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**TITLE:** Development and psychometric properties of the Inflammatory Bowel Disease Distress Scale (IBD-DS): a new tool to measure disease-specific distress

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#### **ABSTRACT**

**Background:** Inflammatory Bowel Disease (IBD) imposes a heavy psychosocial burden, with many patients reporting anxiety, depression and distress. In diseases such as diabetes, disease-specific distress is

associated with concordance with treatments and disease control. IBD-distress, distinct from anxiety and depression, is evident in people with IBD. We aimed to develop a questionnaire for assessing IBD disease-specific distress, validate this against a gold standard distress measure for diabetes, and demonstrate difference between anxiety, depression, and distress.

**Methods:** The 94 item IBD-Distress Scale (IBD-DS), was developed through secondary analysis of three qualitative data sets from previous IBD studies. Items were then refined through cognitive interviews in two stages (n=15; n=3). Three supplementary unscored questions were added to enable patients to identify their overall level of distress, their perceived level of disease activity, and their three most distressing issues. Subsequently the 55 item IBD-Distress scale was subjected to test-retest. 275 people received the test draft IBD-DS, 168 responded (60.4%). Of these, 136 (82%) returned the retest draft IBD-DS three weeks later. Following analysis, further item reduction was informed by response rates, kappa values, and correlation coefficients, and test-retest was repeated. 154 people received the test final 28 item IBD-DS, 123 people responded (58.8%). Of these, 95 (77%) returned the retest final IBD-DS.

**Results:** The 94 items were reduced to 28 items. Good intra-class correlation (ICC) was found between test-retest scores on 72 complete data sets with unchanged disease status (ICC 0.92; 95% CI, 0.88, 0.95). Cronbach's alpha was 0.95 indicating excellent internal consistency. Factor analysis indicated scoring the items as a single domain (score range 0-168).

**Conclusion:** The final IBD-DS performs well and offers a tool for assessing IBD disease-specific distress.

**Key words: distress, assessment, inflammatory bowel disease**

## **INTRODUCTION**

Inflammatory bowel disease (IBD), including Crohn's disease (CD) and ulcerative colitis (UC), can have burdensome psychosocial consequences for those with the condition <sup>1</sup> including distress related to symptoms <sup>2</sup>. Distress may be understood as an 'emotional anguish or suffering' <sup>3</sup>, or as 'a non-specific, biological or emotional response to a demand or stressor that is harmful to the individual' <sup>4</sup>.

Disease-related distress has been identified and researched extensively in other chronic conditions including diabetes <sup>5-9</sup>, asthma <sup>10, 11</sup>, cancer <sup>12-14</sup> and multiple sclerosis <sup>15</sup>. Earlier work from this study team has identified and reported the phenomenon in people with IBD <sup>16</sup>. Studies reporting 'psychological distress' in IBD have often measured only anxiety and depression <sup>17, 18</sup>, although evidence from diabetes <sup>19</sup>, cancer

<sup>13</sup>, and multiple sclerosis <sup>15</sup> demonstrates that whilst it may be related, disease-related distress is distinct from anxiety and depression <sup>6</sup>. However, unlike anxiety and depression, disease specific distress is not a diagnosable condition in the DSM Manual of Psychiatric Diagnoses <sup>20</sup>. Disease-specific distress is a spectrum of emotional experience relating to the disease being experienced by the person <sup>21</sup>. In IBD-distress we define this as the person's experience of feeling overwhelmed by the demands of living with and managing their condition. We hypothesize its distinctiveness from anxiety and depression in that it is uniquely focused in emotional response to disease experience and not generalized to other psychological morbidities. In diabetes, an analysis of the clinical notes of 40 people with elevated distress diabetes estimated that 30% had an additional underlying co-morbid anxiety and/or depression with the majority 70% demonstrating no signs of psychological co-morbidity but experiencing disease specific distress alone <sup>22</sup>. Disease-specific distress could therefore be defined as 'an emotional response to the burden of chronic illness symptoms which may share symptoms of anxiety and depression, but is not diagnosed as such and is attributable only to the emotional response to disease experience'.

Cut offs for elevated distress have been established in diabetes <sup>23-25</sup>. Elevated diabetes distress is associated with higher blood glucose levels and fewer self-care behaviours such as medication concordance and disease monitoring <sup>19</sup>. Addressing diabetes distress improves clinical outcomes in interventional studies in type 1 and type 2 diabetes and in adolescents <sup>8,9</sup> and this may be important for IBD as well, where the problems of concordance with oral medications are also recognised <sup>26,27</sup>. The higher prevalence of symptoms of anxiety and depression in people with IBD, when compared to the general population, is well established <sup>28-30</sup> yet the presence and impact of IBD-distress remains under-explored. There are no tools to assess IBD-distress in IBD patients, and it is likely to be poorly identified and so support may not be offered. An assessment tool for IBD distress may evidence the need for additional support, and in the longer term has the potential to improve patient quality of life and self-management in IBD.

In preliminary work, we collaborated with our Patient and Public Involvement (PPI) group to identify the presence and impact of IBD-related distress, through secondary analysis of existing qualitative data from our previous studies addressing fatigue, stigma, and incontinence in IBD <sup>31-34</sup>. By comparing the findings with the domains of the Diabetes Distress Scale (4), we identified that people with IBD have many similar, but some unique disease-related sources of distress. In previously published work we confirmed findings

via a patient focus group (n=8) and a clinician Delphi study (n=20), resulting in 94 items that could be used to assess IBD distress. These were contained in five distinct domains of emotional, healthcare-related, interpersonal / social, treatment-related and symptom-related distress<sup>16</sup>. This paper builds on our earlier work and reports refinement of the 94 item IBD-DS into the final 28 item IBD-DS; it also reports comparison with a gold standard scale for diabetes distress<sup>35</sup> and with a scale for symptoms of anxiety and depression<sup>36</sup>, and determines the new scale's face, content and construct validity, and reliability via test-retest<sup>37</sup> in people living with IBD.

