

New CRS control tests: development and validation by EUFOREA

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New CRS control tests

Development and validation by EUFOREA

Two New PROMs for CRS Control

CCT - CRS Control Test

- 6 items · Score range 0 – 24
- 4-week recall period
- Mirrors the Asthma Control Test (ACT)

CPCT - CRS Patient Control Test

- 14 items · Score range 0 – 56
- 7-day recall period
- Built on FDA PRO guidance & patient interviews

International Validation Cohort

1,102

CRS patients

19

Centres
7 countries

6

Languages
(EN-ES-NL-
IT-RO-GR)

Robust Psychometric Validation (COSMIN-guided)

- ✓ Construct & structural validity
- ✓ Internal consistency
- ✓ Test-retest reliability
- ✓ Discriminative validity
- ✓ Cross-cultural validity (6 languages)
- ✓ Item Response Theory analysis



Proposed Control Classification

**CCT
(0–24)**

≤ 15

Uncontrolled

16–19

Partially
controlled

≥ 20

Well
controlled

**CPCT
(0–56)**

≤ 12

Well
controlled

13–21

Partially
controlled

≥ 22

Uncontrolled

Conclusion

CCT and CPCT are **valid, reliable,** and **cross-culturally robust** PROMs for classifying CRS control, independent of the phenotype.

CCT: a brief tool for routine practice.

CPCT: an in-depth, FDA-aligned patient measure.

Both are recommended for clinical practice and research.

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Abstract

Background: Measuring control in Chronic Rhinosinusitis (CRS) is important in clinical evaluation. We developed and validated 2 new tests for the evaluation of control in CRS, the 6-item CRS Control Test (CCT) and the 14-item CRS Patient Control Test (CPCT) and investigated their correlations with existing tools.

Methods: An international survey was conducted in 1,102 CRS patients in 19 centres in 7 countries using a questionnaire including the newly developed CCT and CPCT, VAS scores for CRS severity and control, the EPOS control test (EPOSC), the Sino-Nasal Outcome Test 22 (SNOT-22) and the Patient Global Assessment Tool (PGAT). We evaluated convergent and discriminative validity, internal consistency and cross-cultural validity. Furthermore, we performed an Item Response Theory (IRT) analysis and deter-

mined cut-off points for CCT and CPCT. Sub-analyses were performed for CRS patients with and without nasal polyps.

Results: Both CCT (0-24) and CPCT (0-56) demonstrated a high correlation with SNOT-22 and the PGAT. Moderate correlations were observed for all other comparisons. Both tests showed good internal consistency, discriminative validity and cross-cultural validity. We propose for CCT ≤ 15 to indicate uncontrolled, 16-19 partially controlled, and ≥ 20 well controlled disease. For the CPCT we propose ≥ 22 for uncontrolled, 13-21 for partially controlled and ≤ 12 for well controlled disease.

Conclusion: The brief CCT and the longer CPCT are new CRS control tests that show moderate to high correlations with existing tools. Both instruments demonstrated good psychometric properties and therefore can be recommended for use in clinical practice and research.

Key words: chronic rhinosinusitis, CRS control test, EPOS control test, EUFOREA, CRS patient control test

Introduction

Disease control tools have been developed for several chronic respiratory conditions, such as asthma ⁽¹⁻³⁾, COPD ⁽⁴⁻⁶⁾, CRS ⁽⁷⁾ and respiratory allergy ⁽⁸⁾, and implemented in practice ^(9,10). The aims of evaluating disease control for inflammatory conditions are ample: disease burden assessment, outcomes treatment, and to guide further therapeutic approaches ⁽¹¹⁻¹⁵⁾.

Since the introduction of CRS control in the 2012 EPOS document ⁽⁷⁾, its measurement has been fundamental ^(16,17). The EPOS control test (EPOSCT), incorporating the EPOS criteria, includes patients' symptoms, nasal endoscopic findings and rescue medication use, items thought to be most important in recent literature ⁽¹⁷⁾. Parallel to this initiative an 8-item control test was developed: the Chronic Rhinosinusitis Control Test (CRCT) ⁽¹⁸⁾. CRS control is not measured consistently within rhinology clinics. A visual analogue scale (VAS) for total or individual sinonasal symptoms, or the SNOT-22 questionnaire, have been proposed. Both are validated tools that correlate strongly with the EPOS criteria ^(19,20). VAS scores above 3.5 to 5 on a scale of 10 demonstrate strong correlation with the EPOS symptom descriptors discriminating uncontrolled disease ^(19,21,22). Studies have demonstrated strong correlations ($r > 0.8$) between individual SNOT-22 items and corresponding VAS scores for patients, suggesting that VAS reliably reflects disease control ^(20,23). Moreover, global patient-reported control assessments show significant associations with quality-of-life (QoL) scores ⁽²⁴⁾.

The EUFOREA expert panel of CRS/EPOS agreed on the definition of disease states in CRS ⁽¹⁷⁾ including control, remission, cure, recurrence/exacerbation, treatable traits, remodelling, progression and disease modification, aimed to harmonise terminology across clinical care, research and guidelines. Disease severity refers to the underlying inflammatory burden, irrespective of symptom control or treatment response, typically assessed through imaging ⁽²⁵⁾, endoscopic grading, and immunologic profiling, including eosinophilic markers ⁽²⁶⁾. Phenotyping systems such as the Japanese Epidemiological Survey of Refractory Eosinophilic Chronic Rhinosinusitis (JESREC) integrate CT findings, peripheral eosinophilia ($> 10\%$) and comorbidities

to stratify patients into severity classes predictive of recurrence and treatment escalation needs ⁽²⁷⁾. Patient-reported outcomes (PROMs), such as total SNOT-22 scores, also contribute to severity stratification ⁽²⁸⁾. Integrating PROMs with endoscopy, imaging and immunologic data supports personalised CRS management and therapeutic decision-making.

The development of a new PROM that reliably captures patient-perceived disease control in routine clinical settings underlies the current initiative. Two new tests have been developed by EUFOREA and validated with several existing tools for the evaluation of severity and control.

Methodology

Study population

Patients over the age of 18 giving consent, being diagnosed with CRS with or without nasal polyps according to the EPOS criteria and native speakers matching the language of the questionnaire validated at their centre were asked to participate. Those who had undergone sinus surgery within the last three months were excluded.

Data collection

Data was collected using CASTOR EDC ⁽²⁹⁾. All data and protocols were stored in a secured digital environment with controlled access. Each physician who wished to upload data from their respective centre received a unique username and password, which necessitated a two-step authentication process to access CASTOR.

Study design

A Case Report Form (CRF) was developed including the following: severity and control VAS, the EPOS criteria, the CCT, the CPCT, the SNOT-22, and clinical characteristics. Details in the supplement.

