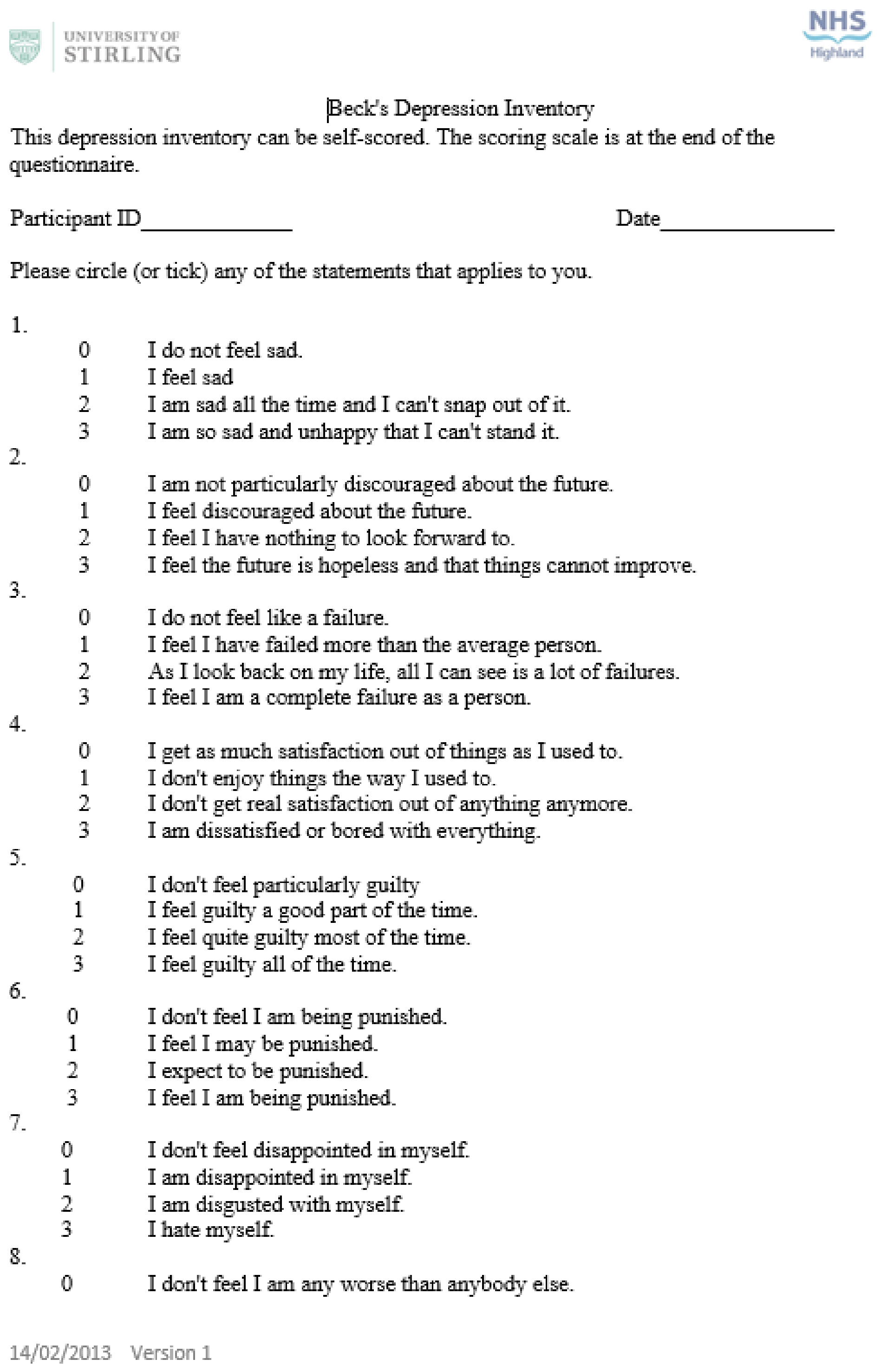
Yours sincerely

Carol Johnstone

Carol Johnstone
Research Development Manager

The University of Stirling is a charity registered in Scotland, number SC 011159

Appendix 8: Questionnaires



Beck's Depression Inventory

This depression inventory can be self-scored. The scoring scale is at the end of the questionnaire.

Participant ID_____________ Date_______________

Please circle (or tick) any of the statements that applies to you.

1.		
	0	I do not feel sad.
	1	I feel sad
	2	I am sad all the time and I can't snap out of it.
	3	I am so sad and unhappy that I can't stand it.
2.		
	0	I am not particularly discouraged about the future.
	1	I feel discouraged about the future.
	2	I feel I have nothing to look forward to.
	3	I feel the future is hopeless and that things cannot improve.
3.		
	0	I do not feel like a failure.
	1	I feel I have failed more than the average person.
	2	As I look back on my life, all I can see is a lot of failures.
	3	I feel I am a complete failure as a person.
4.		
	0	I get as much satisfaction out of things as I used to.
	1	I don't enjoy things the way I used to.
	2	I don't get real satisfaction out of anything anymore.
	3	I am dissatisfied or bored with everything.
5.		
	0	I don't feel particularly guilty
	1	I feel guilty a good part of the time.
	2	I feel quite guilty most of the time.
	3	I feel guilty all of the time.
6.		
	0	I don't feel I am being punished.
	1	I feel I may be punished.
	2	I expect to be punished.
	3	I feel I am being punished.
7.		
	0	I don't feel disappointed in myself.
	1	I am disappointed in myself.
	2	I am disgusted with myself.
	3	I hate myself.
8.		
	0	I don't feel I am any worse than anybody else.

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1 I am critical of myself for my weaknesses or mistakes.
2 I blame myself all the time for my faults.
3 I blame myself for everything bad that happens.

9.
0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.
10.
0 I don't cry any more than usual.
1 I cry more now than I used to.
2 I cry all the time now.
3 I used to be able to cry, but now I can't cry even though I want to.
11.
0 I am no more irritated by things than I ever was.
1 I am slightly more irritated now than usual.
2 I am quite annoyed or irritated a good deal of the time.
3 I feel irritated all the time.
12.
0 I have not lost interest in other people.
1 I am less interested in other people than I used to be.
2 I have lost most of my interest in other people.
3 I have lost all of my interest in other people.
13.
0 I make decisions about as well as I ever could.
1 I put off making decisions more than I used to.
2 I have greater difficulty in making decisions more than I used to.
3 I can't make decisions at all anymore.
14.
0 I don't feel that I look any worse than I used to.
1 I am worried that I am looking old or unattractive.
2 I feel there are permanent changes in my appearance that make me look unattractive
3 I believe that I look ugly.
15.
0 I can work about as well as before.
1 It takes an extra effort to get started at doing something.
2 I have to push myself very hard to do anything.
3 I can't do any work at all.
16.
0 I can sleep as well as usual.
1 I don't sleep as well as I used to.

2	I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
3	I wake up several hours earlier than I used to and cannot get back to sleep.

17.

0	I don't get more tired than usual.
1	I get tired more easily than I used to.
2	I get tired from doing almost anything.
3	I am too tired to do anything.

18.

0	My appetite is no worse than usual.
1	My appetite is not as good as it used to be.
2	My appetite is much worse now.
3	I have no appetite at all anymore.

19.

0	I haven't lost much weight, if any, lately.
1	I have lost more than five pounds.
2	I have lost more than ten pounds.
3	I have lost more than fifteen pounds.

20.

0	I am no more worried about my health than usual.
1	I am worried about physical problems like aches, pains, upset stomach, or constipation.
2	I am very worried about physical problems and it's hard to think of much else.
3	I am so worried about my physical problems that I cannot think of anything else.

21.

0	I have not noticed any recent change in my interest in sex.
1	I am less interested in sex than I used to be.
2	I have almost no interest in sex.
3	I have lost interest in sex completely.

Crohn's Disease Activity Index (CDAI)

Participant ID______________ Date________________

1. Please enter the number of liquid or soft stools each day for the last seven days

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

---

2. For any abdominal pain in the last week, please enter the severity of the pain (0=no pain, 1=mild, 2=moderate, 3=severe) for each day

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

---

3. Please tell us how was your general wellbeing in the last week, subjectively assessed from 0 (being well) 1=slightly below par, 2=poor, 3=very poor, 4=terrible) for each day

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

---

4. Please tell us if you had any of these complications in the last week. Add one tick at each set of complications if present within last week:

- the presence of joint pains (arthralgia) or frank arthritis
- inflammation of the iris or uveitis
- presence of erythema nodosum, pyoderma gangrenosum, or aphthous ulcers
- anal fissures, fistulae or abscesses
- other fistulae
- fever during the previous week.

