

# **Integrated psychological care is needed, welcomed and effective in ambulatory Inflammatory Bowel Disease management: Evaluation of a new initiative**

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Short title: Integrated psychological care in IBD management

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## Conflicts of Interest

Taryn Lores, Charlotte Goess, Antonina Mikocka-Walus, Kathryn Collins, Anna Chur-Hansen, Paul Delfabbro – all declare nil conflicts of interest.

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## Author contributions

Taryn Lores – contributed to the acquisition of data, analysis and interpretation, drafted the article, revised it critically and provided final approval for submission.

Charlotte Goess – contributed to the acquisition of data, drafting of the article, revised it critically, and provided final approval for submission.

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Jane M. Andrews – contributed to the conception and design of the new clinical initiative, implementation, data collection plan, drafting of the article, revised it critically and provided final approval for submission

## Abstract

**Background and Aims:** Inflammatory Bowel Disease is associated with psychosocial issues which reduce quality of life and impair medical management. However, these issues are rarely addressed in routine care. A model of integrated psychological screening and intervention was trialled to measure prevalence, patient participation, and potential benefits to mental health and/or quality of life.

**Methods:** During a 12-month period, 490 adult patients at an established hospital-based service were approached to complete screening instruments for anxiety, depression, general distress, quality of life and medication adherence. Disease-specific and demographic data were also collected. Patients who scored highly on screening questionnaires were offered psychological intervention (in-service or externally referred). Participants were reassessed after 12 months.

**Results:** Psychological screening was well-accepted with 68% ( $N=335$ ) participating. Psychological care was “needed”, with 55% ( $N=183$ ) scoring highly for anxiety, depression and/or general distress. Half of those “in need” ( $N=91$ ) accepted intervention. In those who accepted, levels of anxiety ( $M1=12.11$  vs  $M2=9.59$ ,  $p<.001$ ), depression ( $M1=8.38$  vs  $M2=6.42$ ,  $p<.001$ ), general distress ( $M1=17.99$  vs  $M2=13.96$ ,  $p<.001$ ), mental health quality of life ( $M1=54.64$  vs  $M2=59.70$ ,  $p<.001$ ) and overall quality of life ( $M1=57.60$  vs  $M2=64.10$ ,  $p<.001$ ) each improved between intake and follow-up. Engagement in psychological intervention was six times greater for those treated in-service versus externally referred [ $\chi^2(1)=13.06$ ,  $p<.001$ ,  $OR=6.47$ ].

**Conclusions:** Mental health issues are highly prevalent in people with Inflammatory Bowel Disease. Patients are open to psychological screening and treatment. Psychological care can improve patient mental health and quality of life, and works best when integrated into routine management.

**Keywords:** Inflammatory Bowel Disease, mental health, psychological treatment

## 1. Introduction

Inflammatory bowel disease (IBD) results in considerable disease burden<sup>1</sup> and economic cost<sup>2</sup>.

There is now substantial evidence demonstrating the increased risk of emotional, social and psychological issues in the IBD population<sup>2-4</sup>. Recent investigations have reported prevalence rates in this patient cohort to be around 30-50% for anxiety and 20% for depression<sup>5</sup>, compared to 14% and 6%, respectively, for the general population<sup>6</sup>. On average, one in five IBD patients is thought to meet criteria for a diagnosable mental health disorder, with mental health issues (MHIs) considered to be the most common type of comorbid condition overall<sup>3,7,8</sup>. Additionally, the risk of developing a MHI is greater when disease is active compared to during IBD remission<sup>9</sup>. Social stigma and isolation, difficulties managing pain, fatigue, gastrointestinal symptoms and impairment to occupational functioning are all commonly reported by people with IBD<sup>4,10,11</sup>.

Research suggests that MHIs may negatively influence the experience and management of IBD, in addition to being a consequence of IBD. Psychological stress, in particular, has been implicated as a key factor associated with exacerbation of IBD symptoms (and possibly also increased IBD activity)<sup>12-16</sup>. Anxiety has been linked to greater severity of disease, more frequent flares, and higher rates of treatment non-adherence<sup>5</sup>. The presence of depression and/or anxiety has also been correlated with increased risk of surgery in people with Crohn's disease (CD)<sup>17</sup> and higher rates of hospitalisation and readmission across the broader IBD population<sup>18</sup>. Despite this, MHIs remain under-reported and under-recognised in this population<sup>19</sup>. Moreover, most hospital IBD services are not resourced to incorporate psychological intervention within routine service delivery, with only 4% of services in Australia offering this type of care<sup>8</sup>. This represents a critical gap in the delivery of patient-centred treatment.