Questionnaires were translated into 6 target languages (including English, Spanish, Dutch, Italian, Romanian and Greek) by professional medical translation experts. Each translation was reviewed by a local panel consisting of three native-speaking

physicians with expertise in the respective field to assess semantic, conceptual and contextual equivalence. Each group proposed culturally appropriate adaptations to ensure both scientific accuracy and clinical relevance.

A pilot test was conducted across all language versions to evaluate comprehension and the clarity of the content. In each language group, 5 CRS patients completed the questionnaires and provided structured feedback on the clarity and readability of the items, as well as suggestions for improvement. Minor adjustments were made where deemed necessary.

To assess the test-retest reliability of the questionnaire, separate reproducibility studies were carried out, with 15 CRS patients per language. Each participant completed the questionnaires during three separate visits, with a spacing of 7 to 10 days in between.

Finally, a large-scale validation study with more than 1100 patients was performed to evaluate construct and intercultural validity, internal consistency and cut-off points.

The centres that were invited to support the questionnaire validation and patient recruitment were selected based on the following criteria: academic excellence and presence of a specialized clinic receiving patients who meet the inclusion criteria. Included in the questionnaire were questions that were answered by the health care professionals (HCP) on the severity and control of the patients CRS from the physicians' perspective (using VAS), the phenotype and the EPOSCT (without nasal endoscopy) (EPOSCT by HCP). The data were collected over a period of six months.

We evaluated the test-retest properties, construct validity, structural validity, internal consistency and cross-cultural validity of the CCT (recall time of 4 weeks) and of the CPCT (recall time of 7 days). Construct validity was assessed by correlating the tests with the EPOSCT and patient-reported CRS control of symptoms (VAS) and total symptom severity (VAS). We also evaluated correlations between the reported CRS control vs severity for both patients and HCP.

The development and evaluation of the instruments adhered to the COSMIN methodology for assessing content validity, structural validity, and internal consistency⁽³⁰⁻³³⁾.

To evaluate the item-level psychometric properties of the questionnaires an Item Response Theory (IRT) analysis was performed for CCT and CPCT.

Finally, cut-off points were determined for CCT and CPCT with the EPOSCT as anchor.

The study was approved by the ethical committee of University Hospital Leuven (Protocol S68027, ClinicalTrials.gov NCT06970977, Belgian registration number B3222024001459) and local ethical committees of the other centres involved.

All methods were performed in accordance with the relevant guidelines and regulations of the Declaration of Helsinki. All participants provided written informed consent.

Newly developed instruments

CRS Control Test (CCT)

Experts from the EUFOREA/EPOS working group (n = 16) proposed a questionnaire to measure control of CRS. The development involved structured consensus rounds among international experts from Belgium, Denmark, Germany, Greece, Italy, the Netherlands, Romania, Spain, the UK, and the United States, aligned with COSMIN recommendations, incorporating iterative expert review informed by existing literature and clinical practice. Consensus was defined as unanimous agreement on content and structure, achieved after two physical meetings.

The CCT consists of six questions with a range from 0 (meaning worst situation) to 4 (meaning best situation) assessing the impact of CRS symptoms on QoL, sleep and daily activities, rescue medication use, and overall perceived disease control, with a four-week recall period reflecting routine clinical follow-up intervals (Figure 1). The CCT ranges from 0 to 24.

CRS Patient Control Test (CPCT)

The CPCT followed the US Food and Drug Administration guidance for PRO measure development and understanding the patient experience^(34,35) and was conducted in two stages: 1) A draft version with 19 items was developed based on a target literature^(7,9,11-15,17), review input from EUFOREA/EPOS experts, and feedback from 18 patients with a physician's diagnosis of CRSwNP (n = 9) or CRSsNP (n = 9) during concept elicitation interviews, 2) The draft tool was further tested and refined through two iterative rounds (8 individuals with CRS per round) of cognitive debriefing interviews to support its content validity, including instructions, items, response options, and recall period.

The CPCT consists of 16 items (score 0–4) with a 7-day recall period (following FDA recommendations) assessing severity and frequency of cardinal CRS symptoms, impact on daily activities and mood, use of nasal corticosteroids, a global VAS question, and an open-ended question on the most bothersome symptom. All items except the global VAS and open question were summed to generate a total CPCT score consisting of 14 items (Figure 2).

Reference instruments

Patients' severity and control

Patients rated perceived overall disease severity (VAS-severity by patient) and control (VAS-control by patient) on a VAS scale anchors ranged from "Not controlled at all" to "Completely controlled" and from "Not severe at all" to "Extremely severe".

HCP questionnaire

HCP, usually otolaryngologists, assessed patients' CRS severity (VAS-severity by HCP) and control (VAS-control by HCP), phenotype (CRSwNP/CRSsNP), in- and exclusion criteria and the

developed by



CRS Control Test (CCT)

to be filled by the PATIENT

Please, answer the following questions

Q1 During the last 4 weeks, how much of the time has your Chronic rhinosinusitis (CRS) **kept you from getting as much done at work, school or home?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
0	1	2	3	4

Q2 During the last 4 weeks, to what extent have your CRS symptoms (**loss of smell (anosmia)/nasal congestion/facial pain or pressure/nasal drip or posterior discharge**) been bothersome?

Extremely	Severely	Moderately	Slightly	Not at all
0	1	2	3	4

Q3 During the last 4 weeks, how often have your symptoms **woken you up at night or earlier than usual in the morning?**

4 or more nights a week	2-3 nights a week	Once a week	Once or twice	Not at all
0	1	2	3	4

Q4a During the last 4 weeks, how often have you used **oral/injection CORTICOSTEROIDS treatment on top of the long-term nasal therapy?**

Continuous oral/injection treatment	One/two-week course/treatment	Not at all
0	2	4

Q4b During the last 4 weeks, how often have you used **oral/injection ANTIBIOTICS treatment on top of the long-term nasal therapy?**

Continuous oral/injection treatment	One/two-week course/treatment	Not at all
0	2	4

Q5 How would you **rate your disease control** during the last 4 weeks?

Not controlled at all	Poorly controlled	Somewhat controlled	Well controlled	Completely controlled
0	1	2	3	4

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Figure 1. CRS Control Test (CCT).

EPOSCT (EPOSCT by HCP).

SNOT-22

The SNOT-22 is a validated PROM evaluating symptom burden and QoL in CRS, with scores ranging from 0 to 110, higher scores indicating greater burden ^(36,37).

EPOS Control Test (EPOSCT)

The EPOSCT consisted of the EPOS criteria on CRS control in which patients (EPOSCT by patient) and HCP (EPOSCT by HCP) were asked to answer whether the symptoms of blocked nose, runny nose/secretion in the back of the throat, pain/pressure in the face/headache, smell reduction/loss, sleep disturbance/fatigue were present, whether the patient needed rescue me-

dication (oral corticosteroids, antibiotics) in the past 6 months ⁽³⁸⁾. Endoscopy was excluded, and both versions were identical except for lay language in the patient-reported form.