---

5. Please tell us if you have been taking any medications for diarrhoea in the last week (circle one)

No Yes

---

6. Please tell us if you had presence of an abdominal mass in the last week (circle one)

None
Questionable
Present

7.Please tell us if you know your current Hematocrit level and if you are male or female

Haematocrit level
Male
Female
----

8. Please tell us you current weight and your standard weight if you know

Current weight
Standard weight

Demographic information

The next few questions will give us some basic information about who took part in the study. We will not use your answers to identify you. Please tick one box like this ☑ with a ball point pen. If you change your mind just cross out your old response and make a new choice. Please answer every statement.

1. Are you:

☐ Female

☐ Male

2. Age: ☐

3. What is the highest level of education you have completed?

☐ High School

☐ Diploma

☐ Degree

☐ Masters

☐ Doctoral/MD

4. Your household income:

☐ less than £10,000

☐ £10,000-£19,999

☐ £20,000-£29,999

☐ £30,000-£39,999

☐ £40,000-50,000

☐ over £50,000

5. Marital status:

☐ Single

☐ Married/cohabiting

☐ Separated/divorced

☐ Widowed

Thank you for your time.

The UK Inflammatory Bowel Disease Questionnaire

Patient Identification Number: Date:

The following questions ask about your bowel problem and how it affected your life over the last two weeks. Please tick **ONE** answer for each of the questions. If you are unsure about how to answer any question, just give the best answer you can. Do not spend too much time answering, as your first thoughts are likely to be most accurate.

1	**On how many days over the last two weeks have you had loose or runny bowel movements?**		
	a.	None	
	b.	On one or two days only	
	c.	On three to seven days	
	d.	On eight to fourteen days (ie more than every other day)	
2	**On how many days over the last two weeks have you felt tired?**		
	a.	None	
	b.	On one or two days only	
	c.	On three to seven days	
	d.	On eight to fourteen days (ie more than every other day)	
3	**In the last two weeks have you felt frustrated?**		
	a.	No, not at all	
	b.	Yes, some of the time	
	c.	Yes, most of the time	
	d.	Yes, all of the time	
4	**In the last two weeks, has your bowel condition prevented you from carrying out your work or other normal activities?**		
	a.	No, not at all	
	b.	Yes, for one or two days	
	c.	Yes, for three to seven days	
	d.	Yes, for eight to fourteen days (ie more than every other day)	

5	**On how many days over the last two weeks have you opened your bowels more than *three* times a day?**		
	a.	None	
	b.	On one or two days only	
	c.	On three to seven days	
	d.	On eight to fourteen days (ie more than every other day)	

6	**On how many days over the last two weeks have you felt full of energy?**		
	a.	None	
	b.	On one or two days only	
	c.	On three to seven days	
	d.	On eight to fourteen days (ie more than every other day)	
7	**In the last two weeks have you been worried about being admitted to hospital because of your bowel problem?**		
	a.	No, not at all	
	b.	Yes, some of the time	
	c.	Yes, most of the time	
	d.	Yes, all of the time	
8	**In the last two weeks did your bowel condition prevent you from going out socially?**		
	a.	No, not at all	
	b.	Yes, some of the time	
	c.	Yes, most of the time	
	d.	Yes, all of the time	
	e.	Does not apply to me	
9	**On how many days over the last two weeks have your bowels opened accidentally?**		
	a.	None	
	b.	On one or two days only	
	c.	On three to seven days	
	d.	On eight to fourteen days (ie more than every other day)	
10	**On how many days over the last two weeks have you felt generally unwell?**		
	a.	None	
	b.	On one or two days only	
	c.	On three to seven days	
	d.	On eight to fourteen days (ie more than every other day)	

11	**In the last two weeks have you felt the need to keep close to a toilet?**		
	a.	No, not at all	
	b.	Yes, some of the time	
	c.	Yes, most of the time	
	d.	Yes, all of the time	
12	**In the last two weeks, has your bowel condition affected your leisure or sports activities?**		
	a.	No, not at all	
	b.	Yes, some of the time	
	c.	Yes, most of the time	
	d.	Yes, all of the time	
	e.	Does not apply to me	
13	**On how many days over the last two weeks have you felt pain in your abdomen?**		
	a.	None	
	b.	On one or two days only	

	c.	On three to seven days	
	d.	On eight to fourteen days (ie more than every other day)	
14	**On how many nights over the last two weeks have you been unable to sleep well (days if you are a shift worker)?**		
	a.	None	
	b.	On one or two nights only	
	c.	On three to seven nights	
	d.	On eight to fourteen nights (ie more than every other night)	
15	**In the last two weeks have you felt depressed?**		
	a.	No, not at all	
	b.	Yes, some of the time	
	c.	Yes, most of the time	
	d.	Yes, all of the time	
16	**In the last two weeks have you had to avoid attending events where there was no toilet close at hand?**		
	a.	No, not at all	
	b.	Yes, some of the time	
	c.	Yes, most of the time	
	d.	Yes, all of the time	
17	**On how many days over the last two weeks have you had a problem with large amounts of wind?**		
	a.	None	
	b.	On one or two nights only	
	c.	On three to seven nights	
	d.	On eight to fourteen nights (ie more than every other night)	
18	**On how many days over the last two weeks have you felt off your food?**		
	a.	None	
	b.	On one or two days only	
	c.	On three to seven days	
	d.	On eight to fourteen days (ie more than every other day)	
19	**Many patients with bowel problems have worries about their illness. How often during the last two weeks have you felt worried?**		
	a.	No, not at all	
	b.	Yes, some of the time	
	c.	Yes, most of the time	
	d.	Yes, all of the time	
20	**On how many days over the last two weeks has your abdomen felt bloated?**		
	a.	None	
	b.	On one or two days only	
	c.	On three to seven days	
	d.	On eight to fourteen days (ie more than every other day)	
21	**In the last two weeks have you felt relaxed?**		
	a.	No, not at all	
	b.	Yes, some of the time	
	c.	Yes, most of the time	
	d.	Yes, all of the time	

22	**On how many days over the last two weeks have you noticed blood with your bowel movement?**		
	a.	None	
	b.	On one or two days only	
	c.	On three to seven days	
	d.	On eight to fourteen days (ie more than every other day)	

23	**In the last two weeks have you been embarrassed by your bowel problem?**		
	a.	No, not at all	
	b.	Yes, some of the time	
	c.	Yes, most of the time	
	d.	Yes, all of the time	
24	**On how many days over the last two weeks have you wanted to go back to the toilet immediately after you thought you had emptied your bowels?**		
	a.	None	
	b.	On one or two days only	
	c.	On three to seven days	
	d.	On eight to fourteen days (ie more than every other day)	
25	**In the last two weeks have you felt upset?**		
	a.	No, not at all	
	b.	Yes, some of the time	
	c.	Yes, most of the time	
	d.	Yes, all of the time	
26	**On how many days over the last two weeks have you had to rush to the toilet?**		
	a.	None	
	b.	On one or two days only	
	c.	On three to seven days	
	d.	On eight to fourteen days (ie more than every other day)	
27	**In the last two weeks have you felt angry as a result of your bowel problem?**		
	a.	No, not at all	
	b.	Yes, some of the time	
	c.	Yes, most of the time	

	d.	Yes, all of the time	
28	**In the last two weeks has your sex life been affected by your bowel problem?**		
	a.	No, not at all	
	b.	Yes, some of the time	
	c.	Yes, most of the time	
	d.	Yes, all of the time	
	e.	Does not apply to me	

29	**On how many days over the last two weeks have you felt sick?**		
	a.	None	
	b.	On one or two days only	
	c.	On three to seven days	
	d.	On eight to fourteen days (ie more than every other day)	
30	**In the last two weeks have you felt irritable?**		
	a.	No, not at all	
	b.	Yes, some of the time	
	c.	Yes, most of the time	
	d.	Yes, all of the time	
31	**In the last two weeks have you felt lack of sympathy from others?**		
	a.	No, not at all	
	b.	Yes, some of the time	
	c.	Yes, most of the time	
	d.	Yes, all of the time	
32	**In the last two weeks have you felt happy?**		
	a.	No, not at all	
	b.	Yes, some of the time	
	c.	Yes, most of the time	
	d.	Yes, all of the time	

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Day-to-Day Experiences

Instructions: Below is a collection of statements about your everyday experience. Using the 1-6 scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what *really reflects* your experience rather than what you think your experience should be. Please treat each item separately from every other item.

