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Cross-cultural adaptation of the locally recurrent rectal cancer – Quality of life questionnaire

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ABSTRACT

Aim: The Locally Recurrent Rectal Cancer – Quality of Life (LRRC-QoL) questionnaire was developed as a disease specific measure of health-related quality of life (HrQoL) in locally recurrent rectal cancer (LRRC), it has previously been validated for use in the UK and Australia. The aim of this study was to translate and cross-culturally adapt the LRRC-QoL to enable its use on an international platform.

Materials and methods: Cross-cultural adaptation of the LRRC-QoL was undertaken through a process of 1) Translatability Assessment (TA), 2) forward-backward translation, and 3) pre-testing interviews to establish content validity and conceptual equivalence across all versions. The QQ-10 measure was used to assess face validity and acceptability. The LRRC-QoL was translated into 13 languages: Danish, Dutch, French, Hindi, Italian, Mandarin, Marathi, Portuguese, Russian, Spanish, Swedish, Telugu, and Urdu.

Results: In total, 67 patients and 6 clinicians were recruited to pre-testing interviews across 12 countries: Brazil, Canada, Denmark, France, India, Italy, the Netherlands, New Zealand, Pakistan, Singapore, Spain, and Sweden. TA was also undertaken in the USA and Ireland, and translations were prepared in Russian, Marathi, and Telugu. The LRRC-QoL was found to demonstrate conceptual equivalence and content validity across all versions. Mean QQ-10 Value score 76.80 (SD 13.88) and mean Burden score 20.22 (SD 23.03), confirming face validity and acceptability in this international cohort.

Conclusion: The LRRC-QoL has now undergone cross-cultural adaptation to enable its use in 10 languages and 16 countries. Its psychometric properties will be further examined through external validation in an international cohort.

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1. Introduction

Locally recurrent rectal cancer (LRRC), though now a relatively rare occurrence, with an incidence of 4–8 % [1–5], remains significant given its impact on patients, causing potentially debilitating symptoms such as pain and bleeding [6]. Curative treatment often requires exenterative surgery in combination with chemotherapy±chemoradiotherapy, and is associated with high rates of morbidity [7–9], and significant financial burden from a healthcare service perspective [10]. Over the past decade there have been significant improvements in clinical outcomes [11], alongside important developments in the reporting of clinical outcomes in LRRC due to international collaboration and pooling of clinical outcome data [12]. This has led to more generalisable clinical outcome data, in addition to international collaboration in setting up clinical trials such as the PelvEx II and GRECCAR 15 trials [13,14].

Patient-reported outcomes (PROs) are measurements based on a report coming directly from patients [15]. Health-related quality of life (HrQoL) is the most commonly reported PRO, offering a patient-focused view of the impact of a disease, treatment, or intervention [16]. Reporting PROs including HrQoL is particularly pertinent in LRRC, given that both the disease itself and its treatment are associated with significant morbidity. Recent years have seen increasing focus on reporting PROs in LRRC, however, there have been no studies reporting PROs in LRRC utilising a disease-specific patient-reported outcome measure (PROM) [17]. Most importantly, none of the PROMs currently in use have demonstrated content validity for patients with LRRC [17]. Content validity is the most important psychometric property of a PROM [18], being "*the degree to which the content of a measure is an adequate reflection of the construct to be measured*" [19]. Crucially, it confers that a measure is relevant, comprehensive, and comprehensible [20]. To address this lack of appropriate PROMs for patients with LRRC, the locally recurrent rectal cancer – quality of life (LRRC-QoL) measure was developed in English and validated in the UK and Australia as the first disease-specific measure of HrQoL in LRRC [21].

Cross-cultural adaptation is a process through which PROMs are adapted or translated for use in different cultures; ensuring that they are conceptually, linguistically, and semantically congruent for use internationally. The advancements described regarding clinical outcome reporting in LRRC have only been achieved in this rare disease setting through international collaboration [12]. Replicating this process in reporting PROs presents additional challenges and will only be possible if high-quality tools are available which have undergone a rigorous translation process in a wide range of languages and testing to ensure cross-cultural equivalence across all versions. The aim of this study was to translate the LRRC-QoL measure into several different languages and to confirm its acceptability for use across several cultures and countries.