Patient Global Assessment Tool (PGAT)

Patients rated overall sinonasal symptom severity over the preceding week on a 4-point Likert scale from "No symptoms" to "Severe". Figure S1 shows a copy of the questionnaire.

Statistical analyses

Qualitative data were described using frequency and percentage. Quantitative data were summarised using mean and standard deviation, or median and interquartile range if serious deviations from the normal distribution were noted.

CRS Patient Control Test (CPCT)

to be filled by the PATIENT



Please select one answer to each of the following questions thinking about how your sinusitis (sometimes called "chronic rhinosinusitis") has been during the past 7 days.

1. During the past 7 days, **how would you rate** the severity of your **nasal congestion (stuffy nose)**?

0 None 1 Mild 2 Moderate 3 Severe 4 Very Severe

2. During the past 7 days, **how often** did you have **nasal congestion (stuffy nose)**?

0 Never 1 Rarely 2 Sometimes 3 Often 4 Always

3. During the past 7 days, **how would you rate** the severity of your **runny nose**?

0 None 1 Mild 2 Moderate 3 Severe 4 Very Severe

4. During the past 7 days, **how often** did you have a **runny nose**?

0 Never 1 Rarely 2 Sometimes 3 Often 4 Always

5. During the past 7 days, **how would you rate** the severity of your **facial pressure**?

0 None 1 Mild 2 Moderate 3 Severe 4 Very Severe

6. During the past 7 days, **how often** did you have **facial pressure**?

0 Never 1 Rarely 2 Sometimes 3 Often 4 Always

7. During the past 7 days, **how would you rate** the severity of your **loss of smell**?

0 None 1 Mild 2 Moderate 3 Severe 4 Very Severe

8. During the past 7 days, **how often** did you have **loss of smell**?

0 Never 1 Rarely 2 Sometimes 3 Often 4 Always

9. During the past 7 days, **how would you rate** the severity of your **postnasal drip (dripping from your nose down the back of your throat)**?

0 None 1 Mild 2 Moderate 3 Severe 4 Very Severe

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Figure 2A. CRS Patient Control Test (CPCT).

Test-retest reliability, construct validity, internal consistency, and cross-cultural validity, were evaluated using SAS 9.4 for Windows. All tests and confidence intervals are two-sided and assessed at a significance level of 5%. Full details of the statistical methodology are provided in the supplementary material. The dataset and the Statistical Analysis Plan are available on request. The area under the ROC curve (AUC) values (95% confidence intervals) were calculated to assess the overall discriminative performance of each instrument. Optimal cut-off values were determined based on the Youden index (sensitivity + specificity – 1), calculated across all possible thresholds. Sensitivity and specificity were evaluated for each cut-off point, and the corresponding Youden indices were utilised to identify the optimal thresholds with a minimal specificity of 80% to prevent overdi-

agnosis. Analyses were conducted for the total CRS population and stratified by phenotype (CRS_{NP} and CRS_{SNP}) to evaluate the consistency of the results across subgroups using IBM SPSS Statistics. In a post-hoc analysis, an Item Response Theory (IRT) analysis was performed on both CCT and CPCT to evaluate their item-level psychometric properties (details in the supplement).

Results

A total of 1102 patients were included (344 CRS_{SNP}, 751 CRS_{NP}, 7 unknown) from 19 hospitals in 7 countries (Table 1a). Of these, 1091 and 1094 patients completed the CCT and CPCT, respectively. Patient characteristics and questionnaires are summarised in Tables 1a and 1b.

CRS Patient Control Test (CPCT)

to be filled by the PATIENT



10. During the past 7 days, **how often** did you have **postnasal drip (dripping from your nose down the back of your throat)**?

0 Never 1 Rarely 2 Sometimes 3 Often 4 Always

11. During the past 7 days, **how much** did your sinusitis **interfere with your daily activities**?

0 Not at all 1 A little 2 Moderately 3 A lot 4 Extremely

12. During the past 7 days, **how often** did your sinusitis **interfere with your daily activities**?

0 Never 1 Rarely 2 Sometimes 3 Often 4 Always

13. During the past 7 days, **how much** did your sinusitis affect your **mood or emotions**?

0 Not at all 1 A little 2 Moderately 3 A lot 4 Extremely

14. During the past 7 days, **how often** did your sinusitis affect your **mood or emotions**?

0 Never 1 Rarely 2 Sometimes 3 Often 4 Always

15. What bothers you most about your CRS?

.....

.....

.....

.....

.....

16. How bad are your CRS symptoms at the moment?



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Figure 2B. CRS Patient Control Test (CPCT).

CRS control test (CCT)

Test-retest results for CCT scores are shown in supplementary table S1a and indicate very good reliability. In addition, the Bland-Altman limits of agreement indicate that differences between test-retest measurements can be expected to lie between -4 and 4.

In the main study, 1091 patients completed the CCT questionnaire with mean value 22.2 (SD=5.3).

For convergent validity, correlation coefficients were found to be at least as high as specified a priori for VAS-Control by HCP (0.518, a priori +M), VAS-Severity by HCP (-0.568, a priori -M), PGAT (0.769, a priori -H) and SNOT-22 (-0.778, a priori -H) (see Figure 3a, Table S2a). Both VAS scores by patient, and EPOSCT by HCP and by patient were expected to be high but were found

to be moderate (Figure 3b). The correlation with PGAT and SNOT-22 was found to be >0.7 (as expected). When evaluating CRSwNP and CRSsNP separately, correlations were found to be similar for the CRSwNP group, but lower in the CRSsNP group (see data in supplement).

The CCT showed good discrimination between groups when compared to a priori defined groups for severity and control as assessed by both HCP and patient, the EPOS criteria by both HCP and patient, the PGAT and the SNOT-22 (see figure 4), data in supplement.

The internal consistency of CCT was good with a Cronbach's α for total population of 0.81 ranging from 0.73 in the USA to 0.86 in Romania.