1	2	3	4	5	6
Almost Always	Very Frequently	Somewhat Frequently	Somewhat Infrequently	Very Infrequently	Almost Never

I could be experiencing some emotion and not be conscious of it until sometime later.	1	2	3	4	5	6
I break or spill things because of carelessness, not paying attention, or thinking of something else.	1	2	3	4	5	6
I find it difficult to stay focused on what's happening in the present.	1	2	3	4	5	6
I tend to walk quickly to get where I'm going without paying attention to what I experience along the way.	1	2	3	4	5	6
I tend not to notice feelings of physical tension or discomfort until they really grab my attention.	1	2	3	4	5	6
I forget a person's name almost as soon as I've been told it for the first time.	1	2	3	4	5	6
It seems I am "running on automatic," without much awareness of what I'm doing.	1	2	3	4	5	6
I rush through activities without being really attentive to them.	1	2	3	4	5	6
I get so focused on the goal I want to achieve that I lose touch with what I'm doing right now to get there.	1	2	3	4	5	6
I do jobs or tasks automatically, without being aware of what I'm doing.	1	2	3	4	5	6
I find myself listening to someone with one ear, doing something else at the same time.	1	2	3	4	5	6

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1	2	3	4	5	6
Almost Always	Very Frequently	Somewhat Frequently	Somewhat Infrequently	Very Infrequently	Almost Never

I drive places on ‘automatic pilot’ and then wonder why I went there.	1	2	3	4	5	6
I find myself preoccupied with the future or the past.	1	2	3	4	5	6
I find myself doing things without paying attention.	1	2	3	4	5	6
I snack without being aware that I’m eating.	1	2	3	4	5	6

Simple Clinical Colitis Activity Index

Participant ID __________ Date__________

We would like to find out if you had any of the following symptoms in the last week. Please tick where it applies to you.

Symptom	Please tick	Score
Bowel frequency (day)		
1—3		0
4--6		1
7--9		2
>9		3
Bowel frequency (night)		
1—3		1
4--6		2
Urgency of defecation		
Hurry		1
Immediately		2
Incontinence		3
Blood in stool		
Trace		1
Occasionally frank		2
Usually frank		3
General well being		
Very well		0
Slightly below par		1
Poor		2
Very poor		3
Terrible		4
Extra colonic features (tick all that applies to you): arthritis pyoderma gangrenosum erythema nodosum and uveitis		1 per manifestation

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Can a group self-help program called Mindfulness Based Cognitive Therapy improve the quality of life for Inflammatory Bowel Disease patients? Process evaluation survey.

1. **Did you have any expectations regarding the self-help program?**

Yes (please go to question 2)

No (please go to question 4)

Comment box

2. **If yes, what were they?**

3. **Were your expectations met/unmet in any way? And How?**

4. **Was the length of eight weeks for the program acceptable?**

I would have preferred longer (up to 12 weeks)

I would have preferred shorter (less than 8 weeks)

It was just right

5. **Did you find the program difficult to follow?**

Yes (please go to question 6)

No (please go to question 7)

6. **Please tell us which specific parts of the program you found difficult to follow.**

7. **Do you think this program has brought any benefit to you?**

Yes (please go to question 8)

No (please go to question 9)

Comment box

8. **Please tell us how you think the program benefited you.**

9. **Do you think you will continue to use some of the techniques you learned in the program?**

Yes

No

Comment box

10. **Do you think the process of recruitment was acceptable?**

Yes

No

Comment box

11. **Do you think the patient information sheet was easy to understand?**

Yes

No

Suggestions to make it clearer to understand

Did you feel comfortable with the process of consent and randomisation?

Yes

No

Comment box

12. **Was filling the questionnaires at the start and at the end of the eight weeks too much of a burden?**

Yes (go to question 14)

No (go to question 15)

Comment box

13. **Can you please tell us what difficulties you came across with the questionnaires and perhaps any suggestions of how to overcome those difficulties**

14. **Were there any barriers to attending the program?**

Yes (please go to question 16)

No (please go to question 17)

15. **Can you please tell us what you think were barriers to attendance?**

16. **Did you enjoy the program?**

Yes (please go to question 18)

No (please go to question 19)

Comment box

17. Which parts did you most enjoy?

18. **Do you think this program should be made available to IBD patients thought NHS ?**

Yes

No

Comment box

19. **Any other comment or suggestions you want to add.**

Thank you for your time.

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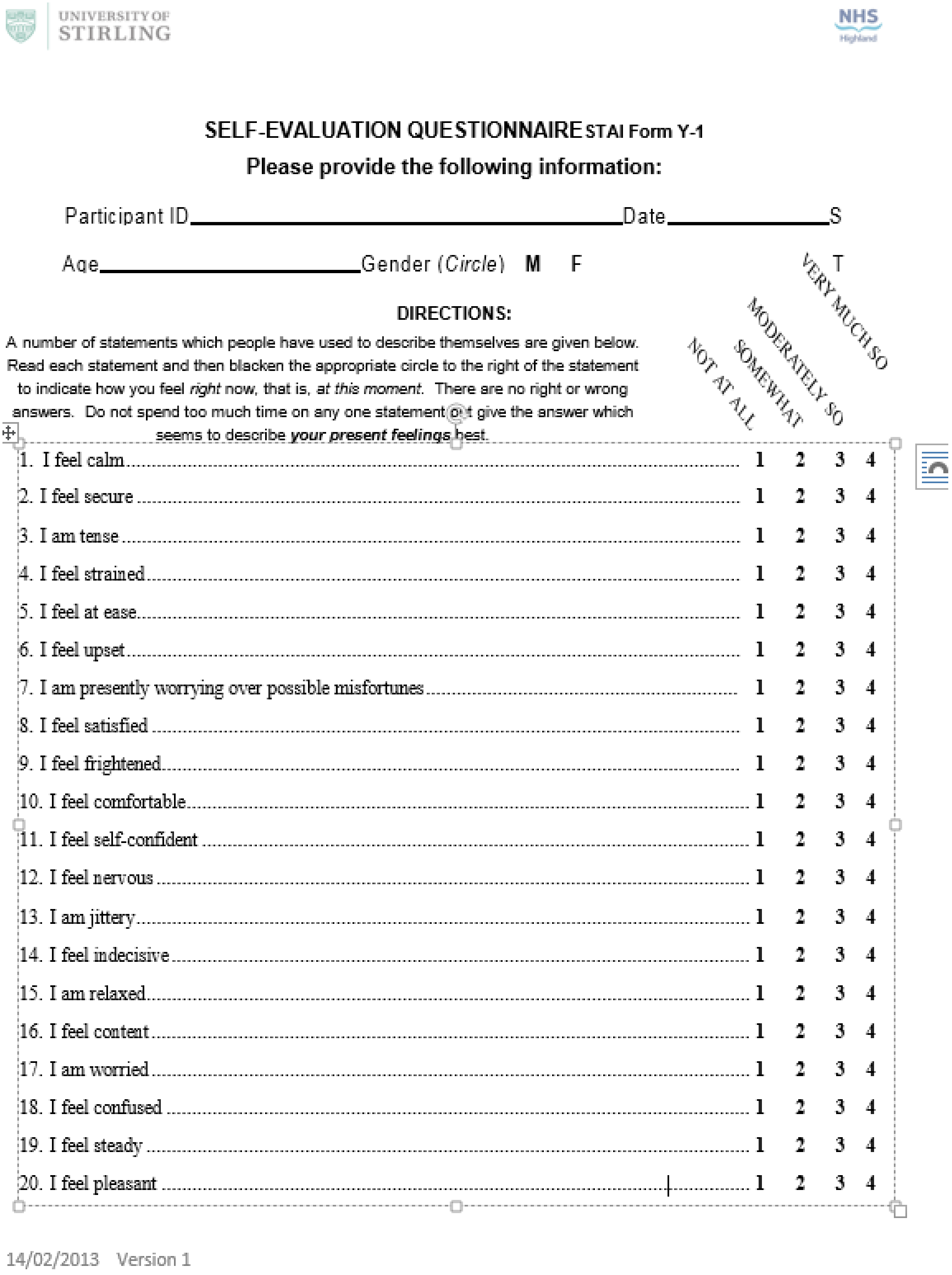

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SELF-EVALUATION QUESTIONNAIRE STAI Form Y-1

Please provide the following information:

Participant ID________________________Date__________S

Age______________Gender (*Circle*) **M** F T

DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then blacken the appropriate circle to the right of the statement to indicate how you feel *right* now, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe ***your present feelings*** best.