A shift towards a model of care that integrates assessment and treatment for MHIs within hospital IBD services is required in order to better meet the psychological needs of people with IBD, and thereby enhance quality of life and disease management<sup>11</sup>. A variety of integrated care models exist, including the chronic care model, the WHO's Innovative Care for Chronic Conditions

framework<sup>20</sup> and the Expanded Chronic Care Model<sup>21</sup>, which take into account broad determinants of health and focus on coordinated interventions across the care continuum<sup>22</sup>. Psychological interventions are an important component of integrated care for patients with chronic disease and have been shown to be effective for people with chronic pain<sup>23</sup>, rheumatoid arthritis<sup>24</sup>, diabetes<sup>25</sup>, cancer<sup>26</sup>, cardiovascular disease<sup>27</sup>, HIV<sup>28</sup> and obesity<sup>29</sup>. There is also evidence that psychological interventions have the potential to significantly reduce healthcare costs<sup>30-35</sup>.

Despite the large body of evidence of effectiveness in other chronic diseases, integrated psychological care and has received little attention in ambulatory IBD management. Fortunately, the evidence base for psychological approaches in gastrointestinal health and disorders more broadly (e.g. irritable bowel syndrome<sup>36</sup>) has been growing over the last decade<sup>37</sup>. Cognitive behaviour therapy (CBT) currently has the greatest empirical support for people with IBD<sup>37</sup>. CBT has been shown to improve mental health quality of life<sup>38</sup> and medication adherence<sup>39</sup>, and reduce levels of anxiety, depression<sup>39, 40</sup> and rates of hospitalisation<sup>39</sup>. However, the demonstrated benefit is largely short-term: more longitudinal studies are needed to determine the long-term benefits. Gut-directed hypnotherapy is another psychological approach currently gaining momentum in IBD care, with trials demonstrating reductions in inflammation in ulcerative colitis<sup>41</sup> and higher remission rates following treatment<sup>42</sup>.

Psychological interventions may therefore offer benefits beyond improved mental health for people with IBD. However, no previous research has looked specifically at the usefulness of an integrated model in ambulatory IBD care. An integrated service delivery model allows for better access to mental health care. This is important given the fact that MHIs are under-recognised and treated in the IBD population. Herein we therefore sought to examine whether routine psychological care is needed, acceptable and/or effective in IBD management, by evaluating an integrated model within an established hospital IBD service. Specific aims of the project were to:

- Assess the willingness of IBD patients to undergo psychological screening;
- Profile the prevalence of MHIs present;

- Measure the practical uptake of psychological intervention (in-service and externally);
- Investigate whether participation in psychological intervention would improve mental health and/or quality of life outcomes.

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## **2. Materials and Methods**

### **2.1. Participants and procedures**

In a prospective observational study design, patients were recruited from the IBD clinic of an Australian teaching hospital between September 2015 and September 2016. To be eligible, participants had to be aged 18 years or over, have sufficient English skills to complete the questionnaires and have an established diagnosis of IBD; patients were excluded if their diagnosis was not yet confirmed.

#### **2.1.1. Intake**

Potential participants were identified from upcoming gastroenterology clinic lists and were sent study information ahead of their scheduled medical appointment; they were also approached in person while awaiting appointments. At intake, participants were presented with four screening questionnaires and a brochure describing the project's aims and requirements. It was made clear that participation was voluntary, and that declining participation would not affect their usual medical care. Completion of questionnaires was regarded as signifying consent.

#### **2.1.2. Psychological treatment**

Participants who scored above clinical cut-off scores on the mental health questionnaires were offered a brief assessment with an in-service psychologist at their gastroenterology appointment (on the day of screening, or, if they completed the questionnaires in advance, at their next scheduled appointment). Psychological support and intervention were offered on the basis of need and willingness as ascertained during the assessment. Psychological intervention was organised either to take place with the in-service psychologist, or by referral to primary care services (due to preference, location or availability of care). The in-service psychological intervention was individually tailored and was not limited to a prescribed number of sessions. The majority of strategies were based in CBT and acceptance and commitment therapy. The type and length of external psychological intervention was also at the discretion of the treating psychologist. Participants who declined

psychological treatment were followed-up by phone four to six weeks after screening to review their support needs.

### 2.1.3. Follow-up

Participants were invited to repeat the questionnaires 12 months after their screening (between September 2016 and September 2017).

## 2.2. Measures

### 2.2.1. MHIs

Anxiety and depression were assessed using the *Hospital Anxiety and Depression Scale* (HADS)<sup>43</sup>; a 14-item self-report measure designed specifically for use in hospital populations. Items are broken into two subscales (Anxiety: A-scale; and Depression: D-scale) for which scores range from 0 to 21, with higher scores indicating greater symptom severity (mild=8-10, moderate=11-14, severe=>15).

General (non-specific) psychological distress was assessed using the *Kessler 6 Scale* (K6)<sup>44</sup>. The K6 is a six-item measure that is summed to give a total score (range: 6-30), with higher scores indicating higher levels of psychological distress. Responses are categorised as being either sub-clinical (6-18) or clinical (>19).

### 2.2.2. Quality of life

Health-related quality of life was quantified via the 35-item *Assessment of Quality of Life Measure* (AQoL-8D)<sup>45</sup>. Overall scores are calculated for Total Quality of Life plus two sub-dimensions: Physical and Mental Health Quality of Life. Total scores range between 0 and 100, with increasing values indicating better quality of life in each dimension.

