

# The Role of Mindfulness in Promoting Subjective Wellbeing and Mood Homeostasis in Patients with Crohn's Disease: A Pilot Randomised Control Trial Protocol

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## ABSTRACT

**Background:** The relationship between stress, symptoms of inflammatory bowel disease (IBD), and depression has not previously been considered using the theory of subjective wellbeing (SWB) homeostasis as a conceptual framework. It is proposed that mindfulness, as a mechanism of down-regulating challenging emotion, can aid in the restoration of mood homeostasis and reduce symptoms of both psychological and physiological stress. The study aims to identify whether individuals with Crohn's disease (CD) and co-occurring psychological depression or stress are experiencing the defeat of SWB homeostasis. Further, the study aims to test whether a Mindfulness Based Stress Reduction (MBSR) intervention can restore homeostasis. The study would also identify whether this restoration of homeostasis is associated with a reduction in disease symptomatology.

**Methods/Design:** An exploratory randomised control trial with 40 participants recruited from public health gastroenterology patients and randomly allocated to an 8-week MBSR program or wait-list control. Measures of SWB, depression, stress, and C-reactive protein (CRP) levels will be collected prior to and after the intervention. Individual HPMood set points will be determined from affect data collected over 7 days through momentary sampling techniques prior to the commencement of the intervention. Measures will be repeated at 6-month follow-up. Following this, the wait-list group will be offered the same 8-week MBSR. Hypotheses will be tested using mixed ANOVA and clinical significance tests.

**Discussion:** This study will be an important contributor to knowledge about psychological vulnerability and resilience for people with CD and will provide initial evidence that could contribute to the development of a larger future trial.

*Trial registration:* ACTRN12618002009291

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# 1. Background

## 1.1 Crohn's disease and psychological symptoms

Crohn's disease (CD) is a type of inflammatory bowel disease (IBD), with relapsing symptoms including abdominal pain, change in bowel habit, weight loss and rectal bleeding (Abautret-Daly et al., 2018). CD is increasing in incidence and prevalence across ethnic groups and geographies (Baumgart & Sandborn, 2012). A number of studies have found relationships between stress and disease outcomes (Bernstein et al., 2010; Cámara et al., 2009; Duffy et al., 1991), and there appears to be a growing consensus that stress plays a role in IBD activity (Knowles & Mikocka-Walus, 2015; Triantafyllidis et al., 2013). Other psychological conditions are also strongly associated with IBD. A longitudinal analysis of more than 2000 patients (56% with CD) over nine years found a significant association between symptoms of depression and anxiety and disease recurrence (Fairbrass et al., 2021; Mikocka-Walus, Pittet, et al., 2016). A systematic literature review confirmed the higher prevalence of anxiety and depression amongst patients with IBD than healthy controls, with the prevalence rising for those with active disease symptoms (Barberio et al., 2021; Mikocka-Walus, Knowles, et al., 2016).

The high levels of co-morbidity have led to an increase in research into appropriate psychological treatments for patients with IBD (Gracie et al., 2017; Triantafyllidis et al., 2013; von Wietersheim & Kessler, 2006). Longitudinal studies have provided evidence that psychological co-morbidity negatively impacts disease course (Fairbrass et al., 2021) and there are growing calls for patients with IBD to be monitored for mood disorders (Gracie et al., 2018). Psychological treatment is not currently part of usual care in IBD treatment. This may be because there are typically only modest or short-term gains, when the IBD populations is considered (Gracie et al., 2017). However, there is a growing awareness that there are groups who, when targeted, may strongly benefit (Gracie et al., 2017; Mikocka-Walus et al., 2015).

There is, however, a theoretical model which may assist in identifying a subset of people who may benefit from psychological intervention: the theory of subjective wellbeing homeostasis (Homeostasis Theory).

## 1.2 Subjective wellbeing homeostasis

Homeostasis Theory was developed to explain constancy in reported levels of SWB across time and populations (Cummins, 1995; Cummins et al., 2018; Cummins et al., 2014; Davern et al., 2007). It proposes that SWB operates as an internal psychological system using homeostatic mechanisms, which maintain SWB within an individual set-point range, even in the face of psychological stressors. It is only when these stressors become overwhelming, and homeostasis is defeated, that chronic psychological consequences emerge (Lyall et al., 2021). The theory proposes that there is, for each person, a set-point for a mood-derived positive-activated affect called Homeostatically Protected Mood (HPMood), and that this underlying mood governs subjective levels of wellbeing (Capic et al., 2017). The level of this set-point is genetically determined and constant. Moreover, the maintenance of this level is supported by a homeostatic system that strives to maintain experienced levels of HPMood within each individual's set-point range (Cummins, 2016). According to the theory, stressors challenge homeostatic control, by shifting conscious awareness of affect to the situationally created emotion, rather than the underlying HPMood. If the challenge is strong and chronic, homeostatic control fails, and the consequence is persistent negative affect, and depression (Cummins, 2010).

