Validation of the German version of the Short Health Scale – a brief, valid and reliable instrument to assess health-related quality of life in German-speaking patients with inflammatory bowel diseases

Validierung der deutschen Version der Short Health Scale – ein kurzes und zuverlässiges Instrument zur Beurteilung der gesundheitsbezogenen Lebensqualität bei Patient:innen mit chronisch-entzündlichen Darmerkrankungen

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Key words

Short Health Scale, Quality of Life, Inflammatory Bowel Disease, Questionnaire, Validation Study

Schlüsselwörter

Short Health Scale, Lebensqualität, Chronisch-entzündliche Darmerkrankung, Fragebogen, Validierung

received 26.04.2022
accepted after revision 06.10.2022
published online 10.01.2023

Bibliography

Z Gastroenterol 2023; 61: 1207–1213
DOI 10.1055/a-1976-9971
ISSN 0044-2771

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ABSTRACT

Background Health-related quality of life (hrQoL) may be the most important patient-reported outcome for patients with chronic disorders. The Short Health Scale (SHS) is a brief four-item instrument to assess hrQoL in patients with bowel disorders. This study examined the validity, reliability and sensitivity of the German translation of the SHS in a cohort of outpatients with inflammatory bowel diseases (IBD).

Methods The study was preregistered in April 2021 (https://doi.org/10.17605/OSF.IO/S82D9). Outpatients with IBD (n = 225) in different stages of disease activity (as determined by the Harvey–Bradshaw index or partial Mayo score) completed the German SHS and the short Inflammatory Bowel Disease Questionnaire (sIBDQ) as an established measure of hrQoL to examine the convergent validity. To assess reliability, a subset of patients (n = 30) in remission completed the same questionnaires after 4–8 weeks. Sensitivity to change was established from questionnaires of patients with either decreased (n = 15) or increased (n = 16) disease activity after 3–6 months.

Results The internal consistency of the German SHS was high (Cronbach's $\alpha = 0.860$). SHS total scores correlated strongly with sIBDQ scores ($\rho = -0.760$, $p < 0.001$) and disease activity ($\rho = 0.590$, $p < 0.001$). Retest reliability was high ($\rho = 0.695$, $p < 0.001$). Sensitivity to change was statistically significant for patients with decreased ($p = 0.013$) but not increased ($p = 0.134$) disease activity.

Conclusion The German version of the SHS is a valid and reliable tool to measure hrQoL in persons with IBD.

ZUSAMMENFASSUNG

Einleitung Chronisch-entzündliche Darmerkrankungen (CED) können die Lebensqualität (QoL) der Betroffenen stark beeinträchtigen. Die Short Health Scale (SHS) ist ein aus 4 visuellen Analogskalen bestehender Fragebogen zur Beurteilung der QoL bei Personen mit Darmerkrankungen, der in Schweden entwickelt und in verschiedenen Sprachen validiert wurde. In dieser Studie wurde die deutsche Übersetzung der SHS validiert.

Methodik Die Studie wurde im April 2021 präregistriert (https://doi.org/10.17605/OSF.IO/S82D9). Ambulante PatientInnen mit CED (n = 225) in verschiedenen Krankheitsstadien (definiert durch Harvey-Bradshaw-Index oder partiellen Mayo-Score) nahmen teil. Sie beantworteten die SHS und als etabliertes QoL-Instrument die Kurzform des Inflammatory Bowel Disease Questionnaire (sIBDQ). Zur Beurteilung der Reliabilität und Änderungssensitivität wurden Subgruppen (n = 30 in Remission bzw. n = 31 mit veränderter Krankheitsaktivität) nach 4–8 Wochen bzw. 3–6 Monaten erneut befragt.

Ergebnis Die interne Konsistenz der SHS war hoch mit einem Cronbachs α = 0.860. SHS-Scores korrelierten stark mit dem sIBDQ (ρ = –0.760, p < 0.001) und der Krankheitsaktivität (ρ = 0.590; p < 0.001). Die Retest-Reliabilität war hoch (ρ = 0.695, p < 0.001), während die Änderungssensitivität bei Pat. mit sinkender (p = 0.013), aber nicht bei steigender (p = 0.134) Krankheitsaktivität signifikant war.

