

Article

Italian Cross-Cultural Adaptation of a Knowledge Assessment Tool (IBD-KID2) for Children with Inflammatory Bowel Disease

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Abstract: Background: For children with inflammatory bowel disease (IBD), understanding their condition may lead to better outcomes. Knowledge assessment is imperative to identify where education may be required. An IBD knowledge assessment tool (IBD-KID2) is available in English; the aim of this study was to translate IBD-KID2 in to Italian and assess its validity/reliability among children with IBD. Methods: IBD-KID2 has fifteen items, scoring one point per correct answer. IBD-KID2 items were assessed for cultural comprehension/relevance by Italian gastroenterologists using a content validity index; those items with a maximum score proportion <0.78 were reviewed. IBD-KID2 was then translated using ‘forward–backward’ process and reviewed for content/meaning. A prospective study among Italian children with IBD enabled score comparisons with established populations (z test), and reliability was assessed using test–retest completion (Pearson correlation (r), paired t-test). Results: Twenty-five children participated: 16 (64%) male, mean age 14.9 years (SD2.4), Crohn’s disease 13 (52%). The mean IBD-KID2 score was 8.8 (SD2.8), with no association with independent variables. Test–retest showed strong correlation between scores (r = 0.78, p < 0.001), with no mean difference (p = 0.39). Comparison with other pediatric IBD populations (NZ/Australia/Canada) showed no score difference (p = 0.62, CI –0.9 to 1.5). Conclusions: The translation of IBD-KID2 to Italian used a rigorous methodology. Scores showed the translated tool has equivalence and generalizability to Italian children with IBD.

Keywords: generalizability; translation; validity; Italian; forward–backward; equivalence

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1. Introduction

Inflammatory bowel disease (IBD) is an immune-mediated chronic condition affecting the gastrointestinal tract. IBD causes relapsing–remitting inflammation and may be associated with physiological and psychosocial symptom burden [1]. The prevalence and incidence of IBD, among the pediatric population specifically, is increasing worldwide [2–4]. While clinical management is the mainstay of pediatric IBD treatment, non-clinical factors have also been associated with improved disease outcomes. The acquisition of disease-specific knowledge may be beneficial to outcomes such as improved adherence [5], self-management skills [6,7], and transition from pediatric to adult care [8]. Unfortunately, children and adolescents with IBD have been shown to have gaps in their knowledge relating to various subjects: medications, nutrition, procedures, growth, and the effect of recreational drugs/smoking/alcohol on IBD [5,8–11]. However, disease knowledge is known to be a modifiable factor through the use of teaching, and education interventions [12]. For children with IBD, the acquisition of fundamental components of health knowledge regarding their own clinical history, IBD management, and general IBD facts contributes to treatment adherence and the development of self-management skills [6,7].

Integral to the importance of knowledge acquisition is the ability to quantitatively assess this variable to determine the presence of misconceptions or the lack of essential

information. Completion of knowledge assessment tools provides an overall score that is an important indicator of overall disease and treatment knowledge, and examination of correct answer patterns may also identify gaps that need targeted education [13]. For children with IBD, a knowledge assessment tool called IBD-KID2 [13] has been well validated and assessed for generalizability among different English speaking populations [11]. As yet, the assessment tool IBD-KID2 is not yet available in languages other than English.

The previous version of IBD-KID2 (IBD-KID [14]) underwent translation into French [15] and Polish [16], but as IBD-KID2 is a revised tool [17] it was considered important also to carry out cross-cultural adaptation and validation in other languages for this version. Cross-cultural adaptation of outcome measures is becoming increasingly important, as they become the standard tools for evaluating patient health status, interventions, and quality of care [18,19]. The process is carried out to account for illness and health having different meanings in different ethnic groups, languages, cultures, and even generations [18,20–22]. The overall goal of developing cross-cultural adaptations is to produce a measure that is equivalent to the original one, not an identical one [22]. In carrying out this process for measures such as IBD-KID2, we not only increases the generalizability of assessment tools to different populations, but also their feasibility and relevance to the wider population, thereby enabling standardized data collection in multi-national studies [18,20,22].