2. Material and methods

A mixed-methods approach was employed to establish the cross-cultural adaptation and validity of the LRRC-QoL. The LRRC-QoL is a disease-specific measure of HrQoL in LRRC, comprising nine scales and 29 items. The development and validation of the LRRC-QoL has previously been reported [22]. However, this work was undertaken only in English including patients from the UK and Australia. Therefore, it was necessary to undertake cross-cultural adaptation to expand the utility of the measure on an international platform. A three-stage approach was applied informed by European Organisation for Research and Treatment of Cancer (EORTC) guidelines and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) clinical outcome assessment taskforce report regarding PROMs in rare disease clinical trials. The stages of this process included translatability assessment, forward-backward translation, and pre-testing interviews.

2.1. Translatability assessment

Translatability assessment (TA) is "*the evaluation of the extent to which a PROM can be meaningfully translated into another language*" [23], with a meaningful translation of a PROM being one that is conceptually equivalent to the original and appropriate for use in the target country and culture [24]. TA has been identified as an appropriate method to provide evidence of cultural equivalence in rare disease settings [25]. TA was performed in keeping with guidance from Acquadro et al. through a process of reviewing the LRRC-QoL with teams from each country, defining its concepts, analysing the translatability of each component, discussing any proposed changes and agreeing a final version [24]. This was employed prior to the formal translation process or prior to pre-testing interviews for participating English-speaking sites.

2.2. Forward-backward translation

A robust translation procedure was undertaken for each language, informed by the EORTC Translation manual [26]. This process involved two independent forward translations by healthcare professionals with background knowledge of LRRC, reconciliation to agree a final forward translation, blinded backward translation into English by professional translators, and comparison of the backward translation with the original English version. The LRRC-QoL was translated into 13 languages including, Danish, Dutch, French, Hindi (India), Italian, Mandarin (Singapore), Marathi (India), Portuguese (Brazil), Russian, Spanish, Swedish, Telugu (India), and Urdu (India and Pakistan).

2.3. Pre-testing interviews

2.3.1. Eligibility criteria

The eligibility criteria were adult patients aged ≥18 years, with a radiological and/or histological diagnosis of LRRC or have undergone treatment for LRRC within the last 2 years, and able to provide written consent to participate. Research Ethics Committee (REC) approval was granted for the study in the UK (reference: 20/WS/0116) and for each participating country and site.

2.3.2. Procedure

Pre-testing interviews were undertaken with an intended sample size of 5–10 patients per version of the questionnaire. In countries and healthcare systems where this was not possible, patient interviews were supplemented with interviews with healthcare professionals [25]. Interviews with English-speaking participants were facilitated by the co-ordinating researcher (NM), all other interviews were facilitated by researchers or clinicians who were native speakers of the target language (JvR, SN, HvT, SW, EG, LS, IB, RS, BA, GK, MBS, NF, CFM, CH, LB). All facilitators undertook online training with NM prior to commencing interviews and were provided with a detailed interview topic guide (see supplementary material). Interviews were conducted either in person, via telephone, or via video-conference software. The interview consisted of six questions, which were posed in turn for each of the LRRC-QoL scales, and one question relating to the overall questionnaire, this procedure was informed by the EORTC translation manual [26].The questions are detailed in the interview topic guide in the supplementary material. Following this, the interview facilitator completed the QQ-10 measure with the participant. The QQ-10 is a measure of face validity and acceptability of PROMs [27]. There were four additional questions for participants in English-speaking countries who completed the LRRC-QoL questionnaire online via REDCap.

2.3.3. Analysis

2.3.3.1. Interview participants. Demographic data for the interview

participants were collected and a descriptive statistical analysis conducted using SPSS Statistics for Mac, version 26 (IBM Corp., Armonk, N. Y., USA).

2.3.3.2. Interview responses. Interview responses were recorded in a form specifically designed for this purpose and compiled to enable analysis for the overall LRRC-QoL measure and each of its constituent items.

