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Article

Further Validation of the Crohn's and Ulcerative Colitis Questionnaire-32 (CUCQ-32) to Measure the Quality of Life in Patients Treated with Biologics Therapy

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Abstract:

Background: Crohn's and Ulcerative Colitis Questionnaire-32 (CUCQ-32) is a validated questionnaire to measure the quality of life (QoL) in inflammatory bowel disease (IBD). However, it does not have stoma specific questions and can be lengthy. This study aimed to validate a subset of the CUCQ-32 that would be suitable for patients with a stoma.

Methods: Baseline data were collected from a cohort of patients with acute ulcerative colitis who were participating in the CONSTRUCT multi-centre clinical trial. A subset of the CUCQ-32 questions was selected by stepwise regression. Further validation was examined using data from the UK IBD biological therapies audit. Construct validity was carried out using the EuroQol 5 dimensions (EQ5D) questionnaire, Simple Clinical Colitis Activity Index (SCCAI) and the Harvey-Bradshaw Index (HBI). Literature review and an expert focus group identified supplementary questions to cover patients with a stoma. Test-retest analysis was performed during the patients' second follow up visits.

Results: Using the data from 124 patients, a short version questionnaire (CUCQ-12) was developed. Further validation using data from 484 patients with IBD as part of the UK IBD biological therapies audit. Using the data from 61 patients with a stoma, we identified 5 stoma specific questions for the CUCQ-12$^+$. The CUCQ-12$^+$ demonstrated excellent internal consistency (Cronbach's α= 0.86); established effective reproducibility (intra-class correlation coefficient= 0.74); correlated well with the EQ5D (r= - 0.48), HBI (r= 0.45) and SCCAI (r= 0.43); and represented good responsiveness statistics (>0.5).

Conclusions: CUCQ-12 plus is a valid and reliable QoL measure that can be used for all patients with IBD in clinical practice including patients with a stoma.

Keywords: crohn's disease; inflmmatory bowel disease; quality of life; ulcerative colitis

INTRODUCTION:

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Inflammatory bowel disease (IBD) is known to impair quality of life (QoL) [1-3] and cause a substantial burden to patients, their families and society [4-6]. The chronic, incurable nature of the condition is characterised by alternating relapsing and remitting episodes with a wide variation in symptom severity and complexity.

QoL measures are important outcome measures that help obtain insight into patients' perception of their condition and how the care they receive may influence this [7]. The tools used to assess QoL are generally characterised into disease-specific or generic measures. Disease-specific measures appraise domains unique to a given disease, and are therefore regarded more sensitive to changes in the patient's state of health[8].

Several condition-specific HRQoL measures for patients with IBD [9-13] have been developed in the past few decades. Despite the availability of these measures, they are not included in conventional daily clinical practice and are generally neglected in large IBD registries due to the limitations on the extent of data collected as well as the high volume of IBD patients looked after in outpatient clinics. Simple to use, quick to complete, and concise tools could reinforce the routine use of QoL measures in patient care.

In severe cases of IBD, patients may need hospitalisation and on occasion surgery resulting in a stoma, which may have a negative impact on QoL [14-18]. Although generic QoL measures have been used, they are not specific for patients with a stoma [14, 19, 20]. Aspects of QoL that are important to patients with a stoma, such as social discomfort and smell, simply have not been included in the current QoL measures [21]. With the emerging new therapies and surgical techniques, a QoL measure in IBD that includes stoma-specific questions is necessary to compare various stoma types, treatments, and interventions in IBD. Studies on patients with a stoma have used generic QoL questionnaires or cancer-related QoL questionnaires [21-25]. It is important to mention that none of the currently available QoL measures in IBD has specifically included stoma related items.

The Crohn's and Ulcerative Colitis Quality of Life Questionnaire-32 (CUCQ-32) is a validated tool to assess the QoL of patients with IBD [26]. However, it contains 32 questions, which some clinicians may perceive to be lengthy for use in routine clinical practice.