### 1.3 Measuring HPMood and homeostatic defeat

Measuring HPMood, and homeostatic defeat, requires the ability to separate out the emotional content of responses to affect-related questions, from the underlying HPMood. This has been demonstrated by a processes that examines the within-person standard deviation of SWB scores over time, demonstrated first by Cummins et al. (2014); and then Capic et al. (2017). Individuals who are experiencing homeostatic failure will have a higher level of emotional content, arising from stress, and this emotional content will dominate their underlying HPMood and mask their responses to either questions of SWB, or the questions used to elicit HPMood (happy, content, alert). Thus, the individual will have much larger variations of those reported measures over time.

A substantial empirical literature supports Homeostatic Theory (see Cummins, 2017, for a summary). Clinical benefits of this theory are that individuals who are experiencing mood homeostasis defeat can be targeted to identify appropriate treatment. However, there has been little research into how the theory may be effectively translated into clinical programs or interventions. Specifically, this theorised relationship has not been empirically tested using a randomised control trial (RCT) with a population known to be a risk of psychological distress. This study aims to explore this research gap by focussing on an intervention that has been proposed to have similar mechanisms to mood homeostasis: mindfulness (Lyall et al., 2021) .

### 1.4 Mindfulness

Mindfulness first came to the attention of western psychologists in the 1970s with the development of Mindfulness Based Stress Reduction (Kabat-Zinn, 2013). There are many approaches and definitions of mindfulness, but a common thread is that mindfulness introduces “a space between one’s perception and response” (Bishop et al., 2004, p. 232). The outcome of mindfulness has been described as equanimity, defined as “an even-minded mental state or dispositional tendency toward all experiences or objects, regardless of their affective valence ... or source” (Desbordes et al., 2015, p. 4). This description is analogous to a conscious awareness of HPMood. If stress precipitates failure of SWB homeostasis, the alleviation of stress should assist the restoration of homeostasis; leading to improvements in both mood and disease symptoms (Lyall et al., 2021).

Few studies have explored the impact of mindfulness on wellbeing in patients with inflammatory bowel disease, and even fewer have focused on the disease of interest in this study, CD, or on the intervention of interest, Mindfulness Based Stress Reduction (MBSR). One study, involving 60 inflammatory bowel disease patients (44 with CD) compared a mindfulness-based intervention with a treatment-as-usual control and found significantly greater improvements in depression at the six-month follow up. Impact on disease symptoms was not measured (Neilson et al., 2015). A pilot RCT involving 44 patients investigated the feasibility of conducting a larger mindfulness-based cognitive therapy RCT (Schoultz et al., 2015). Their exploratory findings found a significant improvement in scores for depression for the intervention group compared to the wait-list control.

Emerging evidence that MSBR interventions may be effective for both psychological and physiological stress comes from a randomised experimental study with 49 healthy participants (Rosenkranz et al., 2013). Both psychological and physiological stress were induced, separately, to participants before and after their training (MBSR or active education-based control) programs. Results showed both groups had comparable post-training cortisol responses; however, the MSBR group had a significantly smaller post-stress inflammatory response despite the similar levels of stress hormones.

It is not known if mindfulness can reduce inflammatory markers of IBD. One small randomized control trial involving 29 IBD patients explored the effectiveness of breathing,

movement and meditation and involved (Gerborg et al., 2015). The treatment group had significant improvements in psychological measures (anxiety, depression and stress) as well as disease measures (C-reactive protein, a marker of disease activity) at the six-month follow-up. The intervention, however, was a collection of techniques, mostly based on the martial art of Qigong, making replication difficult.

Many previous IBD studies have recruited patients with either ulcerative colitis or CD, reducing the size of the sample in each disease category. This approach has been critiqued as creating dilution effects (Cámara et al., 2009), with a recommendation that future studies consider each condition separately. To the authors' knowledge there has been no study of the impact of MBSR training on objective inflammatory markers of CD such as C-reactive protein levels (CRP).

If MBSR is found to improve disease activity in patients with CD, while simultaneously restoring mood homeostasis, it would provide further support for interventions that target psychological stress reduction to improve physiological outcomes.