Schlussfolgerung Die SHS ist ein kurzer und zuverlässiger Fragebogen zur Beurteilung der QoL bei Personen mit CED und kann lizenzfrei klinisch und wissenschaftlich eingesetzt werden.

Introduction

Inflammatory bowel diseases (IBD) are chronic disorders with a substantial impact on quality of life (QoL) [1, 2]. Patients with IBD frequently suffer from abdominal symptoms like pain and diarrhea. However, the burden of IBD extends beyond the physical consequences of intestinal inflammation and comprises extraintestinal manifestations, fatigue, increased prevalence of psychiatric disorders, impaired work productivity and more [3, 4, 5]. Accordingly, while QoL in patients with IBD is certainly influenced by disease activity, absence of inflammation does not always result in normalized QoL. Patient-reported outcomes (PROs), i. e., clinical parameters evaluated by patients, have proven essential in the clinical management and scientific research of IBD [6]. In this regard, health-related QoL (hrQoL) as a subjective measure of how the illness or treatment effects interfere with a patient's life [7] has emerged as one of the most important PROs [8, 9].

To our knowledge, there is currently one German IBD-specific instrument to measure hrQoL [10], which has been used in the majority of studies and is available in a long (IBDQ [10]) and short version (sIBDQ [11]), with 32 and 10 items, respectively. Especially for use in clinical contexts, but also in research, brevity and perspicuity are of utmost importance. To this end, the Short Health Scale (SHS) was developed [12, 13]. The original version was constructed in Swedish and to this date has been translated and found to be valid and reliable in English, Dutch, Korean and Norwegian versions [14, 15, 16, 17]. The SHS consists of four visual analog scales covering different aspects of hrQoL (symptom burden, functional status, disease-related worries and general well-being) with the following questions:

- How severe are the symptoms you suffer from your bowel disease?
- Do your bowel problems interfere with your activities in daily life?
- How much worry does your bowel disease cause?
- How is your general feeling of well-being?

This study aimed to assess the psychometric properties of the German translation of the SHS in a cohort of patients with IBD.

Methods

The present study included outpatients with IBD from the Dept. of Medicine II, University Medical Centre Mannheim, Heidelberg University, who were recruited between April 2021 and December 2021. The study was approved by the ethics committee of the Medical Faculty Mannheim, Heidelberg University (2021–511), and conducted in accordance with the Declaration of Helsinki. All patients gave written informed consent after a thorough explanation of the study procedures.