	NOT AT ALL	SOMEWHAT	MODERATELY SO	VERY MUCH SO
1. I feel calm	1	2	3	4
2. I feel secure	1	2	3	4
3. I am tense	1	2	3	4
4. I feel strained	1	2	3	4
5. I feel at ease	1	2	3	4
6. I feel upset	1	2	3	4
7. I am presently worrying over possible misfortunes	1	2	3	4
8. I feel satisfied	1	2	3	4
9. I feel frightened	1	2	3	4
10. I feel comfortable	1	2	3	4
11. I feel self-confident	1	2	3	4
12. I feel nervous	1	2	3	4
13. I am jittery	1	2	3	4
14. I feel indecisive	1	2	3	4
15. I am relaxed	1	2	3	4
16. I feel content	1	2	3	4
17. I am worried	1	2	3	4
18. I feel confused	1	2	3	4
19. I feel steady	1	2	3	4
20. I feel pleasant	1	2	3	4

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SELF-EVALUATION QUESTIONNAIRE

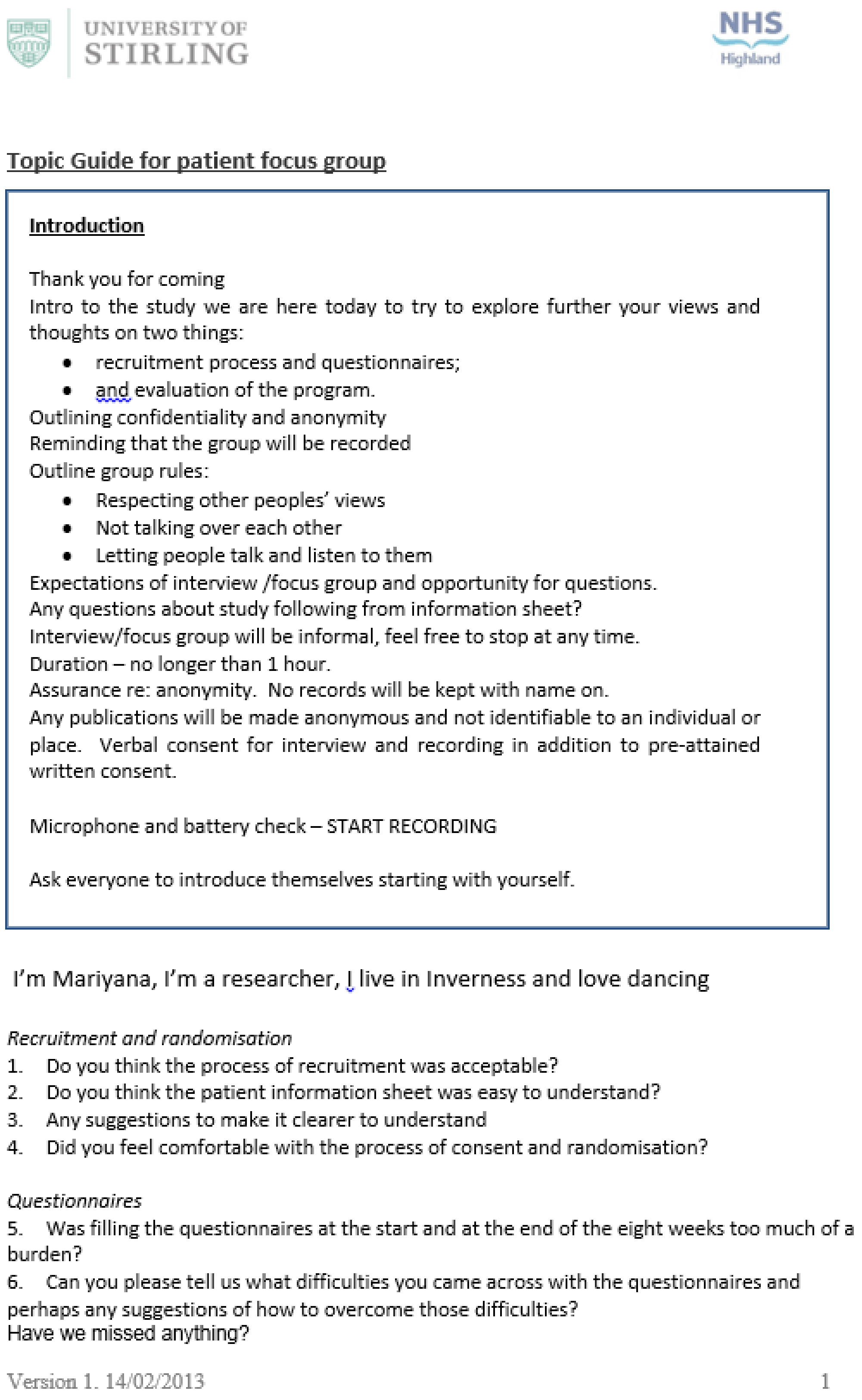
STAI Form Y-2

Participant ID_ ________Date

DIRECTIONS

A number of statements which people have used to describe themselves are given below. Read each statement and then blacken in the appropriate circle to the right of the statement to indicate you ***generally*** feel.

	ALMOST NEVER	SOMETIMES	OFTEN	ALMOST ALWAYS
21. I feel pleasant	1	2	3	4
22. I feel nervous and restless	1	2	3	4
23. I feel satisfied with myself	1	2	3	4
24. I wish I could be as happy as others seem to be	1	2	3	4
25. I feel like a failure	1	2	3	4
26. I feel rested	1	2	3	4
27. I am "calm, cool, and collected"	1	2	3	4
28. I feel that difficulties are piling up so that I cannot overcome them	1	2	3	4
29. I worry too much over something that really doesn't matter	1	2	3	4
30. I am happy	1	2	3	4
31. I have disturbing thoughts	1	2	3	4
32. I lack self-confidence	1	2	3	4
33. I feel secure	1	2	3	4
34. I make decisions easily	1	2	3	4
35. I feel inadequate	1	2	3	4
36. I am content	1	2	3	4
37. Some unimportant thought runs through my mind and bothers me	1	2	3	4
38. I take disappointments so keenly that I can't put them out of my mind	1	2	3	4
39. I am a steady person	1	2	3	4
40. I get in a state of tension or turmoil as I think over my recent concerns and interests	1	2	3	4



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NHS Highland

Topic Guide for patient focus group

Introduction

Thank you for coming
Intro to the study we are here today to try to explore further your views and thoughts on two things:

- recruitment process and questionnaires;
- and evaluation of the program.

Outlining confidentiality and anonymity
Reminding that the group will be recorded
Outline group rules:

- Respecting other peoples' views
- Not talking over each other
- Letting people talk and listen to them

Expectations of interview /focus group and opportunity for questions.
Any questions about study following from information sheet?
Interview/focus group will be informal, feel free to stop at any time.
Duration – no longer than 1 hour.
Assurance re: anonymity. No records will be kept with name on.
Any publications will be made anonymous and not identifiable to an individual or place. Verbal consent for interview and recording in addition to pre-attained written consent.

Microphone and battery check – START RECORDING

Ask everyone to introduce themselves starting with yourself.

I'm Mariyana, I'm a researcher, I live in Inverness and love dancing

Recruitment and randomisation

1. Do you think the process of recruitment was acceptable?
2. Do you think the patient information sheet was easy to understand?
3. Any suggestions to make it clearer to understand
4. Did you feel comfortable with the process of consent and randomisation?

Questionnaires

5. Was filling the questionnaires at the start and at the end of the eight weeks too much of a burden?
6. Can you please tell us what difficulties you came across with the questionnaires and perhaps any suggestions of how to overcome those difficulties?

Have we missed anything?

Expectations

1. Did you have any expectations regarding the self-help program?
2. If yes, what were they?
3. Were your expectations met/ unmet in any way? And How?

Length and difficulty of program

4. Was the length of eight weeks for the program acceptable?
5. Did you find the program difficult to follow?
6. Please tell us which specific parts of the program you found difficult to follow.

Potential benefits

7. Do you think this program has brought any benefit to you?
8. Please tell us how you think the program benefited you.
9. Do you think you will continue to use some of the techniques you learned in the program?

Barriers to attending

10. Were there any barriers to attending the program?
11. Can you please tell us what you think were barriers to attendance?

What did you enjoy?

12. Did you enjoy the program?
13. Which parts did you most enjoy?

Availability of MBCT program

14. Do you think this program should be made available to IBD patients throught NHS ?

Do you want to start monthly meetings? For an hour once a month in the evening? Same place
Does anyone want to do a silent day full of practice?
Any thoughts on the leaflet?