## 1.5 Study objectives

The overarching aim of the study is to explore the relationship between HPMood, stress, inflammation, and depression in a sample of patients with CD.

Specifically, the study aims to explore whether mindfulness training can:

- 1) Reduce symptoms of *stress* following the MBSR course as compared to standard care and to investigate whether this is sustained at 6 month follow up,
- 2) Reduce symptoms of *depression* following the MBSR course as compared to standard care and to investigate whether this is sustained at 6 month follow up
- 3) Reduce *inflammation* following the MBSR course as compared to standard care and to investigate whether this is sustained at 6 month follow up.
- 4) Reduce the fluctuation of *emotional content* in participants' experience of their underlying mood following the MBSR course as compared standard care and to investigate whether this is sustained at 6 month follow up.

## 1.6 Hypotheses

That, prior to the MBSR intervention, levels of perceived stress, depression, CRP and HPMood variance will not differ between the intervention and usual care control groups.

That, following the intervention, levels of perceived stress, depression, CRP and HPMood variance will decrease for the intervention, but not for the usual care control groups.

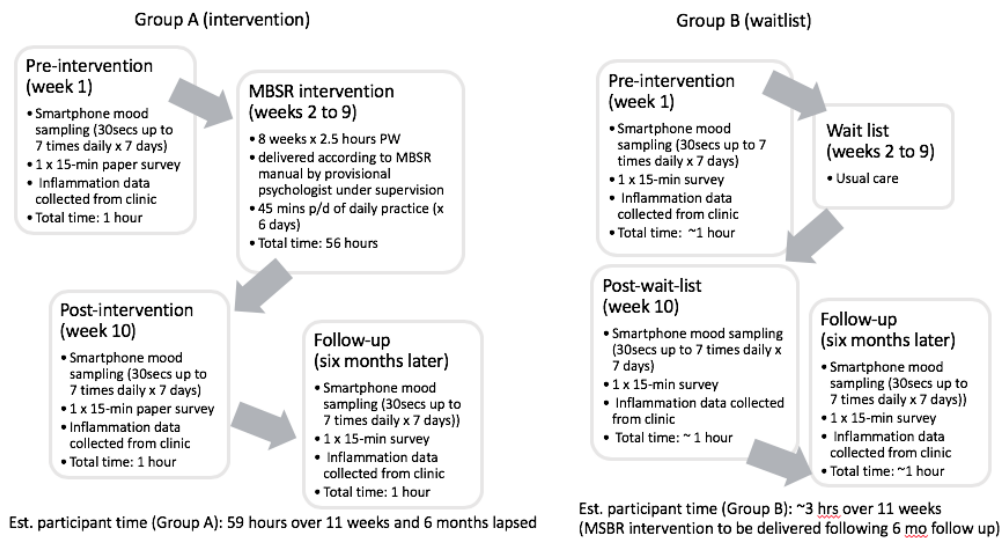
That the effectiveness of the intervention can be predicted from the baseline levels of HPMood, such that only participants whose baseline levels show evidence of homeostatic defeat would be predicted to achieve homeostasis as a result of the intervention.

## 2. Methods/Design

### 2.1 Design

An exploratory randomised single-blind controlled trial, with a sample of approximately 40 CD patients, with 20 forming the mindfulness group and 20 participating in a wait-list control/treatment as usual (Figure 1). Patients will be randomly assigned to either group A (mindfulness) or group B (waitlist/usual care) using a computer-generated block randomisation by a statistician with no patient contact. The intervention group will participate in an 8-week Mindfulness Based Stress Reduction (MBSR program).

**Figure 1.** Study Design and Timeline



## 2.2 Participants

Participants will be CD patients currently receiving treatment at public gastroenterology practices in Victoria (e.g., Barwon Health Gastroenterology).

### *Inclusion Criteria*

- 1) A clinically established diagnosis of Crohn's disease (per usual clinical practice in a tertiary care centre)
- 2) Sufficient knowledge of English to understand the study instructions, answer the questionnaires and participate in the MBSR group.
- 3) 18 years of age or older
- 4) Competence to consent
- 5) Access to the internet by a smart phone and the willingness to download the Instant Survey app.
- 6) A willingness to commit to 2.5 hours of MBSR at the identified times for a period of 8 consecutive or near-consecutive weeks, and engage with the homework sheets in the intervening period.
- 7) Scores of depressive symptoms at mild or moderate levels of the DASS scale

### *Exclusion Criteria*

- 1) Alcohol/substance dependence, as identified by the gastroenterology team
- 2) Severe mental illness (e.g., psychosis, schizophrenia), as identified by the gastroenterology team
- 3) Severe anxiety or depressive symptoms as indicated by a scores >21 on the depression scale or > 15 on the anxiety scale of the DASS measure
- 4) Significant cognitive impairment
- 5) Inability to read or write
- 6) Inability to speak or understand English
- 7) A regular (weekly or more often) mindfulness practice.

