

Original Article

Development of a Short Questionnaire to Assess the Quality of Life in Crohn's Disease and Ulcerative Colitis

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Abstract:

Background and aims: Most of the disease-specific quality of life (QoL) measures for inflammatory bowel disease (IBD) are lengthy and time consuming. None have been established for routine use in clinical practice. We designed this study to develop a short QoL measure in IBD.

Methods: A 32-item questionnaire, the Crohn's and ulcerative colitis questionnaire (CUCQ)-32 was developed by reviewing the literature of the previously validated questionnaires and by consultation with patients and experts. Construct validity was carried out using the Short Form 12 and the EuroQol 5 dimensions questionnaires and two disease severity measures (the Simple Clinical Colitis Activity Index and the Harvey-Bradshaw Index). Test-retest analysis was done by asking patients to complete the CUCQ questionnaire twice within a period of two weeks.

Results: Data were obtained from 205 patients with IBD who completed the CUCQ-32. Psychometric analysis showed that Cronbach's α was 0.88, item-total correlations were good, and there were no ceiling or flooring effects. Stepwise regression identified eight items that accounted for >95% of the variance in the CUCQ-32. The resulting CUCQ-8 demonstrated good internal consistency (Cronbach's $\alpha = 0.84$), had good reproducibility (intraclass correlation coefficient = 0.94), was well correlated with the EuroQol 5 dimensions questionnaire ($r = 0.58$) and the Short Form-12 ($r = 0.65$ for physical component and $r = 0.63$ for mental component), and was responsive to change (responsiveness ratio was 0.64, p -value < 0.05).

Conclusions: CUCQ-8 is a short questionnaire that has the potential to be an efficient tool for assessing the QoL of all patients with IBD in clinical practice.

Keywords: Inflammatory bowel disease; Crohn's disease; colitis; quality of life

Abbreviations

QoL	quality of life	HBI	Harvey-Bradshaw Index
IBD	inflammatory bowel disease	SCCAI	simple clinical colitis activity index
CUCQ	Crohn's and ulcerative colitis questionnaire	EQ5D	EuroQol 5 dimensions
UC	ulcerative colitis	SD	standard deviation
SF-12	short form 12	CD	Crohn's disease
IBDQ	IBD questionnaire	SRM	standardized response mean
FLZ	questions on life satisfaction	HRQoL	health-related QoL
		KMO	Kaiser-Meyer-Olkin



1. Introduction

The inflammatory bowel diseases (IBDs) of Crohn's disease (CD) and ulcerative colitis (UC) are chronic relapsing inflammatory disorders of the gut, which often impair quality of life.¹⁻⁴ The main symptoms of these conditions are urgent and frequent diarrhea, pain, and profound fatigue and anemia, often associated with inflammation of joints, skin or eyes. Malnutrition and weight loss are also common. The disease is not curable and follows an unpredictable relapsing and remitting course with a significant variation in the pattern and complexity of symptoms that affect each patient. IBD affects approximately one person in every 250 in the UK population.⁵ Quality of life (QoL) measures provide an important insight into patients' perception of their health and how the treatments they receive affect it. To measure QoL in clinical practice, it is important to develop instruments that are short and effective and yet valid, reliable and applicable to all IBD patients, whether managed in the community or acutely admitted to hospital. A valid, reliable and short measure would also be of use in research and for IBD registries, particularly to monitor outcomes after treatment with new therapies.⁶

There has been some success in using generic instruments, such as the Short Form (SF)36,⁷ the Psychological General Wellbeing Scale,^{8,9} the generic 15D instrument,^{10,11} and the Questions on Life Satisfaction (FLZ) in the IBD questionnaire (IBDQ).¹² However, there are concerns that these instruments might miss small but clinically important changes.¹³

There are several condition-specific QoL measures for patients with IBD,¹⁴⁻¹⁹ of which the McMaster IBDQ^{14-16,20} is the most widely used. Another common quality of life measure in the UK is the UK-IBDQ,²¹ which was developed in 2000 and validated for use in outpatient clinics. However, these measures have not become a routine part of daily clinical practice and are often overlooked in large-scale registries because of the limitations on the amount of data these registries can collect and the large number of patients with IBD managed in outpatient clinics. A tool that is simple to use, quickly performed and short will increase the regular use of QoL measures in longitudinal patient care.

The aim of this study was to develop a short QoL questionnaire suitable for use with patients with IBD, whether they have stable or mildly active disease managed in outpatient clinics, or more severe disease that may require acute admission to hospital.

2. Materials and methods

2.1 Devising the items

Items were generated through a literature search and an expert panel review of two gastroenterologists, three outcome measurement experts and a statistician. The panel included authors of the UK-IBDQ, a 30 item questionnaire that was validated in 2000 on patients with stable IBD managed in the community²¹. The panel reviewed and modified the UK-IBDQ to develop questions needed to assess the QoL of patients with acute IBD admitted to hospital and also stable patients managed in outpatient clinics. A focus group of patients with IBD was included in the initial development of the QoL questionnaire. The new QoL measure is called the Crohn's and ulcerative colitis questionnaire (CUCQ).

