Gastrointestinal Quality of Life Index: development, validation and application of a new instrument

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At present, an instrument for measuring the quality of life, specifically for patients with gastrointestinal disease, is not available. A new instrument for gastrointestinal disorders that is system-specific has been developed in three phases. In the first phase, questions were collated and then tested on 70 patients with gastrointestinal diseases and those that worked well were retained. In the second phase, the questions were modified and tested on 204 patients and the results verified by international experts. The instrument was also validated against other generic measures of quality of life. During the third phase, the instrument was validated with 168 normal individuals. Reproducibility was tested on 25 patients with stable gastrointestinal disease and responsiveness was tested on 194 patients undergoing laparoscopic cholecystectomy. The result is a bilingual (German and English) questionnaire containing 36 questions each with five response categories. The responses to questions are summed to give a numerical score. It is concluded that the Gastrointestinal Quality of Life Index (GIQLI) is ready to be used in clinical practice and research.

The question 'How are you' is a central component of the doctor–patient interview. The answer reflects the general well-being or health-related quality of life of the patient. Today, innovative treatments such as endoscopic surgery or lithotripsy techniques can no longer be evaluated unless facets of the patient's quality of life are taken into account[1-4].

Quality of life is a multidimensional construct with several dimensions: emotional or psychological well being, physical functioning, social functioning, and symptoms of the disease and treatment[5-7].

Clinicians, especially surgeons, are sceptical about 'soft' data such as patients' reports of symptoms or well-being. Their professional training with an emphasis on pathophysiology leads them to prefer 'hard' clinical data such as laboratory values, imaging results, and survival curves. Techniques are available to 'harden' soft data to make them more manageable and useful[8-11].

A team of four surgeons and three methodologists used these methods to develop and validate a new instrument, the Gastrointestinal Quality of Life Index (GIQLI). The original idea was to have a set of core questions applicable to any patient with gastrointestinal disease and several small organ-specific modules. Dependent upon the site of the impairment of the patient, one of the modules is selected for use with the core questions. The GIQLI was developed in three consecutive phases (*Table 1*). The first phase of development has been reported in detail elsewhere[12]. This paper reports the second and third phases of the development and validation.

Table 1 Phases of development and testing of the Gastrointestinal Quality of Life Index (GIQLI)

Phase I: Question selection, testing and reduction
 – construction of a questionnaire by the study team
 – application of the questionnaire to patients, relatives and health care professionals
 – analysis of the results according to response prevalence and impact on quality of life
 – modification and shortening of the questionnaire

Phase II: Continued development, content verification, and preliminary testing
 – application of the modified questionnaire to patients
 – analysis of the results according to response prevalence and inter-item correlations
 – further modification of the questionnaire by the study team
 – definition of scaling and scoring
 – validation with Spitzer Quality of Life Index, Bradburn Affect Balance Scale and functional activity level
 – evaluation of the questionnaire by 42 gastroenterological experts

Phase III: Assessment of the measurement properties of the GIQLI
 – repeated application of the questionnaire in clinically stable patients to test reliability
 – use with 'normal' individuals to assess validity
 – assessment of patients with symptomatic gallstones before and after laparoscopic cholecystectomy to test responsiveness
 – preoperative and postoperative laparoscopic cholecystectomy scores used to assess internal consistency

Patients and methods

In phase I, a 76-item questionnaire was applied to 70 patients and 53 close relatives[12]. The questionnaire asked about symptoms, physical, emotional and social dysfunction related to gastro-

intestinal diseases or their treatments. If a symptom or dysfunction was present, the patient indicated its importance in influencing their quality of life on a four-point scale.

In this phase of development, only problems that were experienced by at least 25 per cent of the patients and had at least a 'moderate' impact on their quality of life were retained for further assessment. The characteristics of the individuals participating are presented in *Table 2*.

Phase II: Further development, content verification and preliminary validation

From phase I of the study, 32 items emerged that occurred with sufficient frequency and had a 'moderate' impact on the patients' lives. Twelve items were added to focus on the social consequences of being ill and the concerns of the care process. Each of the 44 items was scored on a five-point scale denoting the burden of the particular symptom or dysfunction. The total score ranged from 0 to 176 with higher scores representing better quality of life. Additional questions were included to obtain demographic, clinical and functional information.