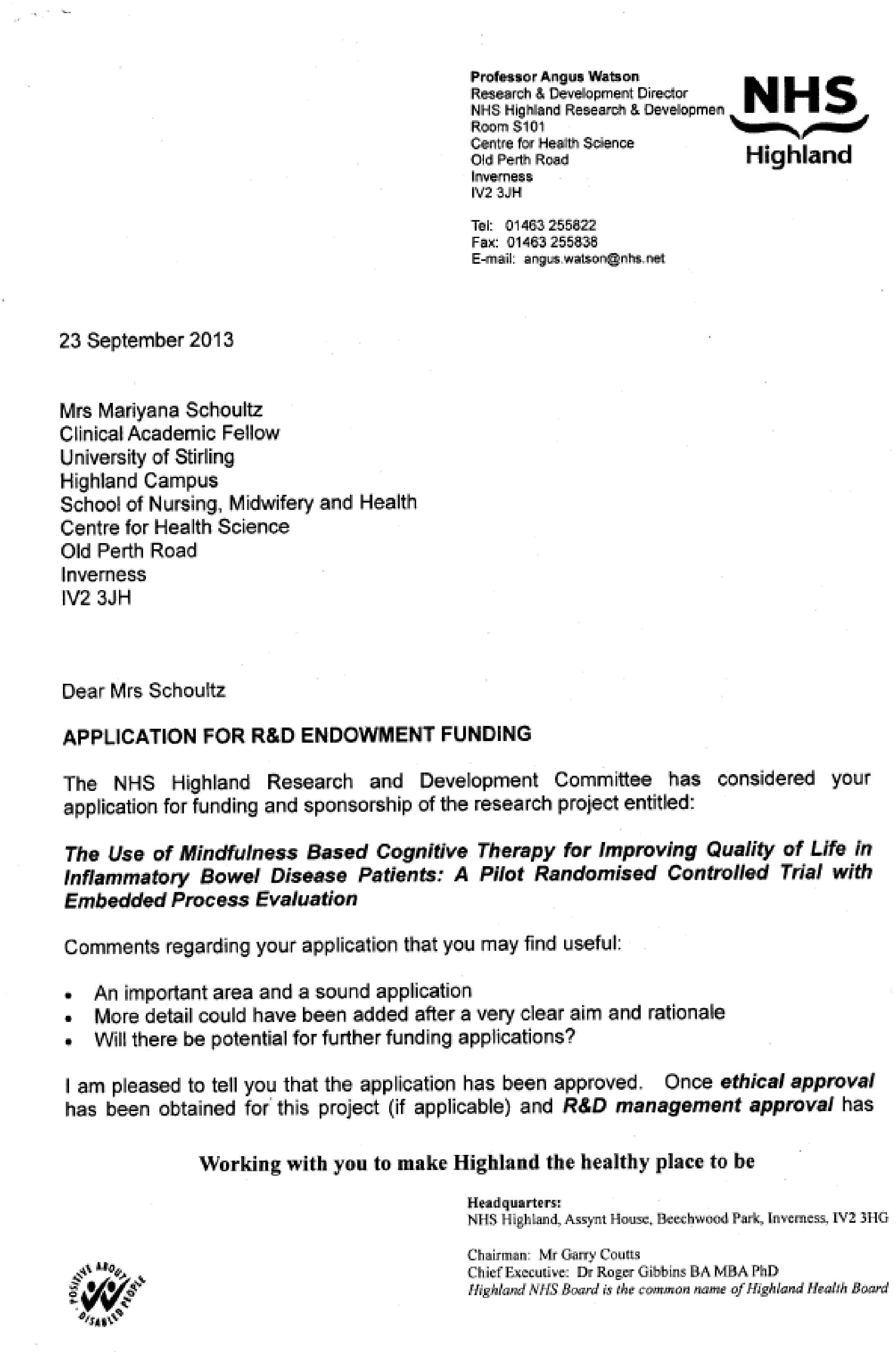
Closing interview remarks/questions

Is there anything else you would like to bring up?

Have you all filled in and given me the expenses sheets?
Thank you very much for your time

Is there anything you would like to ask about the study or the way that your comments will be included?

Appendix 9: Funding



Professor Angus Watson
Research & Development Director
NHS Highland Research & Developmen
Room S101
Centre for Health Science
Old Perth Road
Inverness
IV2 3JH

Tel: 01463 255822
Fax: 01463 255836
E-mail: angus.watson@nhs.net

23 September 2013

Mrs Mariyana Schoultz
Clinical Academic Fellow
University of Stirling
Highland Campus
School of Nursing, Midwifery and Health
Centre for Health Science
Old Perth Road
Inverness
IV2 3JH

Dear Mrs Schoultz

APPLICATION FOR R&D ENDOWMENT FUNDING

The NHS Highland Research and Development Committee has considered your application for funding and sponsorship of the research project entitled:

The Use of Mindfulness Based Cognitive Therapy for Improving Quality of Life in Inflammatory Bowel Disease Patients: A Pilot Randomised Controlled Trial with Embedded Process Evaluation

Comments regarding your application that you may find useful:

- An important area and a sound application
- More detail could have been added after a very clear aim and rationale
- Will there be potential for further funding applications?

I am pleased to tell you that the application has been approved. Once ***ethical approval*** has been obtained for this project (if applicable) and ***R&D management approval*** has

Working with you to make Highland the healthy place to be

Headquarters:
NHS Highland, Assynt House, Beechwood Park, Inverness, IV2 3HG

Chairman: Mr Garry Coutts
Chief Executive: Dr Roger Gibbins BA MBA PhD
Highland NHS Board is the common name of Highland Health Board

also been obtained from the NHS Highland R&D Office (if applicable), a ***Management Approval*** letter will be issued and your project can begin on receipt of that approval. If neither of these is applicable, then your study can start on receipt of THIS letter.

The sum of **£3000** will be then available for you to use as described in Section 6 of your proposal.

The Committee will expect a quarterly update on your progress. You will be alerted to each update submission date a month before it is due. In addition, the Committee expects that you will commit to a number of agreed outputs, as detailed in the form below. If you are agreeable to these outputs please sign and return a copy to Frances Hines, R&D Manager, retaining a copy for your records. If you wish to discuss these outputs please contact Frances at your earliest convenience.

Please direct all enquiries regarding this letter to the NHS Highland Research & Development Manager at the address below or by telephone (01463 255822).

Yours sincerely

Professor Angus Watson
Chair of the Research and Development Committee and NHS Highland R&D Director

cc Frances Hines, R&D Manager, Room S101 Centre for Health Science, Old Perth Road, Inverness, IV2 3JH

Craig Riddle, R&D Accountant, Finance, Management Corridor, Raigmore Hospital, Inverness, IV2 3UJ

Funding

crohn's and
colitis
UK
NACC
Inform
Support
Research

Crohn's and Colitis UK (NACC)
4 Beaumont House,
Sutton Road, St. Albans,
Herts. AL1 5HH

Administration: t. 01727 830038
f. 01727 862550
Information line: 0845 130 2233
enquiries@crohnsandcolitis.org.uk
www.crohnsandcolitis.org.uk

13 December 2013

Mariyana Schoultz
Clinical Academic Fellow
University of Stirling
Highland Campus
School of Nursing, Midwifery and Health
Inverness IV2 3JH

Dear Mrs Schoultz,

Please find enclosed two copies of the agreement for the project entitled:

The use of Mindfulness based cognitive therapy (MBCT) for improving quality of life for inflammatory bowel disease patients: A protocol for pilot randomised controlled trial with embedded process evaluation.

As you requested, the start date of the grant is 1st November 2013.

Please could you get both copies signed, keep one for your department and send the other back to Elina Bloomfield in due course.