### 2.2.3. Medication adherence

Medication adherence was measured by the *Morisky Medication Adherence Scale* (MMAS-8)<sup>46</sup>, an 8-item structured self-report measure of medication-taking behaviour (how well the patient adhered to their medication regime). A total score of 8 indicates high adherence, 6-7 medium adherence and <6 low adherence.



#### 2.2.4. Demographic and IBD information

IBD-specific (including diagnosis, disease activity, disease location, disease duration, perianal disease, age of onset, medications, IBD therapy) and demographic (age, sex) data were collected via medical records and state-wide electronic records.

#### 2.2.5. Participant feedback on the integrated model

At follow-up assessment, participants were additionally invited to complete a feedback form developed specifically to evaluate the new initiative. Participants were asked to rate several statements regarding their experience with the psychological screening process, and (if relevant) the psychological intervention. Statements such as “I am pleased I participated” and “I found my treatment beneficial” were rated on a 5-point scale (“Strongly Agree”, “Agree”, “Neutral”, “Disagree”, “Strongly Disagree”).

#### 2.3. Analytical Approach

Descriptive statistics were used to assess the IBD-specific and demographic characteristics of the sample. Data were inspected for outliers and distributional characteristics using qq-plots and histograms. Participants who scored over 7 on the HADS A-scale or D-scale, and/or above 18 on the K6, were categorised as MHI+ (likely to have a MHI); those who scored below these cut-offs were categorised as MHI-.

For analysis of intake data, Pearson correlations were used to investigate associations between mental health and quality of life variables. Independent samples t-tests and one-way between groups ANOVAs were used to explore the differences between means in anxiety, depression, distress and quality of life variables for participants who were MHI- versus MHI+, and for those who accepted versus declined psychological intervention. Chi-squared tests were used to explore relationships between categorical variables.

For analysis of follow-up (12-month) data, a subgroup (28%,  $N=26$ ) of those who declined intervention at intake were removed as they were discovered to have independently engaged in

external psychological treatment before or after screening, and could therefore not be clearly regarded as either “decliners” or “accepters”. Differences in outcomes at follow-up were investigated using paired t-tests to explore any changes from intake (e.g. changes in anxiety over time), and ANCOVAs and logistic regressions were run to explore any changes between participant groups (e.g. accepted versus declined intervention) while adjusting for baseline differences. In addition, Reliable Change Indices (RCIs) were calculated to determine the proportion of statistically reliable changes in outcome measures from intake to follow-up, for individuals who accepted psychological intervention versus those who declined. This analysis was included to address the risk that group level analyses might disguise significant changes in individual scores and be misleading if reported in isolation<sup>47</sup>.

#### **2.4. Ethical Considerations**

This study was approved by the Research Ethics Committee of the Royal Adelaide Hospital (HREC/15/RAH/304).

### 3. Results

#### 3.1. Participant sample at intake

The flow of participants through intake is shown in Figure 1. A total of 490 outpatients with IBD were approached: half of these were women ( $N=248$ ), mean age was 40 years ( $SD=15.1$ ), the most common IBD diagnosis was CD (71%,  $N=346$ ) and mean duration of illness was 11 years ( $SD=10.1$ ).

#### 3.2. Participation in, and prediction of, psychological screening

Of the outpatients approached, 68% ( $N=335$ ) participated in psychological screening. Approximately one third of these (31%,  $N=104$ ) completed the screening ahead of their outpatient appointment, just over half (57%,  $N=193$ ) when approached in person in IBD clinic, and a smaller number after their appointment (12%,  $N=38$ ). Sample characteristics for screening participants are shown in Tables 1 and 2. In summary, participants were predominantly women with CD and mean age of 40 years. Most were diagnosed in early adulthood (between 18-39 years old), with 18% ( $N=62$ ) having had paediatric onset.

Eighty-eight percent of screening participants ( $N=295$ ) were on some form of IBD therapy at intake: 57% ( $N=189$ ) on immuno-suppressants, 41% ( $N=138$ ) on biologics, 26% ( $N=88$ ) on 5ASAs and 10% ( $N=301$ ) on steroids. Three-quarters (76%,  $N=248$ ) had not experienced any change to their IBD-related medical therapy in the 12 months preceding screening. Forty percent ( $N=134$ ) had undergone a colonoscopy and 36% ( $N=120$ ) had undertaken some form of radiological investigation in the 12 months preceding their screening date. Eleven percent of participants ( $N=37$ ) were taking psychotropic (anti-depressant, anti-anxiety) medication at the time of screening, 10% ( $N=32$ ) were taking some form of analgesia and 16% ( $N=54$ ) were taking nutritional supplements.