To test for acceptability and lack of ambiguity, we carried out a pilot study on 20 patients with IBD. The purpose of this pilot study was to check the clarity of the items and the time required by patients to complete the questionnaires. In addition to the CUCQ, we asked consenting patients to provide verbal or written feedback or annotations regarding the content and format of the questionnaire. At the end of the questionnaire, we asked them four supplementary questions and invited them to explain their responses:

1. Did you find any question difficult to understand?
2. Was there any question you did not want to answer?
3. Do you want to add an additional question?
4. Do you want to remove any of the questions?

2.2 The recruitment process and sample size

We used CUCQ to collect data from a convenience sample of outpatients and inpatients with IBD in four large hospitals in South Wales, UK, between January 2012 and September 2013.

There is no rule in the literature about the number of patients required to validate the QoL measures. However, a ratio of 5 or 10 patients per item was suggested²². Recent studies have suggested that 100 patients or more are sufficient for a proper validation study.²³ We aimed for a sample size of at least 160 patients for the purpose of validating the CUCQ questionnaire. We also checked the Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy (which should be >0.5) and Bartlett's test of sphericity (which should be significant) to confirm that the sample was suitable for principal component analysis, which we will discuss later.²⁴⁻²⁶

The inclusion criteria were: confirmed diagnosis of UC or CD; at least 18 years of age; a native English speaker; and absence of severe mental illness. Patients who met the inclusion criteria were approached when they attended outpatient clinics, during other treatment-related visits (e.g. having biological therapy), when having endoscopic examination, or when admitted to hospital. We explained the study to patients orally and in writing and obtained their consent. The patients completed the CUCQ questionnaire as well as two generic QoL measures which were the EuroQol 5 Dimensions (EQ5D)²⁷ and the Short Form 12 (SF-12).²⁸ The treating IBD specialists were blinded for the patients' CUCQ answers and were asked to fill in a simultaneous assessment of current disease activity using the Harvey–Bradshaw Index (HBI) for CD²⁹ and the Simple Clinical Colitis Activity Index (SCCAI) for UC.³⁰ We reviewed the hospital case records and clinical information systems to extract information regarding diagnosis, disease extent, and demographic data.

2.3 Psychometric analysis

We used the Statistical Package for Social Sciences version 19, to undertake the required psychometric testing.

2.3.1 Assessing internal consistency

Internal consistency is the form of reliability that assesses the correlation between different items in the scale. We assessed the internal consistency of CUCQ by calculating the Cronbach's α , which should exceed 0.7 for good consistency.³¹ We considered individual questions for rejection if their correlations with the total (item–total correlation) score fell below 0.2^{31,32}; or if more than 80% of patients gave the same response, because such questions are not sensitive enough to discriminate between different levels of severity.^{31,32}

2.3.2 Identifying the underlying factors

We carried out principal component analysis to assess the underlying dimensions of the CUCQ.^{32,33} Principal component analysis is a statistical technique for determining those questions which fit together as specific factors (or components or domains) and which account for the most variance in the scale. We considered factors important if their corresponding 'Eigen value' (a statistical measure of power to explain variation between patients) exceeded 1.2 and they explained more than 5% of the variance.^{22,32} We considered questions as making a useful contribution to the scale if they had a factor loading of at least 0.4 on one of these important factors. We considered questions not contributing to any important factor in this way for removal from the final instrument.

2.3.3 Stepwise regression of the individual items on the total score

Stepwise regression is a statistical technique for exploring the relationship between a dependent variable ‘predicted’ (CUCQ total score) and several independent variables ‘or predictors’ (CUCQ questions). It seeks the best combination and the fewest possible number of CUCQ questions that best predicts the total score.^{34,35} We used this method to minimize the number of items in the CUCQ to produce a short version.

2.3.4 Assessing validity

Construct validity assesses the consistency of the scale with other instruments known to assess similar attributes with good validity and reliability.³² It is commonly assessed by Pearson’s correlation coefficient (r). We used two generic QoL measures (SF-12 and EQ5D) and two disease-specific indices (HBI and SCCAI) to assess the validity of CUCQ. If the CUCQ was a valid measure of the effect of IBD on health, we would expect it to show a good correlation ($r > 0.4$) with other measures of QoL and disease severity.^{22,32}

2.3.5 Assessing reproducibility (intraclass correlation)

Reproducibility or test–retest reliability assesses the consistency between successive applications of the CUCQ.^{31,32} We assessed reproducibility by sending a retest questionnaire to a subgroup of patients two weeks after they first completed the CUCQ questionnaire. The retest questionnaire also included a transition question asking participants whether their bowel condition had improved, got worse, or remained the same since completing the first questionnaire. We only included those patients who reported “no” change in their condition in the reproducibility analysis, since the two sets of responses should be consistent. We assessed the reproducibility of scores for these stable patients using the intraclass correlation coefficient.³⁶ An intraclass correlation between the first and second set of questionnaires should exceed 0.75 for good reproducibility.^{31,32}