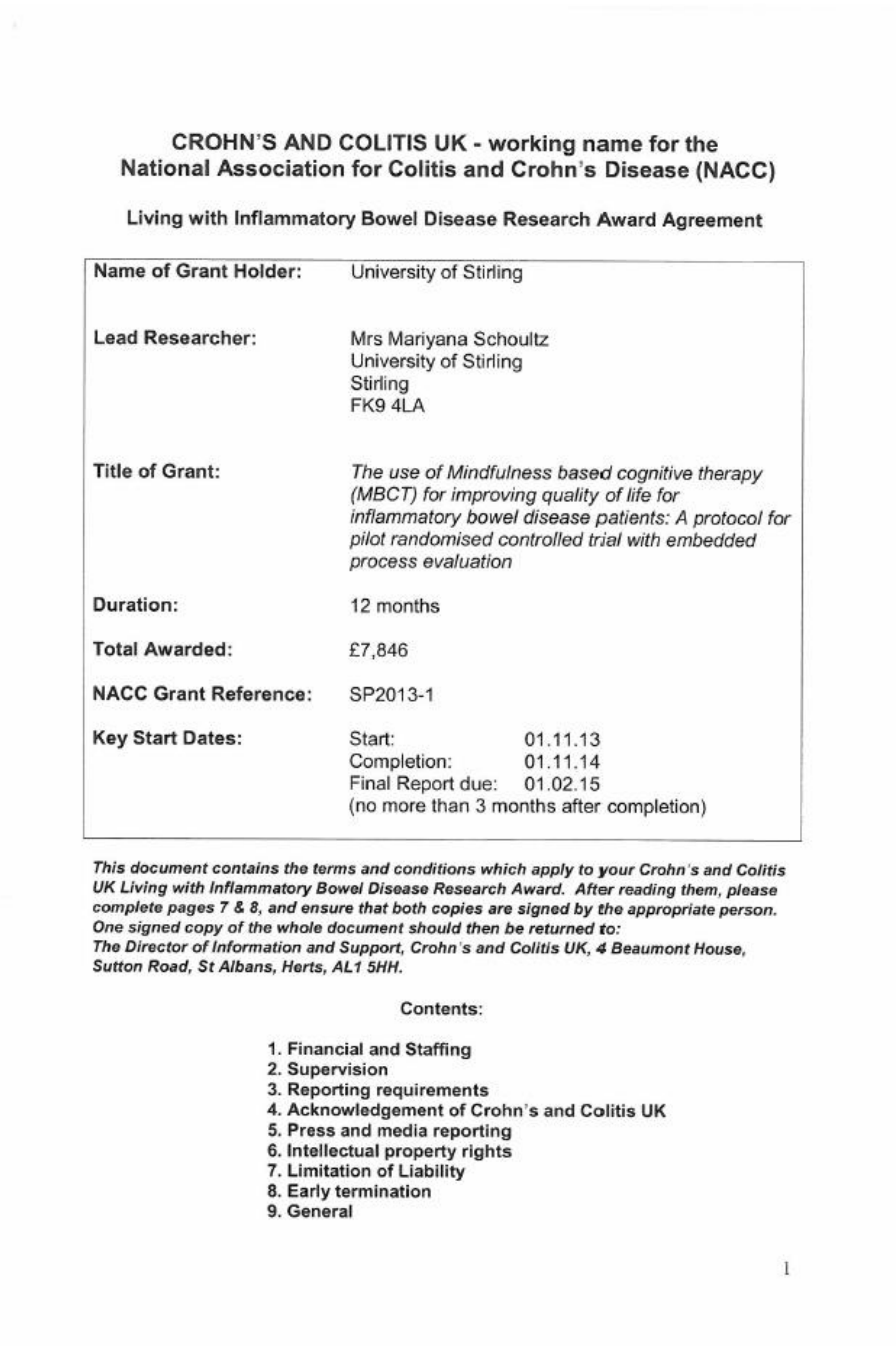
Kindest regards,

Helen Terry
Director of Information and Support
Crohn's and Colitis UK

.OTTERY FUNDED
BIG LOTTERY FUND

David Barker, Chief Executive Keith Stewart, Chairman
Crohn's and Colitis UK is the working name for
The National Association for Colitis and Crohn's Disease (NACC)
Charity registered in England and Wales No. 1117148 and in Scotland No. SC038632
A company limited by guarantee in England: Company number: 5973370

The Information Standard
Certified member



CROHN'S AND COLITIS UK - working name for the National Association for Colitis and Crohn's Disease (NACC)

Living with Inflammatory Bowel Disease Research Award Agreement

Name of Grant Holder:	University of Stirling
Lead Researcher:	Mrs Mariyana Schoultz University of Stirling Stirling FK9 4LA
Title of Grant:	*The use of Mindfulness based cognitive therapy (MBCT) for improving quality of life for inflammatory bowel disease patients: A protocol for pilot randomised controlled trial with embedded process evaluation*
Duration:	12 months
Total Awarded:	£7,846
NACC Grant Reference:	SP2013-1
Key Start Dates:	Start: 01.11.13 Completion: 01.11.14 Final Report due: 01.02.15 (no more than 3 months after completion)

This document contains the terms and conditions which apply to your Crohn's and Colitis UK Living with Inflammatory Bowel Disease Research Award. After reading them, please complete pages 7 & 8, and ensure that both copies are signed by the appropriate person. One signed copy of the whole document should then be returned to:

The Director of Information and Support, Crohn's and Colitis UK, 4 Beaumont House, Sutton Road, St Albans, Herts, AL1 5HH.

Contents:

1. FINANCIAL AND STAFFING

1.1 Crohn's and Colitis UK awards the above grant to the Grant Holder to undertake the specific project approved by the Crohn's and Colitis UK Living with Inflammatory Bowel Disease Research Awards Panel. Grants may not be expended for any other purpose. If during the course of a project, it appears that further work would deviate substantially from the original proposal, Crohn's and Colitis UK's approval must be sought by the Grant Holder prior to this further work being started.

1.2 Crohn's and Colitis UK Living with Inflammatory Bowel Disease research grants are for a fixed period and for a fixed sum of money based on the costings given in the original application. Crohn's and Colitis UK will not agree to meet increased costs arising from price or salary rises partway through a grant. Any requests for extensions of funding for an additional year must be submitted to the annual meeting of the Awards Panel where they will be considered in conjunction with new applications. An application must be submitted on the application form available from the Crohn's and Colitis UK office, before the closing date for that year. Any additional year's funding may be managed by Crohn's and Colitis UK as a separate grant.

1.3 Any unspent grant - arising, for example, from a lower salary being paid than was estimated in the application - will revert to the Crohn's and Colitis UK Research Fund at the end of the agreed grant period.

1.4 Subject to paragraphs 3.2 and 3.5 Crohn's and Colitis UK grants are paid quarterly in arrears, although a different arrangement may be agreed if the grant includes payment for an item of equipment.

1.5 Grant cheques are issued only on receipt of an invoice from the Grant Holder. Invoices should be addressed to the Director of Finance, Crohn's and Colitis UK, 4 Beaumont House, Sutton Road, St Albans, Herts, AL1 5HH and **must quote the Crohn's and Colitis grant reference number (stated on page 1) and the time period to which they apply. Invoices that do not quote these Crohn's and Colitis UK details cannot be paid.**

1.6 The research project should start within one year of the date of this agreement. If there are exceptional reasons why this is not possible, an explanation must be submitted to Crohn's and Colitis UK for the consideration of the Living with Inflammatory Bowel Disease Research Awards Panel. Their decision whether or not to revoke the award will be final.

1.7 The research will be under the supervision of the Lead Researcher. If the Lead Researcher becomes unable or unwilling to continue the research and Crohn's and Colitis UK and the Grant Holder, acting reasonably, cannot agree on a substitute within 30 days after receiving notice that the

Lead Researcher is unable or unwilling to continue the research, each of the parties shall be entitled to terminate this agreement by giving 90 days' notice in writing to the other. Crohn's and Colitis UK will not be responsible in any way for the employment contracts of staff working on the research projects it is funding. Any unexpected costs arising (e.g. maternity leave payments, sickness benefit, unfair dismissal costs etc) must be borne by the Grant Holder.

1.8 The Grant Holder will be responsible for ensuring that any appropriate staffing quota approvals are obtained before employing senior research fellows. Crohn's and Colitis UK does not have access to any quota for such appointments.

2. SUPERVISION

2.1 The Grant Holder will supervise the research project in accordance with its policy (copy attached as an appendix to this agreement) or such policy as shall apply for the time being.

2.2 If a case of fraud is suspected in the course of the research, then Crohn's and Colitis UK should be notified and kept informed of further developments by the Grant Holder. At the initial stages of the Grant Holder's enquiry Crohn's and Colitis UK would not normally suspend the grant. However, if in Crohn's and Colitis UK's reasonable opinion adequate steps are not taken to proceed with the investigation Crohn's and Colitis UK will suspend the grant. If fraud is proven Crohn's and Colitis UK will terminate the grant immediately and will consider a claim against the Grant Holder for Crohn's and Colitis UK funds so lost.

3. REPORTING REQUIREMENTS

3.1 The Grant Holder is required to submit two reports for the research project:
Report to the Trustees of Crohn's and Colitis UK
Report to Crohn's and Colitis UK Members
Final reports should be received at Crohn's and Colitis UK no later than three months after the date agreed with Crohn's and Colitis UK for the completion of the project.