Sex was the main predictor of participants opting into psychological screening: women were 1.5 times (65%) more likely to participate than men (Supplementary Table 1). Additionally, participants tended to have shorter IBD duration ( $M=10.7$  years,  $SD=9.85$ ) than those who declined screening [ $M=13.7$  years,  $SD=10.43$ ,  $t(449)=-2.84$ ,  $p<.01$ , Cohen's  $d=.30$ ]; however, this statistically

significant result does not appear clinically relevant. Participants and non-participants did not differ significantly in relation to age, smoking status, IBD diagnosis or disease activity. Reasons for declining to participate were not assessed.

### 3.3. Prevalence and prediction of MHIs at intake

Fifty-five percent of screening participants ( $N=183$ ) scored highly on either the HADS and/or the K6 (and were categorised as MHI+, indicating the likely presence of a significant MHI). Anxiety was the most common type of MHI with 51% of participants ( $N=170$ ) scoring highly on this HADS subscale; 29% ( $N=96$ ) scored highly on the depression subscale of the HADS and 19% ( $N=64$ ) scored highly on the K6.

Overall, higher levels of anxiety, depression and general distress were all significantly related to lower levels of quality of life and poorer medication adherence. Details of correlations between the different types of MHIs assessed, quality of life dimensions and medication adherence are shown in Supplementary Table 2.

Medication adherence was significantly lower in MHI+ participants ( $M=5.54$ ,  $SD=1.93$ ) compared with MHI- [ $M=6.54$ ,  $SD=1.54$ ;  $t(298.70)=5.01$ ,  $p<.001$ ]. Being MHI+ was also associated with greater analgesic and psychotropic medication use. Participants were three times more likely to be MHI+ if they were taking any form of analgesic medication [ $\chi^2(1, N=25)=8.06$ ,  $p<.01$ ], nearly six times more if on opiates [ $\chi^2(1, N=13)=6.61$ ,  $p<.05$ ] and eleven times more if they were taking psychotropic medication [ $\chi^2(1, N=34)=23.30$ ,  $p<.001$ ]. Numbers and proportions of medication use across the two groups are shown in Supplementary Table 3.

There were no other significant differences between MHI+ and MHI- with respect to other demographic or IBD-specific variables (age, sex, smoking status, IBD diagnosis, IBD duration, disease activity, disease location, perianal disease, or age of onset).

### 3.4. Uptake and prediction of psychological intervention

Fifty percent of MHI+ participants ( $N=91$ ) accepted the psychological intervention offered at intake; 56 (62%) were allocated to treatment in-service, and 35 (38%) were referred to external services. Participants who accepted psychological intervention had higher levels of anxiety, depression and general distress, and lower levels of total, mental and physical health quality of life at intake, compared to those MHI+ who declined treatment (see Table 3).

On average, the scores of participants who accepted psychological intervention were suggestive of moderate anxiety, mild depression and clinical distress, compared to mild anxiety and sub-clinical depression and distress for those who declined intervention (based on score ranges for the HADS and K6). Participants who accepted psychological intervention did not differ from those who declined with respect to age, sex, smoking status, IBD diagnosis, IBD duration, disease activity, disease location, perianal disease, or age of onset.

### 3.5. Follow-up assessment at 12 months

A total of 264 participants (79% of the 335 screened at intake) repeated the psychological screening process at 12 months follow-up, including 136 (74%) of the 183 participants who were offered psychological intervention at intake. Figure 2 illustrates the numbers of participants who completed the follow-up assessment. Successful engagement in treatment could not be confirmed for three of the participants who were referred for external treatment. In addition, two participants who did successfully engage (one in-service, one external) did not complete the follow-up questionnaires.

Of the participants who accepted psychological intervention and were allocated treatment in-service at intake ( $N=56$ ), just over half ( $N=32$ , 57%) were either still engaged with, or had completed, treatment at the time of follow-up, with twelve-month data available on 31. Each participant attended an average of ten sessions,  $M=10.19$ ,  $SD=6.91$ ;  $Min=1$ ,  $Max=27$ . Based on DSM-V criteria, 12 met criteria for an anxiety disorder (38%) and six met criteria for a mood disorder (19%). Sixteen (29%) of the in-service accepters did not end up attending the intervention at all and

a further eight started but dropped out early (with follow-up data available for fifteen of these “non-engagers”).

Participants referred to external services were significantly less likely to successfully engage in treatment [ $\chi^2(1)=13.06, p<.001, OR=6.47$ ], with only five out of the 35 referred at intake (15%) confirmed to have participated in treatment in an ongoing way (and follow-up data only available for four of these). Data on the psychological presentations of these participants (from subsequent assessment with a psychologist) were not collected.

### 3.6. Patient outcomes at follow-up

At twelve-months, participants who had accepted psychological intervention at intake decreased in their levels of anxiety, depression and general distress, and increased in their levels of mental health quality of life and total quality of life (Table 4). However, there was no significant change in physical health quality of life. Participants who declined psychological intervention also improved in their levels of anxiety and general distress (however noting that they had lower levels at intake). The improvements in the group who accepted psychological intervention had larger effect sizes, suggesting a more clinically relevant change.