2.3.6 Assessing responsiveness

Responsiveness is the ability of the CUCQ to detect change. In contrast to reproducibility, we assessed responsiveness in retested patients who “did” report a change in their bowel condition (got worse or improved). To do so we used the responsiveness ratio (RR),³⁶ calculated by dividing the mean change in scores for patients who reported a change by the standard deviation (SD) of the scores of stable patients. We also calculated the standardized response mean (SRM) by dividing the mean change in scores of patients with improvement or deterioration between the baseline and second assessments by the SD of the differences of scores between the two visits.³⁶ The responsiveness statistics should exceed 0.5 for good responsiveness.^{31,32}

3. Results

3.1 Devising and pre-testing items

The expert panel included authors of the UK-IBDQ, a 30-item questionnaire that was validated in 2000 on patients with stable IBD managed in the community.²¹ The initial draft of the CUCQ was derived from the UK-IBDQ. The panel recognized that the UK-IBDQ questions should be modified to cover a wider spectrum of patients with IBD, and with an aim to shorten the questionnaire to include the fewest possible questions. We included two questions to assess nocturnal diarrhea and rectal bleeding to cover inpatients with acute IBD. The process of literature review, patient focus group and expert panel opinion identified 32 questions for assessing the QoL in IBD, named the CUCQ-32 (Appendix 1). The response options

included a mixture of closed-ended ordinal answers and four-level Likert scales. When asking about loose or runny bowel movements, blood in stools, feeling tired, frequent bowel movements, feeling full of energy, opening bowel accidentally, feeling generally unwell, pain in abdomen, unable to sleep well, getting up to use toilet, passing large amount of wind, feeling off food, having bloated abdomen, going back to toilet immediately after emptying bowel, rushing to toilet, and feeling sick, the response options were changed from the four-level Likert scale (not at all, 1–2 days, 3–7 days, and 8–14 days) that was previously used in the UK-IBDQ to closed-ended ordinal answers where patients choose from 0–14 days. This change in response options was done to avoid the ceiling effect²³ when assessing patients with acute IBD. The remainders of the questions were answered on a four-level Likert scale. The final version of the questionnaire included 32 questions (Appendix 1).

3.1.1 Scoring

Responses for the Likert scale were scored 0–3, while responses for the closed-ended questions were 0–14. In order to avoid acquiescence bias (yes-set),^{37,38} which describes the general tendency of a patient to provide the highest possible answers regardless of the content of the questions, three questions about happiness, being relaxed, and having energy were phrased in a way so that the higher the number, the higher the level of QoL for that attribute. Their scores were then reversely coded before adding them to the total score. The resulting CUCQ-32 sums all the 32 question scores to yield the total score; the range of scores can be from 0–272; the higher the score, the worse the QoL.

The pretesting pilot study on 20 patients with stable IBD (10 UC and 10 CD) aged from 30–55 years showed that the questions were clear to patients and there was no ambiguity. No additional questions were added or suggested as a result of the pilot study. The mean completion time for CUCQ-32 was 10 min (± 3 min).

3.2 Patient sample

There were 212 patients who completed and returned the CUCQ-32 questionnaires. Seven patients (3.3%) were excluded from the study analysis because of incomplete responses to the questionnaire and missing data. No specific questions were particularly not answered by patients. A total of 205 patients completed the CUCQ, of whom 104 (50.7%) had CD and 101 (49.2%) had UC. The spectrum of disease severity was very similar between the two forms of IBD (CD vs. UC), with no significant difference in mean scores for EQ5D utility or SF-12 or disease severity as rated by physician global assessment. The characteristics of the patients’ sample at baseline are summarized in Table 2.

3.3 Psychometric analysis of the CUCQ

With respect to internal consistency and item–total correlations, the homogeneity of the CUCQ-32 was excellent, with Cronbach’s α equal to 0.88. Correlations of each of the 32 items with the total score exceeded 0.2 (Table 1). No response rate exceeded 80%. Hence, there was not a redundant item. These findings suggest that the individual items within the questionnaire are measuring aspects of the same construct (health-related quality of life (HRQoL) and that there is a consistency within the questionnaire. Using the 15% recommended value for the percentage of patients who score the highest or the lowest scores²³, there was no ceiling or flooring effects in the CUCQ-32.

The KMO measure of sampling adequacy (=0.816) and Bartlett’s test of sphericity ($p < 0.001$) confirmed that the sample was suitable for principal component analysis. Principal component analysis

Table 1. The initial 32 questions of CUCQ, their item–total correlations, and maximum response rate for all the 32 items in CUCQ-32.

