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Development and psychometric validation of the Chronic Rhinosinusitis Control Test

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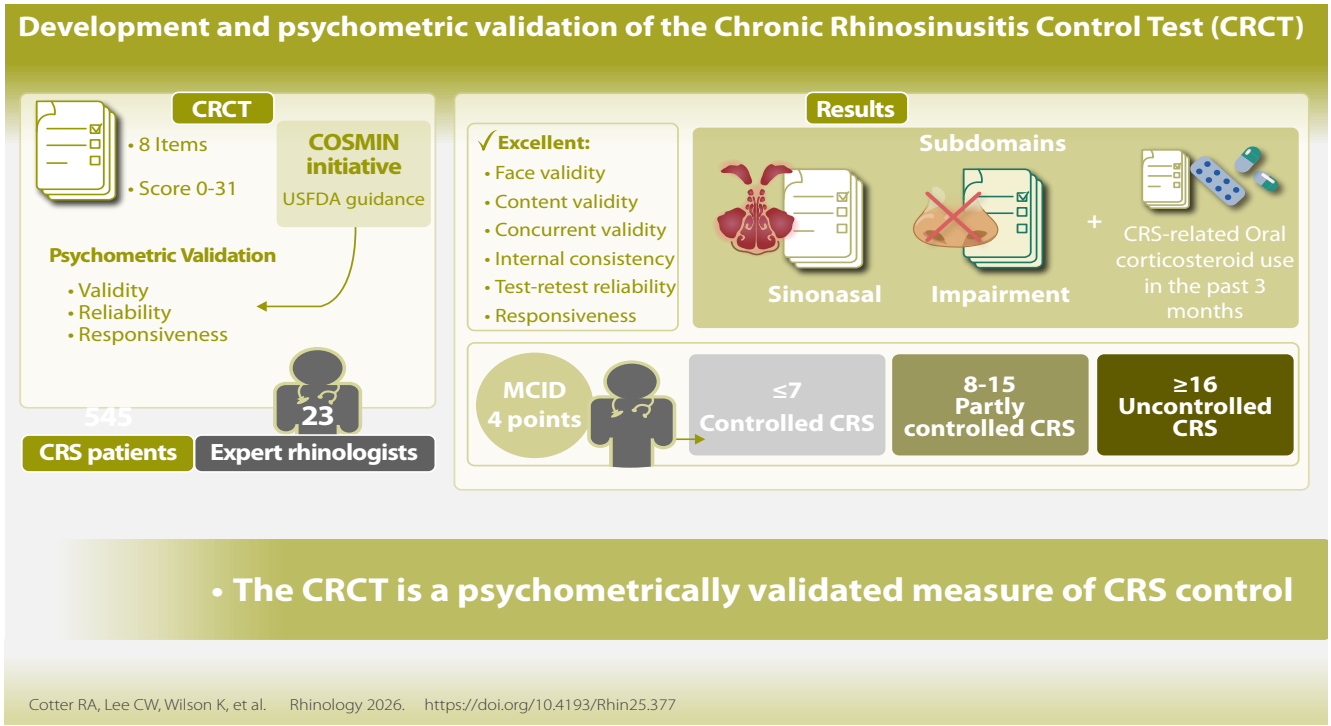

Abstract

Background: Disease control assessment for chronic rhinosinusitis (CRS) remains a challenge. In this study, we develop and psychometrically validate a new patient-reported outcome measure, the Chronic Rhinosinusitis Control Test (CRCT), for assessing CRS control.

Methodology: The CRCT, which includes 8 items and has a score that ranges from 0 – 31, incorporates the perspectives of key stakeholders (patients and healthcare providers) and was developed incorporating methodologic guidance from the COSMIN initiative and United States Food and Drug Administration. Psychometric validation was performed in line with recommendations from the COSMIN initiative to establish validity, reliability and responsiveness in a sample of 545 CRS patients and with the participation of 23 expert rhinologists.

Results: The CRCT has excellent face validity, content validity, concurrent validity, internal consistency, test-retest reliability, and responsiveness. Factor analysis reveals that the CRCT has 2 subdomains: sinonasal and impairment subdomains in addition to a final item related to CRS-related oral corticosteroid usage in the past 3 months. Using a distribution-based and multiple anchor-based methods, the CRCT has a minimal clinically important difference (MCID) of 4 points. After 23 expert rhinologists independently classified all possible combinations of scoring on the CRCT, scores of ≤7 indicate controlled CRS, 8 to 15 (inclusive) partly controlled CRS and ≥16 uncontrolled CRS.
Conclusion: The CRCT is a psychometrically validated measure of CRS control. CRS may be classified as controlled based on CRCT score ≤7, partly controlled with CRCT score of 8 to 15 (inclusive) and uncontrolled with CRCT score ≥16. The MCIDs for improvement and worsening are both 4.

Key words: chronic rhinosinusitis, CRS, control, outcome measure, psychometric, validation, MCID, CRCT, PROM, cut-off, subdomain

Introduction

Disease control, which reflects acceptability—and not necessarily elimination—of disease burden, is an important outcome for chronic rhinosinusitis (CRS) [1]. In contrast to outcomes, such as symptom severity or quality of life (QOL), that assess unidimensional constructs, disease control is a global, multidimensional outcome measure that reflects the diverse ways through which a disease affects patients. As a global reflection of the condition, CRS control has been increasingly recognized as an important outcome measure for assessing CRS disease status as well as an important goal of CRS treatment [2,3].

First formally applied to CRS in the 2012 European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS) [4], the CRS disease control concept has suffered from inconsistencies in definitions and criteria used to assess it [5]. Nevertheless, there has been an increasing trend in recent years for the use of CRS disease control as an outcome measure [5]. This trend reflects increasing recognition for the importance of this construct and highlights the need to develop a tool for assessing CRS disease control that is based on criteria supported by evidence and reflective of the broad, diverse perspectives of key stakeholders. To address this need, a recent international multidisciplinary group identified consensus evidence-based, essential criteria for assessing CRS disease control [6]. However, it has not yet been determined how to implement these consensus criteria to measure, quantify, and classify a patient's CRS control.

The objective of this study is to address the need for a tool to measure, quantify and classify a patient's CRS control by developing a patient-reported outcome measure (PROM) that could be used for this purpose. Our instrument, the Chronic Rhinosinusitis Control Test (CRCT), is developed in a manner that is grounded in the previously reported consensus criteria for CRS disease control [6], and the CRCT's design was directly informed by patient perspectives as well as considerations for psychometric properties. In this study, we report the development and psychometric validation of the CRCT, including details for its interpretation, such as its subdomain structure, minimal clinically important difference (MCID), and score thresholds for classifying a patient's CRS as controlled, partly controlled, or uncontrolled. We believe that the CRCT, which was developed after rigorous scientific study of the disease control construct as applied to CRS and through consensus building, may serve as a useful tool for measuring CRS control.

Materials and methods

Instrument development

This study was approved by the University of Cincinnati (Cincinnati, OH, USA) Institutional Review Board. Our objective was to develop a PROM that would include the most essential criteria for the assessment of CRS disease control, reflective of the perspectives of key stakeholders: healthcare providers and CRS patients. The instrument was designed to have low burden for patients and be scored in a manner that could be clearly interpreted to reflect different levels of CRS control. Much of the foundational background research for the development of this instrument has been previously performed in collaborative, multi-disciplinary fashion [6-8]. However, a process of qualitative content development, piloting and modification, which is described in detail in the Supplementary Materials, was undertaken to develop the instrument and the final assembly was additionally guided by a steering group (ARS, KMP, STG, PHH and SKW).