Medication adherence did not improve for either accepters [intake:  $M=5.38, SD=1.86$ ; follow-up:  $M=5.73, SD=2.00$ ;  $t(61)=-1.47, p=.146$ ] or decliners [intake:  $M=5.96, SD=1.84$ ; follow-up:  $M=7.61, SD=9.09$ ;  $t(41)=-1.23, p=.225$ ]. IBD activity also did not change over time for either group (accepters:  $p=.83$ ; decliners:  $p=1.00$ ).

Comparisons were made to explore for possible differences in effects in those who accepted versus declined psychological intervention from intake to follow-up (using ANCOVAs and logistic regressions); the differences were non-significant. However, benefits in physical health quality of life were seen in the subgroup of accepters allocated in-service treatment, but not for those externally referred ( $F=4.49, p=.038, partial E^2=.063$ ; Supplementary Table 4).

To ascertain a more reliable estimate of change over time, Reliable Change Indices (RCIs) were computed. These were calculated for each outcome measure in both groups (accepters and decliners), and then the number of cases in which participants improved above and beyond this index were tallied. There were significantly greater percentages of reliable change in general distress, mental health quality of life and total quality of life in those who accepted psychological intervention than those who declined (Table 5).

Associated counts were also calculated for subgroups of accepters – specifically for in-service versus external intervention, and successful engagement versus non-engagement. Consistent with a “dose effect”, anxiety and depression reduced for more people who successfully engaged in treatment [ $N=12(47\%)$  and  $N=13(50\%)$ , respectively] compared to those who did not [ $N=9(21\%)$ ,  $p<.05$  and  $N=10(24\%)$ ,  $p<.05$ , respectively]. At this level there were no significant differences between those allocated intervention in-service versus externally referred.

### 3.7. Perceptions of integrated psychological care

Ninety-seven percent of participants who participated in follow-up assessment completed a feedback questionnaire regarding the integrated psychological care initiative. Results are outlined in Supplementary Table 5. In summary, the majority of participants indicated that they ‘agreed’ or ‘strongly agreed’ that the psychological screening process was easy to complete (90%,  $N=233$ ) and a good initiative (90%,  $N=231$ ), that they were pleased to have participated (76%,  $N=191$ ) and would participate again (80%,  $N=202$ ). Negative feedback on the questionnaire was minimal: 9% ( $N=22$ ) reported they found the screening process distressing, and 7% ( $N=15$ ) objected to being asked (although no negative verbal feedback was received during the evaluation period). For those who accepted psychological intervention at intake, most ‘agreed’ or ‘strongly agreed’ that they found the treatment beneficial (78%,  $N=38$ ), would seek support again (98%,  $N=48$ ), would like the integrated psychological service to continue within the IBD service (98%,  $N=48$ ) and would recommend the psychological service to others in need (87%,  $N=40$ ).

#### 4. Discussion

This is the first large study to examine the potential effects of integrated psychological care in routine IBD management despite the obvious potential benefits of this approach<sup>48</sup>. Studies examining a holistic model of care in the management of patients with IBD are limited, even though MHIs are known to be highly prevalent and deleterious to outcomes. This initiative evaluated the introduction of integrated psychological support into routine care, and showed great need, high acceptability and tangible mental health benefits. Moreover, it showed that integration of the psychological intervention within the IBD service is necessary to optimise engagement and benefits. This has clear implications for IBD service delivery.

The first key outcome of this work is that psychological screening was accepted by this population. Over two-thirds of the patients approached opted into the psychological screening process, suggesting excellent acceptance of its inclusion in the hospital service. Participation was equal across age groups and levels of disease activity, although women were more likely to participate than men. This is consistent with research demonstrating that men are often less positive about seeking psychological support<sup>49, 50</sup>, and thus, may be less likely to engage effectively with psychological services.

A second important finding of our study is that MHIs were highly prevalent: over half of the patients who participated in psychological screening had scores suggestive of clinically relevant symptoms. Anxiety was the most common type of MHI indicated. Our results confirm those of previous investigations, which have repeatedly shown that people with IBD experience higher rates of MHIs than is found in the general population; also these rates are comparable to those found in other chronic diseases<sup>1, 3, 5, 9, 10, 51</sup>. As expected, higher levels of anxiety, depression and general distress were all correlated with lower quality of life. Where past studies have demonstrated that disease activity increases the risk of MHIs<sup>3, 9, 51</sup>, we found that the MHI prevalence was independent of disease activity.



Moreover, we demonstrated that MHIs were associated with greater use of analgesic medication, in particular opiates. Although opiates are regularly used by only a fraction of IBD patients<sup>52</sup>, their use significantly increases the risk of mortality in IBD, particularly in heavy opioid users (approximately 5% of individuals within 10 years since diagnosis)<sup>53</sup>. In line with our research, a previous case-control study showed that opiate use in IBD is not only associated with anxiety and depression but also with severe pain, clinical disease activity and having undergone two, or more, previous surgeries: in fact, IBD-related complaints (such as abdominal pain) account for 50% of the opiate indications<sup>52</sup>. Patients using opiate medication should be closely monitored, with an awareness that they are likely to need psychological intervention.