Questions	Item–total correlations	Maximum response rate
1.On how many days over the last two weeks have you had loose or runny bowel movements?	0.832	26.3%
2.On how many days over the last two weeks have you felt generally unwell?	0.811	25.4%
3.On how many days over the last two weeks have you had to rush to the toilet?	0.767	28.8%
4.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?	0.752	48.8%
5.On how many days over the last two weeks have you felt tired?	0.75	36.6%
6.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?	0.732	29.3%
7.In the last two weeks have you felt the need to keep close to a toilet?	0.724	39%
8.On how many days over the last two weeks have you felt pain in your abdomen?	0.72	32.7%
9.On how many days over the last two weeks has your abdomen felt bloated?	0.695	34.6%
10.In the last two weeks did your bowel condition prevent you from going out socially?	0.67	51.7%
11.On how many days over the last two weeks have you opened your bowels more than three times a day?	0.666	26.8%
12.On how many nights over the last two weeks have you been unable to sleep well (days if you are a shift worker)?	0.641	39.5%
13.In the last two weeks, has your bowel condition prevented you from carrying out your work or other normal activities?	0.604	48.3%
14.In the last two weeks, has your bowel condition affected your leisure or sports activities?	0.599	52.7%
15.In the last two weeks have you felt irritable?	0.57	62.4%
16.On how many days over the last two weeks have you felt full of energy?	0.569	56.6%
17.On how many days in the last two weeks have you noticed blood in your stools?	0.559	66.8%
18.On how many days over the last two weeks have you felt off your food?	0.55	52.2%
19.In the last two weeks, has your sex life been affected by your bowel problem?	0.515	59.5%
20.On how many days over the last two weeks, have you had a problem with large amounts of wind?	0.487	26.8%
21.In the last two weeks have you felt angry as a result of your bowel problem?	0.449	62.9%
22.On how many days over the last two weeks have your bowels opened accidentally?	0.44	72.2%
23.In the last two weeks have you felt relaxed?	0.427	40%
24.In the last two weeks have you felt depressed?	0.422	49.3%
25.On how many days over the last two weeks have you felt sick?	0.418	52.2%
26.In the last two weeks have you had to avoid attending events where there was no toilet close at hand?	0.401	62.4%
27.In the last two weeks have you felt frustrated?	0.398	52.2%
28.In the last two weeks have you been embarrassed by your bowel problem?	0.365	55.1%
29.Many patients with bowel problems have worries about their illness. How often during the last two weeks have you felt worried?	0.361	49.8%
30.In the last two weeks have you felt upset?	0.361	48.8%
31.In the last two weeks have you felt happy?	0.208	49.8%
32.In the last two weeks have you felt lack of sympathy from others?	0.168	65.2%

Table 2. The characteristics of the patients who completed the baseline CUCQ-32*.

Variable	All patients	Crohn's disease	Ulcerative colitis
Number of cases	205	104 (50.7%)	101 (49.2%)
Age			
18–39	105 (51.2%)	55 (52.9%)	50 (49.5%)
40–65	81 (39.5%)	40 (38.5%)	41 (40.6%)
>65	19(9.3%)	9 (8.7%)	10 (9.9%)
Gender			
Male (%)	95 (46.3%)	40 (38.5%)	55 (54.5%)
Female (%)	110 (53.7%)	64 (61.5%)	46 (45.5%)
Physician global assessment			
Remission	49 (23.9%)	26 (25.0%)	23 (22.8%)
Mild	110 (53.7%)	60 (57.7%)	50 (49.5%)
Moderate	28 (13.7%)	12 (11.5%)	16 (15.8%)
Severe	18 (8.8%)	6 (5.8%)	12 (11.8%)
Generic HRQoL			
EQ5D utility score	0.61 (0.29)	0.58 (0.36)	0.62 (0.2)
EQ5D VAS	62 (22)	60.6 (22.1)	65 (21.9)
SF-12 MCS	40.6 (12)	41.8 (15.4)	38.8 (13.2)
SF-12 PCS	39 (11)	39 (12.5)	38.9 (6.95)
Disease severity			
HBI		5.2 (4)	
SCCAI			4.1 (3)

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

Table 3. Principal component analysis of the CUCQ-32 items after varimax rotation.

Factors	1 Bowel	2 Psychological	3 Social	4 General
Percentage of factor's contribution	35.2%	9.4%	5.6%	5.5%
Eigen values	11.3	2.99	1.79	1.71
1.Loose or runny bowel movements	0.785			
2.Blood in stools	0.502			
3.Feeling tired				0.579
4.Feeling frustrated		0.601		
5.Carrying out normal activities			0.608	
6.Opened bowels > 3/day	0.625			
7.Feeling full of energy				0.655
8.Going out socially			0.679	
9.Opening bowel accidentally				0.405
10.Feeling generally unwell	0.586			
11.Need to keep close to a toilet	0.681			
12.Effect on leisure			0.727	
13.Pain in abdomen	0.693			
14.Unable to sleep well	0.531			
15.Getting up to use toilet	0.574			
16.Feeling depressed		0.693		
17.Avoiding events with no toilets			0.713	
18.Large amounts of wind	0.468			
19.Feeling off food	0.492			
20.Feeling worried		0.676		
21.Bloated abdomen	0.726			
22.Feeling relaxed		0.719		
23.Embarrassed by bowel problem		0.411		
24.Going back to toilet immediately after emptying bowel	0.702			
25.Feeling upset		0.767		
26.Rushing to toilet	0.819			
27.Feeling angry		0.669		
28.Sex life been affected	0.382		0.409	
29.Feeling sick	0.460			
30.Feeling irritable		0.419		
31.Lack of sympathy from others		0.416		
32.Feeling happy				0.656