Between October 1989 and March 1990, a sample of 204 patients, with benign or malignant disorders of the oesophagus, stomach, gallbladder, pancreas, small intestine, colon, and rectum was asked to complete the questionnaire. Patients with disorders of limited impact on quality of life, such as appendicitis or haemorrhoids, were excluded. Patients were also excluded if they had abdominal hernias or were unable to read German fluently. Approximately 90 per cent of the patients were inpatients. The rest were outpatients.

This phase of the study also incorporated limited validation studies. To test validity, the German version of the Spitzer Quality of Life (QL) Index[13,14] and the Bradburn Affect Balance Scale[15,16] were added to the questionnaire package. Since the Spitzer Index is a global measure of quality of life and the Bradburn Scale assesses emotional well-being, it was hypothesized that these measures should be positively correlated with the GIQLI scores. Pearsons product moments correlations were calculated. Similarly, based on the 'known group technique' as advocated by Bohrnstedt[17], it was postulated that patients with gastrointestinal disease who were mobile in the community would have a higher score on the GIQLI than those who were housebound or bedridden. Information on functional activity levels was collected to test this hypothesis.

Hospital residents, junior staff members, or trained interviewers explained the questionnaire to the patients, obtained informed

consent, left a copy of the questionnaire, and requested that they complete it. These persons were not directly involved in the care of the particular patient. Questionnaires were collected within 48 h.

The final step in phase II was to verify the content of the questionnaire with potential users. After evaluating the responses of the 204 patients, a revised version of the GIQLI containing 24 core questions and eight organ-specific questions was presented to 42 surgeons, physicians and other health professionals from Canada, England, Germany and the USA. They were all experts in providing care for patients with gastrointestinal disease. Their opinions were sought as to the importance and clarity of each question, the scaling, and the ability of the question to evaluate the quality of life of patients with gastrointestinal disease. They were also asked whether they would use the measure in a study.

Phase III: Further assessment of the measurement properties of the GIQLI

The first goal of this phase of the study was to assess the reproducibility of the instrument by repeated testing on stable individuals. A total of 25 clinically stable patients with gastrointestinal disease were asked to complete the questionnaire on two occasions, 48 h apart. The concordance of the two sets of scores was tested by the Intraclass Correlation Coefficient and displayed by a Bland–Altman plot[18].

Up to this time, the GIQLI had only been completed by patients with defined gastrointestinal diseases. Because gastrointestinal symptoms are prevalent in 'normal' individuals either on a temporary or ongoing basis, the authors wished to obtain GIQLI scores in healthy individuals. This information would provide the study with an idea of impairment of quality of life in healthy subjects and of the differences and overlap between patients and normal individuals. For this purpose, a slightly modified questionnaire was given to 168 individuals who stated that they considered themselves to be 'healthy'. In the questionnaire, the words 'due to your disease' were replaced by 'due to your health' but the same list of questions was used. Mean index scores of the normal individuals were compared with those of the patients with gastrointestinal disease.

To assess responsiveness to clinical change, the GIQLI was applied prospectively to consecutive patients with symptomatic gallstone disease. Patients were asked to complete the questionnaire before surgery, and 2 and 6 weeks after laparoscopic cholecystectomy. At the time of surgery, patients were usually experiencing some discomfort and pain from the gallstone disease. Two weeks after surgery patients have most often recovered from the immediate symptoms and problems related to the operative procedures, and by 6 weeks they should have resumed normal activities. It was postulated that scores on the GIQLI should reflect this clinical trend and a *t* test and multiple analysis of variance (ANOVA) were employed to examine this hypothesis.

Finally the preoperative and postoperative data sets were used to assess the internal consistency of the questionnaire. Internal consistency is a reliability estimate determined by calculating item-to-total score correlation and Chronbach's standardized item Alpha. Chronbach's Alpha is an average of the coefficient in a matrix of item-to-item correlation, with its magnitude being a function of the number of items as well as the average correlation among them. Alpha indicates how items relate to each other and to the total score. In other words, high internal consistency (> 0.80) suggests that the scale is measuring an underlying dimension and that the overall score is more important than any of the individual items.