Rhinologists' input: oral corticosteroid item scoring and establishing thresholds for CRS disease control categories

The input of rhinologists was sought for two elements of the instrument: establishing instrument score thresholds for CRS disease control levels/categories as well as determining the scoring for a positive (i.e., yes) response on an item for CRS-related oral corticosteroid usage in the last three months, which was designed with a dichotomous response scale (yes/no). A total of 23 rhinologists (including steering committee members) provided informed consent to participate and were chosen 1) based

on demonstration of expertise in CRS as evidenced by a history as an opinion leader and scholarly activity and 2) to represent different career stages and geographic locales. Their participation was through online questionnaires that were implemented in the University of Cincinnati REDCap.

These rhinologists were then presented with every possible combination of item responses on the instrument and asked to rate each scenario as indicative of "controlled", "partly controlled" or "uncontrolled" CRS as well as to rate the level of CRS control reflected by each scenario on a 7-point Likert scale ranging from 0 (reflecting "controlled disease") to 6 (reflecting "very poorly controlled disease"). Finally, each rhinologist participant was asked what score a positive response to a dichotomously phrased item for CRS-related oral corticosteroid usage in the last three months should be assigned (0, 1, 2, 3, or 4).

Translatability and readability assessments

Translatability assessments for the languages of Mandarin, Spanish, German, and Korean were performed prior to quantitative, psychometric assessments based on best practice recommendations described by the International Society for Quality of Life Research [9]. After discussion with the developer (ARS), linguistic experts (each with doctoral level training and actively involved in scholarly work involving translation) in the respective languages evaluated the instrument and assessed the instructions, each item, and response scale options on the previously recommended 4-point scale [9] for ease of translation corresponding to "1 – No difficulty", "2 – Minor difficulty", "3 – Major difficulty", and "4 – Extreme difficulty". Elements of the text that were considered in the translatability assessment included cultural implications, language, and item construction [9]. A readability assessment was performed using the Flesch Reading Ease (FRE) score Flesch-Kincaid Grade (FKG) level. An FRE score of >80 and FKG < 7 were preferred as indicators of 6th grade reading level or lower [10].

Psychometric validation

All participating CRS patients provided informed consent for inclusion. All patients were recruited and data collected in the setting of real-world rhinology clinics at the University of Cincinnati between July 2024 and June 2025. Inclusion criteria included age 18 years or older and meeting EPOS consensus guideline diagnostic criteria for primary CRS [11]. No inclusion criteria were set based on treatment needs or CRS severity to recruit a range of participants that would be broadly representative of primary CRS patients in general. Patients with comorbid diagnoses of vasculitis, sarcoidosis, or immunodeficiency were excluded. Patients with a history of endoscopic sinus surgery within the prior 3 months were also excluded.

Demographic (age and gender) and clinical characteristics were collected at enrollment. A smoker was defined as any participant who currently smoked or reported a history of tobacco use [12,13]. A history of asthma was determined based on diagnostic guidelines [14] while a history of allergy was determined through skin or serological testing. Participants were interviewed to identify a history of previous sinus surgery or a history of aspirin sensitivity. The presence of nasal polyps and/or prior sinus surgery were confirmed on nasal endoscopy. A modified Lund-Kennedy endoscopy score was determined based on nasal endoscopy [15].

Psychometric validation was performed in line with recommendations from the COSMIN initiative and guidance from the United States Food and Drug Administration (USFDA) for use of PROMs in clinical trials [16,17]. The elements of validity (content, construct, criterion, and structural), internal consistency, reliability, and responsiveness were reported on using outcome measure data collected from study participants. All participants completed the final draft version of the instrument along with a 22-item Sinonasal Outcome Test (SNOT-22) as a reflection of CRS-specific quality of life (QOL) [18], 5-level EuroQol questionnaire from which the visual analog scale (EQ-5D VAS) was used as a reflection of general health-related QOL [19], and an overall symptom severity (OSS) score using a tick-marked visual analog scale (VAS) to reflect overall CRS symptom severity [8] at enrollment. A fraction of participants completed the final version of the instrument again between 3 and 14 days from enrollment for analysis of test-retest reliability. Responsiveness was assessed using the fraction of participants returning for routine clinical follow-up between 1 and 6 months after enrollment, who also completed all study questionnaires as well as 3 global impression of change questions related to their CRS control, symptoms, and general health (respectively) with a 7-item response scale consisting of "much worse", "moderately worse", "mildly worse", "about the same", "a little better", "moderately better", and "much better".

Statistical analysis

All analyses were performed using the statistical software package R (www.r-project.org) [20]. Correlations were performed—as specified—using either Pearson's method, Spearman's method or intraclass correlation, from which corresponding correlation coefficients (r, ρ, or ICC, respectively) were calculated. Internal consistency was measured using Cronbach's alpha (α), mean item-item correlation and mean correlation between each item and the sum of the rest of the items.

Factor analysis to identify subdomains (latent variables [factors]) within the CRCT was performed by first randomly splitting the data into a training set (67% of the full data) and a testing set (33% of the full data). Exploratory factor analysis (EFA) was performed on the training set to identify possible subdomain structures and confirmatory factor analysis (CFA) was performed to validate a final subdomain structure. The details of this factor

Chronic Rhinosinusitis Control Test

Over the last month, how severely have your sinuses caused you to have the following problems: *(circle your answer)*				
Nasal blockage				
None 0	Mild 1	Moderate 2	Severe 3	Worst possible 4
Nasal drainage (out of the front or down the back/post-nasal drip)				
None 0	Mild 1	Moderate 2	Severe 3	Worst possible 4
Decreased sense of smell				
None 0	Mild 1	Moderate 2	Severe 3	Worst possible 4
Sinus discomfort				
None 0	Mild 1	Moderate 2	Severe 3	Worst possible 4
Decreased ability to perform normal day-to-day activities or work				
None 0	Mild 1	Moderate 2	Severe 3	Worst possible 4
Decreased overall quality of life				
None 0	Mild 1	Moderate 2	Severe 3	Worst possible 4
How controlled have your sinus problems been in the last month?				
Completely 0	Very 1	Somewhat 2	A little 3	Not at all 4
In the last 3 months, have you taken any steroids (such as prednisone) **by mouth for your sinuses?**				
No 0			Yes 3	

Figure 1. Chronic Rhinosinusitis Control Test (CRCT).

analysis as well as goodness of fit measures used are described in the Supplementary Materials.

Application of item response theory (IRT) was implemented with the R package "ltm" [21]. Graded response models (GRM) determined item discrimination (α) and threshold (β) IRT-parameters, as previously described [22,23]. Both constrained and unconstrained models were tested and the best fitting model was used. To visualize our IRT results, we plotted item response category characteristic curves for each item and item information curves for each CRCT subdomain.

Receiver operating characteristic (ROC) curve analysis was used to identify threshold scores that differentiated rhinologists' ratings of instrument scores as controlled from partly controlled CRS and differentiated uncontrolled from partly controlled CRS. For every ROC analysis, the area under the ROC curve (AUC) was calculated using the trapezoid rule and the best threshold score was determined as that which maximized the sum of sensitivity and specificity for identifying the dependent variable.