This study aimed to derive and validate a shorter version of the CUCQ-32 that encompasses the different presentations and severity of IBD, including patients with a stoma. The questionnaire will have as few items as possible to be completed in a timely manner, while maintaining its effectiveness through proven validity and reliability on rigorous psychometric testing, [27] using data from the UK IBD biological therapies audit.

MATERIALS AND METHODS:

Developing a shorter version of the CUCQ:

The first phase of this study was to derive a shorter version of the CUCQ-32. Baseline data were collected from a cohort of patients with acute ulcerative colitis who were participating in the CONSTRUCT multi-centre clinical trial [28]. Consented patients from

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22 hospitals across the UK were asked to complete the Crohn's and Ulcerative Colitis Quality of Life Questionnaire-32 (CUCQ-32).

Stepwise regression was used to identify the best combination and the minimum number of CUCQ-32 questions required to accurately reflect the total CUCQ-32 score [29, 30].

A literature search was carried out to identify the changes and supplementary questions needed to cover patients with a stoma. An expert focus group of two gastroenterologists, two colorectal surgeons and two outcome measurement experts guided the process.

Following reduction of the CUCQ by stepwise regression, we undertook cognitive interviews and piloting of the short version of CUCQ-32 on a group of 20 patients (10 patients with CD and 10 with UC) with stable disease to ensure that the shortened questionnaire was clear to patients. A semi-structured approach was taken to encourage patients to participate. The patients were shown the questionnaires at each session and asked to contribute ideas and preferences about the questions' format, layout and response categories. This was done to ensure the questions addressed all IBD related issues that are considered important by patients, and to provide feedback regarding the content of the shortened CUCQ as well as its stoma-specific supplementary questions.

Validation of the short version of CUCQ:

We used the short version of CUCQ to collect data from patients who received biological therapy for their IBD treatment as part of the UK IBD biological therapies audit. All hospitals from across the UK were invited to participate. The study included patients with diagnosed IBD, ulcerative colitis (UC), Crohn's disease (CD) and IBD-type unspecified (IBDU). Patients of all ages were included.

Patients were asked to complete the short CUCQ questionnaire and the EuroQol 5 Dimensions (EQ5D) generic QoL measure [20]. The treating IBD specialists were asked to fill in a simultaneous assessment of the patient's current disease activity, using the Simple Clinical Colitis Activity Index (SCCAI) for UC [32] and the Harvey-Bradshaw Index (HBI) for CD [31]. Each patient was asked to rate their bowel condition on a scale of 0 to 100 (0 being the worst possible and 100 being the best possible bowel condition). A sub-sample of patients who returned to the clinic for a follow-up appointment was asked to complete the same questionnaires a second time.

Psychometric analysis:

We applied the Statistical Package for Social Sciences (SPSS) version 22, to perform the necessary psychometric testing:

Stepwise regression: We used stepwise regression to derive the shorter version of CUCQ by identifying the combination of questions that best predicted the total score of CUCQ [29, 30].

 doi:10.20944/preprints202205.0320.v1

Assessing internal consistency: Cronbach's α was used to evaluate the internal consistency of the short CUCQ. In order to achieve a satisfactory consistency, Cronbach's α must surpass 0.7 [33]. We eliminated certain questions if their correlation to the total score (item-total correlation) was below 0.2 [27, 33] or over 80% of responses were similar (maximum response ratio), due to the low sensitivity of these questions in differentiating between the severity of symptoms [27, 33].

Assessing validity: We used one generic QoL measure EuroQol 5 dimensions (which has two components: the 5-item descriptive (EQ5D) and a visual analogue scale (VAS)) as well as two IBD specific tools (SCCAI and HBI) to evaluate the effectiveness of the short CUCQ. To ensure the short CUCQ is an accurate measure of the impact of IBD on a patient's health, it would need to show positive correlation ($r>0.4$) with QoL measures and disease severity [33, 34].