Treatment adherence is another topical issue in IBD care, and our results showed that IBD-medication adherence was lower in patients with MHI+ than it was in those with better psychological health. This observation is supported by previous findings linking MHI to poor medication adherence in IBD<sup>54</sup>, and improved adherence with high-quality patient-doctor communication<sup>55</sup>. Given the high rates of non-adherence to IBD treatment (typically 30-45%<sup>56</sup>) and the relationship with poorer mental health, behaviour change techniques included in psychotherapies such as CBT might be useful in supporting IBD patients in managing their illness.

The third significant outcome of this initiative is that there was solid uptake of psychological intervention in this cohort when offered. Half of the patients with MHI+ accepted treatment at intake, which demonstrates a willingness to participate in psychological therapy. Furthermore, people with more severe MHIs and lower quality of life identified by the questionnaires (those with likely higher need) were more likely to accept psychological intervention – highlighting the effectiveness of the psychological screening process.

While not all participants who accepted psychological intervention at intake went on to complete a course of treatment, it is important to note that engagement was significantly higher for those who accessed in-service support, compared to participants who were referred externally: over half of the patients who accepted psychological intervention integrated within the hospital service

engaged successfully, compared to less than one-fifth of those referred externally. The dropout rate in the hospital group echoes that of previous research (our study: pre-treatment 28.6%, during treatment 14.3%; for CBT generally pre-treatment 15.9%, during treatment 26.2%<sup>57</sup>). These results again highlight the advantage of integrating psychological intervention into the service itself – to increase engagement, attendance and follow-through.

Our results also show that psychological intervention leads to improved mental health and quality of life outcomes for IBD patients. Participants who accepted psychological treatment showed improvement across a range of outcomes – decreased levels of anxiety, depression and general distress, as well as increased mental quality of life and total quality of life. Surprisingly, physical health quality of life and medication adherence did not change. Participants who declined psychological intervention also showed improvements in their levels of anxiety and general distress, although these had smaller effect sizes and were from a lower level of severity at intake. One explanation for this is that participants who declined may have been able to self-manage and improve their mental health without formal input (recovering naturally), while those who accepted may have been more in need of formal psychological intervention and less able to manage independently (given their higher levels of MHIs at intake).

Nevertheless, more statistically reliable change was seen in the group who accepted intervention at intake. Further, the benefits to mental health and quality of life were in favour of those who accessed the psychological intervention in-service (compared to those externally referred) and those who actively engaged in treatment. Also noteworthy, patients who participated in screening and psychological intervention reported satisfaction with the service, with 98% of participants who completed an evaluation form indicating that they wanted the service to continue – clearly indicative of a very high level of acceptance from IBD patients.

While it can be argued that a randomised controlled trial (RCT) might be the optimal study design for an evaluation of this integrated care model, we chose a naturalistic observational design for this research as it more accurately mirrors real-world care. RCTs are acknowledged as frequently

restricting entry to otherwise relevant participants, which may reduce the external validity of findings<sup>58</sup>; nevertheless, RCTs are required to establish efficacy. In this study, the relatively small numbers in some outcome groups may reduce generalisability of the results. Future research in this area might investigate the different reasons people decline psychological intervention (as we did not collect formal data), as well as implications for healthcare utilisation (as improving patient mental health and self-management is likely to reduce costs, for example, through reducing frequency of medical appointments and hospital encounters).

Based on the results of this investigation, we make the following recommendations (summarised in Supplementary Table 6). Psychological care (screening and intervention) should be integrated into ambulatory IBD management to improve access to support and facilitate engagement. Further, IBD clinicians should routinely ask patients about their mental health, in order to normalise discussions, reduce stigma and increase uptake of psychological intervention where needed. IBD clinicians should actively seek out patients who report moderate to high levels of MHIs, and those taking psychotropic and/or analgesic medication (especially opiate medication), as these patients are at increased risk of serious mental illness; poor medication adherence and low quality of life scores are also indicators of increased risk of MHIs. We recommend that patients be educated regarding brain-gut communication and the potential benefits of psychological input, to promote engagement and follow-through. Finally, IBD clinicians would benefit from familiarising themselves with other psychological care options for when in-service support is not available (e.g. GP mental health care plans, self-directed CBT modules such as [www.tameyourgut.com](http://www.tameyourgut.com)<sup>38, 59</sup> or counselling services). To establish the efficacy and usefulness of integrated psychological care in IBD management, further research in the area is warranted.