showed that there were four main factors (Table 3). Items were attributed to factors if they had a factor loading of at least 0.4. Items with loadings that differed by more than 0.05 on two factors were attributed to the factor with greater loading.³² To facilitate interpretation, we attributed each question to one of the principal factors according to its factor loading. Attribution of the 32 items to their factors showed that the first factor covers bowel symptoms, the second factor covers psychological impact, the third factor covers social impact, and the fourth factor covers general symptoms.

CUCQ-32 had significant ($p < 0.05$) and good correlations with EQ5D ($r = 0.56$), both in the physical ($r = 0.63$) and mental components ($r = 0.58$) of SF-12. A subgroup of 68 patients (30 patients with UC and 36 patients with CD) repeated and returned the CUCQ-32 after 2 weeks (the average return time was 15 ± 5 days). We included 38 patients who reported no change in their health in the reproducibility analysis: the intraclass correlation coefficient was 0.95, which is very good. We included the remaining 30 patients who reported changing health in the responsiveness analysis. The number of patients who reported change in their health ($n = 30$) was not enough to justify separating those who improved from those who deteriorated. The responsiveness statistics for CUCQ-32 were very good. The RR was 0.85 and SRM was 0.99.

We carried out a stepwise regression analysis to identify the smallest possible combination of questions to develop a shorter version of the CUCQ. To avoid having different weights for the different questions when carrying out a stepwise regression, we scaled the 32 answers to a 0–1 score. Scores of the four-level Likert scale answers were divided by 3 and scores of the 0–14 closed-ended ordinal answers were divided by 14 to make sure the questions contributed equally in the stepwise regression model. So, for example, if the score of the four-level Likert scale was 2, it was divided by 3 and its score would have been 0.67 and if the score of a closed-ended ordinal answers was 7, it was divided by 14 and its score would have been 0.50.

Regressing the 32 questions on the total CUCQ-32 score identified eight questions that contributed to more than 95% of the variance (Table 4). These eight items were chosen for the short form of CUCQ, called CUCQ-8 (Appendix 2). Standard psychometric analysis of the data from the 205 patients who filled out the original CUCQ-32 questionnaire indicated that CUCQ-8 items had very good internal consistency, with a Cronbach α value of 0.84. CUCQ-8 had excellent correlation with the original CUCQ-32 ($r = 0.91$, $p < 0.05$). It had significant ($p < 0.05$) and good correlations with EQ5D ($r = 0.58$), both for the physical ($r = 0.65$) and mental components ($r = 0.63$) of SF-12. However, CUCQ-8 had a moderate but positive correlation with the disease severity indices, which were HBI ($r = 0.38$) and SCCAI ($r = 0.35$) (Table 5). Most of the CUCQ-8 items correlated well with SF-12 and EQ5D. There was no ceiling or flooring effect in the CUCQ-8.

A subgroup of 68 patients repeated and returned the CUCQ questionnaire after 2 weeks. We included 38 patients who reported no change in their bowel condition in the reproducibility analysis. The intraclass correlation coefficient of CUCQ-8 was 0.94. We included the remaining 30 patients who reported changing bowel condition in the responsiveness analysis. The RR was 0.64 and SRM was 0.89, which are above the required value of 0.5.

4. Discussion

Assessing the HRQoL in patients with IBD is an important component of medical management and clinical decision-making. The last decade has seen a rapid increase in the number of measures to assess the HRQoL in patients with IBD.^{15,17,21,39–48} The commonly used one

is the McMaster IBDQ.^{14–16,20} However, none has been established in routine clinical practice because of the time and effort required to fill out lengthy questionnaires and the cost of the licensing fees of some questionnaires. Most of the disease-specific QoL measures for IBD in current use have been validated on stable outpatients with IBD. There is a pressing need to develop a short and valid HRQoL measure in patients with IBD that is user friendly and supports patient care. The aim of this study was to develop a new HRQoL measure in IBD that is short, reliable and valid for patients with acute as well as stable IBD.