Assessing reproducibility (Intra-class correlation): We assessed the reproducibility of the short CUCQ by analysis of a retest questionnaire to a subgroup of patients who came for a follow-up visit after they first completed the short CUCQ questionnaire. In order to maintain consistency between the two sets of responses, only patients who reported no change in their bowel condition on the 100-point scale versus their first visit were included in the reproducibility analysis. We applied the intraclass correlation coefficient to evaluate the reproducibility of scores for these stable patients [35]. An intra-class correlation between the two sets of questionnaires should surpass 0.70 to reach adequate reproducibility [36].

Assessing responsiveness: We analysed responsiveness in retested patients that revealed a change in their bowel condition on the 100-point scale. We calculated three common responsiveness statistics: effect size, standardised response, mean (SRM) and the responsiveness ratio (RR) [35]. The acceptable value for responsiveness ratio is 0.5 or 50% [27-29]. The responsiveness ratio (RR) is the ratio of the mean change in score of patients with improvement or deterioration at the baseline and second assessments to the standard deviation (SD) of scores of the stable group at baseline [35] [37, 38]. Effect size (ES) is calculated as the mean change in score of patients with improvement or deterioration at the baseline and second assessments divided by the standard deviation of scores at baseline (of the group that had a change in the health status). The standardised response mean (SRM) is calculated by dividing the mean change in scores of patients with improvement or deterioration at the baseline and second assessments by the standard deviation of the differences of scores between the two visits [25]. The SRM differs from ES because the denominator is the SD of change in scores (rather than baseline scores). The effect size value of 0.2 is considered small, 0.5 is medium and ≥ 0.8 is large [27].

 doi:10.20944/preprints202205.0320.v1

Defining the minimally important change (MIC): We used the difference in patients' rating of their bowel condition change in the second visit as an anchor to calculate the MIC. The MIC was the mean change of the scores of patients who reported a difference of less than 10% in their bowel condition on the 100-point scale.

RESULTS:

Development of the short CUCQ:

We carried out stepwise regression using the data from 124 patients with ulcerative colitis (UC) who participated in the CONSTRUCT multi-centre clinical trial [17] between May and December 2010. Stepwise regression of the 32 questions of CUCQ-32 identified 12 questions that together accounted for 95% of the variance in the total CUCQ-32 scores between patients. The shorter version of CUCQ-32 was called the Crohn's and Ulcerative Colitis Quality of life questionnaire-12 (CUCQ-12) (Table 1 and Appendix 1). The pilot study on 10 patients with stable IBD aged 30-55 years demonstrated clarity of the questions to patients.

The CUCQ-12 questions addressed the following 12 dimensions: sleep, appetite, energy level, urgency, bloatedness, incomplete emptying of bowels, blood in stool, generally unwell, faecal incontinence, nocturnal diarrhoea, passing flatus and abdominal pain. The total CUCQ-12 score ranged from 0 (best) to 168 (poor), with each question scored between 0 (best) and 14 (poor). These numbers correspond to the number of days affected by a parameter in a fortnight.

Table 1: The 32 items of the CUCQ-32 and stoma extension

Rank	Questions ranked by percentage of variance in the total score that they explain	The cumulative percentage of variance explained
CUCQ-32 items		
	1. Unable to sleep well*	45.9
	2. Felt tired*	65.9
	3. Felt off food*	74.0
	4. Had to rush to toilet*	80.8
	5. Bloated abdomen*	84.9
	6. Toilet immediately after emptying bowel*	88.5
	7. Noticed blood in stools*	90.4
	8. Felt generally unwell*	91.7
	9. Bowels opened accidentally*	93.0
	10. Toilet to empty bowel after going to bed*	93.9