Cross-cultural equivalence was assessed through compiling responses from each target language and country to identify any changes required to ensure consistency in the concepts being assessed across all versions.

Content validity has previously been established during the original development of the LRRC-QoL [22]. It was further assessed during this study through identifying any HrQoL issues identified during interviews which were not represented in the current LRRC-QoL.

2.3.3.3. QQ-10 measure. Face validity and acceptability of the LRRC-QoL were assessed using the QQ-10 measure. Responses to the QQ-10 were scored as per Moores et al. [27]: the first six questions comprise a Value score and the final four questions comprise a Burden score, which are transformed onto a 0–100 scale. Mean Value score >70 and Burden score <25 is advised for confirmation of face validity and acceptability [27].

3. Results

3.1. Translatability assessment

TA was undertaken involving clinicians from 19 sites in 15 countries, through meetings via videoconference. Their characteristics are detailed in Table 1. This process resulted in minor changes to the overall measure. These included changes to the order of the scales and small changes in wording, including removing repetition of the words "women/men" prior to gender-specific questions and including in a heading above the items. The heading "Other Symptoms" was also added above the individual items regarding discharge from the rectum and pain or discharge from wounds or scars. The terms "urinary catheter" and "nephrostomy" were added to the skip question prior to the Urostomy scale given their inclusion in the constituent items.

Clinicians in India and Pakistan suggested that the reading level would be too high for some patients and proposed administering the measure through reading aloud. This mode of administration has been demonstrated to be equivalent [28] and was agreed to be acceptable for the LRRC-QoL.

Clinicians working in Singapore felt that the items related to sexual interest and function may not be tolerated from a cultural perspective, however, were happy to explore this further through pre-testing interviews with patients. All changes are discussed in-depth in the supplementary material.

Table 1
Characteristics of clinicians involved in TA.

Characteristics of Clinicians Involved in TA, Translations, and Interviews	
Country	
Brazil	3
Canada	5
Denmark	2
France	2
India	2
Ireland	3
Italy	2
The Netherlands	6
New Zealand	2
Pakistan	2
Russia	3
Singapore	2
Spain	6
Sweden	3
USA	6
Role	
Consultant Colorectal Surgeon	28
Consultant Oncologist	1
Surgeon in Training/Research Fellow	11
Specialist Nurse	3
Medical Student	2

3.2. Pre-testing interviews

3.2.1. Sample

In total, 67 patients and 6 healthcare professionals participated, the demographic and clinical characteristics for the patients are detailed in Table 2. It was not possible to collect demographic data from French participants as this was not permitted in keeping with local ethical approvals. Over 60 % of participants (n = 43) were male, median age was 64.0 years (IQR 12.0), the majority were of white ethnicity (n = 42, 62.7 %) and over 50 % were married (n = 35). In relation to level of education, each group was well represented. The majority of patients (n = 48, 71.6 %) were diagnosed through surveillance and most patients received treatment with curative intent (n = 57, 85.1 %). Fourteen (20.9 %) patients had metastatic disease. Median interval between diagnosis with LRRC and participation in the study was 6.0 months (IQR 22.0). The six healthcare professionals interviewed were from sites in Brazil, Canada, Singapore, and Spain.

3.2.2. Interview analysis

Comments from patients regarding the overall LRRC-QoL and its items are detailed in the supplementary material alongside reasoning for decisions made regarding changes to items. There were no comments or issues identified during interviews undertaken in Brazil, France, India, or Pakistan. Minor revisions were made to the Dutch, Italian, and Mandarin translations, which are detailed in the supplementary material.