### ***Withdrawal criteria***

Participants will be free to withdraw at any time without any aspect of their IBD care being affected by their decision to withdraw from the study.

### **2.3 Recruitment**

Potentially eligible patients will be identified by the IBD nurse and/or gastroenterologists and contacted in person, via letter, or email and invited to participate. The study objectives and procedure will be outlined in an initial conversation between the study investigators and potential participant. The potential participant will be provided with the participant information and consent form. Participants will be assured their participation is voluntary and will not impact their treatment.

### **2.4 Intervention and control condition**

The MBSR intervention will be delivered following the procedure on the Palouse Mindfulness training course, as shown in Table 1. Each week consists of a 2.5 hour group session and up to 45 minutes of daily mindfulness practice using homework exercises. The group sessions involve a combination of watching videos explaining various mindfulness techniques, practicing those techniques and group discussion. Homework sessions will involve daily practice of the techniques learned.

The waitlist control group will be provided with the opportunity to complete the same MBSR course, following the completion of the 6-month follow-up period. In the event that the intervention is of no benefit or produces some undesired effects it will not be offered to the control group. However, the control group will then receive information on other free evidence-based tools for self-care, e.g., [www.tameyourgut.com](http://www.tameyourgut.com).

**Table 1.** *Session Structure of the MBSR program*

| Week   | Content                              | Format/materials   | Homework tasks           |
|--|--------------------------------------|--|--------------------------|
| 1 “Simple Awareness”                                 | Introduction to the body scan        | Videos, and introductory reading, participation in 30 minute body scan, group discussion | Reading, practice sheets |
| 2 “Attention and the brain”                          | Introduction to sitting meditation   | Videos, formal sitting meditation practice (10 minutes), group discussion                | Reading, practice sheets |
| 3 “Dealing with Thoughts”                            | Introduction to yoga                 | Videos, formal introduction to yoga practice (30 minutes), group discussion              | Reading, practice sheets |
| 4 “Stress: responding vs reacting”                   | Stop: the one-minute breathing space | Videos, formal introduction to yoga 2, Group discussion                                  | Reading, practice sheets |
| 5 “Dealing with Difficult emotions or physical pain” | Turning toward                       | Videos, the Turning Toward meditation, group discussion                                  | Reading, practice sheets |

|                                   |                                   |   |                          |
|-----------------------------------|-----------------------------------|---|--------------------------|
| 6 “Mindfulness and Communication” | Mountain and Lake meditations     | Videos, Mountain and Lake meditation, communication calendar, group discussion. | Reading, practice sheets |
| 7 “Mindfulness and compassion”    | Lovingkindness meditation         | Videos, Lovingkindness meditation, group discussion                             | Reading, practice sheets |
| 8 “Conclusion”                    | Developing a practice of your own | Videos, group discussion and certificates                                       |                          |

As part of the introduction in the first session of the course, participants will be informed about the possibility that some aspects of mindfulness practice could result in some distress and recommended actions to take should this occur. This information will also be prominently feature in the participant manual.

## 2.5 Measures

Subjective Wellbeing (SWB) will be measured with the Personal Wellbeing Index (International Wellbeing Group, 2013). HPMood will be measured by three items: right now, how happy do you feel, right now, how content do you feel, right now, how alert do you feel (Davern et al., 2007). Symptoms of depression and stress will be measured through the relevant sub-scales of the Depression, Anxiety and Stress Scale (Lovibond & Lovibond, 1995). Inflammation will be measured through c-reactive protein levels.

## 2.6 Procedure

At T1, participants will be prompted, via a smartphone app known as Instant Survey, to answer a short series of questions relating to their HPMood. These will include the 3 HPMood variables, along with additional questions, “how depressed do you feel” and “how stressed do you feel”. They will be prompted to answer these questions up to 7 times per day for 7 days. Each questionnaire will take approximately 30 seconds to complete. At the end of the 1-week period, participants will be asked a series of general questions about their SWB, depression and stress, once only and also via the smart-phone app. These questions will take approximately 15 minutes to complete. Following the completion of these initial surveys, participants in the intervention group will be provided with the 8-week MBSR intervention; while those in the wait-list will be provided with usual treatment, including anti-inflammatory medication if indicated. At completion of the MBSR course, the 1-week moment sampling questions and the longer survey will be repeated; along with an evaluation of the MSBR course. Participants will also be asked to provide a log of their homework practice. Participants will then be asked to participate in a follow-up 6 months later, which will repeat the 1-week moment sample and longer surveys. Participants in the control group will be provided with the surveys eight weeks after they completed them in T1.