Although DIF analyses for the CCT identified statistically signi-

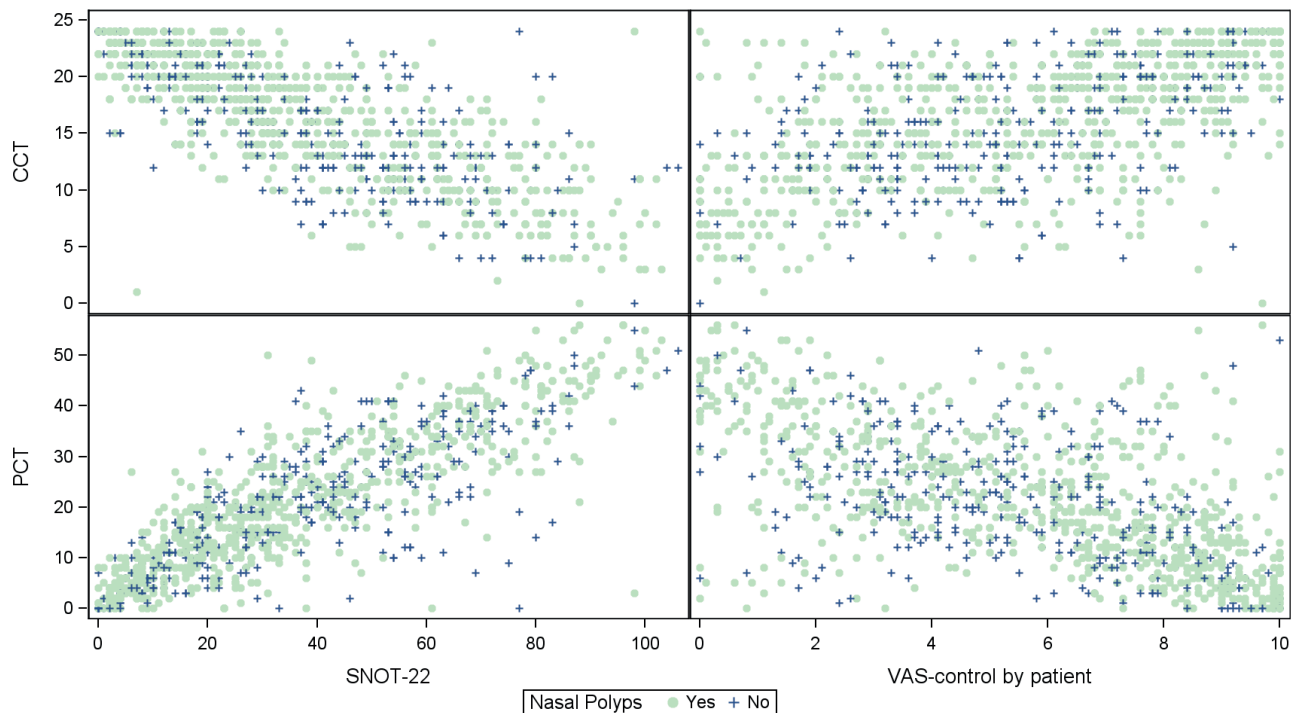


Figure 3. Correlations between tools. a. Correlation between CCT and SNOT-22 (Upper left), b. Correlations between CCT and VAS-control by patient (Upper right), c. Correlations between CPCT and the SNOT-22 (Lower left), d. Correlations between CPCT and VAS-control by patient (Lower right).

significant differences between countries, the magnitude was small, with absolute differences in predicted item scores below clinically meaningful thresholds. Visual plots inspection confirmed minimal deviation across countries, supporting the cross-cultural equivalence of the instruments.

The AUC for CCT using EPOS-defined controlled disease (EPOS-control test=0) was 0.89 (95% CI 0.87, 0.91), with AUC 0.89 (95% CI 0.85, 0.93) for CRSsNP and 0.88 (95% CI 0.86, 0.91) for CRSwNP. The optimal CCT cut-off was 20 for the total CRS population, 19 for CRSsNP and 20 for CRSwNP.

For uncontrolled disease the AUC for CCT using EPOS-defined uncontrolled disease was 0.87 (95% CI 0.85, 0.89), with AUC 0.85 (95% CI 0.80, 0.89) for CRSsNP and 0.88 (95% CI 0.86, 0.90) for CRSwNP. The optimal CCT cut-off was 16 for the total CRS population, with 15 for CRSsNP and 17 for CRSwNP.

Post-hoc IRT analyses supported retention of all six items of the CCT while clarifying that the total score reflects both general disease control and treatment-related severity. For further details see the supplementary material.

CRS patient control test (CPCT)

Test-retest results for CPCT scores are shown in supplementary table S1b and indicate good reliability for all languages (all ICC > 0.77), except for Romanian. In addition, the Bland-Altman limits of agreement indicate that differences between test-retest measurements can be expected to lie between -15 and 15.

In the main study, 1094 patients completed the CPCT question-

naire with mean value 21.3 (SD=13.2).

For convergent validity, correlation coefficients were found to be at least as high as specified a priori for VAS-Severity by patient (0.739, a priori +H), EPOSCT by patient (-0.739, a priori -H), PGAT (0.836, a priori +H) and SNOT-22 (0.834, a priori +H) (see Figure 3c and Figure 3d). Correlations with VAS-Control by HCP and by patient, VAS-Severity by HCP and EPOSCT by HCP were all expected to be high but were found to be moderate instead. When evaluating CRSwNP and CRSsNP separately, correlations were found to be similar for the CRSwNP group, but lower in the CRSsNP group.

The CPCT showed good discrimination between groups when compared to a priori defined groups for severity and control as assessed by both HCP and patient, the EPOS criteria as assessed by both HCP and patient, the PGAT and the SNOT-22 (Figure 5, Table S2b).

The internal consistency of CPCT was excellent with a Cronbach's α for total population of 0.94 ranging from 0.91 in the Belgium to 0.95 in Italy.

For cross-cultural validity, cultural differences for all items were statistically significant ($p < 0.0001$) except for severity and frequency of effect on mood ($p > 0.7$). Nevertheless, examinations of plots reveal actual differences are low between countries/languages. Also, DIF analyses for the CPCT identified statistically significant differences between countries, but the magnitude was small, with absolute differences in predicted item scores below clinically meaningful thresholds. Visual plots inspection