In relation to the content validity of the LRRC-QoL, fifty-two issues were identified during the pre-testing interviews. Five (9.6 %) of these issues were felt to be represented within the current LRRC-QoL measure. A significant proportion (n = 13, 25.0 %) were identified during the original development of the LRRC-QoL provisional item pool and were subsequently removed from the questionnaire during the development and testing process, these included post-operative recovery and reduced confidence. The LRRC-QoL was designed to be used in combination with the EORTC QLQ-C30 and several HrQoL issues identified (n = 14, 26.9 %) are represented in this measure, including fatigue, financial impact, and low mood. Other issues were not identified during the LRRC-QoL development or represented in the EORTC QLQ-C30 and decisions regarding potential changes to the questionnaire are detailed in the supplementary material. Reasons for not adopting additional issues included them being identified by healthcare professionals only and not patients (n = 8, 15.4 %), issues being identified by only one patient (n = 16, 30.8 %), or the issues described not reflecting specific concepts (n = 3, 5.8 %).

The overall mean Value score for the QQ-10 was 76.80 (SD 13.88), mean Burden score was 20.22 (SD 23.03), confirming the face validity and acceptability of the LRRC-QoL.

4. Discussion

This study details the successful cross-cultural adaptation of the LRRC-QoL into French, Italian, Dutch, Swedish, Urdu (India and Pakistan), Spanish, Mandarin (Singapore), Portuguese (Brazil). The English-language version has now undergone extensive pre-testing in the UK, Australasia, and North America, in addition to TA involving clinicians from Ireland and the USA, it should therefore be considered acceptable for use across these regions. The LRRC-QoL has therefore

Table 2
Demographic and clinical characteristics of the overall cohort.

Demographic and Clinical Characteristics (%)	
Country	
Brazil	1 (1.5)
Canada	4 (6.0)
Denmark	7 (10.4)
France	8 (11.9)
India	6 (9.0)
Italy	10 (14.9)
The Netherlands	10 (14.9)
New Zealand	7 (10.4)
Pakistan	2 (3.0)
Singapore	1 (1.5)
Spain	3 (4.5)
Sweden	8 (11.9)
Language	
Danish	7 (10.4)
Dutch	10 (14.9)
English	11 (16.4)
French	8 (11.9)
Italian	10 (14.9)
Mandarin	1 (1.5)
Portuguese	1 (1.5)
Spanish	3 (4.5)
Swedish	8 (11.9)
Urdu	8 (11.9)
Gender	
Male	43 (64.2)
Female	24 (35.8)
Median Age (IQR)	64.0 (12.0)
Ethnicity	
White	42 (62.7)
Black	0 (0.0)
Asian	9 (13.4)
Other	1 (1.5)
Unknown	15 (22.4)
Marital Status	
Married	35 (52.2)
Civil partnership	1 (1.5)
Living with partner	3 (4.5)
Widowed	2 (3.0)
Divorced	2 (3.0)
Single	4 (6.0)
Other	3 (4.5)
Unknown	17 (25.4)
Education Status	
Secondary school	17 (25.4)
College	9 (13.4)
University	15 (22.4)
Other	9 (13.4)
Unknown	17 (25.4)
Employment Status	
Self-employed	8 (11.9)
Looking after home/family	5 (7.5)
Full time employment	8 (11.9)
Part time employment	4 (6.0)
Sick leave	3 (4.5)
Retired	22 (32.8)
Unknown	17 (25.4)
Median interval between primary and recurrence (months)	17.0 (25.3)
Locally Recurrent Rectal Cancer (LRRC)	
Median interval between diagnosis with LRRC and participation in the study (IQR)	6.0 (22.0)
Mode of Detection	
Symptomatic	14 (20.9)
Surveillance	48 (71.6)
Other Unknown	5 (7.5)
Pattern of LRRC	
Anterior	12 (17.9)
Central	16 (23.9)
Lateral	18 (26.9)
Posterior	11 (16.4)
Unknown	10 (14.9)
Presence of Metastatic disease	
Yes	14 (20.9)
No	48 (71.6)
Unknown	5 (7.5)
Number of Sites of Metastases	
1	11 (16.4)
2	3 (4.5)
Unknown	5 (7.5)
Not applicable	48 (71.6)
Sites of Metastases	
Liver	5 (35.7)
Lung	4 (28.6)
Bone	1 (7.1)
Liver and lung	3 (21.4)
Other	1 (7.1)
Treatment Intent	
Curative	57 (85.1)
Palliative	5 (7.5)
Unknown	5 (7.5)
Pre-operative Treatment	
None	10 (14.9)
Short course radiotherapy (SCRT)	5 (7.5)
Long course chemoradiotherapy (LCCRT)	22 (32.8)
Chemotherapy	10 (14.9)
SCRT followed by chemotherapy	1 (7.1)
LCCRT followed by chemotherapy	8 (11.9)
Immunotherapy	1 (1.5)
Other	1 (1.5)
Unknown	9 (13.4)
Margin Status	
R0	29 (50.9)
R1	7 (12.3)
R2	2 (3.5)
Unknown	19 (33.3)
Palliative Treatment	
Chemotherapy	2 (40.0)
Best supportive care	2 (40.0)
Unknown	1 (20.0)