Table 2 Characteristics of individuals participating in the three phases of development and testing of the Gastrointestinal Quality of Life Index (GIQLI)

Phase	Procedure	Participants	No.	Mean (range) age (years)	Per cent women
I	Question testing and reduction	Patients	70	52 (18–86)	44
		Relatives	53	–	–
		Professionals	25	–	–
II	Question testing, reduction, validation	Patients	204	58 (22–82)	45
	Content verification	Surgeons	24	–	–
		Gastroenterologists	12	–	–
		General practitioners	6	–	–
III	Assessing measurement properties				
	Reliability	Patients	25	50 (33–78)	45
	Validity	Normal subjects	168	42 (25–60)	45
	Responsiveness	Patients	194	50 (20–82)	82
	Internal consistency	Patients	194	50 (20–82)	82

Results

Question selection and content verification

In phase II of the study, 70 per cent of the patients with gastrointestinal disease had to indicate that a symptom or dysfunction was present for it to be retained as a core item (*Fig. 1*). In addition, if two 'acceptable' questions were highly correlated (> 0.60 threshold of correlation) and reflected the same symptom or dysfunction, a clinical judgement was

made and only one of the two questions was kept. For example, the prevalence of both 'depression' and 'sadness' was high (83 per cent and 88 per cent) and the variables were strongly correlated (0·76). Only 'sadness' was retained in the questionnaire. This process, displayed in *Fig. 1*, resulted in the removal of 21 questions from the core questionnaire (information available from the authors). However, when the questions were reassessed in terms of their impact on quality of life and patients were stratified as to disease site, questions relating to eight items (regurgitation, speed of eating, dysphagia, urgent bowel movements, diarrhoea, constipation and nausea) were added as possible organ-specific questions for content verification. In addition, questions dealing with finding blood in the stool and the impact of treatment were included.

The results of the content verification for both the core questions and the organ-specific questions are presented in *Appendix 1*. Although suggestions were made for modifying individual items, two-thirds of the experts felt that the collection of items was appropriate to evaluate the quality of life of patients with gastrointestinal disease and 85 per cent said that they would use it in their own research. The ratings and suggestions by the experts were taken into consideration in creating the 36-question version of the English GIQLI that is presented in *Appendix 2*. Specifically, questions dealing with heartburn, uncontrolled stools, sexual life and personal relations were added to the questionnaire. It should be noted however that the versions of the questionnaire used with the patients undergoing laparoscopic surgery in phase III did not include these last four items.

Validity

Results from the preliminary validation studies, conducted during phase II, are based on 204 patients completing 44 items of the questionnaire. The Pearson product moment correlations of the GIQLI with the QL Index and the Affect Balance Scale were 0·53 and 0·42 respectively. The moderately strong correlations suggest that the measures have a common, underlying dimension.

This sample was also divided according to reported levels of daily activity and the mean GIQLI scores were compared using ANOVA. The observed mean(s.d.) scores were 105(12·5) for individuals mobile in the community, 89(16·5) for those confined to home and 45(14·8) for bedridden

patients. The direction and magnitude of the differences were as hypothesized and statistically significant (ANOVA: $P < 0.02$). These two tests of validity provided preliminary evidence that the GIQLI was assessing the quality of life of individuals with gastrointestinal disease.

Further evidence of validity was gathered from the 168 normal individuals who completed a modified version of the questionnaire (36 items; scale range 0–144) during phase III. The mean(s.d.) score for the 168 normal individuals was 125·8(13·0). The 95 per cent confidence interval about the mean had a lower confidence limit of 121·5 and an upper confidence limit of 127·5. When compared with the 'stable' patients tested in the reliability study for whom the average GIQLI score was approximately 90, it can be seen that the mean score for the normal subjects was significantly higher than that of patients with gastrointestinal disease.

Reliability

Data from the 25 consecutive clinically stable patients with gastrointestinal disease, assessed and reassessed within 48 h, were used to estimate the stability of GIQLI scores. The mean(s.d.) score of the first test was 90·1(22·9) and the retest score was 93·6(22·8). The Bland–Altman plot of the test and retest scores is displayed in *Fig. 2*. The Intraclass Correlation Coefficient (0·92) denotes a high level of reliability. The related confidence interval ranged from 0·77 to 0·97.