The MCID was calculated using best practices including both distribution-based and anchor-based methods [24]. The distribution-based method used was 0.5*SD (where SD is the standard deviation of patients' instrument scores at enrollment), which also represents a change of medium effect size. Anchor-based methods included the mean change method, ROC method, and correlations with rhinologists' ratings of CRS disease control. The full details of anchor-based MCID calculations are in the Supplementary Materials. Finally, a linear regression was determined between rhinologists' rating of CRS disease control on a 7-point Likert scale and instrument scores that were derived from every possible combination of responses on the instrument. Since the upper limit of discrimination by individuals appears to be a 7-point scale and a 1 point change equates to 0.5 * SD effect size [25], we calculated the instrument MCID as the linear regression coefficient (reflecting the expected change in instrument score corresponding to a 1-point [out of 7] change in rhinologists' ratings of CRS disease control).

Several sample size needs were considered for determination of recruitment goals. These needs included detecting correlations of large effect size ($r \geq 0.5$) for criterion validity, reliability and responsiveness analyses, and detecting significant thresholds using ROC analysis with AUC of at least 0.8, assuming 10% positive rate for MCID. For factor analysis with an 8-item instrument, we additionally had a goal of 20 patients per item for each of the training and testing sets that would be used for EFA and CFA, respectively. Recruitment of patient participants was performed to meet sample size needs for all these analyses.

Results

Instrument development and content validity

The results of patients' qualitative perspectives related to the consensus and near-consensus essential CRS disease control criteria derived from an international Delphi study [6] have been previously reported [7]. These qualitative perspectives were utilized to develop a preliminary instrument with the previously reported essential CRS disease control criteria as the foundation [6]. Based on these patient interviews, an item related to facial pain/pressure was included in the instrument. Moreover, during our preliminary piloting and modification phase, patients overwhelmingly expressed they felt that nasal "blockage" was a more specific and unambiguous term than "obstruction" or "congestion". Patients also felt that the term "drainage" was the clearest descriptor of mucus or discharge, and that a drainage item in the instrument should explicitly specify that drainage could be anterior and/or post-nasal.

Review of the preliminary instrument by the steering committee led to rephrasing of the "facial pain/pressure" item as "sinus discomfort". Additionally, the item for use of CRS-related oral corticosteroids was determined to be best presented as a question with dichotomous response (yes/no) querying use in the prior 3 months—which has been previously validated for assessment of CRS-specific oral corticosteroid use [26]—to reduce the possibility of recall bias, either from remembering exactly how many courses were taken or by the length of a longer recall period, such as 6 months [6,11].

The score assigned for a positive response to the instrument question about use of CRS-related oral corticosteroids was de-

Table 1. Characteristics of study participants.

	All study participants (N = 585)	Included in responsiveness analyses (N = 205)
Demographics		
Age, mean in years, (SD)	52.7 (16.1)	53.3 (16.2)
Gender, %		
Male	43.9%	39.0%
Female	56.1%	61.0%
Smoking, %	21.4%	23.9%
Comorbidities, %		
Aeroallergen hypersensitivity	63.1%	62.0%
Asthma	30.3%	31.2%
Aspirin sensitivity	5.1%	3.4%
CRS characteristics		
Polyps, %	29.9%	28.3%
Prior ESS, %	45.6%	38.0%
SNOT-22 score, mean (SD)	37.9 (23.1)	45.2 (21.9)
OSS score, mean (SD)	5.6 (2.8)	6.6 (2.3)
CRCT, mean (SD)	12.5 (6.9)	14.9 (6.4)
EQ-5D VAS, mean (SD)	70.4 (19.3)	67.3 (20.2)
Modified Lund-Kennedy endoscopy score, mean (SD)	4.3 (2.8)	5.1 (2.8)

CRCT = Chronic Rhinosinusitis Control Test, EQ-5D VAS = 5-level EuroQol questionnaire visual analog scale, ESS = endoscopic sinus surgery, OSS = overall symptom severity, SNOT-22 = 22-item Sinonasal Outcome Test.

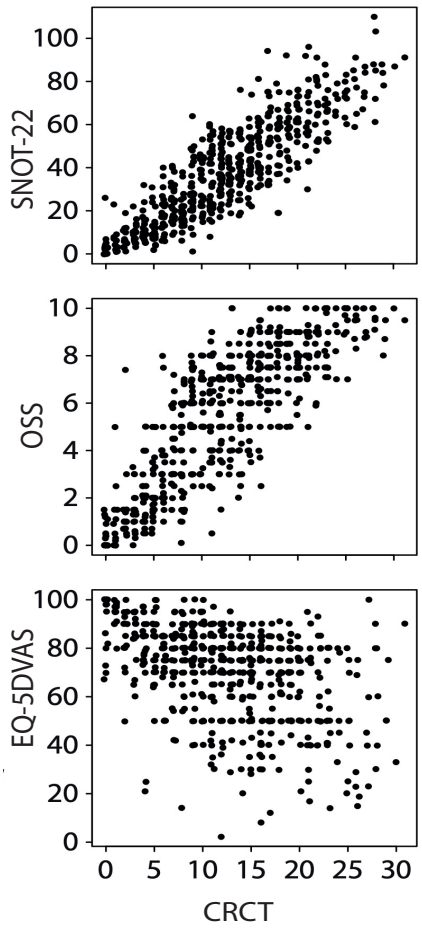

Figure 2. Dot plots of CRCT score vs. SNOT-22, OSS, and EQ-5D VAS scores.

termined by asking participating rhinologists' explicit opinions about how a positive response to this item should be scored after they had time to think about the instrument and how to use it to classify a patient's CRS control. The median score that rhinologists felt a positive response to the oral corticosteroid item should be scored was 3 (mean 2.8), so a score of 3 was assigned for a positive response to the oral corticosteroid question. All other items on the instrument were a priori developed to have a recall period of 1 month with a 5-item Likert response scale (corresponding to an item score of 0 – 4), as previously determined to maximize patient preferences [27] and also validated for assessing patient-reported CRS control [28]. The instrument, which was titled the Chronic Rhinosinusitis Control Test (CRCT), is shown in Figure 1.

Translatability and readability assessments

In the readability assessment, the CRCT achieved an FRE score of 78.3 (indicating that the instrument is fairly easy for most adults/patients to understand, i.e., middle school students' reading skills) and an FKG of 5.9 (indicating that the instrument is readable by an average patient with 5th- or 6th-grade reading skills), reflecting ideal readability. The mean ease-of-translatability score in the translatability assessment was 1.6 for Mandarin, 1.1 for Spanish, 1.0 for German and 1.0 for Korean. For all languages, no element of the questionnaire scored worse than "minor difficulty", indicating acceptable translatability across all languages tested [9].

Criterion and structural validity

The CRCT was completed by 585 patients (175 [29.9%] CRSwNP and 410 [70.1%] CRSsNP); their characteristics are shown in Table 1. The CRCT score was significantly correlated (Figure 2) with those patients' SNOT-22 score (r=0.87, 95%CI: 0.85 – 0.89, p<0.001), OSS score (r = 0.81, 95%CI: 0.78 – 0.84, p<0.001), and EQ-5D VAS (r= -0.44, 95%CI: -0.50 – -0.37, p<0.001).

The subdomain structure of the CRCT was studied by partitioning the CRCT responses from the 585 patients into a training set (N = 391 [67%]) for EFA and a testing set (N = 194 [33%]) for CFA. Bartlett's test of sphericity yielded $p < 0.001$, and the overall KMO value was 0.862 for the training set, indicating the suitability of the data for factor analysis. EFA followed by validation with CFA revealed a 3-factor structure reflecting a sinonasal

Table 2. Internal consistency of the CRCT.