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## Tables

**Table 1.** Demographic characteristics of patients who participated in psychological screening ( $N=335$ )

	<i>N (%) or M (SD)</i>
Sex	
Women	181 (54%)
Men	154 (46%)
Mean age (years)	39.87 (14.91)
Smoking status	
Current smoker	61 (18%)
Ex-smoker	50 (15%)
Non-Smoker	212 (64%)

**Table 2.** Disease characteristics of patients who participated in psychological screening ( $N=335$ )

	<i>N (%) or M (SD)</i>
IBD Diagnosis	
Crohn's disease	241 (72%)
L1 Terminal ileum	71

L2 Colon	62
L3 Ileocolon	96
Ulcerative colitis	82 (24%)
E1 Proctitis	11
E2 Distal	22
E3 Pancolitis	36
IBD-unspecified	12 (4%)
L2 Colon	6
L3 Ileocolon	1
E2 Distal	1
E3 Pancolitis	3
Duration of illness (years)	10.68 (9.85)
Age of Onset (years)	29.13 (14.32)
Childhood (0-12yrs)	14 (4%)
Adolescence (13-17yrs)	48 (14%)
Early adulthood (18-39yrs)	201 (60%)
Adulthood	71 (21%)
IBD activity	
Remission	148 (44%)
Active	185 (56%)
Perianal disease	77 (23%)

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*\*location data missing for 26 cases*

**Table 3.** Group comparisons of MHI and quality of life variables

	Acceptance of Psychological Intervention							
	Declined ( <i>N</i> =92)			Accepted ( <i>N</i> =91)				
	<i>M (SD)</i>	<i>SD</i>	<i>N</i>	<i>M (SD)</i>	<i>SD</i>	<i>N</i>	<i>t</i>	<i>df</i>
Anxiety	10.28	3.22	92	12.29	3.95	90	-3.75***	171.38
Depression	6.89	4.52	92	8.59	3.70	90	-2.77**	180
General distress	14.96	4.96	91	18.59	4.95	90	-4.93***	179
Physical QoL	76.99	15.42	85	70.72	13.79	88	2.82**	171
Mental QoL	60.91	15.89	85	50.80	14.47	88	4.38***	171
Total QoL	66.15	14.51	85	56.90	13.01	88	4.42***	171

\*\**p*<.01, \*\*\**p*<.001; QoL = Quality of Life**Table 4.** Twelve-month outcomes for participants who declined and accepted psychological Intervention

	Declined Intervention ( <i>N</i> =48)				Accepted Intervention ( <i>N</i> =71)			
	Intake	Follow-Up		<i>t</i>	Intake	Follow-Up		<i>t</i>
	<i>M (SD)</i>	<i>M (SD)</i>	<i>Eta</i> <sup>2</sup>		<i>M (SD)</i>	<i>M (SD)</i>	<i>Eta</i> <sup>2</sup>	
Anxiety	9.17 (1.80)	7.56 (4.22)	2.79**	.139	12.11 (3.79)	9.59 (4.28)	5.60***	.310
Depression	5.54 (4.07)	4.56 (3.88)	1.63	.053	8.38 (3.49)	6.42 (4.95)	4.62***	.234
General distress	13.04 (3.69)	11.74 (4.43)	2.08*	.086	17.99 (4.60)	13.96 (5.55)	8.18***	.488
Physical QoL	81.27 (21.86)	81.98 (13.73)	-1.97	.006	71.17 (13.37)	72.85 (17.17)	-1.16	.019
Mental QoL	67.09 (14.06)	71.02 (12.23)	-.51	.078	54.64 (14.21)	59.70 (17.78)	-5.19***	.281
Total QoL	71.99 (12.69)	74.74 (11.36)	-1.63	.054	57.60 (12.72)	64.10 (16.89)	-4.36***	.216

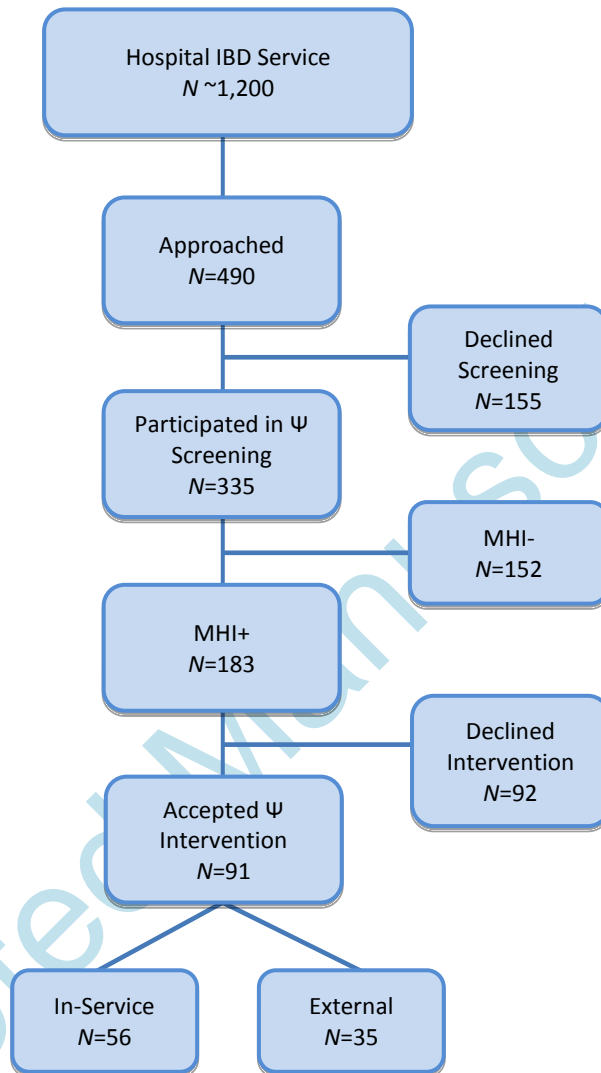
\**p*<.05 \*\**p*<.01 \*\*\**p*<.001, QoL = Quality of Life