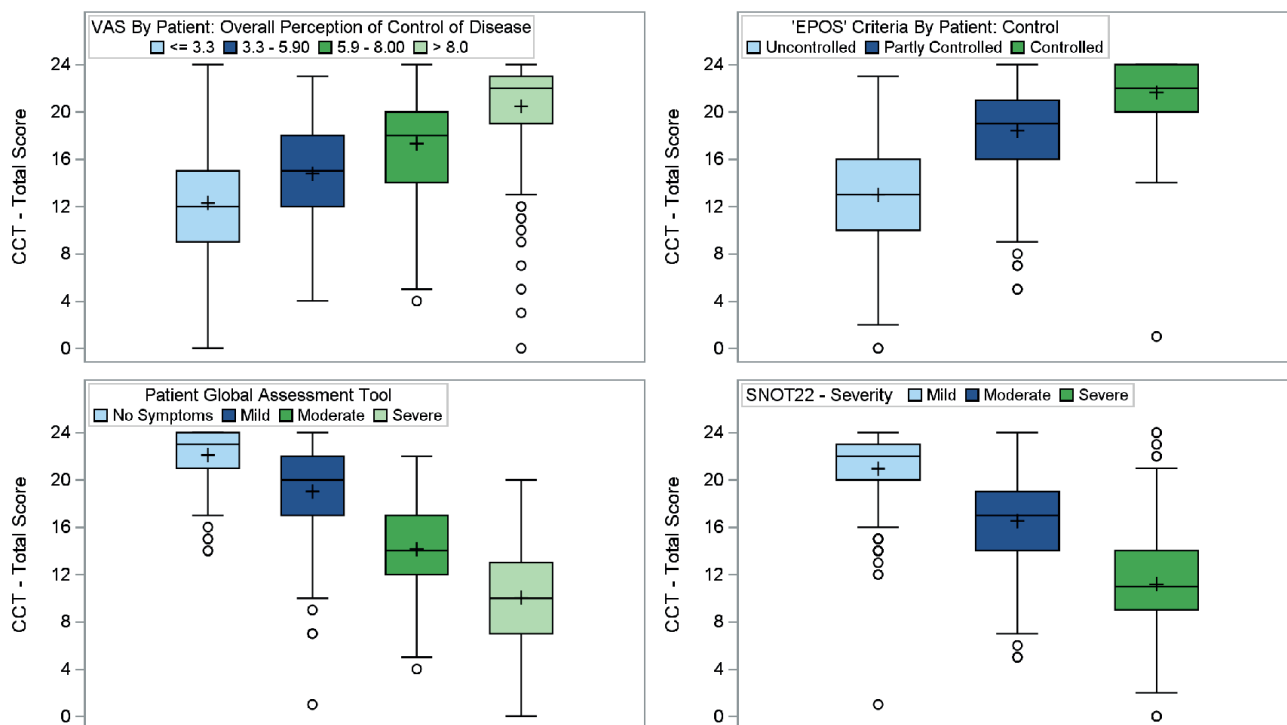


Figure 4. Discriminative Validity of the CCT.

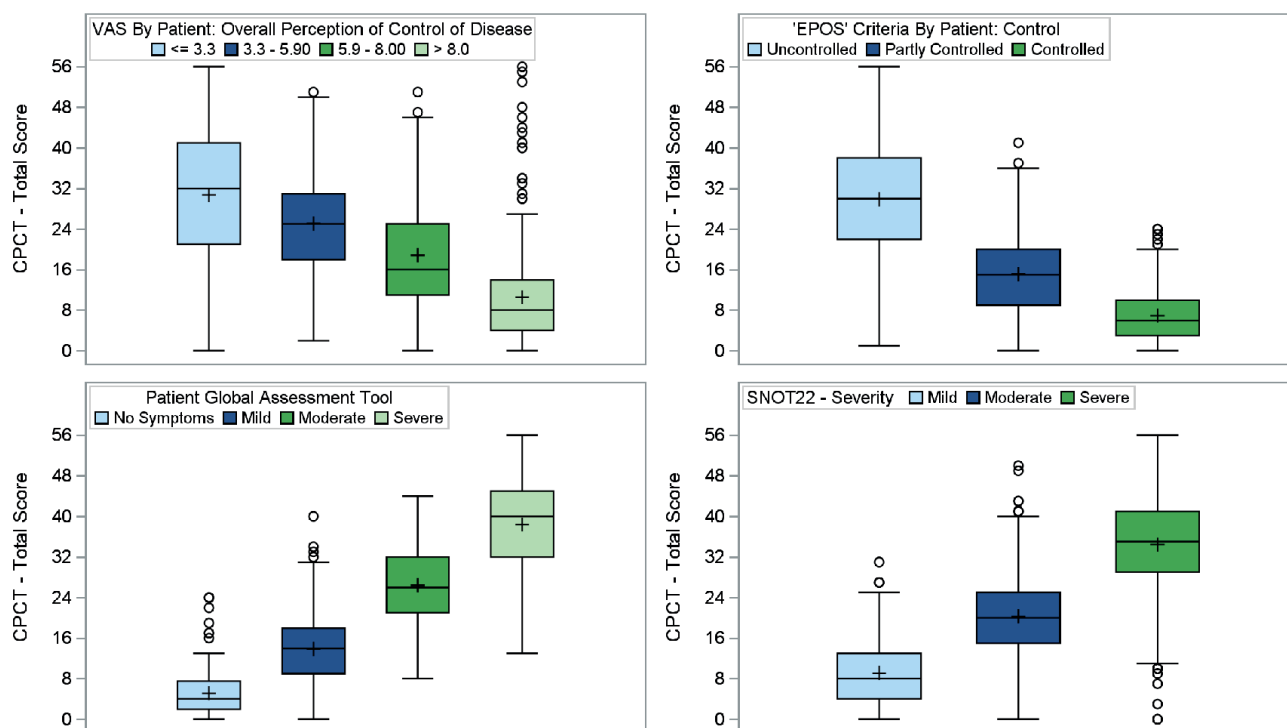


Figure 5. Discriminative Validity of the CPCT.

confirmed minimal deviation across countries, supporting the cross-cultural equivalence of the instruments. The AUC for CPCT using EPOS-defined controlled disease (EPOS-control test=0) was 0.91 (95% CI 0.89, 0.93), with AUC 0.88(95%

CI 0.84, 0.93) for CRSsNP and 0.92 (95% CI 0.90, 0.94) for CRSwNP. The optimal CPCT cut-off was 12 for the total CRS population, 12 for CRSsNP and 14 for CRSwNP. For uncontrolled disease the AUC for CPCT using EPOS-defined

Table 1a. CRS Patient characteristics.

Characteristics	Total study population N=1102
Country (n=1102) (Missing data = 0)	n (%)
Spain	372 (33.8%)
Italy	229 (20.8%)
Romania	200 (18.1%)
United States	109 (9.9%)
Belgium	78 (7.1%)
Netherlands	71 (6.4%)
Greece	43 (3.9%)
Phenotype (n=1095) (Missing data = 7)	n (%)
CRSsNP	344 (31.4%)
CRSwNP	751 (68.6%)
Age (years) (n=1080)	Mean (SD) 50.1 (16.1)
Gender (n=1098) (Missing data = 4)	n (%)
Male	558 (50.8%)
Female	540 (49.2%)
Exposure to irritants, gases, dust or chemicals (n=1073) (Missing data = 29)	185 (17.2%)
Tobacco (n=1096) (Missing data = 6)	n (%)
Never smoked	848 (77.4%)
Past smoker (Stopped > 6 months ago)	97 (8.9%)
Ex-smoker (Stopped < 6 months ago)	29 (2.6%)
Current smoker	122 (11.1%)
Alcohol (n=1095) (Missing data = 7)	n (%)
Never	583 (53.2%)
Occasional consumption	459 (41.9%)
Daily consumption	53 (4.8%)
Recreational drugs (n=1094) (Missing data = 8)	n (%)
Marijuana	25 (2.3%)
Cocaine	6 (0.5%)
Number of years with sinus symptoms (years) (n=1044)	Mean (SD) 15.91 (14.24)
Sinus surgery (n=1081) (Missing data = 21)	n (%)
No surgery	548 (50.7%)
1 surgery	224 (20.7%)
2 to 3 surgeries	225 (20.8%)
4 to 5 surgeries	49 (4.5%)
More than 5 surgeries	35 (3.2%)
Patients with allergy / any sensitisation (n=1095) (Missing data = 7)	634 (57.9%)
Sensitisation to:	n (%)
House dust mites (n=1091) (Missing data = 11)	438 (40.1%)
Pollen (n=1092) (Missing data = 10)	437 (40.0%)
Animals (n=1088) (Missing data = 14)	261 (24.0%)
Other (n=1088) (Missing data = 8)	150 (13.8%)
Asthma diagnosis (n=1094) (Missing data = 8)	463 (42.3%)
Duration of asthma (years) (n=437)	Mean (SD) 18.85 (14.88)