Responsiveness

From the data file of patients undergoing laparoscopic cholecystectomy it was possible to create two smaller data sets. The first included 194 patients who had GIQLI scores before and 2 weeks after surgery (paired data) and the second incorporated 103 patients who had points before operation, and 2 and 6 weeks after operation (triplets of data). *Table 3* presents the descriptive statistics of the paired data and the results of the paired *t* test. The difference is statistically significant and in line with clinical expectations of improved health-related quality of life 2 weeks after operation. These data are shown in *Fig. 3*. Similarly, *Table 4* displays the descriptive information and the results of the multiple ANOVA for the data set with measures repeated three times. As can be seen, the confidence intervals of the means at each time point do not overlap. After a large
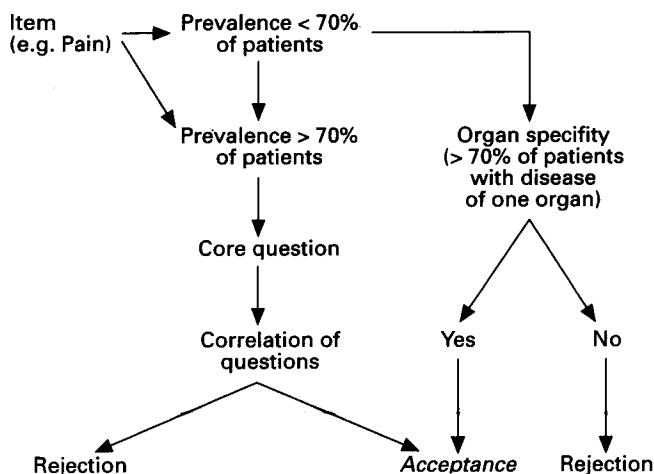

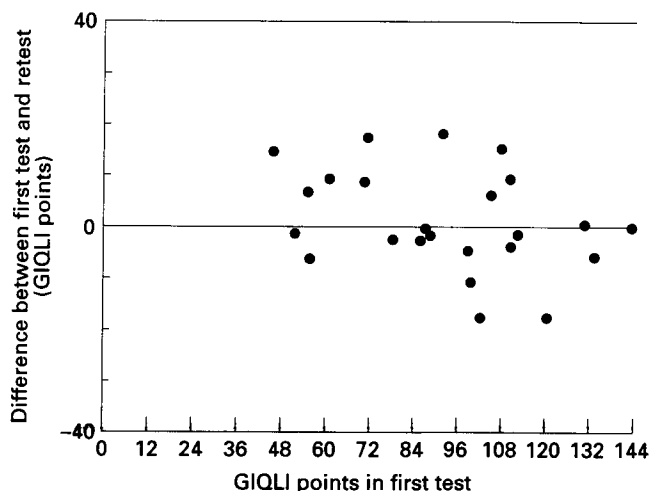**Fig. 1** Algorithm for the selection of questions for the Gastrointestinal Quality of Life Index

Fig. 2 Bland–Altman plot[18] of the repeated measurement to test reliability of the Gastrointestinal Quality of Life Index (GIQLI)

Table 3 Quality of life of 194 patients before and 2 weeks after laparoscopic cholecystectomy as assessed by the Gastrointestinal Quality of Life Index (GIQLI) (Paired t test)

Measurement point	Mean(s.d.)	95% confidence interval
Before operation	84·80(19·39)	82·05–87·54
After operation	102·34(17·84)	99·81–104·87

Scale 0–128. $t = -11\cdot38$; $P < 0\cdot001$

Table 4 Quality of life of 103 patients before, and 2 and 6 weeks after laparoscopic cholecystectomy as assessed by the Gastrointestinal Quality of Life Index (GIQLI)

Measurement point	Mean(s.d.)	95% confidence interval
Before operation	87·27(17·25)	83·90–90·64
2 weeks after operation	104·49(17·52)	101·06–107·91
6 weeks after operation	111·71(14·42)	108·89–114·53