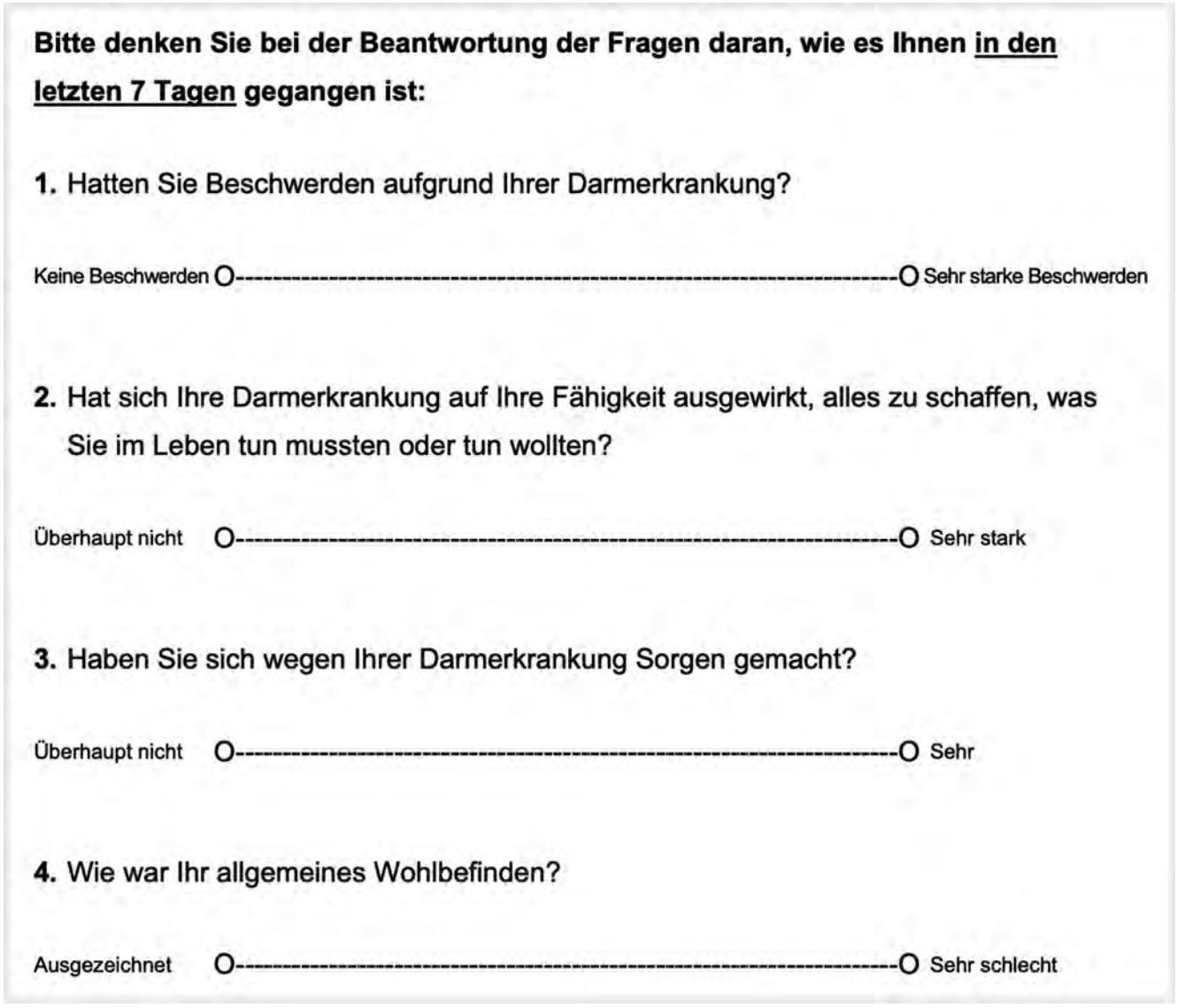
The study protocol, sample size, inclusion and exclusion criteria and planned analyses were preregistered before data collection and can be accessed at https://doi.org/10.17605/OSF.IO/S82D9.

Questionnaires

The SHS is a self-administered, disease-specific four-item questionnaire assessing symptoms, activities in daily life, disease-related worry and general well-being in the last seven days. Patients answer each question with a mark on a 100 mm visual analog scale ranging from 0–100, with 0 indicating no impairment in the respective domain of hrQoL and 100 indicating the poorest hrQoL (▶ **Fig. 1**). The SHS was translated by the MAPI Institute (www.mapi-institute.com) from Swedish to German with forward and backward translation steps and provided to us by the authors of the original version [12, 13].

Each item of the SHS is rated with 0–100 points, summing up to a maximum of 400 points, with higher scores indicating lower hrQoL.

As an established instrument to evaluate hrQoL and determine the convergent validity of the SHS, we used the short version of the Inflammatory Bowel Disease Questionnaire (sIBDQ [11]). It contains 10 items covering different aspects (such as abdominal



▶ **Fig. 1** Original questions in the German version of the Short Health Scale.

symptoms and several psychosocial factors) of hrQoL in the past two weeks. Answers are given on seven-point Likert scales, summing up to a maximum total score of 70 points, with higher scores indicating higher hrQol.

Disease activity

To determine disease activity, the Harvey–Bradshaw index (HBI) was used for patients with Crohn's disease (CD) and partial Mayo score (pMS) for patients with ulcerative colitis (UC). Each patient was assigned to one of four stages of disease activity (remitted, mild, moderate, severe), according to their HBI or pMS scores: in HBI, scores of 0–4 points define remitted disease, 5–7 define mild disease, 8–16 points are considered moderate and 17 and above severe disease. For patients with UC, a pMS score of < 2 indicates remission, 2–4 mild disease, 5–7 moderate disease and > 7 severe disease. HBI and pMS scores for all patients were determined by the attending physicians at the outpatient unit without knowledge of the QoL scores reported in the study.