## **MATERIALS AND METHODS**

Following preliminary work reported elsewhere<sup>16</sup>, we conducted a three-phase study guided by recommended procedures for development of a patient reported outcome measure (PROM)<sup>38</sup>. We aimed to: Phase 1: use cognitive interviews to refine the initial 94 item IBD-Distress Scale (IBD-DS), reducing the number of items; Phase 2: use scale validation methods<sup>38</sup> to undertake psychometric validation of the draft IBD-DS via test-retest, and statistical analysis to determine the possibility of further item reduction; Phase 3: test-retest and psychometric validation of the reduced final IBD-DS with newly-recruited participants.

### **Study sample**

Phase 1 and 2 participants were recruited from IBD clinics at two large UK university hospitals and invited to participate in both phases. Inclusion criteria were: confirmed diagnosis of IBD by endoscopy, and aged over 18 years. Four hundred and twenty three consecutive eligible clinic attenders were invited to participate and 338 (80%) agreed to participate. Eighteen of 41 volunteers for Phase 1 were purposefully selected for cognitive interviews to represent a broad spread of gender, age, diagnosis and geographic location. 297 patients agreed to participate in Phase 2.

Phase 3 participants were recruited from members of a United Kingdom IBD charity via social media platforms and website advertising, with 209 registering an interest and 123 participating.

### **Sample size**

Phase 1: It is not possible to calculate sample size for cognitive interviewing, since the number of interview rounds needed to finalize adjustments to the draft PROM cannot be pre-empted. Evidence<sup>39,40</sup> and our

previous experience<sup>32, 41</sup> indicates that three to four rounds, with approximately five interviews per round, is usually sufficient. We continue to interview from our pool of 41 potential participants until the Phase 1 aim of developing a coherent and understandable draft questionnaire was achieved.

Phases 2 and 3: Sample size for a new questionnaire is impossible to determine *a priori* as there is no data on the width of confidence intervals. A minimum sample size of 30 – 40 has been recommended<sup>40</sup>, increasing with the number of items to be tested<sup>42</sup>, but an accepted ‘rule of thumb’ indicates 10 participants per item although this has never been verified<sup>43, 44</sup>.

### **Data collection tools**

Demographic data (age, gender and IBD diagnosis) were collected from all participants. In Phases 2 and 3, disease activity was self-assessed by participants using the Crohn’s Disease Activity (Harvey Bradshaw) Index (HBI)<sup>45</sup> for those with CD, and the Simple Clinical Colitis Activity Index (SCCAI)<sup>46</sup> for those with UC. We have successfully collected remote patient completion of the HBI and SCCAI in previous studies<sup>32, 41</sup>. A disease activity score of 4 or below indicated remission, whilst a score of 5 or above indicated relapse.

To enable comparison with distress in other conditions, and with anxiety and depression, participants also completed the modified Diabetes Distress Score<sup>35</sup> in Phase 2, and the Hospital Anxiety and Depression Score<sup>36</sup> in Phases 2 and 3.

**The Diabetes Distress Scale** (DDS)<sup>35</sup> is a self-administered 17- item validated tool with a score range of 17-102, for detecting emotional distress in patients with diabetes. For this study, we replaced the word ‘diabetes’ with the acronym ‘IBD’ but retained all other features of the scale. Our preliminary work<sup>16</sup> identified some similarities between DDS domains and draft IBD-DS items, thus providing the support for this rationale.

The DDS comprises four sub-scales: emotional burden (5 items), physician-related distress (4 items), regimen-related distress (5 items), and interpersonal distress (3 items). Responses to each item are rated on a 6-point frequency scale. A mean score of three or more (moderate distress) indicates elevated

distress likely to impact on glycaemic control and self-care behaviours in people with diabetes, warranting clinical attention <sup>35</sup>. The DDS was chosen to enable comparison of IBD distress with another validated disease-related distress tool.

**The Hospital Anxiety and Depression score (HADS)** <sup>36</sup> is a 14-item self-administered validated tool comprised of two subscales (Anxiety and Depression) each with a score ranging from 0 – 21. Scores of 0-7 indicate normal levels of anxiety and depression; 8 -10 indicates borderline abnormal anxiety and depression; 11-14 indicates moderate anxiety and depression and 15-21 suggests severe levels of anxiety and depression. HADS was selected because it is a recognized generic tool for assessing anxiety and depression in people with physical disease and was used in this study with permission and under license from GL Assessments.

## **Patient and Public Involvement**

A patient and public involvement (PPI) team of two men and two women with IBD was recruited from the membership of the funding charity, and from a UK IBD charity. The team had significant involvement in the preliminary work to identify distress in IBD <sup>16</sup>. In this study, they participated in designing the layout of the new IBD Distress Scale, in the item reduction process after the Phase 1 cognitive interviews and in planning dissemination activities. PPI involvement in research is widely encouraged and potential benefits of the role of PPI in PROM development have been reported <sup>47</sup>. These benefits reflect those seen in clinical trials and other engagement projects – including ‘increasing the quality and quantity of patient relevant priorities and outcomes’ <sup>48</sup>.

## **Data collection**

An overview of the full development and testing process is provided in Fig.1.

### ***Phase 1: IBD-DS item generation and item reduction (Fig.1 Box A)***

Development of patient-reported measures usually begins by interviewing people with the condition of interest to identify potential content <sup>38</sup>. Our preliminary work <sup>16</sup>, which provided 94 items for the first draft of the new Inflammatory Bowel Disease Distress Scale (IBD-DS), replaced this stage.

### ***Establishing face and content validity (Fig.1 Box B)***

Addressing face validity (the ease with which the completing person can understand each question) and content validity (the relevance of questionnaire content) are the next stages in developing a new questionnaire<sup>38</sup>. During an initial three rounds of cognitive interviews (n=15), face and content validity of the 94-item draft IBD-DS were explored. Cognitive interviews are used to detect problems participants may have in understanding / interpreting the questions, and in being able to give the response they wish to give<sup>49</sup>. Attention is also paid to grammar, layout, ease of use and item completion rate, using 'think aloud' and verbal probing techniques<sup>50</sup>. Cognitive interviews help to identify ambiguous or misleading questions, and whether the response and scoring options are appropriate. These initial 15 interviews were digitally audio-recorded, and transcribed. Between interview rounds, revisions were made to the developing IBD-DS, using simple thematic analysis of transcripts and notes, and discussion between three of the authors (LD, CN, SW).