CRCT item	Cronbach alpha if item dropped	Mean item-item Spearman correlation coefficient	Item-total Spearman correlation coefficient [1]
Nasal blockage	0.83	0.60	0.73
Nasal drainage	0.84	0.60	0.62
Decreased sense of smell	0.86	0.44	0.47
Sinus discomfort	0.83	0.69	0.75
Decreased ability to perform normal day-to-day activities or work	0.84	0.52	0.69
Decreased overall quality of life	0.83	0.59	0.72
How controlled have your sinus problems been in the last month?	0.84	0.63	0.66
In the last 3 months, have you taken any steroids (such as prednisone) by mouth for your sinuses?	0.88	0.19	0.29

[1] Corrected item-total correlation coefficient where the item itself was not included in the total score. CRCT = Chronic Rhinosinusitis Control Test.

Table 3. Item response theory parameter estimates for CRCT items based on the unconstrained graded response model stratified by subdomain.

	α	β_{j1}	β_{j2}	β_{j3}	β_{j4}
Sinonasal subdomain					
Nasal blockage	3.577	-1.128	-0.360	0.426	1.312
Nasal drainage	2.093	-1.625	-0.541	0.468	1.790
Decreased sense of smell	1.143	-0.612	0.281	1.122	2.020
Sinus discomfort	3.121	-1.098	-0.239	0.467	1.488
Patient-reported CRS control	2.487	-1.934	-0.883	0.172	1.033
Impairment subdomain					
Decreased ability to perform normal day-to-day activities of work	3.687	-0.228	0.616	1.282	2.114
Decreased overall QOL	3.619	-0.531	0.265	1.119	2.115

CRCT = Chronic Rhinosinusitis Control Test, CRS = chronic rhinosinusitis, QOL = quality of life.

subdomain (nasal obstruction, nasal drainage, decreased sense of smell, sinus discomfort, patient-reported CRS control), and an impairment subdomain (ability to perform day-to-day activities and overall QOL), with the item relating to need for CRS-related oral corticosteroids segregating on its own. CFA of this 3-factor model revealed acceptable goodness of fit (RMSEA = 0.067 [95%CI: 0.018 – 0.107], CFI = 0.979, TLI = 0.967). Similarly, the multivariable sinonasal and functional impairment domains had acceptable convergent validity (CR = 0.838 and 0.865, respectively; AVE = 0.510 and 0.762, respectively) and divergent validity (HTMT = 0.818). The full details of the factor analysis results are described in the Supplementary Materials (including Table S1 and Figure S1).

Internal consistency

The internal consistency of the CRCT was assessed in several ways, and the results are summarized in Table 2. Cronbach's alpha for the entire CRCT was measured at 0.86 (95%CI: 0.84 – 0.88), and this value ranged from 0.83 – 0.88 when dropping any individual CRCT item, suggesting that none of the items were unrelated to the common underlying construct. All item-item correlations were statistically significant, with mean correlation coefficient of 0.45 (range: 0.17 – 0.78), with the item related to CRS-related oral corticosteroid usage least correlated with the other items (Figure 3). The mean item-CRCT total score correlation was 0.72 (range: 0.44 – 0.83). The mean correlation coefficient between each item and the sum of the remaining items was 0.62 (range: 0.29 – 0.75).

Test-retest reliability and responsiveness

A total of 62 patients completed the CRCT at two time points with an interval of 3 – 14 days during which time the patients were not receiving any new intervention/treatment. These patients' CRCT scores at the two time points were strongly corre-

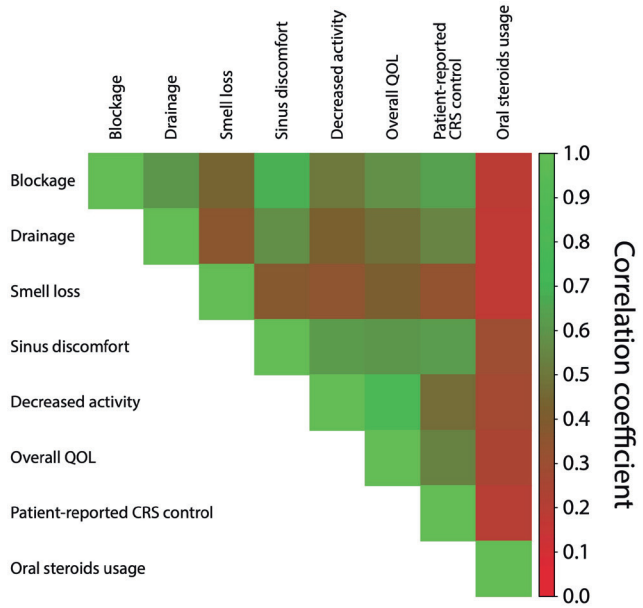

Figure 3. Correlation matrix of CRCT items represented as heatmap.

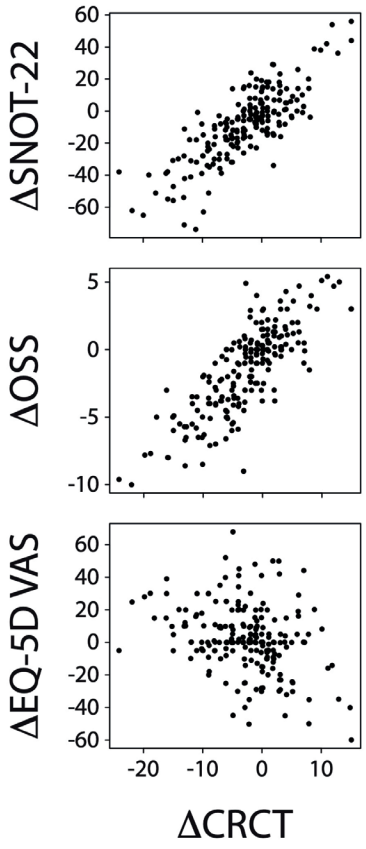

Figure 5. Dot plots of change in CRCT score vs. change in SNOT-22, OSS, and EQ-5D VAS scores for patients completing all questionnaires 31 to 175 days (mean: 75 days, median: 70 days) apart.

lated (Intraclass correlation coefficient = 0.96, 95%CI: 0.94 – 0.98, p<0.001), indicating excellent test-retest reliability (Figure 4).

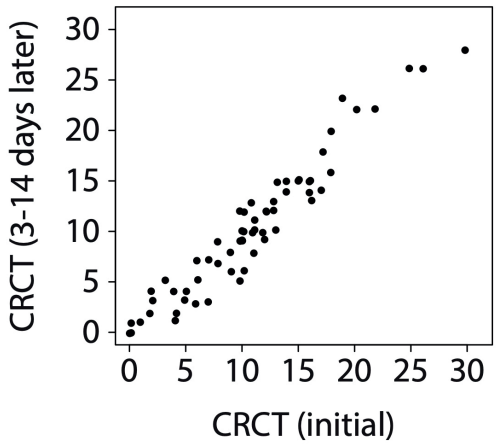

Figure 4. Illustrating test-retest reliability, dot plot of CRCT vs. CRCT completed 3 – 14 days later.

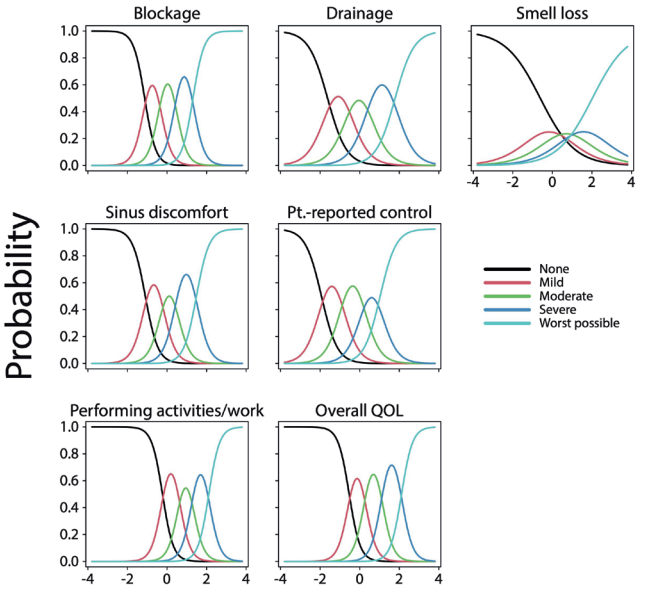

Figure 6. Item characteristic curves for items of the CRCT sinonasal (top two rows) and impairment (bottom row) subdomains.