Metrics and statistical analysis

Statistical analysis was conducted with SPSS (version 28.0.1.0). We used Cronbach's alpha to analyze internal consistency of the SHS and Spearman correlations between total SHS and sIBDQ scores and between total SHS and disease activity to test the scale's validity. Sixty-one patients answered the questionnaires a second time. Of these, n = 30 patients with unchanged disease activity (change in HBI or pMS of </ = 2 points) were examined after a period of 4–8 weeks to assess retest reliability by correlating initial and follow-up SHS scores with the Spearman rank correlation coefficient. Thirty-one patients with changes in disease activity repeated the questionnaires after 3–6 months. A change in disease activity was defined as changes in HBI or pMS of at least three points. In the latter group, differences in the SHS total

scores after disease activity changes were analyzed by separate t-tests for patients with increased and reduced disease activity, respectively.

Results

Study sample

A total of 232 patients were recruited. The data of 7 patients were removed because of missing answers in the sIBDQ, resulting in 225 participants. The mean age was 43 years and there were slightly more females (58 %) than males in the cohort. Fifty-four patients had a diagnosis of UC (24 %) and 171 (76 %) of CD. Disease activity was rated as "remitted" in 44.9 % (n = 101), "mild" in 25.8 % (n = 58), "moderate" in 24 % (n = 54) and "severe" in 5.3 % (n = 12) of the patients. The majority of patients (68.9 %, n = 155) were under current treatment with biologicals. Demographics and clinical characteristics of the sample are summarized in ▶ **Table 1**.

▶ **Table 1** Demographics and clinical characteristics of the study sample.

Diagnosis	
Crohn's disease, n (%)	171 (76)
Ulcerative colitis, n (%)	54 (24)
Sex	
Female, n (%)	130 (58)
Male, n (%)	95 (42)
Age in years, mean (SD)	43 (16)
Disease duration in years, mean (SD)	14 (11.7)
sIBDQ total score, mean (SD)	45.90 (12.85)
SHS total scores, mean (SD)	181.27 (109.1)
SHS subscale scores, mean (SD)	
Symptoms	35.1 (30.2)
Social function	48.15 (34.8)
Worries	55.25 (36.8)
General well-being	42.77 (27.1)
Current Medication	
Steroids, n (%)	35 (15.6)
Immunosuppressants, n (%)	14 (6.2)
Biologicals, n (%)	155 (68.9)
5-ASA, n (%)	36 (16.0)
Small molecules, n (%)	3 (1.3)
Clinical disease activity	
Remission, n (%)	101 (44.9)
Mild disease, n (%)	58 (25.8)
Moderate disease, n (%)	54 (24.0)
Severe disease, n (%)	12 (5.3)

Abbreviations: SD, standard deviation; SHS, Short Health Scale; sIBDQ, short Inflammatory Bowel Disease Questionnaire; 5-ASA, 5-aminosalicylate/mesalamine

Properties of the SHS

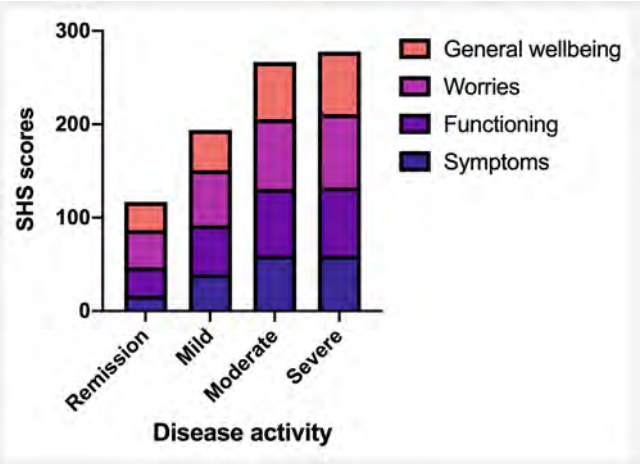
Internal consistency of the SHS was good with a Cronbach's α = 0.860 [18]. As expected, SHS total scores were highly negatively correlated with sIBDQ scores (ρ = –0.760, p < 0.001 in the overall sample, -.761, p <.001 for CD and –.744, p <.001 for UC, respectively) and positively correlated with disease activity (ρ = 0.590, p < 0.001 in the overall sample and .584, p <.001 for CD and .622, p <.001 for UC, respectively). ▶ **Fig. 2** shows the increase in SHS total scores and subscores with increasing disease activity.

The high correlation of repeated test results (ρ = .695, p <.001) indicates good retest reliability. Exploratory subgroup evaluation with regard to diagnosis revealed that retest reliability was only significant in patients with CD (ρ = .764, p <.001), but not UC (ρ = .143, p = .736).