#### *Initial item reduction (Fig. 1 Box C)*

Over three interview rounds, the draft IBD-DS was reduced from 94 to 88 items and wording was refined. The study team, including PPI representatives, conducted a simple analysis of the spread of responses from each participant. Twenty-four questions were deleted and 15 were combined to create six new questions. In response to interview participants' comments, the rating scale was amended from 0–10, to 0–6. Three supplementary unscored questions were added: a 0 – 6 scale for current overall level of distress (0 = not distressed; 6 = highly distressed); a scale for reporting perceived current level of disease activity (in remission; mild flare; moderate flare; severe flare); and a free-text item for prioritizing their top three current causes of distress.

The 55 item draft IBD-DS was then tested via three further cognitive interviews (*Fig. 1 Box D*). No further substantive changes were required, confirming a 55- item draft IBD-DS (each item scored 0-6, score range 0-330), plus three supplementary unscored questions.

## **Phase 2**

#### *Determining construct validity and reproducibility (Fig.1 Box E)*

Our aim was to determine how well the 55 item draft IBD-DS performed by assessing response rates to individual questions; sensitivity (identifies respondents who are distressed as different from those who are

not); and test-retest reliability (questionnaire performs similarly on more than one occasion when the underlying condition is unchanged). A further aim was to determine whether the draft IBD-DS correlated with the validated Diabetes Distress Scale (DDS) (7) and with the HADs.

Participants completed paper copies of the draft IBD-DS on two occasions (test and re-test), approximately three to four weeks apart. They indicated with a Yes/No response whether a question was relevant to them, completing a distress score (0-6) for that question if they answered 'yes'. A 'no' answer scored zero. Participants also completed three supplementary questions. On the first occasion (test) participants also completed a study-specific demographic details form, the HADS <sup>36</sup>, and the modified DDS; the HBI <sup>45</sup>, or the SCCAI <sup>46</sup> were completed at both test and retest. One email was sent to remind participants to return their documents by post. Microsoft Excel (2010) and Stata (Version 13.2) were used to manage and analyze data. After data analysis (see results section), the draft IBD-DS was reduced to 28 items (*Fig. 1 Boxes F & G*).

### **Phase 3**

*Confirming construct validity and reliability (reproducibility) (Fig. 1 Boxes H & I)*

The test-retest phase was repeated with the 28-item questionnaire and a new cohort of community-based participants using identical processes as described above for Phase 2. As the purpose was to confirm the reproducibility, further associations with the DDS <sup>35</sup> were not tested.

### **Statistical methods**

Data from the various scores were summarized using mean and standard deviation (normal distribution), and median and inter-quartile range (positively skewed distribution). Analyses of the association between the IBD-DS scale and HADS <sup>36</sup> were performed using Pearson's correlation, and was restricted to the Phase 2 'test' data only.

The internal consistency of the items making up the IBD-DS scale were assessed using Cronbach's alpha. A high value (close to +1) would suggest good internal consistency of the score.

Two sets of repeatability analyses were performed on the test and retest data in Phase 3. Patients whose disease status changed from active to inactive (or vice versa) between the two sets of measurements were excluded. The first analysis examined the agreement in the actual measured scores using the Bland-Altman limits of agreement method. This method quantifies the size of differences between pairs of values that are likely to occur.

A second repeatability analysis examined agreement using the intra-class correlation (ICC) method. This method divides the total variability in the IBD-DS measurements into two sources: the variation between patients, and the variation in repeat measurements of the same patient. The ICC is the proportion of total variation that is between patients. If there is good agreement between patients, there should be little variability between repeat measurements of the same patient, and thus most variability should be between patients, giving ICC values close to 1.

A final analysis examined patterns between individual items within the scale using a factor analysis. The importance of the factors identified was determined by the size of the eigenvalue associated with each factor. Factor loadings were given a Varimax rotation to aid interpretation of results. Items with factor loadings of 0.5 or higher were deemed to be associated with a particular factor.

### **Ethical considerations**

Ethical approval for this study was granted by the NRES Committee South West - Cornwall & Plymouth [REC Reference 14/SW/0132] (Phases 1 and 2), and by the Research Ethics Committee at King's College London [REC reference LRS-15/16-3674] (Phase 3). Written informed consent was collected from participants immediately prior to the individual cognitive interviews in Phase 1; consent to participate in Phases 2 and 3 was implied by return of completed questionnaires.

### **RESULTS**

Demographic details of all study participants are provided in Table 1.

#### **Phases 1 and 2**

Of the 297 people who initially volunteered for Phases 1 and 2, 24 could not take part (n=18 could not be contacted, n=4 had changed their minds about taking part, and n=2 had died). Fifteen people participated in

cognitive interviews in Phase 1, and following initial item reduction, three further cognitive interviews were conducted to verify the changes to the questionnaire. 273 people received the 55-item test draft IBD-DS in Phase 2. 168 (61.5%) participants responded. Of these, 136 (81%) returned the retest draft IBD-DS.

Statistical analysis using Spearman's rank correlation indicated a positive correlation between the IBD-DS and the modified DDS (CC 0.85,  $p < 0.001$ ), and between the IBD-DS and the HADS (Anxiety: CC 0.64,  $p < 0.001$ ; Depression: CC 0.54,  $p < 0.001$ ) [Table 2]. All correlations were positive, suggesting that higher IBD-DS values were associated with higher values on all other measures. Scatterplots demonstrating the association between the IBD-DS, the HADS and the DDS are available online [Online DSF 1].

#### *Secondary item reduction*

Further statistical analysis using weighted kappa, calculation of mean scores and percentage of non-zero scores, and observation of response rates was conducted. Principle Component Factor Analysis was not used at this stage because there was no pre-defined grouping of the items, making even a partial confirmatory factor analysis difficult to perform.

Following team discussion, a further 27 items were removed resulting in a 28-item final IBD-DS (each item scored 0-6, score range 0-168), plus three supplementary unscored questions. This version was circulated to a sub-sample of Phase 2 participants who had returned their test-retest questionnaires promptly ( $n=20$ ). Twelve responded, endorsing the changes.