Characteristics	Total study population N=1102
Asthma exacerbations in previous year * (n=456) (Missing data = 7)	n (%)
None	315 (69.1%)
1 exacerbation	50 (11.0%)
2 to 3 exacerbations	52 (11.4%)
4 to 5 exacerbations	14 (3.1%)
More than 5 exacerbations	25 (5.5%)
Hospitalisations for asthma in previous year * (n=464) (Missing data = 638)	n (%)
None	411 (88.6%)
1 hospitalisation	25 (5.4%)
2 to 3 hospitalisations	14 (3.0%)
4 to 5 hospitalisations	6 (1.3%)
More than 5 hospitalisations	8 (1.7%)
COPD (n=1088) (Missing data = 14)	116 (10.7%)
History of Aspirin Intolerance (n=1084) (Missing data = 18)	142 (13.1%)
Use of medication for sinus disease within the last 3 months (n=1100) (Missing data = 2)	995 (90.5%)
Nasal irrigation with salt water (n=1100) (Missing data = 2)	588 (53.5%)
Nasal spray/drops (n=1100) (Missing data = 2)	798 (72.5%)
Oral treatment (n=1100) (Missing data = 2)	453 (41.2%)
Corticosteroids (n=1096) (Missing data = 6)	183 (16.7%)
Antibiotics (n=1096) (Missing data = 6)	181 (16.5%)
Antihistamines (n=1096) (Missing data = 6)	272 (24.8%)
Injection treatment (n=1100) (Missing data = 2)	274 (24.9%)
Corticosteroids (n=1095) (Missing data = 7)	16 (1.5%)
Antibiotics (n=1095) (Missing data = 7)	4 (0.4%)
Biologics (n=1095) (Missing data = 7)	249 (22.7%)
Other treatment (n=1102) (Missing data = 0)	33 (3.0%)

* Numbers extracted from the total number of patients with a positive asthma diagnosis

uncontrolled disease was 0.90 (95% CI 0.89, 0.92), with AUC 0.90 (95% CI 0.86, 0.93) for CRSsNP and 0.91 (95% CI 0.89, 0.93) for CRSwNP. The optimal CPCT cutoff for uncontrolled CRS (total population), was 22, with 22 for CRSsNP and 20 for CRSwNP. Post-hoc IRT analyses identified substantial local dependence between paired severity and frequency items, supporting the removal of five frequency items to reduce redundancy and improve adherence to model assumptions for further IRT analyses. Strong evidence for a bifactorial model was found comprising a factor for general CRS burden factor and a specific factor reflecting disease impact and quality of life. For further details see supplementary material.

Discussion

This multicentre study evaluated two novel CRS control instruments by EUFOREA: CCT and CPCT. The CCT, designed by clinical experts, includes 6 questions with a recall window of 4 weeks, mirroring the asthma control test (ACT). The CPCT, developed

following US FDA PRO guidance and based on in-depth patients' interviews about the most bothersome symptoms, includes 14 questions with a recall window of 1 week. Both tools were compared with standard questionnaires and assessments, such as the VAS for control and severity, the EPOSCT, the PGAT and SNOT-22, presenting cut-off points of CCT ≤ 15 for uncontrolled, 16-19 for partially controlled, ≥ 20 for well controlled, and CPCT ≥ 22 for uncontrolled, 13-21 for partially controlled, ≤ 12 for well controlled.

Both instruments showed good correlations with the EPOSCT and the SNOT-22 and moderate to good correlations with other tools. The discriminative validity was good for both. Parallel to these two tests another test assessing CRS control was recently developed ⁽¹⁸⁾. This 8-item CRCT was only validated in English in 545 patients (CRSsNP 70%) visiting the rhinology clinics at the University of Cincinnati, with a recall period of 1 month for symptoms and 3 months for (only) oral corticosteroid use. The 6-item CCT and 14-item CPCT were validated in

Table 1b. Descriptive statistics.

PROM/Tool	Total group (median (Q1; Q3))	CRSsNP (me- dian (Q1; Q3))	CRSwNP (me- dian (Q1; Q3))	Total group (mean (s.d.))	CRSsNP (mean (s.d.))	CRSwNP (mean (s.d.))		
CCT	17.0 (12.0; 21.0)	15.0 (12.0; 20.0)	18.0 (13.0; 21.0)	16.2 (5.3)	15.5 (5.0)	16.5 (5.4)		
CPCT	20.0 (11.0; 31.0)	21.0 (12.0; 30.0)	19.0 (10.0; 31.0)	21.3 (13.2)	21.3 (12.1)	21.3 (13.7)		
VAS-Severity by HCP	4.8 (2.1; 6.8)	4.9 (2.7; 6.4)	4.8 (1.9; 7.2)	4.6 (2.8)	4.6 (2.3)	4.6 (2.9)		
VAS-Control by HCP	5.8 (3.1; 8.1)	5.2 (3.3; 7.6)	6.4 (3.0; 8.2)	5.5 (2.8)	5.3 (2.5)	5.7 (3.0)		
VAS-Severity by Patient	5.5 (2.4; 7.3)	5.8 (3.7; 7.2)	5.2 (1.9; 7.4)	5.0 (2.9)	5.4 (2.4)	4.8 (3.0)		
VAS-Control by Patient	5.9 (3.3; 8.0)	5.3 (3.4; 7.3)	6.4 (3.2; 8.3)	5.6 (2.8)	5.3 (2.5)	5.8 (2.9)		
SNOT-22	33.0 (18.0; 56.0)	38.0 (20.0; 56.0)	32.0 (17.0; 57.0)	38.0 (25.0)	39.5 (23.0)	37.3 (25.9)		
PROM/Tool	Uncontrolled (n/N (%))		Partly controlled (n/N (%))		Controlled (n/N (%))			
Phenotype	CRSsNP	CRSwNP	CRSsNP	CRSwNP	CRSsNP	CRSwNP		
EPOSCT by HCP	160/341 (46.92%)	321/736 (43.61%)	137/341 (40.18%)	228/736 (30.98%)	44/341 (12.90%)	187/736 (25.41%)		
EPOSCT by patient	191/332 (57.53%)	361/736 (49.05%)	92/332 (27.71%)	228/736 (30.98%)	49/332 (14.76%)	147/736 (19.97%)		
PROM/Tool	No symptoms (n/N (%))		Mild (n/N (%))		Moderate (n/N (%))		Severe (n/N (%))	
Phenotype		CRSwNP	CRSsNP	CRSwNP	CRSsNP	CRSwNP	CRSsNP	CRSwNP
PGAT	35/343 (10.20%)	102/752 (13.56%)	126/343 (36.73%)	295/752 (39.23%)	119/343 (34.69%)	195/752 (25.93%)	63/343 (18.37%)	160/752 (21.28%)