The mean difference between baseline and follow-up SHS total scores in patients with decreased disease activity was 62.87 (SD 98.29, p = 0.013). The respective mean differences in SHS total scores of patients with increased disease activity were not statistically significant with –42.81 (SD 148.58, p = 0.134). Results of the statistical analyses are summarized in ▶ **Table 2**. An exploratory analysis of the responsiveness of the single items of the SHS revealed that in patients with increased disease activity, sensitivity to change was significant for the item covering general well-being, but not the other three items.

In patients with decreased disease activity, change was significant for the two items covering symptoms and worries, but not general well-being or interference with activities of daily life.

The mean duration needed by participants to complete the SHS was approximately 1 min.



▶ **Fig. 2** Column chart of SHS scores and color-coded subscores in four different disease activity groups.

▶ **Table 2** Properties of the German SHS.

Measure	Method	Statistics	Sample (n)	Mean scores (SD)	Results	p
Internal consistency		Cronbach's α	All patients (225)		0.860	
Validity	SHS-t/sIBDQ	Spearman's ρ	All patients (225)		$\rho = -0.760$	$<0.001^{***}$
	SHS-t/DA	Spearman's ρ	Remission (101) Mild (58) Moderate (54) Severe (12)	116.8 (97.1) 194.0 (84.6) 266.7 (77.1) 277.8 (77.3)	$\rho = 0.590$	$<0.001^{***}$
Reliability	Pre/post SHS-t	Spearman's ρ Intraclass correlation	Unchanged disease activity		$\rho = 0.695$ 0.789 (CI 0.561–0.899)	$<0.001^{***}$ $<0.001^{***}$
	(4–8 weeks)		baseline (30)	152.4 (105.5)		
			followup (30)	157.2 (107.4)		
Sensitivity to change	Pre/post SHS-t	t-test	Increased disease activity		t = –1,2, df = 15, d = –0.29	n.s. (0.134)
	(3–6 months)		baseline (16)	169.9 (110.1)		
			followup (16)	212.8 (113.3)		
	Pre/post SHS-t	t-test	Decreased disease activity		t = 2.5, df = 14, d = 0.6	0.013^{*}
	(3–6 months)		baseline (15)	236.3 (93.7)		
			followup (15)	173.4 (101.1)		

Abbreviations: d, Cohen's d; df, degrees of freedom; n.s., not statistically significant; SD, standard deviation; SHS-t, Short Health Scale total scores; $^{*} = p < 0.05$, $^{***} = p < 0.001$

Discussion

The present study examined validity, reliability and sensitivity to change of the German translation of the SHS.

HrQoL refers to health-related, and in cases of illness, to disease-specific factors of QoL. In chronic relapsing disorders such as IBD, disease activity is an important factor influencing QoL, but several other factors have been shown to have an impact on hrQoL in persons with IBD [2]. Therefore, instruments to measure hrQoL must assess relevant parameters beyond disease activity. From a patient's perspective, it is essential that a questionnaire is easy to understand, is quick to answer and asks relevant questions. For physicians and researchers, simplicity is also crucial for repeated monitoring, e. g., in treat-to-target and tight control approaches, and ideal tools are standardized, reliable and easy to evaluate. Especially in clinical studies, it is also desirable to detect and quantify changes in patients' well-being. Therefore, an instrument needs to be sensitive to change to reliably mirror effects of, e. g., therapeutic changes or interventions.

The present study indicates that the German SHS is a valid and reliable tool to assess hrQoL in patients with IBD. Completing the SHS in this study took patients approximately one minute and did not cause any difficulties in understanding. Due to the open questions, patients could individually decide which aspects they consider important in each domain. The calculated Cronbach's alpha in the present study indicates that the internal consistency of the German SHS is high. Moreover, large correlations with an established instrument to measure hrQoL and with the current state of disease activity confirm the validity of the German SHS to reflect hrQoL. The large correlation of longitudinally assessed SHS total scores also confirms retest reliability. Sensitivity to change was detected for patients with decreasing but not increasing disease activity.