### **Phase 3**

Of the 209 people who volunteered for Phase 3 and received the 28-item test final IBD-DS, 123 (58.8%) responded. Of these 95 (77%) returned the retest final IBD-DS.

#### *Data summaries and correlation between scores*

Test and retest data for Phase 3 are summarised in Table 3. IBD-DS scores were approximately normally distributed suggesting an absence of a floor or ceiling effect.

#### *Construct validity*

Examination of the association between the IBD-DS score and the HADS <sup>36</sup>, HBI <sup>45</sup> and SCCAI <sup>46</sup> revealed that higher IBD-DS values were associated with higher values on all other measures. The highest correlation ( $r = 0.77$ ) was with the stand-alone self-reported distress item of the IBD-DS [Table 2], although there were correlations with both HADS scores (anxiety,  $r = 0.68$ ; depression,  $r = 0.62$ ) as well (all  $p < 0.001$ ).

#### *Internal consistency*

The calculated value for Cronbach's alpha was 0.95, and for Guttman's Lambda 2 statistic was 0.94. Both suggest that the final IBD-DS scale has a high degree of internal consistency.

#### *Reproducibility and stability over time (repeatability)*

There were 95 participants with both test and retest data. Of these, 19 experienced a change in their disease activity (remission to relapse, or vice versa) between test and retest and three had significant missing data. These participants were excluded from the test-retest analysis. Two analyses were performed on the remaining 72 data sets. Analysis using the intra-class correlation (ICC) calculated an ICC value of 0.92 (95% CI, 0.88, 0.95) indicating fairly good to excellent agreement between test and retest values. Bland-Altman analysis suggested a mean difference between time-points of 0.5, with a range of -29.4 to +30.4 between the 95% limits. Thus the score could vary by +/- 30 units between occasions. Clinical judgement is required as to whether this is an acceptable amount of variation.

#### *Factor analysis*

Factor analysis identified four factors, with importance indicated by eigenvalue. Factor 1 (eigenvalue 13.2) was much larger than the remaining factors (Factor 2: 1.9; Factor 3: 1.3; Factor 4: 1.2), and explained almost half of all variation in the data. On the basis that there is no statistical suggestion that it is logical to combine the remaining factors, a single domain with an overall score (range 0-168, plus three supplementary unscored questions) is recommended. The final version of the IBD-DS is provided as supplementary online material [Online DSF 2].

## **DISCUSSION**

The IBD-DS demonstrates good content validity, internal consistency, construct validity, moderate reliability (agreement and reproducibility), and absence of floor and ceiling effects ( $\leq 15\%$  of respondents achieved the highest or lowest possible scores). The remaining criteria (responsiveness to change and interpretability) will be addressed in full psychometric validation during future intervention studies. A particular strength of the new scale is the robust developmental process which has included our PPI team throughout, ensuring that the IBD-DS reflects the needs and concerns of patients with IBD <sup>48</sup>. The scale can be printed on a single sheet (two sides) of paper (A4), and scoring and identification of the patient's priority issues is rapid.

There are some similarities between items of the IBD-DS and those of the DDS. This is unsurprising given the key role of the DDS in the early development of items for the IBD-DS <sup>16</sup>. The DDS domains (emotional burden, physician-related distress, regimen-related distress, and interpersonal distress) were not identified as separate domains in the IBD-DS, yet the final items of IBD-DS are similar to the DDS in terms of treatment/regimen distress and in emotional/psychosocial burden. Differences appear to relate to the role of others in each disease. In diabetes, over-monitoring and criticism by family members <sup>51</sup> can cause distress and are contained within the interpersonal distress items of the DDS as a result of the surveillance role close family and friends feel the need to perform. In IBD it is the perceived burden of the disease on family that causes the distress. Both are socially constructed distresses but with different roots. Diabetes does not appear to limit people's life choices in the way that IBD does. This may relate to a perception of good public awareness of diabetes in contrast to IBD.

Inflammatory bowel disease is manifested in many complex symptoms which have a negative impact on patients' quality of life (QoL). The IBD-DS is an addition to a range of disease-specific patient-reported outcome measures (PROMs) which assess, for example, and QoL <sup>52</sup>, fatigue <sup>41</sup>, continence <sup>32</sup>, and perceptions of disease control <sup>53</sup>, in people with IBD. The use of PROMs in all areas of clinical research and practice is increasingly recognised as being the best indicator of the impact of clinical interventions, whilst also keeping the patient perspective at the heart of research and clinical care <sup>54</sup>. Data from disease-specific PROMS enable monitoring of IBD treatment and interventions, whilst data from generic health-related quality of life (HRQoL) measures enable comparison with other chronic conditions <sup>55</sup>. Generic and disease-specific measures may also assess different but equally important aspects of disease impact, and can therefore be used together to gain a composite view <sup>56</sup>. Test data analysis shows IBD-DS scores to

have a significant positive correlation (all  $p < 0.001$ ) with existing validated tools. Indications are that the new IBD-DS detects and measures disease-related distress in IBD, as the DDS<sup>35</sup> does for diabetes<sup>6</sup>.

The significant correlation with both HADS scores is indicative of the inter-relationship often co-exists in chronic illnesses<sup>12,13</sup>. This symptom overlap is potentially considerable and is complex for patients and clinicians to unravel what is physical disease (IBD), psychiatric diagnosis (clinical depression) psychological morbidity (depressive symptoms) and emotional consequences of living with physical disease (IBD-distress). Disease specific distress is conceptually different from other commonly assessed patient reported outcomes such as quality of life and depression, because it derives purely from the disease itself and not from any extraneous factors. Different types of intervention may be required to manage it<sup>6</sup>. The IBD-DS addresses distress associated with the unique features of living with this specific disease, rather than the more generic aspects of emotional wellbeing addressed in the HADS. Previous identification of IBD-related concerns<sup>57-59</sup> identify bothersome issues amongst IBD populations but do not assess the impact of these issues on the individual.