Responsiveness

A total of 205 patients completed the CRCT at two time points ranging from 31 – 175 days (mean: 75 days, median: 70 days) apart during which time patients received treatment for their CRS. At the first time point, the patients had mean scores for CRCT of 14.9 (SD: 6.4), SNOT-22 of 45.2 (SD: 21.9), OSS of 6.6 (SD: 2.3), and EQ-5D VAS of 67.3 (SD: 20.2). At the second time point, the patients had mean scores for CRCT of 12.1 (SD: 7.0), SNOT-22 of 36.7 (SD: 22.2), OSS of 5.2 (SD: 2.9), and EQ-5D VAS of 69.4 (SD: 19.4). The change in CRCT score between the two time points (second time point minus the first time point) was significantly correlated (Figure 5) with the corresponding changes in those patients' SNOT-22 score (r=0.81, 95%CI: 0.75 – 0.84, p<0.001),

Table 4. CRCT score cut-offs for identifying "controlled" and "uncontrolled" CRS.

	Controlled CRS				Uncontrolled CRS			
Rhinologist participant	**Cut-off**	**AUC (95% CI)**	**Sensitivity**	**Specificity**	**Cut-off**	**AUC (95% CI)**	**Sensitivity**	**Specificity**
1	< 8	0.993	100%	94.8%	> 20	0.989	95.9%	94.1%
2	< 7	0.991	95.7%	93.6%	> 13	0.988	91.8%	95.7%
3	< 8	0.990	100%	93.3%	> 17	0.922	88.2%	78.4%
4	< 10	0.893	90.5%	67.7%	> 14	0.925	83.1%	87.3%
5	< 9	0.896	79.2%	81.3%	> 14	0.950	90.4%	82.4%
6	< 11	0.976	91.5%	92.3%	> 19	0.910	69.3%	92.8%
7	< 7	0.895	87.5%	70.8%	> 11	0.968	87.9%	93.3%
8	< 6	0.997	100%	98.0%	> 24	0.992	100%	96.6%
9	< 8	0.973	100%	84.5%	> 15	0.909	75.4%	88.5%
10	< 9	0.865	80.0%	74.8%	> 14	0.854	72.7%	82.2%
11	< 2	0.999	100%	99.8%	> 17	0.968	90.5%	90.8%
12	< 8	0.882	83.3%	75.0%	> 14	0.850	67.3%	86.5%
13	< 2	1.00	100%	100%	> 13	0.818	76.0%	69.1%
14	< 8	0.927	85.7%	83.5%	> 14	0.908	77.6%	86.2%
15	< 9	0.979	100%	89.3%	> 19	0.987	100%	94.4%
16	< 8	0.988	100%	94.7%	> 21	0.703	68.0%	87.5%
17	< 5	0.944	100%	79.6%	> 9	0.973	92.3%	89.8%
18	< 7	0.888	76.2%	82.2%	> 12	0.919	82.1%	87.8%
19	< 9	0.958	94.1%	86.5%	> 17	0.985	91.4%	95.5%
20	< 5	0.996	100%	98.4%	> 24	0.956	95.5%	97.9%
21	< 6	0.966	100%	91.2%	> 13	0.929	82.8%	84.1%
22	< 4	0.775	66.7%	98.1%	> 19	0.665	34.9%	91.7%
23	< 7	0.923	92.9%	73.2%	> 11	0.931	85.4%	85.9%

AUC = area under the receiver operating characteristic curve, CRCT = Chronic Rhinosinusitis Control Test, CRS = chronic rhinosinusitis.

Table 5. CRCT MCID values for improvement and worsening calculated using anchor-based methods.

	Anchor					
	General health		**Sinus symptoms**		**CRS control**	
MCID for improvement						
Mean change method	> 3.7		> 3.2		> 4.9	
ROC method	> 4.5		> 4.5		> 3.5	
	AUC	p-value	AUC	p-value	AUC	p-value
	0.872	< 0.001	0.914	< 0.001	0.958	< 0.001
MCID for worsening						
Mean change method	> 2.7		> 3.3		> 4.6	
ROC method	> 5.5		> 3.5		> 3.5	
	AUC	p-value	AUC	p-value	AUC	p-value
	0.823	< 0.001	0.879	< 0.001	0.935	< 0.001

AUC = area under the receiver operating characteristic curve, CRCT = Chronic Rhinosinusitis Control Test, CRS = chronic rhinosinusitis, MCID = minimal clinically important difference, ROC = receiver operating characteristic.

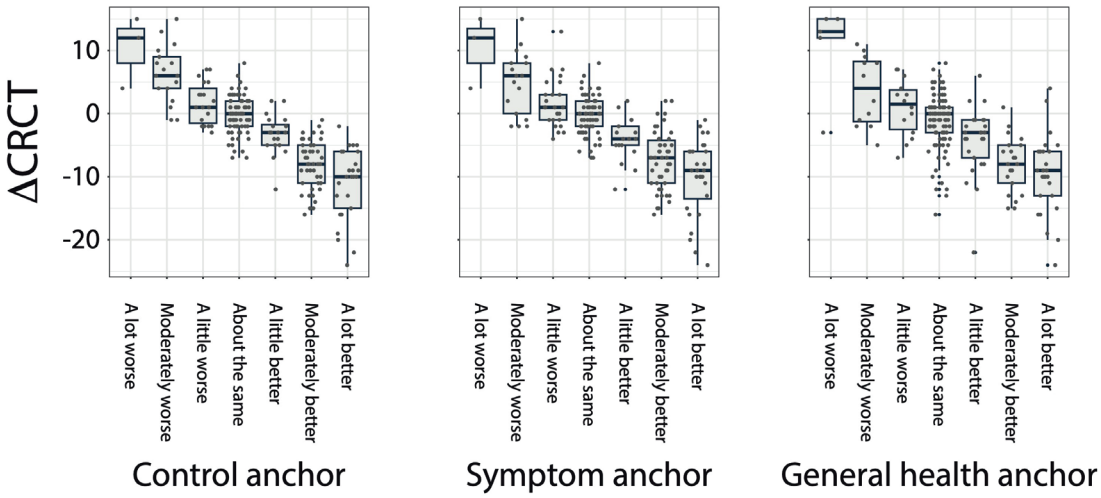

Figure 7. Boxplot with individual data points overlaid showing the distribution of changes in CRCT score for each corresponding CRS control-based, CRS symptom-based and general health-based anchor response for study participants.

OSS score (r=0.80, 95%CI: 0.75 – 0.85, p<0.001), and EQ-5D VAS (r= -0.32, 95%CI: -0.44 – -0.20, p<0.001).