The language IBD-KID2 was first considered for translation into was Italian. In Italy, the reported incidence of pediatric IBD ranges from 1.39 to 8.7 per 100,000 person-years [23,24], and the incidence has been shown to be increasing in line with the rest of the world [2,4,23], thereby highlighting the importance of making assessment tools applicable to their population. The aim of this study was to undertake a translation study of IBD-KID2 between pediatric gastroenterology specialists in Italy and New Zealand to develop an Italian version of this knowledge assessment tool.

2. Results

2.1. Conceptual and Semantic Equivalence

Three Italian experts in pediatric gastroenterology, with 15 years-experience between them, carried out the CVI for cultural/language/practice comprehension and relevance. CVI scores for each individual item ranged from 0.63 to 0.97 for comprehension, and 0.57 to 0.97 for relevance, with scores of 0.84 to 0.85, respectively for IBD-KID2 overall (Table 1).

Seven items required review and underwent discussion between the Italian and NZ teams to revise wording and/or terms to improve relevance and/or comprehension while maintaining the overall meaning and intention of the items. Once complete, agreement was reached that all items satisfied relevance and comprehension requirements, and the tool was considered to have conceptual equivalence. Following the forward–backward translation process, all 15 items were reviewed by the NZ team, with five items discussed with the Italian team to ensure semantic equivalence and readability was maintained. The final version of the Italian IBD-KID2 was agreed (Supplementary Material S1).

Table 1. Cultural/language/practice relevance and comprehension for each IBD-KID 2 item, and overall.

| Item # | Relevance | Comprehension |
|--------|-----------|---------------|
| 1 | 0.73 | 0.93 |
| 2 | 0.63 | 0.57 |
| 3 | 0.83 | 0.93 |
| 4 | 0.90 | 0.73 |
| 5 | 0.90 | 0.83 |
| 6 | 0.73 | 0.80 |
| 7 | 0.93 | 0.93 |

Table 1. *Cont.*

| Item # | Relevance | Comprehension |
|---------------|-----------|---------------|
| 8 | 0.93 | 0.93 |
| 9 | 0.97 | 0.97 |
| 10 | 0.93 | 0.97 |
| 11 | 0.70 | 0.77 |
| 12 | 0.97 | 0.97 |
| 13 | 0.80 | 0.77 |
| 14 | 0.97 | 0.97 |
| 15 | 0.70 | 0.67 |
| Overall score | 0.84 | 0.85 |

Items in italics were reviewed between teams to discuss relevance and/or comprehension.

2.2. Measurement Equivalence

2.2.1. Participants

Twenty-five children participated in the study, with a mean age of 14.9 years (SD 2.4, range 9–17) and median age of 16.3 years, of which 16 (64%) were male. IBD clinical sub-types were represented by 13 (52%) having Crohn's disease and 12 (48%) ulcerative colitis. The mean time since diagnosis was 4.1 years (SD 3.1), the mean age at diagnosis 10.8 years (SD 4.1), and 3 (12%) had a family history of IBD. When categorized into age groups it was seen that 5 (20%) participants were aged 12 years and under, 6 (24%) aged 13 to 15 years, and 14 (56%) aged 16 years and over.

2.2.2. IBD-KID2 Scores

The mean Italian IBD-KID2 score (maximum 15) was 8.8 (SD 2.8, range 4–14), equivalent to 59%. IBD-KID2 scores for the group were not associated with any independent variable (Table 2).

Table 2. Association of IBD-KID2 scores with demographic and disease specific variables.

| Linear Variable | R | p Value |
|-----------------------------|-----------------|---------|
| Age | 0.267 | 0.198 |
| Time since diagnosis | 0.108 | 0.607 |
| Age at diagnosis | 0.075 | 0.723 |
| Categorical variable | Mean difference | p value |
| Age group (all) | - | 0.255 |
| Age group (<16 y vs. ≥16 y) | −0.46 | 0.691 |
| Gender | 1.4 | 0.222 |
| IBD sub-type | −1.51 | 0.177 |
| Family history of IBD | 2.04 | 0.235 |

y = years.

2.2.3. Reliability

All 25 children returned the repeat IBD-KID2 sent out two weeks after their baseline completion. Mean scores on second completion were 8.5 (SD 3.1), or 57%. Test–retest analysis showed a strong correlation between scores ($r = 0.78$, $p < 0.001$), with no significant difference in mean scores ($p = 0.394$, CI −0.5 to 1.1) between the two time points (Figure 1).