We produced a set of 32 questions (Appendix 1) to assess the QoL on the basis of a thorough literature review and by consulting with a group of experts and patients who reviewed and modified a previously validated QoL measure for use in patients with IBD managed in the community, the UK-IBDQ.²¹ The CUCQ-32 differs from the UK-IBDQ questionnaire. We added two questions to cover the symptoms of patients with acute and severe IBD (rectal bleeding and nocturnal diarrhea). We also chose a combination of closed-ended ordinal answers and four-level Likert scale answers to avoid the ceiling effect and improve the discriminative ability of CUCQ in acute unwell patients. This generated an initial set of 32 questions, named the CUCQ-32, covering acute unwell as well as stable patients. A pilot study confirmed the clarity and relevance of the items. We tested the validity of the CUCQ-32 on 205 patients. From this we derived the CUCQ-8 (Appendix 2), a short QoL measure for IBD patients using a stepwise regression process. Stepwise regression helped the reduction of the CUCQ-32 by selecting the smallest number of items that represented the majority of the scores. The eight validated questions in the CUCQ-8 explained more than 95% of the variance of the CUCQ-32 questions in both UC and CD.

The CUCQ-32 differs from the McMaster IBDQ^{14–16,20} in several aspects. The wording of the questions in the CUCQ-32 is modified and Anglicized for use in the UK. The response options of the CUCQ-32 were simplified using a combination of closed-ended ordinal answers and four-level Likert scale answers instead of the seven-level Likert answers used in the IBDQ. In order to avoid acquiescence (yes-set) bias^{37,38}, three questions about happiness, being relaxed, and having energy were phrased in such a way that the higher the number, the higher the level of QoL for that attribute. Their scores were then reversely coded before adding them to the total score. The items covered by both the CUCQ-32 and the IBDQ-32 are relatively the same. Therefore we did not use the IBDQ in the construct validity testing of the CUCQ-32, but used the SF-12, EQ5D, and disease severity indices instead. However, the CUCQ-32 includes a question about urgency and rushing to toilet, which does not exist in the IBDQ-32. The IBDQ-32 asks about the need to get up at night to go to the toilet and lack of good sleep in one question, while the CUCQ-32 ask about these two items in two separate questions. The advantage of using the CUCQ-32 is its simplicity, the wider coverage of symptoms of acute IBD, and the fact that it is free to use by healthcare professionals.

The potential drawback of shortening any measure is the possibility of compromising its psychometric properties of validity and reliability. However, we analyzed the data from the 205 patients who completed the CUCQ-32 questionnaire, and the results showed that the CUCQ-8 has excellent validity and reliability. It had good internal consistency, with a Cronbach's α value of 0.84, well above the threshold of 0.70 proposed by Nunnally.²² The CUCQ-8 was consistent with CUCQ-32 and the generic measures of QoL (SF-12 and EQ5D). The CUCQ-8 had a moderate but positive correlation with disease-specific indices. One would expect such correlation, because the QoL questionnaires and disease severity indices measure different disease outcomes. The CUCQ-8 will, however, need

Table 4. Stepwise regression of the CUCQ-32 questions.

Items of CUCQ-32	Cumulative % of variance
1.On how many days over the last two weeks have you felt generally unwell?	64.7%
2.On how many days over the last two weeks have you felt pain in your abdomen?	80.5%
3.In the last two weeks did your bowel condition prevent you from going out socially?	86.1%
4.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?	90.2%
5.On how many days over the last two weeks has your abdomen felt bloated?	92.4%
6.On how many days over the last two weeks have you felt tired?	93.8%
7.In the last two weeks have you felt upset?	95.0%
8.On how many days over the last two weeks have you had to rush to the toilet?	95.9%
9.On how many days over the last two weeks have you felt full of energy?	96.7%
10.On how many days in the last two weeks have you noticed blood in your stools?	97.1%
11.On how many days over the last two weeks, have you had a problem with large amounts of wind?	97.5%
12.On how many days over the last two weeks have you opened your bowels more than three times a day?	97.9%
13.In the last two weeks, has your bowel condition prevented you from carrying out your work or other normal activities?	98.2%
14.In the last two weeks have you been embarrassed by your bowel problem?	98.5%
15.On how many days over the last two weeks have you had loose or runny bowel movements?	98.7%
16.In the last two weeks have you felt frustrated?	98.9%
17.In the last two weeks, has your sex life been affected by your bowel problem?	99.0%
18.On how many days over the last two weeks have you felt sick?	99.2%
19.On how many nights over the last two weeks have you been unable to sleep well (days if you are a shift worker)?	99.4%
20.In the last two weeks have you felt lack of sympathy from others?	99.5%
21.In the last two weeks have you had to avoid attending events where there was no toilet close at hand?	99.6%
22.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?	99.7%
23.Many patients with bowel problems have worries about their illness. How often during the last two weeks have you felt worried?	99.7%
24.In the last two weeks have you felt depressed?	99.8%
25.On how many days over the last two weeks have your bowels opened accidentally?	99.9%
26.In the last two weeks have you felt the need to keep close to a toilet?	99.9%
27.On how many days over the last two weeks have you felt off your food?	99.9%
28.In the last two weeks have you felt relaxed?	99.9%
29.In the last two weeks have you felt irritable?	99.9%
30.In the last two weeks, has your bowel condition affected your leisure or sports activities?	100%
31.In the last two weeks have you felt angry as a result of your bowel problem?	100%
32.In the last two weeks have you felt happy?	100%

Table 5. Correlation between CUCQ-8 and with other measures.