 doi:10.20944/preprints202205.0320.v1

	11. Problem with wind*	94.8
	12. Pain in abdomen*	95.4
	13. Bowel condition affected leisure	96.2
	14. Irritable	96.8
	15. Full of energy (reverse coded)*	97.4
	16. Runny bowel movement*	97.8
	17. Felt sick*	98.5
	18. Felt frustrated	98.8
	19. Opened bowels > 3 times a day*	99.0
	20. Felt worried	99.2
	21. Avoid events with no toilet at hand	99.5
	22. Felt depressed	99.6
	23. Sex life affected	99.7
	24. Feeling happy (reverse coded)	99.8
	25. Felt embarrassed by bowel problem	99.8
	26. Prevented from going out socially	99.9
	27. Felt angry	99.9
	28. Felt the need to keep close to a toilet	99.9
	29. Felt upset	100.0
	30. Felt lack of sympathy from others	100.0
	31. Prevented from normal activities	100.0
	32. Felt relaxed (reverse coded)	100.0
Stoma supplementary items		
	1. Feeling less attractive	74.7
	2. Problems with stoma care	84.3
	3. Afraid others may hear about stoma	91.7
	4. Feeling less feminine or masculine	93.8
	5. Embarrassed	95.6
	6. Worried about leakage	97.2

 doi:10.20944/preprints202205.0320.v1

	7. Worried of smell	98.2
	8. Dissatisfied with body	99.0
	9. Skin irritation	99.7
	10. Feeling less complete	100.0

To include patients with a stoma, the literature review and the expert focus group identified 10 supplementary questions that were added to the CUCQ-12. These questions (Table 1) covered body and sexual image, stoma function and skin irritation. The resultant CUCQ-12 questionnaire was called the Crohn's and Ulcerative Colitis Quality of Life Questionnaire-12 plus (CUCQ-12 plus). No additional questions were recommended as a result of the pilot study. The mean completion time for CUCQ-12 was 5 minutes (+/- 3 minutes).

Validation of the CUCQ-12 plus:

A total of 507 patients from 181 hospital sites completed the CUCQ-12 questionnaires as part of the UK IBD biological therapies audit between September 2011 and February 2014. We set a cut-off of 9 questions (75%) for the inclusion of individual responses. The data from 23 patients who answered less than 9 questions were excluded from the study. Missing data were replaced by the means of the remaining questions scores for each patient. The data from the remaining 484 patients (382 CD, 76 UC, 26 IBDU) were analysed. None of the questions were particularly not answered. The spectrum of disease severity and the characteristics of the patients' sample at baseline are summarised in Tables 2 and 3.

Table 2: The characteristics of the patients in stage 2 who completed the baseline CUCQ-12*.

Variable	Crohn's disease	Ulcerative colitis	IBDU
Number of cases (n=484)	382	76	26
Age			
< 18	5	2	0
18-39	202	41	15
40-65	141	31	7
>65	34	2	4
Gender			
Male (%)	156	41	14
Female (%)	218	35	12

 doi:10.20944/preprints202205.0320.v1

Non IBD co-morbidities	27	2	0
Smoking			
Current	82	3	2
Never	171	46	16
Ex-smoker	129	25	8
Generic HRQoL			
EQ5D utility score	0.65 (0.31)	0.69 (0.25)	0.63 (0.27)
EQ5D VAS	48.26 (28.55)	42.03 (30.24)	45.68 (27.56)
Had a postgraduate degree or qualification			
Yes	104	29	12
No	278	48	14
Disease Severity			
HBI	5.19 (4.86)		
SCCAI		4.88 (4.02)	4.92 (3.97)

* Categorical data are presented as numbers (percentages). Continuous data are presented as means (standard deviation)

Table 3: The clinical classifications of patients with IBD according to the Montreal classification (50).

	CD	UC	IBDU
Colitis			
Proctitis		5	2
Left sided (distal) colitis		41	14
Extensive (pancolitis)		30	10
Crohn's disease 1. Location			
Ileal	96		
Colonic	117		
Ileocolonic	80		
No location was specified	89		
CD Perianal	67		

 doi:10.20944/preprints202205.0320.v1

2. Behaviour			
Fistulating	73		
Inflammatory	255		
Stricturing	55		

The homogeneity of CUCQ-12 was excellent with Cronbach's α equal to 0.864. The correlations of each of the 12 items with the total score exceeded 0.2 (Table 4). Reassuringly, none of these correlations was greater than 0.8, showing that all items added extra information. In addition, no single response was chosen by more than 80% of patients, showing that all items achieved some discrimination. Using the 15% recommended value for the percentage of patients who scored the highest or the lowest scores [26], there were no ceiling or flooring effects in the CUCQ-12.