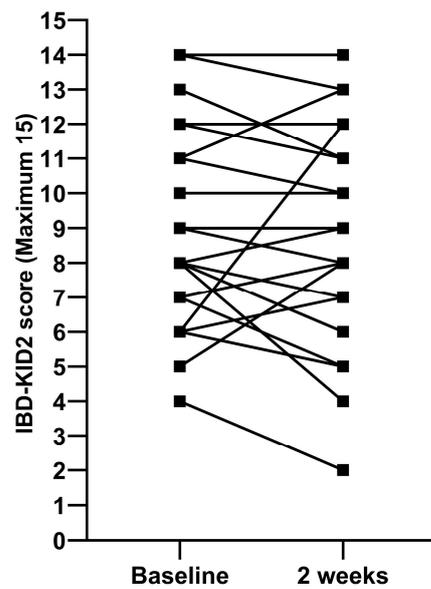


Figure 1. Test-retest completion IBD-KID2 scores for each study participant.

2.2.4. Generalizability

The scores for the cohort completing the Italian version of IBD-KID2 were compared to scores achieved in previous research involving 130 children with IBD in New Zealand, Australia, and Canada completing the original English version [11] There was no difference in scores between the countries ($p = 0.62$, CI -0.9 to 1.5).

2.2.5. Areas of Knowledge

On examination of the individual IBD-KID2 items, 8 (53%) of the 15 items were answered correctly by more than 50% of the cohort (Figure 2). The four lowest scoring items were regarding the cause of IBD, extra-intestinal manifestations, food triggers, and nutrient absorption. When the effect of participant age was explored, it was shown that no IBD-KID2 items were scored correctly with greater frequency by children aged less than 16 years or 16 years and over ($p > 0.05$).

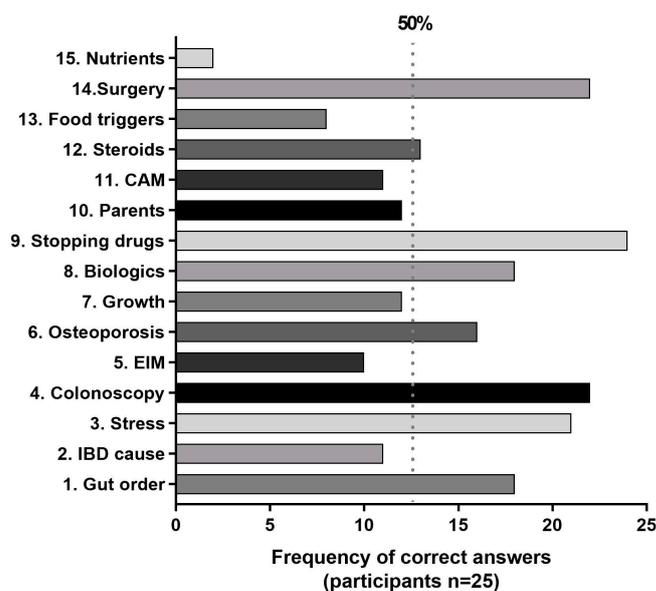


Figure 2. Individual IBD-KID2 item scores for the study cohort.

2.2.6. Internal Consistency

The KR-20 score was 0.704, indicating the Italian version of IBD-KID2 had acceptable internal consistency.

3. Discussion

The translation process undertaken in this study has shown that an Italian version of IBD-KID2 has content and semantic equivalence with the original English version, as well as validity, reliability, and generalizability to children with IBD in Italy.

The two items in this Italian IBD-KID2 study with the lowest frequency of correct answers related to diet/nutrition, specifically whether certain foods could trigger IBD symptoms, and nutrient absorption. The item regarding food triggers for IBD symptoms has previously been scored correctly by 45–55% of children and adults with IBD in English speaking countries [11,14,25]. However, 12–32% of cohorts using translated versions of this item, including the current study, scored this item correctly [15,16]. Discrepancies such as this may reflect a number of factors, not simply due to a deficit of topic specific knowledge but also due to different education or information given to children in other countries [15], or cultural practices and beliefs. For the Italian cohort in this study, the importance of food to Italian people should be considered, as it is central to their culture and identity [26] and may influence willingness to exclude items from their diet. Previous surveys have shown that up to 53% of children with IBD practice food avoidance due to symptom exacerbation [27], while, in an Italian cohort, 48% of children with IBD agreed that food may exacerbate symptoms but only 36% had modified their diet to exclude foods [28]. Approximately 23% of children with IBD in remission continue to experience symptoms of functional abdominal pain disorders [29], a factor which may impair food-related quality of life in domains such as food avoidance, food enjoyment, and adjusting eating habits [30]. Children with CD have impaired food-related quality of life compared to their siblings and healthy controls [31], findings that may highlight food management as a significant burden for children with IBD. For Italian children, this may be in contrast with their culture and thereby influence their opinion or understanding of this item.