Correlation of CUCQ-8 with:	Pearson correlation co-efficient*
IBD-specific	
CUCQ32	0.91*
HBI	0.38*
SCCAI	0.35*
Generic outcome measures	
SF-12-PCS (physical component)	-0.65*
SF-12-MCS (mental component)	-0.63*
EQ5D	-0.58*

* p -value < 0.05.

Negative coefficients show that generic measures increase while disease-specific measures decrease.

further validation studies in a variety of groups of patients, and the correlation with other disease-specific clinical indexes will need to be assessed. Reproducibility was excellent, with an intraclass correlation coefficient of 0.94. The good RR of 0.64 suggests that the CUCQ-8 is responsive to changes in a patient's clinical condition, and is suitable for longitudinal monitoring of QoL. Validation is an ongoing process, and further studies are needed to validate the CUCQ-8 in a variety of groups of patients with IBD.

We limited the validation of the CUCQ-8 to patients without perianal disease. It therefore needs further development and testing

before we can use it in this subgroup of patients. Currently we are working to develop and validate two CUCQ supplementary extensions to cover symptoms of patients with perianal disease and patients with stoma.

As we chose patients whose first language was English, further studies are needed to confirm the validity, or modify the CUCQ-8, for patients who are not fluent in English.

We assessed responsiveness to change from participants' subjective perceptions of their bowel condition using transition questions. A retest questionnaire was sent to patients within 2 weeks. In addition to the CUCQ-8, the retest questionnaire asked patients for a general rating of changes in their bowel condition since completing the first questionnaire. Transition questions in test-retest validation analysis has been used in several outcome measures studies and is considered advantageous over other methods for assessing the QoL because it directly addresses patients' perceptions of change over time and is short and simple.^{21,39,49-51} Those who reported "no" changes were included in the reproducibility analysis, while those who reported a change in their bowel condition were included in the responsiveness analysis. Subjective measures give insights into matters of human concern, such as pain, suffering or depression that cannot be deduced solely from physical measurements or laboratory test results.⁵² Further studies are needed to assess the reproducibility and responsiveness of CUCQ-8 using other health indicators, such as clinical judgment or endoscopy.

There is no rule in the literature about the number of patients required to validate the QoL measures. However, a ratio of 5 or 10 patients per item has been suggested.²² Recent studies suggest that a minimum of 100 patients is sufficient for a proper validation study.²³ We analyzed data from 205 patients, and the KMO measure of sampling adequacy (KMO = 0.816) and Bartlett's test of sphericity ($p < 0.001$) confirmed that the sample was suitable for principal component analysis. The sample size we had was not sufficient enough for a reliable subanalysis of the different phenotypes of IBD (i.e. CD versus UC). However, we are undertaking an ongoing validation process to validate the CUCQ-32 in a larger group of patients with different presentations of IBD.

There is unavoidable selection bias when asking patients to fill in questionnaires, as not all of them will be willing to participate. However, the sample was drawn from four of the main hospitals in south Wales to ensure a good representation of patients and to mirror routine clinical practice. The CUCQ-8 needs to be validated in a larger group of patients with more diverse demographic and clinical characteristics. In the meantime, the CUCQ-8 performed well in its present form and showed very good psychometric properties in the current study.

Our findings support the validity, internal reliability, reproducibility and responsiveness of the CUCQ-8, a short QoL tool for patients with IBD. Furthermore, this new tool has been shown to be acceptable to patients in the UK, and is shorter and more easily applied in clinical practice than existing QoL measures. It will be available free for healthcare providers to support patient care without licensing fees. We therefore anticipate that it will be widely used, both in normal clinical practice and in health care evaluation to assess the effect of interventions on QoL. The simplicity, validity and reliability of the CUCQ-8 make it a strong candidate for IBD registries and databases, and in audits that assess the efficacy of new treatments in IBD, for example biological therapy.⁵³

Funding statement

This work was supported by the Welsh Clinical Academic Training (WCAT) scheme and stems from collaboration between Swansea University, the Wales Postgraduate Deanery and the Welsh Government.

Conflict of interest statement

None declared.

Acknowledgments

Authors' contributions: LA is the chief investigator and the guarantor of the study. He contributed in writing the manuscript, designing the questionnaires, data collection and analysis. WYC contributed to the initial development and modification of the CUCQ-32 questions. PD contributed in recruiting patients, data collection and all drafts of the manuscript. HAH, ITR, and JGW contributed to designing the questionnaires, all drafts of the manuscript and data analysis. AW contributed to the statistical analysis and the revision of the manuscript drafts. All authors approved the final version of the manuscript.