Item response theory

Because item response theory calculations are performed only on multivariable constructs, our analyses were only performed on items in the sinonasal subdomain and impairment subdomain and not the oral corticosteroid item, which performed distinctly from the other subdomains. First, unconstrained GRMs were found to best fit both the sinonasal and impairment subdomains ($p \leq 0.004$ by ANOVA) and therefore used. We next calculated item discrimination (slope parameter, α) and threshold parameters (β) for each CRCT item in relation to the CRCT subdomain to which it belonged (Table 3). The item discrimination parameter was moderate for the decreased sense of smell item and very high for all other items [29], with threshold parameters demonstrating a broad coverage of disease burden by the different items. The item response category characteristic curves for each item are shown in Figure 6 while the item information curves for the respective subdomains are shown in Supplementary Figure S2.

Classification of disease control

The best CRCT score cut-offs for each participating rhinologist's classification of controlled and uncontrolled CRS are shown in Table 4. The mean CRCT score cut-off for identifying controlled CRS was < 7.1 (median < 8), while the mean CRCT score cut-off for identifying uncontrolled CRS was >15.8 (median >14). Based on these results, we propose that CRCT scores of 0 – 7 (inclusive) serve to indicate controlled CRS, CRCT scores of 8 – 15 (inclusive) as indicative of partly controlled CRS and CRCT scores ≥16 to be indicative of uncontrolled CRS.

Minimal clinically important difference

We next calculated the MCID using several methods. The distribution-based method for MCID calculation, using patients' baseline CRCT scores, yielded an MCID of 3.2. We additionally calculated a possible MCID value for the CRCT as the linear regression coefficient (β = 2.8, 95%CI: 2.7 – 2.9, p<0.001) between rhinologists' rating of CRS disease control on a 7-point Likert scale and CRCT scores from every possible combination of responses on the instrument to yield an MCID of 2.8.
Finally, we used the mean change and ROC curve anchor-based methods to calculate the CRCT MCIDs for improvement and worsening. Because CRS disease control is a multifaceted construct and even patient-reported CRS control is included as one item in the CRCT, we used three different anchors to calculate the CRCT MCID based on patients' global ratings of change in: general health, sinus symptoms and CRS control. Changes in CRCT score in comparison to patients' responses to each anchor are shown in Figure 7. The calculated MCIDs for improvement and worsening using the mean change and ROC anchor-based methods for each of the three anchors are shown in Table 5, with possible values of MCID for improvement ranging from 3.2 – 4.6 (mean: 4.1, median: 4.1) and MCID for worsening ranging from 2.7 – 5.5 (mean: 3.9, median: 3.5). Balancing all these results, we recommend the MCID for both improvement and worsening to be ≥4 points.

Discussion

To date, the measurement and assessment of CRS control has been a challenge. As a reflection of disease acceptability, the construct of disease control is naturally nebulous and therefore difficult to measure since its criteria could span the entire breadth of CRS manifestations ranging from direct measures of the pathophysiology to their downstream consequences

such as symptoms, QOL or treatment needs. A validated means for evaluating CRS control could be of great utility in directing treatment decisions, including the need for escalation or the possibility of de-escalation, for CRS. Despite the well-accepted importance of the construct of disease control, however, CRS-specific rubrics and outcome measures previously developed for this purpose have been underutilized, possibly due to a lack of consensus building around, or scientific derivations for, how to measure CRS control [5]. To address these limitations, a large international multidisciplinary panel of experts recently developed a consensus list of broadly applicable criteria deemed to be essential for assessing CRS disease control [6]. However, there is still a need to determine how to translate these criteria to the measurement, quantification, and classification of CRS disease control. In this study, we report the development and validation of the Chronic Rhinosinusitis Control Test (CRCT), a PROM that is grounded in previously reported consensus criteria and subsequently developed based on guidance for PROM development from the COSMIN initiative and USFDA. We demonstrate the robust psychometric validity of the CRCT and derive key benchmarks for interpreting the CRCT, including its subdomain (or latent) structure, MCID as well as CRCT score thresholds for classifying a patient's level of CRS control as controlled, partly controlled or uncontrolled.

Several previous rubrics have been developed for evaluating CRS control. The 2012 and 2020 EPOS described a guideline that was developed based on expert opinion to classify CRS as controlled, partly controlled or uncontrolled based on the burden of 5 symptoms, nasal endoscopy findings and need for CRS-related oral antibiotics or corticosteroids [4,11]. However, these guidelines are limited in several ways including their criteria identified by expert opinion without formal consensus determination and an inability to use this rubric to quantify CRS control. More recent studies have also suggested these EPOS guidelines may classify CRS as more uncontrolled compared to what both patients and expert providers perceive [30,31]. PROMs have also been used to measure CRS control. The Sinus Control Test [32] was designed as a 4-item PROM but with limitations in its development including limited consensus-building around its criteria [33], as well as a recall period of 2 weeks, which many patients feel is too short a time period to use for treatment decisions or accurately reflect their disease state [27]. More recently, patient-reported CRS control [28] has been validated as a PROM to directly assess patients' perspectives of their own level of CRS control, while other PROMs such as OSS score [34], and the SNOT-22 [35] have been shown to be reflective of patients' perspectives of their own CRS control. However, these PROMs are not comprehensively reflective of the global CRS control construct since they only very broadly reflect the patient perspective, but not the perspectives of healthcare providers.

In this study, we report the development and validation of the CRCT, a novel instrument and PROM for quantitatively measuring and classifying CRS control. The CRCT was developed based on international consensus criteria—chosen from CRS disease manifestations supported by scientific evidence as important determinants of control—for assessing CRS control by a large international and multidisciplinary expert group. The CRCT was further shaped with the input of CRS patients and evidence regarding optimal CRS PROM design [7,27]. The CRCT, an 8-item PROM, ranges in score from 0 (fully controlled) to 31 (maximally uncontrolled) with a score of 7 or less indicating controlled CRS, a score of 8 to 15 indicating partly controlled CRS, and a score of 16 or greater indicating uncontrolled CRS. The CRCT has two subdomains and an additional item that assesses the need for CRS-related oral corticosteroids in the last 3 months. The CRCT's "sinonasal" subdomain includes items assessing nasal obstruction, nasal drainage, smell loss, sinus discomfort and patient-reported CRS control while the CRCT's "impairment" subdomain queries the impact of CRS on overall QOL and ability to perform routine daily activities or work. Additionally, the MCID for both improvement and worsening for the CRCT was measured to be 4. However, any CRCT score change that leads to a change in the classification of the patient's CRS control, which would be expected to impact a patient's treatment or care, could also be considered clinically important.

Several details of the CRCT's psychometric properties may stand out. Among the items included in the CRCT, the item related to the need for oral corticosteroids correlated least with the other items in the instrument, which is consistent with prior work showing CRS-related oral corticosteroid usage correlates—albeit without strong effect size—with symptom burden and QOL [36]. Nevertheless, we did find the oral corticosteroid item to better correlate with the overall sum of other item scores, and its removal from the CRCT would not significantly change the overall internal consistency of the CRCT, all suggesting that it reflected a common construct as the other items. Consistent with previous studies of the SNOT-22, we also found that the CRCT item for decreased sense of smell provided the least information to the sinonasal subdomain [37,38]. This finding has been previously attributed to olfactory dysfunction due to irreversible or non-sinogenic causes that may not reflect active sinus disease. In any case, the inclusion of items related to the need for CRS-related oral corticosteroids and decreased sense of smell was felt necessary for the content and face validity of the CRCT [6]. The CRCT was also found to correlate strongly with the SNOT-22 and OSS. These findings were not surprising given the strong influences of symptom severities and QOL impact on the CRCT score.