Scale 0–128. $F = 101\cdot42$, 2204 d.f., $P < 0\cdot001$. (ANOVA)
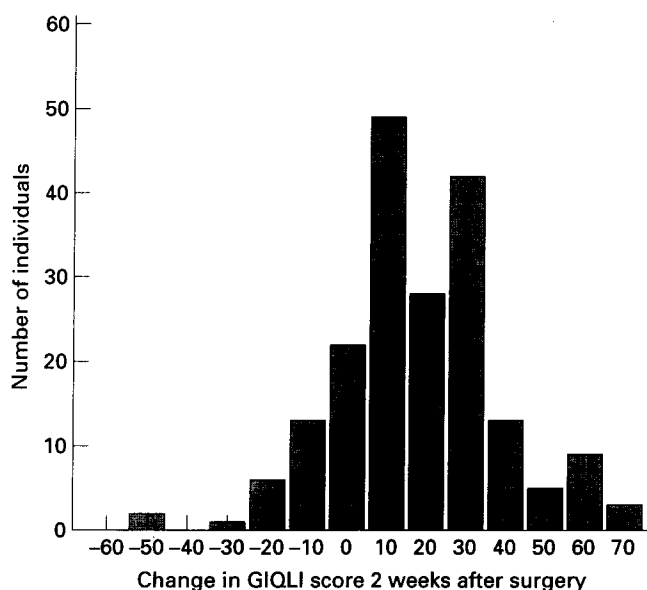

Fig. 3 Mean change of the Gastrointestinal Quality of Life Index (GIQLI) score between two measurements before and 2 weeks after laparoscopic cholecystectomy in 194 patients displayed as a Bland–Altman plot[18]. The mean(s.d.) change was 17(20·69) points

improvement from before operation to 2 weeks after operation, the gradient of improvement in scores declined.

Internal consistency

The value of Chronbach's Alpha was above 0·90 in the data sets before operation (0·901), 2 weeks after operation (0·932) and 6 weeks after operation (0·929) suggesting that the covariation in the items reflects an underlying dimension which may be more important than any single item. Internal consistency is high.

Discussion

The present study indicates that the quality of life can become a measurable entity in research and clinical practice.

Validity was assured in several ways. The items were chosen to reflect the patients' perceptions of the impact of disease and treatment on their lives. The patients' answers were confirmed by the responses of close relatives who independently rated the patients' quality of life[12]. After the first two phases of research, the content was assessed by professional experts in four countries and, although minor modifications were suggested, the index was accepted as being able to assess quality of life. Of the responding experts 85 per cent stated that they would consider using the index in their own research.

The GIQLI is moderately correlated with established generic measures of quality of life – the Spitzer Quality of Life Index and the Bradburn Affect Balance Scale. The three measures therefore reflect a common underlying construct. Moreover, the index moderately differentiated across three known clinical groups as predicted: mobile patients in the community, housebound patients, and bedridden patients. Whether it can also discriminate between normal individuals and those with gastrointestinal disease is not relevant since this is not the purpose of the instrument.

Reproducibility and internal consistency were well above accepted levels suggesting that the index is homogeneous and measures a single phenomenon – quality of life. The index is also responsive to changes in the clinical status of patients. After cholecystectomy the index scores closely reflected the anticipated course of recovery and return to routine activities.

The original intention was to create a system-specific (gastrointestinal) instrument with a fixed set of core questions that would be supplemented by a subset of organ-specific questions. This approach is currently being used by the European Organization for the Research and Treatment of Cancer[19]. During the developmental process, however, only a few organ-specific items could be identified by their higher prevalence. For example, patients with oesophageal disease more frequently reported difficulties with swallowing. For the majority of organs, however, no organ-specific items could be found. Therefore, modules for specific organs could not be described and a few organ-specific oesophageal and colon symptoms were incorporated into the main questionnaire.

The GIQLI is not a diagnostic tool. While it can moderately differentiate between patients with gastro-enterological diseases and healthy individuals, it will not discriminate between diseases. The GIQLI is a measure of the subjective perception of well-being of a patient which may vary unexpectedly between diagnostic groups. For example, in patients with symptomatic gallstone disease, the score was 87 points with a range of 70–104 points. On the other hand, patients with oesophageal or rectal cancer scored a mean of 89 and 115 points respectively. Only tracking individual changes in GIQLI scores over time on large numbers of individuals will provide insight into these issues. A computer program for database purposes and graphic printouts of the GIQLI data are ready for use and can be obtained from the authors on request.