Competing interests: None.

Ethics and dissemination: This study was approved by the South East Wales Research Ethics Committee (Reference 11/WA/0239). The National Health Service (NHS) code of confidentiality and data protection was adhered to.

Crohn's and ulcerative colitis questionnaire (CUCQ): The CUCQ is used by Swansea University for any academic and non-commercial clinical purposes including publicly funded clinical trials and routine clinical use in the National Health Service (NHS). The CUCQ will not be used by Swansea University in commercial studies.

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Appendices

Appendix 1. Crohn's and ulcerative colitis questionnaire-32 (CUCQ-32)

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 over the last two weeks have you had loose or runny bowel movements? days
2. On how many days in the last two weeks have you noticed blood in your stools?
..... days
3. On how many days over the last two weeks have you felt tired?
..... days
4. In the last two weeks have you felt frustrated?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time
5. In the last two weeks, has your bowel condition prevented you from carrying out your work or other normal activities?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time
6. On how many days over the last two weeks have you opened your bowels more than three times a day? days
7. On how many days over the last two weeks have you felt full of energy?
..... days
8. In the last two weeks did your bowel condition prevent you from going out socially?
 - a) No, not at all
 - b) Yes, some of the time
 - c) Yes, most of the time
 - d) Yes, all of the time

9. On how many days over the last two weeks have your bowels opened accidentally? days
10. On how many days over the last two weeks have you felt generally unwell?
..... days
11. In the last two weeks have you felt the need to keep close to a toilet?
- No, not at all
 - Yes, some of the time
 - Yes, most of the time
 - Yes, all of the time
12. In the last two weeks, has your bowel condition affected your leisure or sports activities?
- No, not at all
 - Yes, some of the time
 - Yes, most of the time
 - Yes, all of the time
13. On how many days over the last two weeks have you felt pain in your abdomen?
..... days
14. 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)
15. 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
16. In the last two weeks have you felt depressed?
- No, not at all
 - Yes, some of the time
 - Yes, most of the time
 - Yes, all of the time
17. In the last two weeks have you had to avoid attending events where there was no toilet close at hand?
- No, not at all
 - Yes, some of the time
 - Yes, most of the time
 - Yes, all of the time
18. On how many days over the last two weeks, have you had a problem with large amounts of wind? days
19. On how many days over the last two weeks have you felt off your food?
..... days
20. Many patients with bowel problems have worries about their illness. How often during the last two weeks have you felt worried?
- No, not at all
 - Yes, some of the time
 - Yes, most of the time
 - Yes, all of the time
21. On how many days over the last two weeks has your abdomen felt bloated?
..... days
22. In the last two weeks have you felt relaxed?
- No, not at all
 - Yes, some of the time
 - Yes, most of the time
 - Yes, all of the time
23. In the last two weeks have you been embarrassed by your bowel problem?
- No, not at all
 - Yes, some of the time
 - Yes, most of the time
 - Yes, all of the time
24. On how many days over the last two weeks have you wanted to go back to the toilet immediately after you thought you had emptied your bowels?
..... days
25. In the last two weeks have you felt upset?
- No, not at all
 - Yes, some of the time
 - Yes, most of the time
 - Yes, all of the time
26. On how many days over the last two weeks have you had to rush to the toilet?
..... days
27. In the last two weeks have you felt angry as a result of your bowel problem?
- No, not at all
 - Yes, some of the time
 - Yes, most of the time
 - Yes, all of the time
28. In the last two weeks, has your sex life been affected by your bowel problem?
- No, not at all
 - Yes, some of the time
 - Yes, most of the time
 - Yes, all of the time
29. On how many days over the last two weeks have you felt sick?
..... days
30. In the last two weeks have you felt irritable?
- No, not at all
 - Yes, some of the time
 - Yes, most of the time
 - Yes, all of the time
31. In the last two weeks have you felt lack of sympathy from others?
- No, not at all
 - Yes, some of the time
 - Yes, most of the time
 - Yes, all of the time
32. In the last two weeks have you felt happy?
- No, not at all
 - Yes, some of the time

- c) Yes, most of the time
- d) Yes, all of the time

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.

Appendix 2. Crohn's and ulcerative colitis questionnaire-8 (CUCQ-8)

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 over the last two weeks have you felt tired?
..... days
2. In the last two weeks did your bowel condition prevent you from going out socially?
a) No, not at all

- b) Yes, some of the time
- c) Yes, most of the time
- d) Yes, all of the time

3. On how many days over the last two weeks have you felt generally unwell? days
4. On how many days over the last two weeks have you felt pain in your abdomen? days
5. 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
6. On how many days over the last two weeks has your abdomen felt bloated? days
7. In the last two weeks have you felt upset?
a) No, not at all
b) Yes, some of the time
c) Yes, most of the time
d) Yes, all of the time
8. 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.