#### *Establishing cut-off points*

Further work is needed to establish cut-off points. The normal distribution of scores suggests that there is a range of experience of distress amongst IBD patients. Elevated diabetes distress across diabetes populations are around 22%<sup>5</sup> and it is therefore to be expected that many people with IBD will not experience levels of distress that impact their self-management. Cut-off points, denoting no, mild, moderate and severe distress, may emerge from future studies. Data from a larger, more generalized study population would establish clinically concerning levels of distress for IBD which might inform scoring by determining the threshold at which distress levels would warrant clinical attention. A single summative score is indicated by statistical analysis which did not support retaining separate domains.

#### ***Clinical usefulness***

Disease-related distress impacts on clinical outcomes and self-care behaviours in numerous other long-term conditions<sup>3,12,13</sup>. A recent European-wide survey of people with IBD reports the immense impact the illness has, and that patients do not always have the opportunity to raise their concerns during clinical consultations<sup>60</sup>. The availability of the IBD-DS to assess disease-related distress offers patients a means of

indicating and prioritising their concerns, and gives clinicians a guide to understand how best to support the patient. Assessing distress levels routinely in IBD consultations may inform clinical decision-making by providing insight into the impact of IBD or a specific treatment on distress levels, and reveal the extent of distress amongst this population. Alleviating IBD-distress has the potential to improve patient QoL and improve their clinical outcomes.

Psychological therapies have been shown to be beneficial for disease-related distress in cancer <sup>61-64</sup>, and have been used for psychological distress (anxiety and/or depression) in IBD <sup>65</sup>, although evidence for the latter is conflicting <sup>66</sup> and therapies were not used specifically for disease-related distress. In diabetes, interventions addressing psychological and education needs, delivered by the clinical disease specialist team rather than by psychology specialists, are most effective <sup>8</sup>. Evidence of the relationship between distress, clinical outcomes, self-management behaviors, and therapeutic interventions could support the introduction and routine availability of psychological / counselling / education support services for IBD patients.

### **Strengths and Limitations**

This study has benefitted from patient (PPI) team involvement which has carried through from our preliminary phase <sup>16</sup>. PPI engagement and contribution at all stages of project design, delivery and reporting strengthens the relevance of the IBD-DS in ensuring it meets and reflects the needs and concerns of patients. There has also been considerable qualitative work to generate and reduce items, and these developmental processes are reported robustly.

There are also some limitations to consider. Phase 1 and 2 participants were recruited from only two tertiary care hospitals which receive referrals from a wide geographical area; overall, patients may have a more complex disease than those attending regional services, and may also therefore experience higher levels of distress. Phase 3 participants were recruited from a single IBD charity whose membership profile is predominantly middle-income, white female. Social class, with its relationship to education, may influence ability to access social support, and thus mitigate disease-related distress to some extent. The overall sample includes a higher proportion of women, and of patients with CD, and thus may not be

representative of the wider IBD population. Conversely, this may suggest that distress is associated more with CD than with UC, prompting those with CD to participate. Although Asian and Afro-Caribbean groups were represented, the majority of participants were Caucasian.

We only had self-reported disease activity scores on which to assess if IBD was in remission or relapse. Disease scores are known not to be highly correlated with objective measures of inflammation<sup>67</sup>, so our definition of “stable disease” between test and retest is possibly open to inaccuracy. Further, the low cut off point for remission ( $\leq 4$ ) excludes patients who are clinically in remission but score  $\geq 5$  due to permanent extra-intestinal manifestations. Finally, the amendment to the DDS (using the acronym ‘IBD’ in place of the word ‘diabetes’) was not tested for validity prior to use.

## Conclusion

The 28-item IBD-DS has face and content validity with people with IBD. During refinement it has performed well alongside existing validated measures of disease-specific (diabetes) distress and symptoms of anxiety and depression. The IBD-DS offers a useful clinical and research tool for assessing IBD-distress. Further testing, to include responsiveness to change and determining cut-off points is needed.

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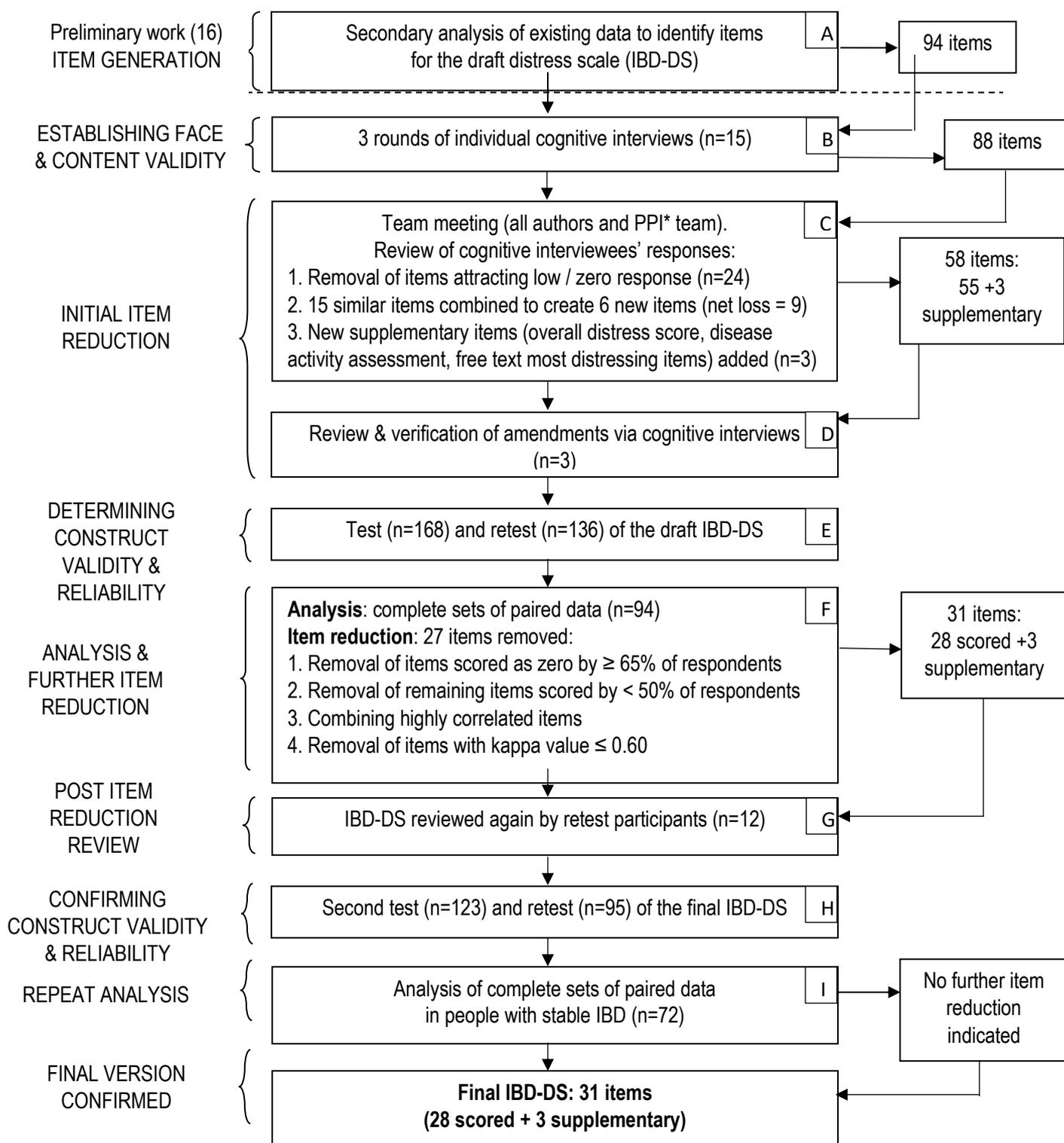
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**Figure 1: Flow chart of stages of development of the Inflammatory Bowel Disease Distress Scale (IBD-DS)**