The IBD-KID2 item regarding nutrient absorption is consistently answered correctly by less than 50% in cohorts of children with IBD [11,13,16], and consistently answered correctly by more than 50% of parents of children with IBD and adults with IBD [25,32]. This may indicate that an understanding of the function of the bowel, and how this may be impaired by IBD, is not well understood by children but this knowledge may be acquired when increased responsibility for IBD management is evident, such as for adults with IBD or parents. While knowledge on the role of nutrients in the etiology of IBD is increasing, this topic may be more likely discussed with children at high risk of micronutrient deficiencies, or who have required treatment such as iron infusions or vitamin D supplementation [33].

The lack of association between independent variables and IBD knowledge scores has been seen in other pediatric cohorts [13,15,34,35]. Furthermore, other studies have shown an association between scores and children's diagnosis [14], age [11,16], age at diagnosis [11,35], and sex [16]. This suggests that variability in knowledge scores among pediatric cohorts may be dependent on the individual cohort and not the knowledge assessment tool specifically. During development of IBD-KID2 the survey underwent a process of item-response analysis to review and modify items, with those included having acceptable levels of readability, difficulty, and discriminatory ability; a metric to distinguish between children with good and poor knowledge [17]. This analysis was carried out using responses from English-speaking children with IBD only, and, therefore, may not capture nuances of language and culture present in translated versions. However, when this translated version was completed by a cohort of Italian children there was no score difference compared to English speaking cohorts, and, as such, this factor may be present but is not significant enough to affect the overall score.

3.1. Strengths

The translation process undertaken to develop the Italian version of IBD-KID2 was rigorous and evidence-based. The findings in this study are consistent with previous published literature that utilized IBD-KID2, which therefore shows further generalizability of the knowledge assessment tool outside English-speaking countries. Work is ongoing to translate and validate IBD-KID2 in additional languages.

3.2. Limitations

This study was not designed to elucidate the variations in cultural attitudes to food, or variances in FRQoL, as alluded to. However, the findings of this study indicate that future research with higher participant numbers, and additional variables collected may provide a more in-depth insight into cultural variability. This study established the generalizability of IBD-KID2 to children with IBD in Italy. However, the study was carried in one center, thereby limiting generalizability to other centers in Italy. It is important to add to the validity, reliability, and generalizability results shown in this study to establish wider generalizability and sensitivity to change among a cohort of Italian children with IBD.

4. Materials and Methods

4.1. IBD-KID2

IBD-KID2 is a fifteen item knowledge assessment tool that contains nine true/false items and six multiple-choice items, with topics covering general IBD, treatment, lifestyle and nutrition as previously described in detail [13]. Participant responses are scored as one for each correct answer, to a maximum total of fifteen.

4.2. Translation Process

The central concern of any translation process is to yield a linguistic and cultural equivalent of the original that has a comparable connotative meaning [36]. There are a number of methodologies outlined in the literature for the translation of questionnaires, but the focus should be to test the translational equivalence, which should be measured across a number of dimensions [21,37]:

Conceptual equivalence

- Concept: the instrument is measuring the same theoretical construct in each culture.
- Content: the content of each item is relevant to the phenomenon of each culture studied

Semantic equivalence

- Semantic: the meaning of items is the same in each culture after translation

Measurement equivalence

- Technical: the method of assessment is comparable with respect to the data it yields.
- Criterion: the interpretation of results is the same in both cultures

The process for cross-cultural adaptation from the English to Italian version of IBD-KID2 was, therefore, developed to progress through three distinct phases of conceptual, semantic, and measurement equivalence (Figure 3).