3.2 Where a project extends over a period longer than one year, an interim report to the Trustees of Crohn's and Colitis UK must be submitted by the end of the thirteenth month after the date agreed with Crohn's and Colitis UK as the start of the project. A member of the Living with Inflammatory Bowel Research Awards Panel will be asked to review the interim report within one month of its receipt and advise the Crohn's and Colitis UK Trustees whether progress seems satisfactory.

The first instalment of the second year of the award will not be paid until this review has taken place.

3.3. **The Report to the Trustees of Crohn's and Colitis UK** is to be the substantive report of the work carried out and will cover in the following order:

For the first year report of a two-year project:

- An assessment of progress so far, any difficulties identified or anticipated and any matters which the Grant Holder feels should be brought to the attention of the Awards Panel.

For the final report of a one or two-year project:

- The aims and methodology of the project, any changes to these in the course of the project, the research findings, the significance of the findings, whether the results suggest further research should be undertaken and a statement of how the results will be disseminated. We would also appreciate any recommendations that you would like to make to Crohn's and Colitis UK as a result of the research.

3.4. **The Report to Crohn's and Colitis UK Members** will be a simple explanation **in not more than 500 words** of the aims of the research, the results obtained and any conclusions that can be drawn.

3.5. Crohn's and Colitis UK reserves the right to withhold up to 10% of the grant until the final report has been received.

3.6. The Grant Holder will send copies of any subsequent publications arising from the project to Crohn's and Colitis UK within 8 weeks of publication.

3.7. Crohn's and Colitis UK may wish to report to its members the outcome of research that it is funding. This will normally be through its newsletters which are published quarterly and Crohn's and Colitis UK may wish to place part or all of the reports received on its web-site.

3.8. In line with Crohn's and Colitis UK's charitable objectives to disseminate the results of research, Crohn's and Colitis UK reserves the right to use the information from research it has funded to promote public or professional awareness of the research.

4. ACKNOWLEDGEMENT OF CROHN'S AND COLITIS UK

The Grant Holder will give appropriate acknowledgement of Crohn's and Colitis UK in any publication or presentation of research findings.

5. PRESS AND MEDIA REPORTING

The Grant Holder will notify the Director of Information and Support of Crohn's and Colitis UK at the earliest opportunity if it believes that the research may be mentioned by the press or broadcast media. Any press statement issued by the Grant Holder concerning the research must be approved in advance by Crohn's and Colitis UK.

6. INTELLECTUAL PROPERTY RIGHTS

6.1 Intellectual Property Rights (IPRs) shall mean all patents, copyrights, design rights, trade marks, service marks, trade secrets, know-how and other intellectual property rights (whether registered or not) and all applications of the same.

6.2 The Grant Holder will promptly notify Crohn's and Colitis UK of any IPRs conceived and/or made in the course of the research.

6.3 The Grant Holder will not transfer, assign, exploit or otherwise deal with any such IPRs without the prior written consent of Crohn's and Colitis UK. Any arrangement between the parties to share the receipts of such exploitation shall be recorded in a separate written agreement between the parties.

7. LIMITATION OF LIABILITY

7.1 The Grant Holder accepts full responsibility for the management, monitoring and control of all the research work funded under this grant award and all those staff employed or involved in any research funded under this grant award, including compliance with the requirements of all applicable laws and regulations.

7.2 Crohn's and Colitis UK accepts no responsibility, financially or otherwise, for the expenditure or liabilities arising out of the research work funded under this grant award other than as expressly stated in this agreement.

7.3 Under no circumstances will Crohn's and Colitis UK be liable to the Grant Holder or to any third party in excess of the amount of the grant awarded pursuant to this agreement or for any expenses incurred following the date of termination of this agreement.

7.4 Crohn's and Colitis UK shall not be responsible for any injury to or for the death of any person, or for any loss of or any damage to property of any kind, occasioned by or arising out of the Grant Holder's own negligence or the negligence of any other person employed by the Grant Holder. Crohn's and Colitis UK will not indemnify the Grant Holder against any claim for compensation or against any other claim for which the Grant Holder may be liable.

8. EARLY TERMINATION

8.1 Crohn's and Colitis UK or the Grant Holder may terminate this agreement upon 28 days prior written notice where it considers that the other has committed a fundamental breach of this agreement. Such notice will only be given after full discussion between the parties of the reasons for the proposed early termination.

8.2 Crohn's and Colitis UK may terminate this agreement in writing with immediate effect if in its reasonable opinion it considers that the Grant Holder has committed an act or omission which damages the reputation of Crohn's and Colitis UK.

9. GENERAL

9.1 The Grant Holder shall not assign or otherwise transfer any rights or obligations under this agreement without the prior written agreement of Crohn's and Colitis UK.

9.2 This agreement may only be amended in writing signed by duly authorised representatives of Crohn's and Colitis UK and the Grant Holder.

9.3 This agreement sets out the entire agreement between Crohn's and Colitis UK and the Grant Holder relating to the research project and supercedes all prior oral or written agreements, arrangements or undertakings between relating to the project. Crohn's and Colitis UK and the Grant Holder acknowledge that they are not relying upon any representation, agreement, term or condition which is not set out in this agreement.

DETAILS OF THE GRANT HOLDER

(Please complete these details on BOTH copies)

Grant Holder (Full name): MARIYANA SCHOULTZ

Address: University of Stirling, School of NMH, Old Perth Road, Inverness

Postcode: IV2 3PA JH

Telephone: 01463255647 Fax:

E-mail: m884@stir.ac.uk

We confirm the following key dates for the project:

The start date for the project will be :	**01.11.13**
The completion date for the project will be :	**01.11.14**
The final report will be provided by :	**01.02.15**

We have read and understand the above terms, conditions and notes in respect of the Crohn's and Colitis UK Living with IBD research grant and agree to comply with and be bound by them.

We confirm that supervision of the project has been arranged in accordance with section 2.

Signed for and on behalf of the Grant Holder:

Name: MARIYANA Schoultz

Position: Clinical Academic Fellow

Date: 15/12/13

I confirm that Crohn's and Colitis UK has now allocated the funds agreed for this project and that the research may now proceed.

Signed on behalf of the Crohn's and Colitis UK Trustees:

Name: ______________________

Helen Terry

Director of Information and Support
Crohn's and Colitis UK

Date: 13-12-13.

Appendix 10: MBCT sessions agendas

AGENDA SESSION 1

THEME: AWARENESS AND AUTOMATIC PILOT

1. Establish the orientation of the class
2. Set ground rules regarding confidentiality and privacy
3. Ask participants to pair up and introduce themselves to each other than to the group as a whole, giving their first names and if they wish, saying what they hope to get out of the program
4. The raisin exercise
5. Feedback and discussion of the raisin exercise
6. Body scan practice-starting with short breath focus
7. Feedback and discussion of body scan
8. Home practice assignment:
   - Body scan for 6 out of 7 days
   - Mindfulness of a routine activity
   - Distribute audio files: cd's for those that not have email and session 1 participant hand-outs.
9. Discuss in pairs:
   - Timing for home practice
   - What obstacles may arise
   - How to deal with them
10. End the class with a short 2-3 minute focus on the breath.

Planning and preparation

In addition to your personal preparation before the class, remember to bring a bowl with raisings and a spoon as well as copies of audio files.