Validity of the German translation of the SHS was assessed by comparing SHS scores to those of an established hrQoL instrument, the sIBDQ. All previous studies examining the original [12, 13] or translated [14, 15, 16, 17] versions of the SHS also chose the sIBDQ or its longer version (IBDQ) to examine the validity of the SHS and found comparably strong correlations. Furthermore, SHS total scores significantly correlated with the state of disease activity as determined by the Harvey–Bradshaw index or partial Mayo score, which confirms the findings of previous translations [14, 15, 17].

Retest reliability in this study was measured after a period of 4–8 weeks in order to stay in line with clinical follow-up appointments of patients that were scheduled independently of this study. Shorter follow-up intervals such as used in previous studies (e. g., 2 weeks [13, 15]) can result in even stronger correlations and thus higher retest reliability. However, we chose this approach to reduce contact, as the study was conducted during the COVID-19 pandemic. The results of our exploratory subgroup

evaluation indicating that retest reliability may be stronger in CD compared to UC need to be cautiously interpreted because of the very limited subgroup sample sizes.

Sensitivity to change was assessed by examining changes in SHS scores in patients for whom disease activity changed during the time of the study. In previous validation studies of the SHS, this has also been done for the Korean [14] and Norwegian [16] versions. The Korean version, with a slightly smaller subset of patients with changed disease activity (n = 21), was not found to be sensitive to change. However, only six patients in the Korean cohort were reassessed with decreased disease activity, and the sample might have been too small to detect responsiveness. In line with our findings, the Norwegian version showed sensitivity to change only for decreased symptoms, and – with separate measurement of the four domains – for questions 3 and 4 in the case of increased disease activity. The original Swedish version of the SHS [12, 13], which was examined in considerably larger samples, was sensitive to changes in both increased and reduced disease activity. In our study, we examined patients with both increased and decreased disease activity at follow-up, and calculated sensitivity separately. Changes in SHS scores reliably mirrored changes in disease activity in patients with a decrease in disease activity, comparable to the findings in the Norwegian cohort. In addition, there were numeric, but not significant changes in SHS scores in patients with a more active disease at follow-up. The lack of a significant increase in SHS scores in patients with increasing disease activity might relate to the small sample sizes in our follow-up cohorts. Our exploratory analysis of single-item responsiveness, comparable to the analyses conducted in the Norwegian cohort [16], shows a change in well-being (SHS item 4) but not the other domains (SHS items 1–3) in patients with increased disease activity, and in the items covering symptoms (SHS item 1) and worries (SHS item 3) but not general well-being (SHS item 4) or interference with activities of daily life (SHS item 2) in patients with decreased disease activity. Again, these findings should only be interpreted with caution, as the samples that were reassessed for responsiveness were also quite limited in size, which is a limitation of this study.

Further limitations need to be addressed: the combination of patients with CD and UC in a mixed IBD cohort may mask diagnosis-specific findings. Moreover, the study was conducted during a pandemic. We need to recognize that this may have influenced our participants' QoL to different degrees and partly independent of their chronic illness. While brevity was emphasized as a positive characteristic of the SHS, it may also be an issue for individual patients if they feel that important questions have not been asked in enough detail. In clinical practice, the SHS might be useful as a screening tool and considered as a starting point for a deeper discussion that helps to identify individual hrQoL-relevant factors and understand the patients' experiences of how the disease influences their daily lives.

In conclusion, especially in clinical settings, but also in IBD-related research, there is a need for brief, easily understandable and universal questionnaires to measure important patient-reported outcomes such as hrQoL. Our study shows that the German version of the SHS is a valid and reliable tool that meets these demands and is now at unlicensed disposal for future clinical and scientific use.

Ethical considerations

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of the Medical Faculty Mannheim, Heidelberg University (2021–511). Written informed consent was obtained from all individual participants included in the study.

Contributors' Statement

AKT and WR designed the study. SD recruited the patients. SD and NK performed the statistical analyses. SD, WR and AKT analyzed the data. SD, WR, MPE, PAT and AKT interpreted the data. AKT and SD wrote the manuscript. HH provided the original and translated SHS and documentation of the translation process. PAT, MPE, WR, HH and NK critically revised the manuscript. All authors approved the final version of the manuscript.

Funding

Land Baden-Württemberg (BW-ZDFP) | Deutsche Forschungsgemeinschaft | http://dx.doi.org/10.13039/501100001659 (GRK 2350, GRK2727,RE 2706 ,TH2341)

Conflict of Interest

The authors declare that they have no conflict of interest.

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