\*PPI = Patient & Public Involvement;

	<b>Sex</b> (n; %)	<b>Age</b> range (mean)	<b>Ethnic group</b> (n; %)	<b>Diagnosis</b> n (% of total participants)	<b>Disease activity</b> HBI or SCCAI; Remission ≤ 4; relapse = ≥5 (n; % of participants per diagnosis)
<b>Phase 1</b> <i>n</i> =18	female (12;66.6%)	24-67 (40.4 years)	Data not collected	Crohn's disease (14; 77.7%) Ulcerative colitis (4; 22.2%)	Not recorded
<b>Phase 2 (test)</b> <i>n</i> =168	female (92; 54%)	18-88 (40.7 years)	Afro-Caribbean (5; 2.9%) Asian (14; 8.3%) Caucasian (149; 88.7%)	Crohn's disease (105; 62.5%) Ulcerative colitis (58; 34.5%) IBD Unclassified (4; 2.4%) Missing (1; 0.6%)	CD remission (59; 56%); relapse (40; 38%); missing (6; 5%) UC remission (38; 66%); relapse (20; 34%); missing (0; 0%) IBDU remission (2; 50%); relapse (2; 50%); missing (0; 0%)
<b>Phase 2 (retest)</b> <i>n</i> =136	female (71; 52%)	18-88 (41.2 years)	Afro-Caribbean (3; 2.2%) Asian (13; 9.5%) Caucasian (88.2%)	Crohn's disease (88; 65%) Ulcerative colitis (44; 32%) IBD Unclassified (4; 3%) Missing (0; 0%)	CD remission (53; 60 %); relapse (34; 38.9%); missing (1; 1.1%) UC remission (31; 70.5%); relapse (12; 27.3%); missing (1; 2.2%) IBDU remission (2; 50%); relapse (2; 50%); missing (0; 0%)
<b>Phase 3 (test)</b> <i>n</i> =123	female (98; 79%)	17-64 (35.7 years)	Afro-Caribbean (2; 1.6%) Asian (9; 7.3%) Caucasian (112; 91.1%)	Crohn's disease (62; 50.4%) Ulcerative colitis (58; 47.1%) IBD Unclassified (3; 2.5%)	CD remission (21; 33.9%); relapse (41; 66.1%); missing (0; 0%) UC remission (25; 43.1%); relapse (32; 55.2%); missing (1; 1.7%) IBDU remission (0; 0%); relapse (3; 100 %); missing (0; 0%)
<b>Phase 3 (retest)</b> <i>n</i> =95	female (76; 80%)	17-64 (35.3 years)	Afro-Caribbean (1; 1.05%) Asian (7; 7.3%) Caucasian (87; 91.65%)	Crohn's disease (52; 54.7%) Ulcerative colitis (41; 43.2%) IBD Unclassified (2; 2.1%)	CD remission (21; 40.3%); relapse (31; 59.7%); missing (0; 0%) UC remission (27; 65.8%); relapse (13; 31.7%); missing (1; 2.4%) IBDU remission (0; 0%); relapse (2; 100 %); missing (0; 0%)

**Table 1: Demographic details of study participants**

CD = Crohn's Disease or Crohn's Colitis; HBI = Harvey Bradshaw Index; IBDU = Inflammatory Bowel Disease-Unclassified; SCCAI = Simple Clinical Colitis Activity Index; UC = ulcerative colitis or proctitis.

Variable 1	Variable 2	N	Correlation Coefficient	P-value
<b>Phase 2</b>				
IBD-DS	HADS anxiety	138	0.64	<0.001
	HADS depression	136	0.54	<0.001
	DDS	131	0.85	<0.001
<b>Phase 3</b>				
IBD-DS	HADS Anxiety	121	0.68	<0.001
	HADS Depression	121	0.62	<0.001
	Self-reported distress	122	0.77	<0.001
Self-reported disease activity	HBI	62	0.70	<0.001
	SCCAI	62	0.70	<0.001