**Table 5.** Numbers of participants with reliable changes in outcomes

	RCI	Accepted (N=71) N (%)	Declined (N=48) N (%)
Anxiety	-3.53	23 (32%)	16 (33%)
Depression	-3.79	25 (35%)	12 (25%)
General distress*	-5.30	24 (34%)	6 (13%)
Physical QoL	19.64	5 (7%)	1 (2%)
Mental QoL*	8.15	30 (43%)	13 (28%)
Total QoL*	7.64	30 (43%)	12 (26%)

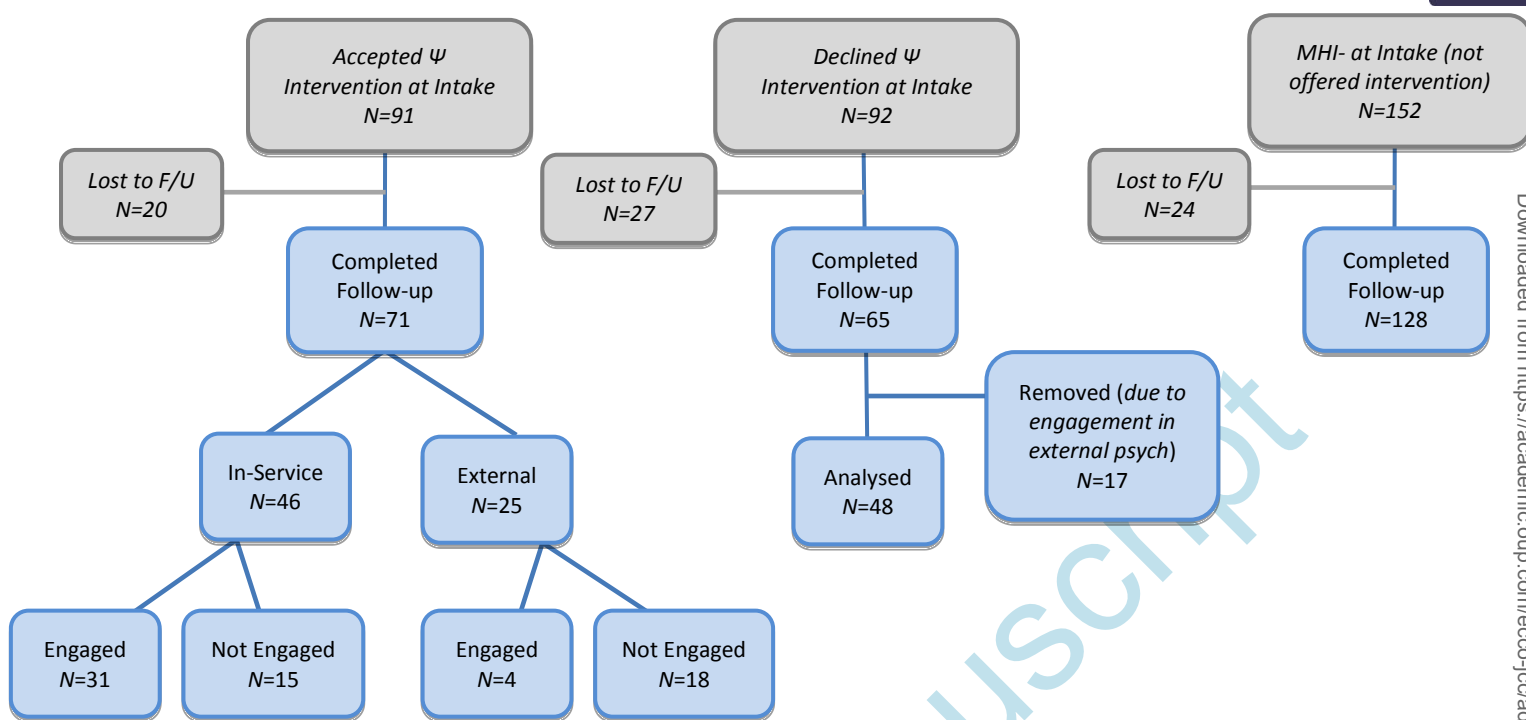
QoL = Quality of Life

## Figures



**Figure 1.** Flow chart of participants through intake





**Figure 2.** Participant numbers at follow-up