Table 4: item total correlations for all the 12 items in CUCQ-12 plus

Questions	Item-total correlations
1. On how many days over the last two weeks have you felt generally unwell?	0.79
2. On how many days over the last two weeks have you had to rush to the toilet?	0.76
3. On how many nights in the last two weeks have you had to get up to use the toilet because of your bowel condition after you have gone to bed?	0.67
4. On how many days over the last two weeks have you felt tired?	0.70
5. On how many days over the last two weeks have you wanted to go back to the toilet immediately after you thought you had emptied your bowels?	0.75
6. On how many days over the last two weeks have you felt pain in your abdomen?	0.74
7. On how many days over the last two weeks has your abdomen felt bloated?	0.67
8. On how many nights over the last two weeks have you been unable to sleep well (days if you are a shift worker)?	0.69
9. On how many days in the last two weeks have you noticed blood in your stools?	0.50
10. On how many days over the last two weeks have you felt off your food?	0.59
11. On how many days over the last two weeks, have you had a problem with large amounts of wind?	0.60

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12. On how many days over the last two weeks have your bowels opened accidentally?	0.52
Stoma supplementary questions	
1. In the last two weeks have you felt less attractive as a result of your stoma?	0.80
2. On how many days over the last two weeks have you had problems with care for your stoma?	0.34
3. On how many days over the last two weeks have you been afraid that other people might hear about your stoma?	0.64
4. In the last two weeks have you felt less feminine / masculine as a result of your stoma?	0.74
5. In the last two weeks have you felt embarrassed because of your stoma?	0.80

CUCQ-12 had significant ($p < 0.05$) and demonstrated effective correlations with generic QoL measures EQ5D ($r = -0.48$) and VAS (-0.39) as well as disease severity indices HBI ($r = 0.45$) and SCCAI ($r = 0.43$) (Table 5).

Table 5: Pearson correlation coefficient between CUCQ-12 and with other measures

Correlation of CUCQ-8 with:	All patients	Patients with CD	Patients with UC
HBI		0.45*	
SCCAI			0.43*
EQ5D	-0.48*	-0.51*	-0.50*
VAS	-0.36*	-0.37*	-0.23*

* P value < 0.005. Negative coefficients show that generic measures increase while disease-specific decrease.

A total of 61 patients (60 with CD and 1 with UC) had a stoma and completed the CUCQ-12 plus. The internal consistency of the supplementary stoma questions was excellent (Cronbach's $\alpha = 0.84$). None of the items had a correlation of more than 0.8 or a single response of more than 80%. The supplementary stoma questions correlated very well with the rest of the CUCQ-12 questions ($r = 0.59$, $p < 0.05$). However, we noted a positive but poor correlation of the stoma questions with the generic QoL measures, with EQ5D ($r = 0.03$) and VAS ($r = 0.19$).

Using stepwise regression analysis we were able to shorten the 10 supplementary stoma questions to 5 questions that represent more than 95% of the 10 questions variance (Table1). The final version of the CUCQ-12 plus included 12 questions related to IBD and 5 questions that are stoma specific (Appendix 1).

 doi:10.20944/preprints202205.0320.v1

A subgroup of 36 patients repeated and returned the CUCQ-12 in their second visit within a year (the average return time was 3 months). In the reproducibility analysis, we included 11 patients who reported no change in their bowel condition, which demonstrated a good intra-class correlation coefficient of 0.75. The remaining 25 patients who reported changing bowel conditions were included in the responsiveness analysis. The responsiveness statistics for CUCQ-12 were good (RR= 0.52; SRM = 0.51; and the effect size (ES) = 0.57). Using the patients' change in bowel condition as an anchor, we defined the minimally important change (MIC) of CUCQ-12 as a change of 9 points.

DISCUSSION:

Evaluating QoL in patients with IBD is essential in order to assess patient response to treatment. In the last few decades, there has been a rapid increase in the number of measures to evaluate the QoL in patients with IBD [9-13]. However, these measures were limited to clinical trials and are not being used in routine clinical practice. This is primarily because the questionnaires are lengthy and there are often licensing costs associated with using some of the questionnaires.