demonstrated cross-cultural equivalence for use in 10 languages across 16 countries overall, through the inclusion of 67 patients in pre-testing interviews. This expands its utility on an international platform and making it accessible to a wider cohort of patients experiencing LRRC and its treatment. The minor modifications implemented for the Dutch, Italian, and Mandarin versions of the measure were not felt to require further pre-testing with interviews.

Content validity is the most important psychometric property of a PROM [18]. The results of this study confirm the content validity of the LRRC-QoL in an international setting, emphasising its position as the most appropriate and only disease-specific measure of HrQoL in LRRC [29]. Although several conceptual issues were identified during interviews, none were adopted into the measure. Robust reasoning supported this decision; several issues identified had previously been considered during the PROM development process, were represented in the EORTC QLQ-C30, or were not identified by sufficient numbers of patients to suggest their generalisability. The changes which will be implemented to the LRRC-QoL measure were not felt to require further pre-testing for content validity, though further testing of face validity may be advisable. The results QQ-10 measure in the current study have demonstrated the face validity and acceptability of the LRRC-QoL.

Undertaking cross-cultural adaptation in rare disease settings can be particularly challenging, there are a number of existing guidelines regarding this process [15,26,30–33]. The majority of which advise undertaking pre-testing interviews, including from at least 5 patients to 10–15 per version, as advised by the EORTC [26]. Satisfying these standards in rare disease groups, such as LRRC, can be very difficult given the much smaller, often heterogenous populations eligible to participate. Despite this, developing PROMs specifically for patients with rare diseases, such as LRRC remains important given that these patients experience a unique set of issues, as demonstrated by the development of the LRRC-QoL conceptual framework. An important contributor to the success of this study was the application of approaches outlined by the ISPOR task force for rare diseases [25], including undertaking TA and additional pre-testing interviews with clinicians for

versions of the questionnaire where recruitment was particularly challenging, such as Brazil, Canada, Singapore, and Spain.

Limitations of this study include cross-cultural adaptation not being completed for all the languages intended. Though the LRRC-QoL was translated into Russian, Telugu, Hindi, and Marathi, pre-testing did not occur for these versions. In the case of the Russian version, it was not possible to continue working with the team based in Saint Petersburg following the Russian invasion of Ukraine, as communication broke down and collaboration was sanctioned. The site working on the Hindi and Marathi versions of the questionnaire did not open to recruitment due to difficulties implementing a satisfactory Data Sharing and Collaboration Agreement for both institutions. It was not possible to recruit patients to pre-test the Telugu version. The small number of patients receiving palliative treatment included is a further limitation of the study, however this is a challenging group of patients to recruit given their burden of disease and poor prognosis.

The next stage in the ongoing development of the LRRC-QoL will consist of external validation to confirm the scale structure, reliability, validity, and responsiveness of the measure. The success of this study supports the requirement to incorporate flexibility in the cross-cultural adaptation of PROMs in rare disease settings, as described in ISPOR guidance [25], and demonstrates the value of translatability assessment. This flexibility will also extend to including the 67 patients recruited to this study in the external validation analysis of the LRRC-QoL, these cohorts will be combined given the challenges of recruiting a large number of patients with LRRC. In the future, undertaking further cross-cultural adaptation of the LRRC-QoL in additional languages and cultures will further expand its utility and reach an even greater number of patients worldwide.