In conclusion, the GIQLI is an appropriate, validated and potentially useful tool to assess health-related quality of life in clinical studies of patients with gastrointestinal disease and in daily clinical practice. Moreover, the authors believe it is the only general gastrointestinal index available. Other measures have been developed for specific disease entities[20]. Some surgical investigators have used well known generic assessments of health status or quality of life for patients with gastrointestinal diseases[3,21] and others have adapted or

developed scales for a specific study[14,22] but, to the best of the authors' knowledge, no similar index exists.

The GIQLI is now being used in several settings in Germany to describe, compare and differentiate the outcomes of surgical treatment in patients with gastrointestinal disease. Although the measure was developed in both German and English, it has been validated primarily with German-speaking patients but has also been applied in Canada[23].

In general terms, validation of any measure is an ongoing process and the results reported here require confirmation by other investigators. Specifically, the GIQLI needs testing in English speaking settings and studies are in progress that will provide information on the measurement properties of the English version. Meanwhile, in Germany the GIQLI is ready for use by clinicians for assessing their patients, monitoring them over time and as a basis for treatment planning. The index is also ready for use in clinical investigations to establish baseline values and as an outcome variable in those surgical studies targeted at improving overall health-related quality of life.

Appendix 1 Judgement of item importance by the international experts during content verification

Item	Per cent of experts*	Mean importance score†
Core symptoms		
Pain	100	1·0
Bloating	98	1·7
Epigastric fullness	98	1·7
Flatus	81	2·0
Belching	81	2·0
Bowel frequency	97	1·6
Abdominal noises	45	2·5
Restricted eating	98	1·7
Enjoyed eating	90	1·7
Fatigue	93	1·5
Physical items		
Strength	95	1·5
Feeling unwell	100	1·4
Feeling unfit	86	1·7
Endurance	90	1·7
Wake up at night	81	1·8
Appearance	81	1·8
Psychological items		
Sadness	82	1·8
Nervousness	85	1·8
Frustration	87	1·8
Happiness	90	1·6
Bothered by treatment	95	1·7
Cope with stress‡	—	—
Social items		
Daily activities	100	1·5
Leisure activities	95	1·7
Disease-specific items		
Regurgitation	90	1·6
Dysphagia	100	1·1
Eating speed	64	2·2
Nausea	95	1·7
Diarrhoea	100	1·3
Bowel urgency	95	1·6
Constipation	90	1·7
Blood in stool	98	1·3

*Per cent of experts rating the item as 'important' or 'very important'; †Mean importance score: 1 = very important; 2 = important, 3 = not important; ‡variable: 'cope with stress' inadvertently left off experts' check list

Appendix 2 The Gastrointestinal Quality of Life Index (GIQLI)

1. How often during the past 2 weeks have you had pain in the abdomen?
   all of the time, most of the time, some of the time, a little of the time, never

2. How often during the past 2 weeks have you had a feeling of fullness in the upper abdomen?
   all of the time, most of the time, some of the time, a little of the time, never

3. How often during the past 2 weeks have you had bloating (sensation of too much gas in the abdomen)?
   all of the time, most of the time, some of the time, a little of the time, never

4. How often during the past 2 weeks have you been troubled by excessive passage of gas through the anus?
   all of the time, most of the time, some of the time, a little of the time, never

5. How often during the past 2 weeks have you been troubled by strong burping or belching?
   all of the time, most of the time, some of the time, a little of the time, never

6. How often during the past 2 weeks have you been troubled by gurgling noises from the abdomen?
   all of the time, most of the time, some of the time, a little of the time, never

7. How often during the past 2 weeks have you been troubled by frequent bowel movements?
   all of the time, most of the time, some of the time, a little of the time, never

8. How often during the past 2 weeks have you found eating to be a pleasure?
   all of the time, most of the time, some of the time, a little of the time, never

9. Because of your illness, to what extent have you restricted the kinds of food you eat?
   very much, much, somewhat, a little, not at all

10. During the past 2 weeks, how well have you been able to cope with everyday stresses?
    extremely poorly, poorly, moderately, well, extremely well