While the SNOT-22 and OSS have been previously described as indicators of CRS control [34,35,39], neither the SNOT-22 or OSS was developed or has the content validity to measure the construct of CRS control in the manner that the CRCT directly measures it. It is important to consider how the CRCT measures the construct

of disease control, which is traditionally reflected by criteria that fall under the domains of patient impairment and future risk of adverse outcomes to the patient [14,40,41]. Indeed, the items of the CRCT specifically reflect the domains of patient impairment (by its measurements of patient-reported outcomes, such as symptom burden and functional impairment) and risk to the patient (in assessing oral corticosteroid usage). Nasal endoscopy findings—previously identified as a near consensus essential criterion for assessing CRS disease control [6]—have traditionally been considered to reflect the domain of risk to the patient (e.g. risk for disease progression or exacerbations), although there is a paucity of evidence to support that assertion [42-44]. Despite the lack of scientific evidence to provide direction for using nasal endoscopy to judge CRS control, recent work based on the practice patterns of an international and diverse group of rhinologists has suggested that endoscopic control of CRS may be gauged using well-established staging systems (modified Lund-Kennedy [MLK] score [15] and nasal polyp score [NPS] [45]), with guidance that MLK score < 4 or NPS < 3 may serve to indicate endoscopic control of CRS [46]. In any case, other determinants of CRS disease control – for example, if evidence ultimately supports nasal endoscopy findings, other clinician-reported outcomes or biomarkers as indicative of patient impairment or risk –may also be used in conjunction with the CRCT to direct treatment decisions.

The CRCT should be used and interpreted within the constraints of its limitations. Although the CRCT was developed using consensus criteria for assessing CRS disease control, the CRCT is limited by including only items that could be reported on by patients since it is a PROM and excludes nasal endoscopy, which was the only clinician-reported outcome that has been identified as a near-consensus essential determinant of CRS disease control. Moreover, other clinician-reported outcomes or biomarker indicators for CRS disease control may also be identified. However, just as guidance for the use of nasal endoscopy in CRS control assessment may be used to complement the CRCT, similar guidance for any other clinician-reported outcome or biomarker may be used to complement CRS disease control assessment with the CRCT. Finally, although the CRCT exhibited excellent psychometric validity, we also acknowledge that it was validated in one geographic patient population.

Conclusion

The CRCT is a valid PROM for measuring CRS control that has 8 items reflecting previously reported consensus criteria for assessing CRS disease control and CRS patient perspectives. The CRCT has excellent psychometric performance, readability and translatability. The CRCT consists of two subdomains reflecting sinonasal symptoms and impairment (overall QOL and activity impairment). The CRCT has an MCID of 4. CRCT scores of ≤ 7 indicate controlled CRS, scores of 8 to 15 indicate partly controlled CRS and scores ≥16 indicate uncontrolled CRS. Classification of CRS control using the CRCT may have direct clinical significance to inform treatment decisions for CRS patients.

Conflict of interest

The authors declare that they have no conflicts of interest related to the contents of this study.

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Authors' contributions

ARS: concept of study, study design, collection of data, statistical analysis, interpretation of results, write up of manuscript, critical review of all contents. KMP, STG, PHH and SKW: study design, collection of data, interpretation of results, write up of manuscript, critical review of all contents. RAC, CWL, KW, SFA, SA, WTAL, MBeSp, RKC, JC, WJF, AAH, CH, ECK, BNL, VJL, JCM, SDP, JR, MBSo, EWW, MBW, BAW: collection of data, interpretation of results, write up of manuscript, critical review of all contents. HP, TH, YSG, and JS: translatability assessment, interpretation of results, write up of manuscript, critical review of all contents.

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SUPPLEMENTARY MATERIALS

Qualitative content development, piloting and modification

The perspectives of healthcare providers in the identification of essential criteria for the assessment of chronic rhinosinusitis (CRS) disease control have been previously determined in an international, multidisciplinary consensus study, with a design that included qualitative identification of a long list from which consensus and near-consensus criteria were identified using modified Delphi methodology [1]. These consensus essential criteria (overall symptom severity [OSS], severity of nasal obstruction, patient-reported CRS control and the need for CRS-related oral corticosteroids) and near-consensus essential criteria (nasal endoscopy, decreased ability to perform normal activities/work, overall quality of life (QOL), and the severities of nasal drainage and decreased sense of smell) were then studied to determine patient perspectives regarding their validity, relevance, and completeness for assessing CRS control [2]. The results of this study, which was implemented through semi-structured one-on-one interviews with patients, have been reported previously [2] and found that all items were considered relevant, but completeness from the patient perspective required the addition of an item related to facial pain/pressure.

A preliminary instrument was therefore developed using facial pain/pressure and the previously reported consensus and near-consensus CRS control criteria as items, except for OSS which has been shown to be redundant to and less comprehensive of a global patient-centered CRS assessment than patient-reported CRS control [3]. A nasal endoscopy item was also excluded since patients would not be expected to report this in a patient-reported outcome measure (PROM). To test for acceptability, content validity, and clarity, we pretested a preliminary instrument in a group of CRS patients, from which preliminary insights related to numerical, psychometric performance of the instrument could be gleaned. Additionally, face validity was tenable as verbal feedback about the instrument was ascertained from patients about comprehensibility. Upon a final review by the steering committee of the psychometric performance of the draft instrument as well as patient perspectives, final decisions were made by the steering committee for inclusion of items and their specific phrasing, as well as choice of response scale, scoring, and recall period to generate a final draft. The final draft of the instrument was presented to 20 CRS patients who were asked to complete it and with whom one-on-one qualitative interviews were performed to confirm acceptability, content validity and clarity. This final draft of the instrument then underwent full psychometric validation.

Factor analysis methodology

The subdomain structure of the instrument was studied by randomly partitioning the instrument responses from 585 patients into a training set (N = 391 [67%]) for exploratory factor analysis (EFA) and a testing set (N = 194 [33%]) for confirmatory factor analysis (CFA). A Kaiser-Meyer-Olkin (KMO) test was performed on the training set to determine the suitability of the data for factor analysis (KMO values > 0.8 being preferred [4]) and Bartlett's test of sphericity was then performed to assess for an adequate amount of collinearity ($p<0.05$) between variables. To determine the optimal number of factors (i.e., subdomains), we applied the Kaiser rule (retaining factors with eigenvalues ≥1). However, we also created a scree plot to visualize the proposed factors and to determine a natural drop-off in their relative eigenvalues as another means to identify the number of possible factors [5,6]. Once a possible factor structure was identified, EFA was performed on the training data set to determine variable loadings on each factor using an oblique PROMAX rotation due to the assumption that underlying factors may not be entirely independent [7,8]. Each instrument item was loaded onto a single factor in all EFAs. CFA was then performed with the testing data set on possible models identified from EFA. The factors obtained from the EFA were used for the corresponding CFA models. Modification indices and residual matrices were reviewed to confirm the relationship between items and factors. Goodness of fit for CFA models was assessed using root mean square error of approximation (RMSEA), standardized root mean square residual (SRMR), comparative fit index (CFI), and Tucker-Lewis index (TLI). Construct validity of the model was also determined by calculating the composite reliability (CR), average variance extracted (AVE), and heterotrait-monotrait ratio (HTMT). Thresholds for goodness of fit and validity measures included < 0.08 for RMSEA, < 0.05 for SRMR, >0.95 for CFI, >0.95 for TLI, >0.7 for CR, >0.5 for AVE, and <0.85 for HTMT (9-13). The fits of different CFA models were directly compared using ANOVA.