AGENDA SESSION 2 THEME: LIVING IN OUR HEADS

1. BODY SCAN PRACTICE
2. Practice review
3. Home practice review-including difficulty with home practice
4. Thoughts and feelings exercise (walking down the street) +triangle of thoughts, emotions and bodily sensations
5. Pleasant experience calendar
6. Ten minute sitting meditation of the breath
7. Distribute session 2 participant handouts
8. Home practice assignment:

- Body scan for 6 out of 7 days
- Ten minutes of mindfulness of the breath
- Pleasant experience calendar (one example daily)
- Mindfulness of a routine activity

9. End the class with a short 5 minute sit.

Planning and preparation

In addition to your personal preparation before the class, remember to bring a flip chart/white board and marker pen for thoughts and feelings exercise

AGENDA SESSION 3 THEME: GATHERING THE SCATTERED MIND

1. 5 minute ‘seeing’ (or hearing) exercise
2. Practice review
3. 30 minutes sitting meditation (awareness of breath and body, how to respond to intense physical sensation
4. Home practice review-(including body scan, mindfulness of the breath, routine activity and pleasant experiences calendar)
5. 3 minute breathing space
6. Practice review
7. Mindful stretching
8. Practice review
9. Setting up Unpleasant experiences calendar practice.
10. Distribute session 3 participant handouts
11. Home practice assignment:

- Mindful movement on days 1, 3 and 5 form CD or from handout
- Body and breath sitting meditation day 2, 4, 6
- Unpleasant experience calendar (different experience each day)
- 3 minutes breathing space 3 times daily

12. End the class with a short 5 minute sit.

Planning and preparation

In addition to your personal preparation before the class, remember to bring exercise handouts

AGENDA SESSION 4 THEME: recognizing aversion

1. 5 minute 'seeing' (or hearing) exercise
2. Practice review
3. 30 -40 minutes sitting meditation (awareness of breath and body, sounds, then thoughts and choiceless awareness (reading a poem wild geese)
4. Practice review
5. Home practice review-(including sitting meditation, movement, unpleasant experiences, 3 minute breathing space)
6. Automatic thoughts questionnaire
7. Practice review
8. 3 minute breathing space
9. Practice review
10. Mindful stretching/walking
11. Practice review
12. Setting up Neutral experiences calendar practice.
13. Distribute session 4 participant handouts.
14. Home practice assignment:

- Sitting meditation Mindful movement on days 1, 3 and 5 form CD or from handout
- 3 minutes breathing space 3 regular
- 3 minute breathing space responsive times daily
- Neutral experiences

15. End the class with a short 5 minute sit.

AGENDA SESSION 5 THEME: ALLOWING/LETTING BE

1. 30 -40 minutes sitting meditation (awareness of breath and body, AWARENESS OF BREATH AND BODY,NOTICING HOW WE RELATE TO OUR EXPERIENCES THROUGH the reactions we have to thoughts, feelings or body sensations; introducing a difficulty (pain or discomfort) within the practice and noting its effects on the body and reactions to it)+ read poem the **Guest house**
2. Practice review
3. Home practice review
4. Discussion approx. 20 min-Cultivating a different relationship to experience of difficulty (read the story about the king with the tree sons? page 269 in the book)
5. 3 minute breathing space with added instructions (poem autobiography in 5 chapters)
6. Practice review
7. Mindful stretching/walking (if time permits)
8. Practice review
9. Distribute session 5 participant handouts.
10. Home practice assignment:

- Working with difficulty meditation on days 1, 3 and 5 from CD, guide yourself through practice on days 2,4and 6 .
- 3 minutes breathing space 3 regular
- 3 minute breathing space responsive times daily

11. End the class with a short 5 minute sit+ poem autobiography in 5 chapters.

AGENDA SESSION 6 THEME: THOUTGHTS ARE NOT FACTS

1. 30 -40 minutes sitting meditation -awareness of breath and body, sounds and thoughts/feelings particularly noticing how we relate to thoughts that arise -poem the Cookie Thief)
2. Practice review
3. Home practice review (includes sitting meditation without recorded guidance and breathing spaces)
4. Mention preparation for end of course
5. Moods, thoughts and alternative viewpoints exercise.
6. Breathing space and review
7. Discuss breathing space as a 'first step' before taking a wider view of
8. Discuss stress triggers
9. Mountain meditation
10. Distribute session 6 participant hand-outs.
11. Home practice assignment:

- Practice with a selection of guided meditations for a minimum of 40 minutes a day
- 3 minutes breathing space 3 regular
- 3 minute breathing space responsive times daily

12. End the class with a short 5 minute sit.

AGENDA SESSION 7 THEME: HOW CAN I BEST TAKE CARE OF MYSELF

1. 30 -40 minutes sitting meditation -awareness of breath and body noticing how we relate to our experiences through the reactions we have to whatever thoughts feelings or body sensations arise, especially when difficulties arise within the practice, noting their effects and reactions to them on the body) poem 'The Summer day '
2. Practice review
3. Home practice
4. Exercise to explore links between activity and mood
5. Plan how to best schedule activities for when mood threatens to overwhelm
    - Rebalancing nourishing and depleting activities
    - Generating list of pleasure and mastery activities
6. 3 minute Breathing space as a 'first step' before choosing whether to take mindful action
7. Identifying actions to deal with threat of relapse/recurrence.
8. 3minute breathing space or mindful walking
9. Distribute session 7 participant handouts.
10. Home practice assignment:

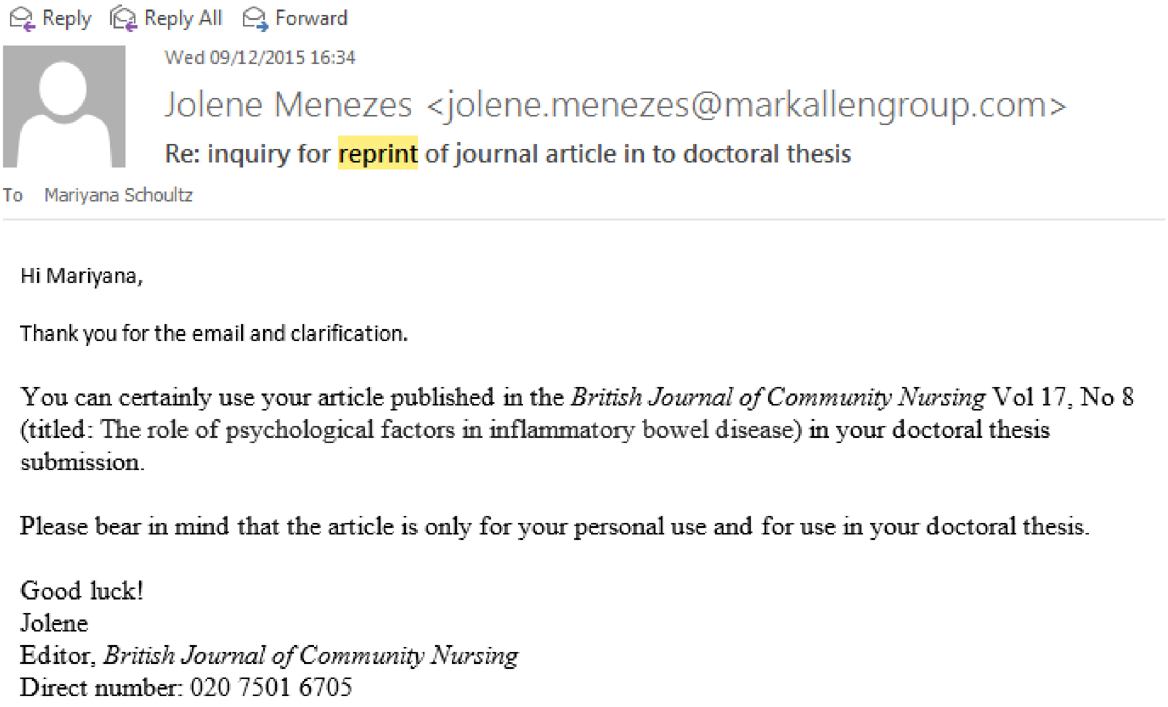
- Select from all the different forms of practice a pattern you intend to use on regular basis
- 3 minutes breathing space 3 regular
- 3 minute breathing space whenever you notice unpleasant feelings
- Develop action plan to be used in the face of lowered moods

11. End the class with a short 5 minute sit.

AGENDA SESSION 8 THEME: PLANNING FOR A NEW WAY OF LIVING

1. BODY SCAN
2. PRACTICE REVIEW
3. Home practice review (including early warnings and stress relapse prevention action plans)
4. Review whole course: what has been learned-in pairs, then in the whole group
5. Give out questionnaire for participants to give personal reflections on the program
6. Discuss how best to keep the momentum developed over the past 7 weeks in both formal and informal practice
7. Check and discuss plans and link them to positive reasons for maintaining the practice.
8. Distribute session 8 participant handouts.
9. End the class with a concluding meditation (marble, stone or bead) or participants wishing each other well.

Appendix 11: Journal licence



Wed 09/12/2015 16:34

Jolene Menezes <jolene.menezes@markallengroup.com>

Re: inquiry for reprint of journal article in to doctoral thesis

To Mariyana Schoultz

Hi Mariyana,

Thank you for the email and clarification.

You can certainly use your article published in the *British Journal of Community Nursing* Vol 17, No 8 (titled: The role of psychological factors in inflammatory bowel disease) in your doctoral thesis submission.

Please bear in mind that the article is only for your personal use and for use in your doctoral thesis.

Good luck!
Jolene
Editor, *British Journal of Community Nursing*
Direct number: 020 7501 6705