1,102 patients across 19 centres in 7 countries and 6 languages. The CCT contains questions about oral/injected corticosteroid and antibiotics use (in the last month). Limitations of our tools include recruitment from specialised centres, adult-only population, predominance of CRSwNP, and lack of MCID values. Future work should assess real-world differences between the tests, validation of cut-off points in different populations, the ideal recall period which probably depends exact goal of the control test and implementation in daily practice⁽³⁹⁾.

Of note, some users apparently did not understand the VAS question about control, with low scores despite the absence of severe symptoms. This might be a reason to use other measures to evaluate control, or to educate users better on the use of VAS. Furthermore, for the CPCT, the post hoc IRT analysis showed substantial local dependence between paired severity and frequency items, thus supporting the removal of e.g. the five frequency items from the questionnaire in the future to reduce redundancy. This would result in a more efficient and user-friendly 9-item version of the instrument. A subsequent analysis would determine the cut-off values indicating the level of control applicable.

Conclusions

The brief CCT and the longer CPCT are new CRS control tests that show good correlation with SNOT-22 scores, good construct validity, structural validity, internal consistency, discriminative validity and cross-cultural validity, with CCT being a short, attractive test for clinical use.

List of abbreviations

CRD: Chronic Respiratory Diseases; CRS: Chronic Rhinosinusitis; CCT: CRS Control Test; CRSsNP: Chronic Rhinosinusitis without Nasal Polyps; CRSwNP: Chronic Rhinosinusitis with Nasal Polyps; EPOS: European Position Paper on Chronic Rhinosinusitis and Nasal Polyps; EPOSCT: EPOS Control Test; HCP: Health Care Provider; NPS: Nasal Polyp Score; CPCT: CRS Patient Control Test; PGAT: Patient Global Assessment Tool; PROM: Patient-Reported Outcome Measures; QoL: Quality of Life; SNOT-22: Sino-Nasal Outcome Test; UZL: University Hospital Leuven; VAS: Visual Analogue Scale

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Author contributions

All the authors have made substantial contributions to the conception or design of the work, the acquisition, analysis, and interpretation of data for the work. They have drafted the work and revised it critically for important intellectual content, have provided approval for publication of the content, and have agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of interest

DMC: Serves as Academic Manager at the European Forum for Research and Education in Allergy and Airway Diseases (EUFOREA) and as Associate Editor at *Frontiers in Allergy, Rhinology* Section. WJF: The department of Otorhinolaryngology of the Amsterdam University Medical centre, location AMC received grants for research in Rhinology from: Chordate, Novartis, EU, GSK, Sanofi-Aventis, and Zon-MW. She received consultation and/or speaker fees from Dianosis, GSK, Novartis and Sanofi-Aventis/ Regeneron and is chair of EPOS and board member of EUFOREA. GKS: Honoraria for articles, speaker and advisory boards: ALK, Bayer, Chiesi, GlaxoSmithKline, Haleon, Noucor, Sanofi- Regeneron, and Viartis. Chair of BSACI rhinitis guidelines, Scientific Chief Editor, Rhinology Section of *Frontiers in Allergy*, Vice President and AR lead for EUFOREA, and Chair member Data Monitoring Committees on SLIT for ALK. VB: Has received personal fees from AstraZeneca, GSK, TEVA, Sanofi Genzyme, MSD, Chiesi, Boehringer-Ingelheim, Novartis, ALK-Abello, Mundipharma, BIRK NPC, Menarini and Pharmaxis. SL: Received honoraria for lectures and/or participation at advisory boards of Sanofi-Aventis, Allergopharma, ALK, Leo Pharma, Leti, Viartis, Lilly, GSK, DBV during the last 3 years. XB: No conflict of interest to declare in relation to this initiative. KA: Has received personal fees from AstraZeneca, GSK, and Sanofi Genzyme. MPAQ: No conflicts of interest to declare related to this initiative. AA: No conflicts of interest to declare related to this initiative. IA: Consultant for Sanofi, Novartis, AstraZeneca, GSK, Viartis, Salvat, Storz, Olympus, Metronic, MSD and Roche. MC: Speaker honorarium GSK and Sanofi. MEC: Has given presentations, participated in advisory boards, and received research grants from Sanofi-Regeneron, GSK, ALK, Mylan, Stallergens Greer, and Medtronic. EDC: Speaker honorarium for GSK, Sanofi, Astrazeneca, Regeneron, Firma. PG: Has participated in advisory boards and received speaker fees from ALK-Abelló, Argenx, AstraZeneca, Genentech, GSK, Novartis, Regeneron, Roche, Sanofi Genzyme, and Stallergens-Greer. JH: Research consultant for Sanofi, Regeneron, GlaxoSmithKline and AstraZeneca. SLe: AstraZeneca, Genentech, GSK, Lyra Therapeutics, OptiNose, Sanofi Regeneron. CM: Received honorarium for lecture from Sanofi and GSK.

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Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

References

- Nathan RA, Sorkness CA, Kosinski M, et al. Development of the asthma control test: a survey for assessing asthma control. *J Allergy Clin Immunol*. 2004;113(1):59-65.
- Schatz M, Sorkness CA, Li JT, et al. Asthma Control Test: reliability, validity, and responsiveness in patients not previously followed by asthma specialists. *J Allergy Clin Immunol*. 2006;117(3):549-56.
- Juniper EF, O'Byrne PM, Guyatt GH, Ferrie PJ, King DR. Development and validation of a questionnaire to measure asthma control. *Eur Respir J*. 1999;14(4):902-7.
- Soler-Cataluña JJ, Alcázar-Navarrete B, Miravittles M. The concept of control of COPD in clinical practice. *Int J Chron Obstruct Pulmon Dis*. 2014;9:1397-405.
- Jones PW, Harding G, Berry P, Wiklund I, Chen WH, Kline Leidy N. Development and first validation of the COPD Assessment Test. *Eur Respir J*. 2009;34(3):648-54.
- van der Molen T, Willemse BW, Schokker S, ten Hacken NH, Postma DS, Juniper EF. Development, validity and responsiveness of the Clinical COPD Questionnaire. *Health Qual Life Outcomes*. 2003;1:13.
- Fokkens WJ, Lund VJ, Mullol J, et al. EPOS 2012: European position paper on rhinosinusitis and nasal polyps 2012. A summary for otorhinolaryngologists. *Rhinology*. 2012;50(1):1-12.
- Bousquet J, Hellings PW, Agache I, et al. ARIA 2016: Care pathways implementing emerging technologies for predictive medicine in rhinitis and asthma across the life cycle. *Clin Transl Allergy*. 2016;6:47.
- Backer V, Aanaes K, Hansen S, Petersen J, von Buchwald C. Global airways, a novel standard tests for asthma, allergic rhinitis, and chronic Rhinosinusitis (STARR-15). *Rhinology*. 2022;60(1):63-72.
- Seys SF, De Bont S, Fokkens WJ, et al. Real-life assessment of chronic rhinosinusitis patients using mobile technology: the myS-