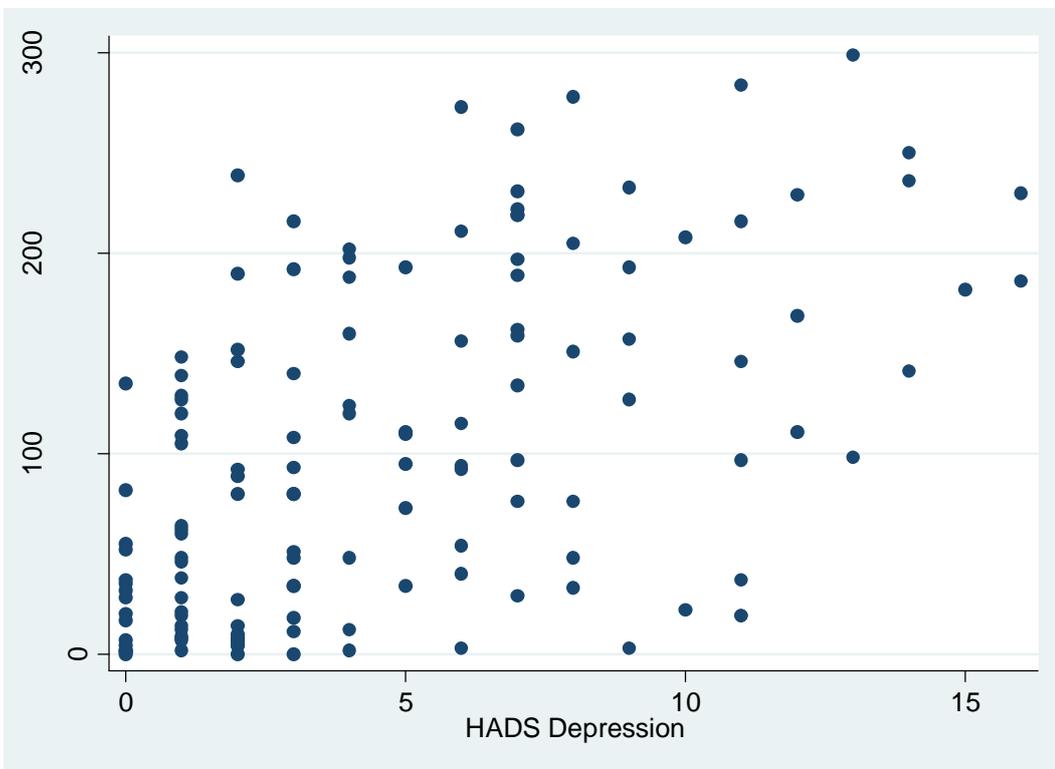
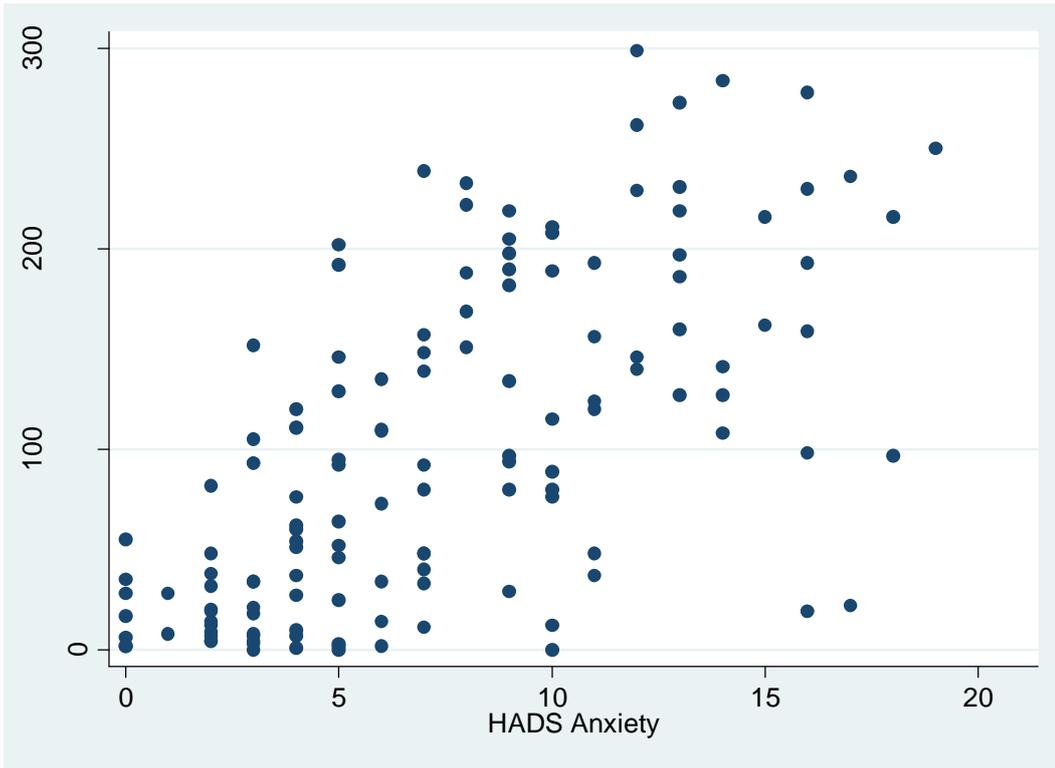
**Table 2: Data summaries showing correlations between the IBD-DS, the HADS and the DDS, and between self-reported disease activity and formal disease activity scores.**