5. Conclusions

The LRRC-QoL has now undergone cross-cultural adaptation in 9 new languages and for use in 14 countries, in addition to the UK and Australia, in which the measure was originally developed. The LRRC-QoL has also demonstrated content validity, face validity, and acceptability in this setting. Following on from this work, external validation of the LRRC-QoL in an international cohort will further confirm its additional psychometric properties.

Ethical approval

Ethical approval was granted for all components of the study, REC references: 20/WS/0116. All patients included in the study provided written consent.

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Declaration of competing interest

Prof. Galina Velikova. Honoraria: Pfizer, Novartis, Eisai. Advisory boards: Consultancy fees from AstraZeneca, Roche, Novartis, Pfizer, Seagen, Eisai, Sanofi Institutional grant from Pfizer. All are unrelated to the content of this manuscript.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejso.2025.110363.

References

[1] van Gijn W, Marijnen CAM, Nagtegaal ID, Kranenbarg EM-K, Putter H, Wiggers T, et al. Preoperative radiotherapy combined with total mesorectal excision for resectable rectal cancer: 12-year follow-up of the multicentre, randomised controlled TME trial. Lancet Oncol 2011;12(6):575–82.
[2] Heald RJ, Moran BJ, Ryall RDH, Sexton R, MacFarlane JK. Rectal cancer: the basingstoke experience of total mesorectal excision, 1978-1997. JAMA Surg 1998;133(8):894–8.
[3] Palmer G, Martling A, Lagergren P, Cedermark B, Holm T. Quality of life after potentially curative treatment for locally advanced rectal cancer. Ann Surg Oncol 2008;15(11):3109–17.
[4] Bakx R, Visser O, Josso J, Meijer S, Slors JFM, Lanschot vJJB. Management of recurrent rectal cancer: a population based study in greater Amsterdam. World J Gastroenterol 2008.
[5] Sebag-Montefiore D, Stephens RJ, Steele R, Monson J, Grieve R, Khanna S, et al. Preoperative radiotherapy versus selective postoperative chemoradiotherapy in patients with rectal cancer (MRC CR07 and NCIC-CTG C016): a multicentre, randomised trial. Lancet 2009;373(9666):811–20.
[6] Waldenstedt S, Haglind E, Angenete E. Symptoms and diagnosis of local recurrence after rectal cancer treatment. Acta Oncol 2022;61(9):1043–9.
[7] Nielsen MB, Laurberg S, Holm T. Current management of locally recurrent rectal cancer. Colorectal Dis 2011;13(7):732–42.
[8] Heriot AG, Byrne CM, Lee P, Dobbs B, Tilney H, Solomon MJ, et al. Extended radical resection: the choice for locally recurrent rectal cancer. Dis Colon Rectum 2008;51(3):284–91.
[9] Harris CA, Solomon MJ, Heriot AG, Sagar PM, Tekkis PP, Dixon L, et al. The outcomes and patterns of treatment failure after surgery for locally recurrent rectal cancer. Ann Surg 2016;264(2):323–9.
[10] PelvEx C. The global cost of pelvic exenteration: in-hospital perioperative costs. BJS 2020;107(11):e470–1.
[11] The PelvEx C. Contemporary results from the PelvEx collaborative: improvements in surgical outcomes for locally advanced and recurrent rectal cancer. Colorectal Dis 2024;26(5):926–31.
[12] PelvEx C. Factors affecting outcomes following pelvic exenteration for locally recurrent rectal cancer. BJS 2018;105(6):650–7.
[13] Denost Q, Frison E, Salut C, Sitta R, Rullier A, Harji D, et al. A phase III randomized trial evaluating chemotherapy followed by pelvic reirradiation versus chemotherapy alone as preoperative treatment for locally recurrent rectal cancer – GRECCAR 15 trial protocol 2021;23(7):1909–18.
[14] PelvEx C. Induction chemotherapy followed by chemoradiotherapy versus chemoradiotherapy alone as neoadjuvant treatment for locally recurrent rectal cancer: study protocol of a multicentre, open-label, parallel-arms, randomized controlled study (PelvEx II). BJS Open 2021;5(3):zrab029.