4.2.1. Conceptual Equivalence

Each of the fifteen IBD-KID2 items from the English version were assessed for conceptual equivalence by assessment of cultural/language/practice comprehension and relevance by gastroenterologists in Italy using an adapted content validity index (CVI) [38]. Items were scored for cultural/language/practice comprehension and relevance on a ten-point Likert scale, with the overall proportion of maximum scores for each item and the tool overall required to be above 0.78 [38]. Items scoring less than 0.78 would be required to undergo review by the Italian and New Zealand team together to identify where barriers to comprehension and relevance may exist and how to address these in the wording of IBD-KID2 prior to translation into Italian.

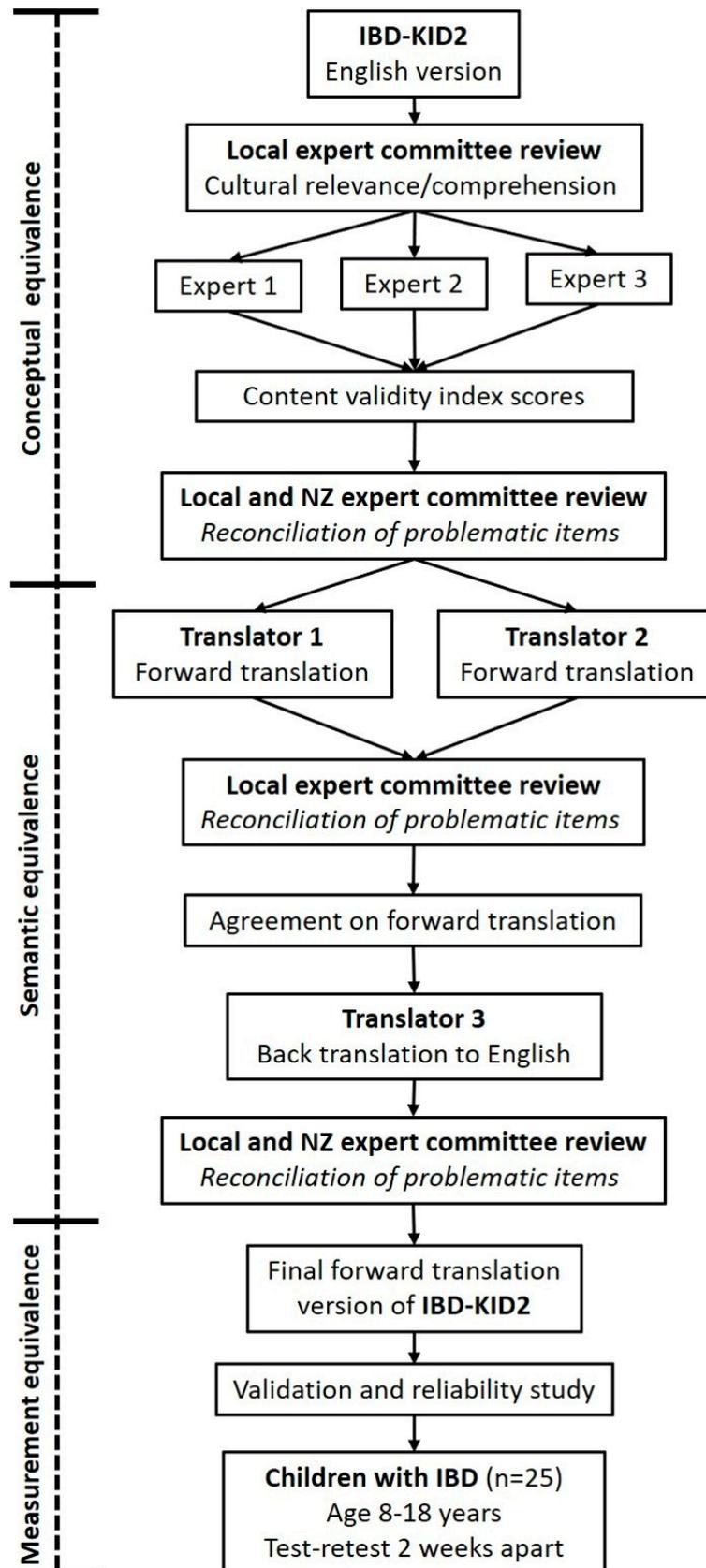


Figure 3. Flow chart of translation process, with phases for content, semantic and conceptual equivalence.