## 2.7 Data analysis

### *Analysis of quantitative data*

Given the exploratory nature of this pilot RCT, no *a priori* power analysis was conducted. The sample size of 40 was chosen as being an achievable size for the study’s resources, and will allow up to four MBSR groups, each containing 10 participants.

Data analyses conducted for the hypotheses are as follows:

**Analyses:** For all outcome variables (stress, depression, SWB and CRP levels, HPMood variance), mixed ANOVA (with both between-subjects and within subject factors) analyses will be conducted to compare the results for the intervention and control groups. For mood homeostasis, the outcome measure is the level of within-person variance, calculated by analysing each individual's scores contributed over the one-week period (Capic et al., 2017).

To account for the likely lack of power, data from the intervention group will also be analysed using clinical significance testing to identify whether their scores are closer to known normative data or to known pathological levels (Jacobson & Truax, 1991). Normative range for each outcome measure will be sourced as follows: For SWB and HPMood: Capic et al. (2017); for depression and stress, the DASS severity scales; for CRP levels, based on Australian Clinical Laboratories reference range.

For the intervention group, analyses for the six-month follow-up will control for whether the individual is continuing to engage in regular mindfulness practice. This will be assessed via self-report, by asking participants to report how often they continue to engage in mindfulness practice.

### 3. Discussion

The psychological cost of Crohn's disease (CD) is high. Given the prevalence of the disease in Australia, and the high levels of psychological symptoms associated with the condition, it is important that potential treatments that might help to improve both psychological and physiological outcomes are explored (Häuser et al., 2014; Lores et al., 2021). While many IBD patients are increasingly exploring the use of non-traditional psychological treatments such as mindfulness, more research is needed to identify the specific benefits on both disease activity and psychological symptoms (Torres et al., 2019). More broadly, there is a growing call for research that more comprehensively understands the environmental triggers associated with IBD (Ho et al., 2019), and in particular to do this with longitudinal research that can provide insight into causal relationships. In addition, studies that identify the role of resilience in combatting the psychological and physiological symptoms associated with IBD are needed, building on emerging evidence of resilience protecting wellbeing in IBD patients (Sehgal et al., 2021; Wang et al., 2021).

Our proposed study can contribute to these known research gaps. The study has been framed within a clear theoretical context, outlining the likely relationship between stress, mood, depression, and inflammation. This pilot trial has the potential to contribute to further research in three ways. First, its randomised control design will allow between-group comparisons that will provide pilot data for subsequent effectiveness studies. Second, data from the participants can be analysed on an individual basis to determine whether progress made was clinically significant. Third, the ability to identify whether individuals are in HPMood homeostatic defeat could help to identify likely targets of people who could benefit from MBSR interventions.

There are some limitations with our proposed study. The small sample size would mean that the results can be considered indicative only; however, they will add to the growing literature and provide useful guidance for larger, future studies. Our focus on CD patients would mean results could not be generalised to other populations with IBD; however this is also a strength as it supports calls to research interventions with each IBD disease cohort separately (Cámara et al., 2009) and also responds to evidence that people with CD have more psychological complaints than those with another common subtype of IBD, ulcerative colitis (Mikocka-Walus, Knowles, et al., 2016; von Wietersheim & Kessler, 2006). Another potential limitation could emerge should coronavirus-19 pandemic continue and result in restrictions preventing



group work. Given the MBSR protocol involves weekly group sessions, it will be important to consider the impact on the study should an on-line alternative need to be developed.

Strengths of the proposed study are the RCT design, and the collection of inflammatory markers as well as subjective symptoms. Recruitment through the gastroenterology unit is also likely to include a wide cohort of patients experiencing both active and inactive disease, responding to a known challenge in prior studies that more commonly involve only patients with inactive or mild disease symptoms (Knowles et al., 2013). Finally, the ability to determine the clinical significance of any improvement of each individual participant, which can provide direct guidance for future research as well as inform clinical decisions, is the study's clear strength.

## Declarations

**Competing interests:** The authors declare that they have no competing interests.

**Funding statement:** No external funding has been received.

**Ethical approval and trial registration:** This protocol has been approved by the Barwon Health Human Research Ethics Committee (ref: 18/182) and registered with the Australian New Zealand Clinical Trials Registry (ACTRN12618002009291).

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