[15] Health USDo, Human Services FDACfDE, Research. Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims. 2009.
[16] Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life: a conceptual model of patient outcomes. JAMA 1995;273(1):59–65.
[17] McKigney N, Houston F, Ross E, Velikova G, Brown J, Harji DP. Systematic review of patient-reported outcome measures in locally recurrent rectal cancer. Ann Surg Oncol 2023.
[18] Mokkink LB, de Vet HCW, Prinsen CAC, Patrick DL, Alonso J, Bouter LM, et al. COSMIN Risk of Bias checklist for systematic reviews of Patient-Reported Outcome Measures. Qual Life Res 2018;27(5):1171–9.
[19] Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. J Clin Epidemiol 2010;63(7):737–45.
[20] Terwee CB, Prinsen CAC, Chiarotto A, Westerman MJ, Patrick DL, Alonso J, et al. COSMIN methodology for evaluating the content validity of patient-reported outcome measures: a Delphi study. Qual Life Res 2018;27(5):1159–70.
[21] Harji DP, Koh C, McKigney N, Solomon MJ, Griffiths B, Evans M, et al. Development and validation of a patient reported outcome measure for health-related quality of life for locally recurrent rectal cancer: a multicentre, three-phase, mixed-methods, cohort study. eClinicalMedicine 2023:101945.
[22] Harji DP, Koh C, McKigney N, Solomon MJ, Griffiths B, Evans M, et al. Development and validation of a patient reported outcome measure for health-related quality of life for locally recurrent rectal cancer: a multicentre, three-phase, mixed-methods, cohort study. eClinicalMedicine 2023;59:101945.
[23] Conway K, Acquadro C, Patrick DL. Usefulness of translatability assessment: results from a retrospective study. Qual Life Res 2014;23(4):1199–210.
[24] Acquadro C, Patrick DL, Eremenco S, Martin ML, Kuliś D, Correia H, et al. Emerging good practices for Translatability Assessment (TA) of Patient-Reported Outcome (PRO) measures. J Patient-Rep Outcomes 2018;2(1):8.
[25] Benjamin K, Vernon MK, Patrick DL, Perfetto E, Nestler-Parr S, Burke L. Patient-Reported outcome and observer-reported outcome assessment in rare disease clinical trials: an ISPOR COA emerging good practices task force report. Value Health 2017;20(7):838–55.
[26] Dagmara Kulis AB, Velikova Galina, Greimel Eva, Koller Michael. EORTC quality of life group translation procedure. EORTC Quality of Life Group 2017.
[27] Moores KL, Jones GL, Radley SC. Development of an instrument to measure face validity, feasibility and utility of patient questionnaire use during health care: the QQ-10. Int J Qual Health Care 2012;24(5):517–24.

[28] Gundy CM, Aaronson NK. Effects of mode of administration (MOA) on the measurement properties of the EORTC QLQ-C30: a randomized study. Health Qual Life Outcome 2010;8(1):35.
[29] McKigney N, Houston F, Ross E, Velikova G, Brown J, Harji DP. Systematic review of patient-reported outcome measures in locally recurrent rectal cancer. Ann Surg Oncol 2023;30:3969–86.
[30] Reeve BB, Wyrwich KW, Wu AW, Velikova G, Terwee CB, Snyder CF, et al. ISOQOL recommends minimum standards for patient-reported outcome measures used in patient-centered outcomes and comparative effectiveness research 2013;22(8): 1889–905.
[31] Wild D, Grove A, Martin M, Eremenco S, McElroy S, Verjee-Lorenz A, et al. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR task force for translation and cultural adaptation. Value Health 2005;8(2):94–104.
[32] PROMIS®. PROMIS® Instrument Development and Validation Scientific Standards Version 2.0. 2013.
[33] Mokkink LB, Prinsen CA, Patrick DL, Alonso J, Bouter LM, Vet HCd, et al. COSMIN Study Design checklist for Patient-reported outcome measurement instruments. 2019 July. 2019.