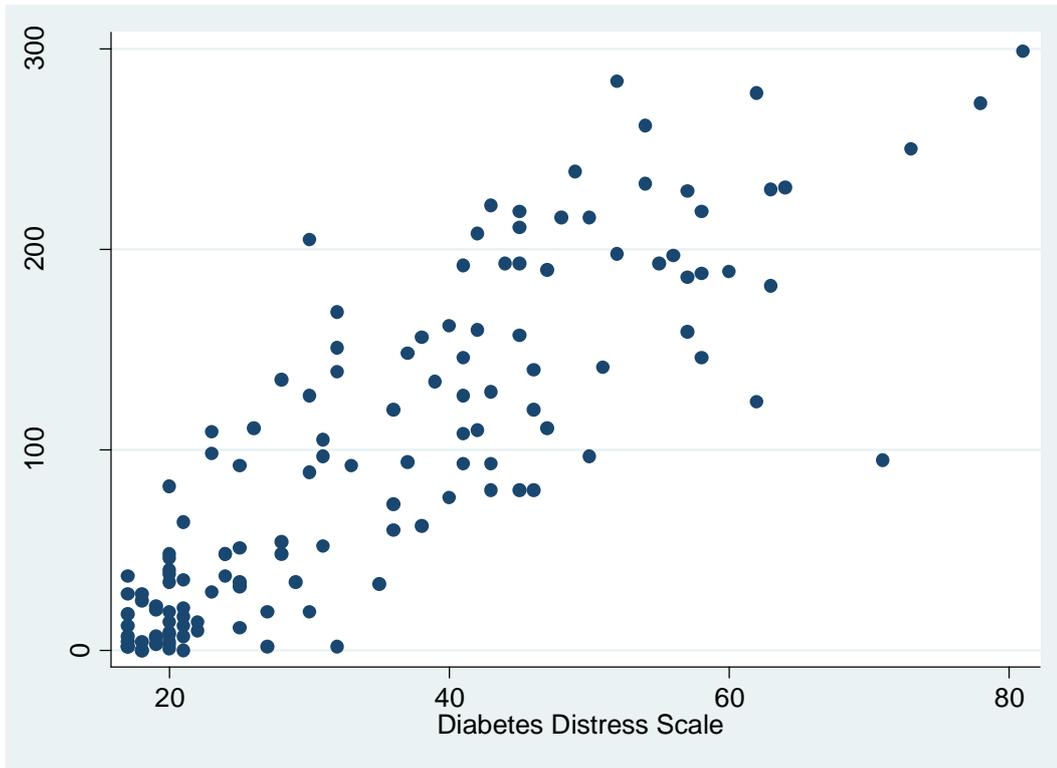
DDS = Diabetes Distress Scale; HADS = Hospital Anxiety and Depression Scale; HBI = Harvey Bradshaw Index; SCCAI – Simple Clinical Colitis Activity Index.

Scale	N	Test data		N	Retest data	
			Mean (SD) or Median [IQR]			Mean (SD) or Median [IQR]
HBI	62		5 [2, 7]	52		4 [2, 6]
SCCAI	60		6 [3, 9]	42		5 [2, 7]
HADS anxiety	122		9.9 (4.5)			-
HADS depression	122		6.5 (4.2)			-
IBD Distress scale	122		100 (36)	94		98 (37)

**Table 3: Summary of Phase 3 test and retest data**

HADS = Hospital Anxiety and Depression Scale; HBI = Harvey Bradshaw Index; SCCAI – Simple Clinical Colitis Activity Index.





**Online DSF 1: Graphical illustrations of the associations between each of the variables (HADS Anxiety, HADS Depression, and DDS) with the IBD-DS score**

DDS = Diabetes Distress Scale; HADS = Hospital Anxiety and Depression Score

Please think about how your IBD has been making you feel **during the last three months**, and whether the issues listed below cause you distress. IBD distress means 'emotional burden or suffering'. Please read each statement carefully and tick 'Yes' or 'No' in the relevant column. If your answer is 'Yes', please then circle the appropriate response on the scale to indicate how distressing the issue is for you. If a question is not applicable to you, please enter a tick in the 'No' column.

I am distressed because ...		Yes	No	If yes, how distressing is this?					
				Mildly distressing			Highly distressing		
1	... I feel embarrassed by the symptoms of my IBD			1	2	3	4	5	6
2	... I may need a temporary or permanent stoma, or other surgery for my IBD			1	2	3	4	5	6
3	... I worry about how the disease will progress and how this will affect me			1	2	3	4	5	6
4	... I sometimes do not have access to IBD health professionals when I need it			1	2	3	4	5	6
5	... some of the health professionals I see don't always take my concerns seriously enough			1	2	3	4	5	6
6	... I worry that the treatment I am having for my IBD will not work			1	2	3	4	5	6
7	... I worry that my IBD treatment will cause unpleasant side-effects			1	2	3	4	5	6
8	... I feel that the symptoms of IBD are difficult to cope with			1	2	3	4	5	6
9	... I worry that there is no cure for IBD			1	2	3	4	5	6
10	... I feel that IBD has reduced my opportunities in life			1	2	3	4	5	6
11	... it is difficult to talk to my employer, work colleagues or fellow students about my IBD			1	2	3	4	5	6
12	... I worry about how I will cope financially if I am unable to work			1	2	3	4	5	6
13	... I worry about the future (planning for a career or ongoing education)			1	2	3	4	5	6
14	... I worry about how other people will react if they find out I have IBD			1	2	3	4	5	6
15	... IBD takes up too much of my energy every day and can be overwhelming			1	2	3	4	5	6
16	... IBD controls my life and prevents me from doing the things I want to do			1	2	3	4	5	6
17	... I find the uncertainty of the disease and its potential to disrupt important events, difficult at times			1	2	3	4	5	6

I am distressed because ...		Yes	No	If yes, how distressing is this?					
				Mildly distressing			Highly distressing		
18	... I worry that when I am stressed about IBD, I make my symptoms worse			1	2	3	4	5	6
19	... I feel that IBD prevents me from being the person I <i>want</i> to be			1	2	3	4	5	6
20	... I feel that IBD negatively affects my intimate relationships			1	2	3	4	5	6
21	... I feel fatigued, unable to think straight and unable to motivate myself much of the time due to IBD			1	2	3	4	5	6
22	... I feel that other people sometimes do not understand I am unwell			1	2	3	4	5	6
23	... I worry that any children of mine might develop IBD			1	2	3	4	5	6
24	... social situations can be uncomfortable due to my IBD			1	2	3	4	5	6
25	... I feel that my IBD sometimes causes me to let other people down			1	2	3	4	5	6
26	... I often feel concerned about food and eating			1	2	3	4	5	6
27	... whenever I leave the house, I worry about finding or needing the toilet, having a bowel accident or passing loud or smelly wind			1	2	3	4	5	6
28	... when I am in crowded public places I do not feel in control			1	2	3	4	5	6

29	On a scale of 0 to 6, where 0 is 'Not distressed' and 6 is 'Highly distressed', how would you rate your current level of distress? <i>Please circle one option</i>						
	0	1	2	3	4	5	6
Not distressed							Highly distressed

30	Please indicate your current level of disease activity: <i>Please circle one option</i>			
	In remission	Mild flare	Moderate flare	Severe flare

**Finally, please identify the issue(s) causing you the most distress at the moment, and write them in the box below ....**