Anchor-based MCID calculations

The mean change method calculated the MCID for improvement as the difference in the change in instrument score for patients who reported "a little better" and "moderately better" in the global impression for change scales at follow up and the MCID for worsening as the difference in the change in instrument score for patients who reported "a little worse" and "moderately worse" in the global impression for change scales at follow up. The ROC method determined the MCID for improvement as the change in instrument score that best identified patients who reported "moderately better" or "much better" in their global impression for change scales while the MCID for worsening was determined as the change in instrument score that best identified patients who reported "moderately worse" or "much worse"

in their global impression for change scales at follow up.

Factor analysis results

A scree plot was generated for the training data set (Supplementary Figure S1) to determine the number of possible factors. Although a scree plot of the unrotated EFA demonstrated only one factor meeting the Kaiser criterion of eigenvalue greater than 1 and there appeared to be a natural plateau in the scree plot after the first factor, we noticed that a second plateau could potentially be identified after the 4th factor with all factors after the 4th having eigenvalues less 0.5 (Supplementary Figure S1). We therefore considered the possibility of not just a 1-factor structure for the Chronic Rhinosinusitis Control Test (CRCT) but also 2, 3 and 4 factor models. Using a PROMAX oblique rotation (which allows for correlation of the underlying factors), 1-, 2-, 3- and 4-factor solutions for the EFA yielded the results shown in Supplementary Table S1. CFA was performed on the 1-, 2-, 3- and 4-factor solutions identified from the EFA and goodness of fit measures for all models are shown in Supplementary Table S2. Based on accepted benchmarks for goodness of fit measures (9,10) for RMSEA (< 0.08), SRMR (< 0.05), CFI (>0.95), TLI (>0.95), the 1-factor and 2-factor models appeared suboptimal on CFA, while the 3-factor (which explained 75% of the total variance) and 4-factor (which explained 84% of the total variance) models met these goodness of fit benchmarks. Comparison of the 3- and 4-factor models revealed no statistically significant difference ($p = 0.080$ by ANOVA) in fit. In order to minimize the number of 1-item factors, and based on the logical grouping of items, the 3-factor model was chosen consisting of a "sinonasal" subdomain (consisting of nasal obstruction, nasal drainage, decreased sense of smell, sinus discomfort, and patient-reported CRS control items) and an "impairment" subdomain (consisting of ability to perform day-to-day activities and overall QOL items), and the need for CRS-related oral corticosteroids item.

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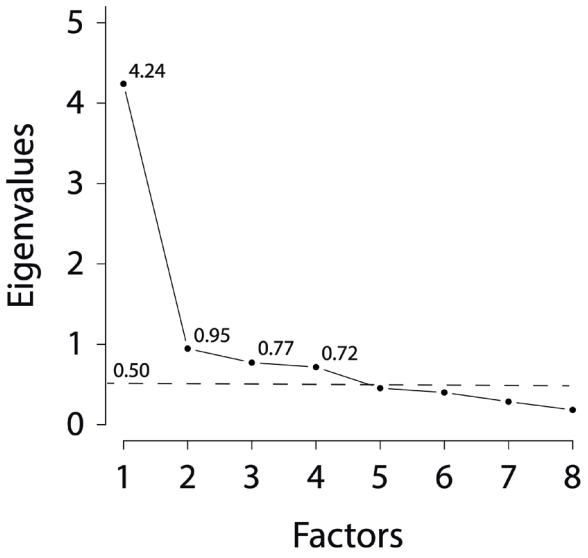

Figure S1. Scree plot for CRCT items after exploratory factor analysis. The eigenvalues for the first four factors are provided next to their corresponding points. The dashed line reflects an eigenvalue of 0.5.

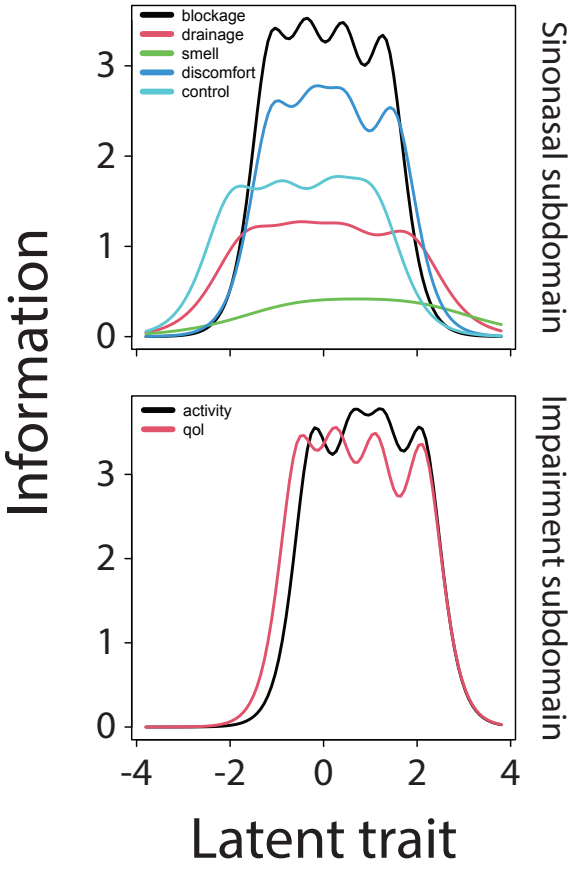

Figure S2. Item information curves for the sinonasal (top) and impairment (bottom) subdomains of the CRCT.

Table S1. Loadings on CRCT items from exploratory factor analysis.

	One-factor Solution	Two-factor solution		Three-factor solution			Four-factor solution			
	Factor 1	Factor 1	Factor 2	Factor 1	Factor 2	Factor 3	Factor 1	Factor 2	Factor 3	Factor 4
Nasal blockage	**0.83**	**0.90**	-0.14	**0.84**	0.06	-0.04	**0.80**	0.07	-0.05	0.09
Nasal drainage	**0.73**	**0.82**	-0.18	**0.93**	-0.19	0.04	**0.94**	-0.17	0.02	-0.02
Decreased sense of smell	**0.58**	**0.58**	0.01	**0.53**	0.13	-0.09	0.02	0.00	0.01	**0.99**
Sinus discomfort	**0.85**	**0.81**	0.08	**0.61**	0.28	0.09	**0.64**	0.30	0.07	-0.07
Decreased ability to perform activities	**0.78**	**0.66**	0.28	-0.08	**0.99**	0.04	-0.05	**0.99**	0.03	-0.04
Overall QOL	**0.82**	**0.74**	0.18	0.06	**0.91**	-0.05	0.04	**0.89**	-0.05	0.06
Patient-reported control	**0.77**	**0.82**	-0.10	**0.85**	-0.05	0.00	**0.86**	-0.02	-0.02	-0.01
Need for oral corticosteroids in last 3 months	**0.37**	-0.08	**0.97**	0.02	0.01	**0.99**	-0.01	-0.01	**1.00**	0.01
Proportion of variance explained by the factor	0.54	0.51	0.14	0.37	0.25	0.13	0.34	0.24	0.13	0.13

CRCT = Chronic Rhinosinusitis Control Test, QOL = quality of life.

Table S2. Goodness of fit measures from confirmatory factor analysis.

	1-factor model	2-factor model	3-factor model	4-factor model
RMSEA, (95%CI)	0.131 (0.098 – 0.165)	0.131 (0.098 – 0.165)	0.067* (0.018 – 0.107)	0.063* (0.000 – 0.107)
SRMR	0.053	0.053	0.039	0.033
CFI	0.909	0.909	0.979	0.983
TLI	0.872	0.872	0.967	0.970

*Not statistically different than having RMSEA < 0.05 ($p > 0.20$). CFI = Comparative fit index, RMSEA = root mean square error of approximation, SRMR = standardized root mean square residual , TLI = Tucker-Lewis index.