11. How often during the past 2 weeks have you been sad about being ill?
    all of the time, most of the time, some of the time, a little of the time, never

12. How often during the past 2 weeks have you been nervous or anxious about your illness?
    all of the time, most of the time, some of the time, a little of the time, never

13. How often during the past 2 weeks have you been happy with life in general?
    never, a little of the time, some of the time, most of the time, all of the time

14. How often during the past 2 weeks have you been frustrated about your illness?
    all of the time, most of the time, some of the time, a little of the time, never

15. How often during the past 2 weeks have you been tired or fatigued?
    all of the time, most of the time, some of the time, a little of the time, never

16. How often during the past 2 weeks have you felt unwell?
    all of the time, most of the time, some of the time, a little of the time, never

17. Over the past week, have you woken up in the night?
    every night, 5–6 nights, 3–4 nights, 1–2 nights, never

18. Since becoming ill, have you been troubled by changes in your appearance?
a great deal, a moderate amount, somewhat, a little bit, not at all

19. Because of your illness, how much physical strength have you lost?
a great deal, a moderate amount, some, a little bit, none

20. Because of your illness, to what extent have you lost your endurance?
a great deal, a moderate amount, somewhat, a little bit, not at all

21. Because of your illness, to what extent do you feel unfit?
extremely unfit, moderately unfit, somewhat unfit, a little unfit, fit

22. During the past 2 weeks, how often have you been able to complete your normal daily activities (school, work, household)?
all of the time, most of the time, some of the time, a little of the time, never

23. During the past 2 weeks, how often have you been able to take part in your usual patterns of leisure or recreational activities?
all of the time, most of the time, some of the time, a little of the time, never

24. During the past 2 weeks, how much have you been troubled by the medical treatment of your illness?
very much, much, somewhat, a little, not at all

25. To what extent have your personal relations with people close to you (family or friends) worsened because of your illness?
very much, much, somewhat, a little, not at all

26. To what extent has your sexual life been impaired (harmed) because of your illness?
very much, much, somewhat, a little, not at all

27. How often during the past 2 week, have you been troubled by fluid or food coming up into your mouth (regurgitation)?
all of the time, most of the time, some of the time, a little of the time, never

28. How often during the past 2 weeks have you felt uncomfortable because of your slow speed of eating?
all of the time, most of the time, some of the time, a little of the time, never

29. How often during the past 2 weeks have you had trouble swallowing your food?
all of the time, most of the time, some of the time, a little of the time, never

30. How often during the past 2 weeks have you been troubled by urgent bowel movements?
all of the time, most of the time, some of the time, a little of the time, never

31. How often during the past 2 weeks have you been troubled by diarrhoea?
all of the time, most of the time, some of the time, a little of the time, never

32. How often during the past 2 weeks have you been troubled by constipation?
all of the time, most of the time, some of the time, a little of the time, never

33. How often during the past 2 weeks have you been troubled by nausea?
all of the time, most of the time, some of the time, a little of the time, never

34. How often during the past 2 weeks have you been troubled by blood in the stool?
all of the time, most of the time, some of the time, a little of the time, never

35. How often during the past 2 weeks have you been troubled by heartburn?
all of the time, most of the time, some of the time, a little of the time, never

36. How often during the past 2 weeks have you been troubled by uncontrolled stools?
all of the time, most of the time, some of the time, a little of the time, never

Calculation of the score:
most desirable option: 4 points
least desirable option: 0 points
GIQLI score: sum of the points
(for details see computer program and manual; available on request from the authors)

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Editors' announcement

Randomized controlled trials

Prospective authors are requested to consult, digest and apply the Instructions to Authors in any submission they may wish to make to the Journal. The presentation of manuscripts following these guidelines greatly facilitates the editorial process. Readers and prospective authors are particularly asked to note the instructions pertaining to the identification of randomized controlled trials. The UK Cochrane Centre, along with many other institutes and journals, is keen to identify all randomized controlled trials. Current literature searches identify with certainty only 50–60 per cent of such publications from the title or abstract as published. Authors are encouraged to ensure that randomized controlled trials are fully identified as such in title and summary as requested in the Instructions to Authors. Cooperation in these matters will be appreciated by editors and referees alike.

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