The CUCQ-32 is a validated measure for use in mild and moderate IBD [26]. CUCQ-32 was proven to be a valid and reliable measure for QoL in IBD. However, it contains 32 questions and its length may affect its routine use in clinical practice. CUCQ-32 was not validated on patients with a stoma. Therefore, this study aimed to determine the feasibility of developing and validating a shorter version of the CUCQ for use in patients with different presentations of IBD, including patients with a stoma.

The first stage of the study involved identifying the questions that could be included in a shortened version of the CUCQ. We used data from a cohort of patients with acute UC who participated in the CONSTRUCT clinical trial. The resulting 12-item questionnaire, the CUCQ-12, was able to predict 95% of the total CUCQ-32 score. The literature review and the expert focus group identified supplementary questions that included patients with a stoma, which covered body and sexual image, stoma function and skin irritation. The CUCQ-12 questionnaire was called the Crohn's and Ulcerative Colitis Quality of Life Questionnaire-12 plus (CUCQ-12 plus).

In stage two of our study, we assessed the data from the 484 respondents of the CUCQ-12 questionnaire that were recruited as part of the UK IBD biological therapies audit [39]. The results demonstrated that CUCQ-12 had good reliability and validity. It displayed excellent internal consistency with a Cronbach's α value of 0.84, above the 0.70 threshold proposed by Nunnally [34]. The CUCQ-12 showed good correlations with other QoL measures and disease-specific severity indices. An intra-class correlation coefficient of 0.75 demonstrated a satisfactory reproducibility. The good responsiveness ratio, SMR and ES of more than 0.5 suggests that the CUCQ-12 is responsive to changes in patients' clinical conditions and suitable for longitudinal monitoring of QoL. A change of 9 points in the total CUCQ-12 score was found to be the minimally important change as perceived by patients.

 doi:10.20944/preprints202205.0320.v1

A total of 61 patients had a stoma and completed the CUCQ-12 plus questionnaire. The results showed that the supplementary stoma questions had a good internal consistency, item-total correlations and correlated well with the CUCQ-12 questions. The stoma specific questions correlated poorly with the generic QoL measures (EQ5D and VAS). EQ5D and VAS questionnaires do not address any stoma specific QoL domains, such as body image. Therefore, this poor correlation results from the other generic QoL measures and the CUCQ-12 questions. We were able to identify 5 stoma specific questions that best predict the QoL of patients with a stoma. The sample was not enough to carry out a full test-retest reliability analysis.

Although there is a short version of the McMaster IBDQ (the SIBDQ) [40], the CUCQ-12 plus is different in several aspects. The phrasing of the questions in the CUCQ-12 plus has been customized for use in the UK. The response options of the CUCQ-12 plus were simplified using a combination of close-ended and open 0-14 scores answers. The CUCQ-12 plus also includes a question about urgency, which does not exist in the IBDQ-32 [41]. CUCQ-12 is the first IBD specific QoL measure that includes stoma specific questions. The advantage of using the CUCQ-12 plus is in its simplicity, wide coverage of the symptoms of acute IBD, and free use by healthcare professionals.

As transition questions are considered advantageous to other methods in evaluating the QoL by directly addressing patients' insights of change over time, they were used in several outcome measures studies [41-45]. Based on this, we assessed responsiveness to change and minimally important change (MIC) using patients' individual perceptions of their bowel condition via transition questions. Respondents with no changes in their bowel condition were included in the reproducibility analysis, while respondents with a change were included in the responsiveness and MIC analysis. Our test-retest validation was carried out over an average of a 3-month period. Future research is required to evaluate the reproducibility, responsiveness and MIC of CUCQ-12; using other disease indicators such as endoscopic evaluation and clinical judgment, over a shorter period of 2-4 weeks as recommended in the literature [46].