4.2.2. Semantic Equivalence

Once the conceptual equivalence of IBD-KID2 was established using the CVI process, translation of IBD-KID2 into Italian was carried out using the 'forward-backward' process. This process involved the forward translation of IBD-KID2 into Italian by one bilingual expert in the field of gastroenterology and a second translator who has a working knowledge of the terminology used in IBD-KID2. The two translators met to agree on a 'forward' draft. This draft was submitted to the original experts, who reconciled any differences in translation that may have changed the overall meaning of items. Once the final 'forward' draft was agreed upon, a third independent translator back-translated the tool to English and sent this version to the researchers in New Zealand for review of the content and format. Any items with a perceived change of meaning were discussed with the Italian and New Zealand teams together and revised, and then the final Italian version of IBD-KID2 was ready to be tested among the target population of children with IBD.

4.2.3. Measurement Equivalence

- Participants and site

Children with IBD aged between eight and eighteen years were recruited from the Pediatric Gastroenterology and Liver Unit, Umberto I Hospital, Sapienza University of Rome, Italy.

- Methodology

Clinicians collected basic demographic (age, gender) and diagnosis data (diagnosis, date of diagnosis, family history of IBD) from medical records. The children were asked to complete IBD-KID2 at baseline, and then again after two weeks.

- Ethics and consent

Institutional approval was obtained from the Institutional Review Board of Umberto I Hospital, Sapienza University of Rome for the investigator in Italy to recruit participants from their out-patient clinics. Written, informed consent was obtained from all parents of children participating in the study, and assent obtained from all child participants.

4.3. Statistics

4.3.1. Conceptual Equivalence

On completion of the CVI assessment for cultural/language/practice comprehension and relevance, the scored Likert ratings given by the experts were used to calculate the CVI scores for items and the tool overall. These were both calculated as a proportion of the maximum possible score from all experts using the formula $\frac{\text{actual score}}{\text{maximum possible score}}$, with the highest possible CVI proportion score therefore being 1.0 [39]. CVI scores were considered acceptable with a score greater than 0.78 [39].

4.3.2. Measurement Equivalence

Measurement equivalence was tested by calculating the mean IBD-KID2 scores for the cohort overall, and associations between the variables age, gender, diagnosis, and disease duration were tested using analysis of variance for categorical variables and linear regression for continuous variables. Test-retest reliability was examined by comparing means between the baseline and repeat assessments using a paired *t*-test and Pearson correlation. Generalizability was assessed by comparing the results from this cohort to those previously completing the English version using a *z*-test. Internal consistency was examined with the Kuder-Richardson 20 (KR-20) formula. IBD-KID2 responses were examined for patterns of knowledge deficiencies—considered as those items answered correctly by under 50% of the cohort of children with IBD. The effect of age (<16 years or ≥16 years) was explored against the frequency of correct answers using contingency tables and the chi squared test. *p* values were considered significant at level <0.05. In the absence of an established participant number for validating translated assessment tools, the study sample

size was determined by the original IBD-KID2 validation study [13]. The recruitment of twenty-five participants was considered sufficient to assess our stated outcomes, provided there was an appropriate distribution between sex and diagnoses in order to reduce the chance of bias. Sample size was approved by an institutional biostatistician. Statistical analysis was performed using SPSS for Windows, version 27.0 [40].

5. Conclusions

The importance of assessing metrics such as IBD knowledge has been well established for children with IBD, as well as in adolescents transitioning from pediatric to adult care teams. This Italian translated version of IBD-KID2 has been proven to be a valid and reliable tool that can now be utilized in the clinical and research settings. This would enable knowledge assessments that may highlight where additional education may be beneficial, particularly in areas that may be influenced by cultural practices or beliefs.

Supplementary Materials: The following supporting information can be downloaded at: <https://www.mdpi.com/article/10.3390/gidisord5020016/s1>, Supplementary Material S1: Italian IBD-KID2.

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Informed Consent Statement: Informed consent or assent (participant dependent) was obtained from all subjects involved in the study.

Data Availability Statement: Data are available upon reasonable request to the corresponding author, A.V.-R.

Conflicts of Interest: The authors declare no conflict of interest.

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