The number of patients required to validate the QoL measures in the literature is lacking. The literature lacks guidance on the number of patients needed to confirm the QoL measures. However, a ratio of 5 or 10 patients per item was suggested [34]. Recent studies suggested that at least 100 patients are sufficient for a validation study [47]. Therefore our sample of 484 patients is more than sufficient to validate the 12 questions of CUCQ-12.

To avoid any possible sampling bias, patients were recruited from 181 different hospitals across the UK to ensure a good representation of patients and to mirror routine clinical practice. Validation is an ongoing process, and the CUCQ-12 plus needs to be validated in a varied demographic and diverse clinical setting. In the meantime, the CUCQ-12 performed well in its present form and showed very good psychometric properties in the current study.

The CUCQ-12 plus, a short QoL tool for patients with IBD, has demonstrated itself as a robust evaluation tool with positive internal reliability, reproducibility, validity and responsiveness. In comparison to current QoL measures, this new tool has proven to be

 doi:10.20944/preprints202205.0320.v1

acceptable to patients in the UK, concise and readily applicable in clinical practice. These qualities support the use of CUCQ-12 plus in national IBD registries and databases as well as in audits, such as the UK IBD biological therapies audit [39].

Authors' contributions: LA contributed to writing the manuscript, designing the questionnaires, data collection and analysis. RS contributed to data analysis and writing the manuscript. IA contributed to recruiting patients, data collection and all drafts of the manuscript. HAH and JGW contributed to designing the questionnaires, all drafts of the manuscript and data analysis. All authors approved the final version of the manuscript

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APPENDICES:

Appendix 1. Crohn's and ulcerative colitis questionnaire-12 (CUCQ-12) plus

The following questions ask for your views about your bowel problem and how it has affected your life over the last two weeks. Please answer all the questions. If you are unsure about how to answer any question, just give the best answer you can. Do not spend too much time answering, as your first thoughts are likely to be the most accurate. If you do not wish to answer any of these questions, please leave it blank and complete the details of the question and reason(s) why it was not answered.

1. On how many days in the last two weeks have you noticed blood in your stools?

…… days

2. On how many days over the last two weeks have you felt tired?

…….days

3. On how many days over the last two weeks have your bowels opened accidentally? ……..days

4. On how many days over the last two weeks have you felt generally unwell?

…….days

5. On how many days over the last two weeks have you felt pain in your abdomen?

…….. days

6. On how many nights over the last two weeks have you been unable to sleep well (days if you are a shift worker)?

…… nights (or days)

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7. On how many nights in the last two weeks have you had to get up to use the toilet because of your bowel condition after you have gone to bed?

……. nights

8. On how many days over the last two weeks, have you had a problem with large amounts of wind? ……..days

9. On how many days over the last two weeks have you felt off your food?

…….. days

10. On how many days over the last two weeks has your abdomen felt bloated?

…….days

11. On how many days over the last two weeks have you wanted to go back to the toilet immediately after you thought you had emptied your bowels?

…… days

12. On how many days over the last two weeks have you had to rush to the toilet?

……. days

If you did not complete any of these questions, please record the question number(s) below and, if possible, give a reason why it was not completed.

Stoma questions

Please answer the following questions only if you have stoma. These questions ask you about your stoma and how it has affected your life over the last two weeks. Please choose only one answer for each of the questions. If you are unsure about how to answer any question, just give the best answer you can. Do not spend too much time answering, as your first thoughts are likely to be the most accurate.

1. In the last two weeks have you felt less attractive as a result of your stoma?

0. No, not at all.
1. Yes, some of the time
2. Yes, most of the time
3. Yes, all of the time.

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2. On how many days over the last two weeks have you had problems with care for your stoma?..... days

3. On how many days over the last two weeks have you been afraid that other people might hear your stoma? …… days

4. In the last two weeks have you felt less feminine / masculine as a result of your stoma?

0. No, not at all.
1. Yes, some of the time
2. Yes, most of the time
3. Yes, all of the time.

5. In the last two weeks have you felt embarrassed because of your stoma?

0. No, not at all.
1. Yes, some of the time
2. Yes, most of the time
3. Yes, all of the time.