- inusitisCoach project by EUFOREA. *Allergy*. 2020;75(11):2867-2878.
11. Hellings PW, Scadding G, Bachert C, et al. EUFOREA treatment algorithm for allergic rhinitis. *Rhinology*. 2020;58(6):618-622.
 12. Scadding GK, Smith PK, Blaiss M, et al. Allergic Rhinitis in Childhood and the New EUFOREA Algorithm. *Front Allergy*. 2021;2:706589.
 13. Hellings PW, Fokkens WJ, Orlandi R, et al. The EUFOREA pocket guide for chronic rhinosinusitis. *Rhinology*. 2023;61(1):85-89.
 14. Diamant Z, Jesenak M, Hanania NA, et al. EUFOREA pocket guide on the diagnosis and management of asthma: an educational and practical tool for general practitioners, non-respiratory physicians, paramedics and patients. *Respir Med*. 2023;107361.
 15. Hellings PW, Alobid I, Anselmo-Lima WT, et al. EUFOREA/EPOS2020 statement on the clinical considerations for CRSwNP care. *Allergy*. 2024;79(5):1123-1133.
 16. Sedaghat AR, Fokkens WJ, Lund VJ, et al. Consensus criteria for chronic rhinosinusitis disease control: an international Delphi Study. *Rhinology*. 2023 Dec 1;61(6):519-530.
 17. Fokkens WJ, De Corso E, Backer V, et al. EPOS2020/EUFOREA expert opinion on defining disease states and therapeutic goals in CRSwNP. *Rhinology*. 2024;62,3,287-298.
 18. Cotter RA, Lee CW, Wilson K, et al. Development and psychometric validation of the Chronic Rhinosinusitis Control Test. *Rhinology*. 2026;64(1):38-50.
 19. Sedaghat AR, Singerman KW, Phillips KM. Discordance of chronic rhinosinusitis disease control between EPOS guidelines and patient perspectives identifies utility of patient-rated control assessment. *Rhinology*. 2022;1,60(6):444-452.
 20. Phillips KM, Singerman KW, Sedaghat AR. Individual symptom visual analogue scale severity scores for determining EPOS guideline-based chronic rhinosinusitis disease control. *Rhinology*. 2022;1,60(3):229-235.
 21. van der Veen J, Seys SF, Timmermans M, et al. Real-life study showing uncontrolled rhinosinusitis after sinus surgery in a tertiary referral centre. *Allergy*. 2017;72(2):282-290.
 22. Zhou J, Yuan F, Huang T, Zhu L, Wu D. Current understanding of disease control and its application in patients with chronic rhinosinusitis. *Front Cell Infect Microbiol*. 2023;5,13:1104444.
 23. Doulaptsi M, Prokopakis E, Seys S, Pugin B, Steelant B, Hellings P. Visual analogue scale for sino-nasal symptoms severity correlates with sino-nasal outcome test 22: paving the way for a simple outcome tool of CRS burden. *Clin Transl Allergy*. 2018, 3;8:32.
 24. Phillips KM, Houssein FA, Singerman K, Boeckermann LM, Sedaghat AR. Patient-reported chronic rhinosinusitis disease control is a valid measure of disease burden. *Rhinology*. 2021;59(6):545-551.
 25. Zinreich SJ. Imaging of chronic sinusitis in adults: X-ray, computed tomography, and magnetic resonance imaging. *J Allergy Clin Immunol*. 1992;90(3 Pt 2):445-51.
 26. Lund VJ, Kennedy DW. Staging for rhinosinusitis. *Otolaryngol Head Neck Surg*. 1997;117(3 Pt 2):S35-40.
 27. Tokunaga T, Sakashita M, Haruna T, et al. Novel scoring system and algorithm for classifying chronic rhinosinusitis: the JESREC Study. *Allergy*. 2015;70(8):995-1003.
 28. Toma S, Hopkins C. Stratification of SNOT-22 scores into mild, moderate or severe and relationship with other subjective instruments. *Rhinology*. 2016;54(2):129-33.
 29. Castor helpdesk. 07 August 2025. Castor webpage. <https://helpdesk.castoredc.com/hc/en-us>.
 30. Mokkink LB, Terwee CB, Patrick DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. *Qual Life Res*. 2010;19(4):539-49.
 31. Mokkink LB, de Vet HCW, Prinsen CAC, et al. COSMIN risk of bias checklist for systematic reviews of patient-reported outcome measures. *Qual Life Res*. 2018;27(5):1171-79.
 32. Ioannidis JP. How to make more published research true. *PLoS Med*. 2014, 11(10):e1001747.
 33. Gagnier JJ, Lai J, Mokkink LB, et al. COSMIN reporting guideline for studies on measurement properties of patient-reported outcome measures. *Qual Life Res*. 2021;30(8):2197-2218.
 34. Food and Drug Administration. Patient-Focused Drug Development: Methods to Identify What Is Important to Patients. Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders. February 2022a. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-methods-identify-what-important-patients>. Accessed November 30, 2022.
 35. Food and Drug Administration. Guidance Document. Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. Guidance for Industry. December 2009. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-reported-outcome-measures-use-medical-product-development-support-labeling-claims>. Accessed November 30, 2022.
 36. Hopkins C, Gillett S, Slack R, Lund VJ, Browne JP. Psychometric validity of the 22-item Sinonasal Outcome Test. *Clin Otolaryngol*. 2009;34(5):447-54.
 37. Khan AH, Reaney M, Guillemin I, et al. Development of Sinonasal Outcome Test (SNOT-22) domains in chronic rhinosinusitis with nasal polyps. *Laryngoscope*. 2022;132(5):933-941.
 38. Fokkens WJ, Lund VJ, Hopkins C, et al. European position paper on rhinosinusitis and nasal polyps 2020. *Rhinology*. 2020;58(Suppl S29):1-464.
 39. Mosnaim G, Carrasquel M, Snedden M, Oppenheimer J, Lang D, Rathkopf M. Patient-reported outcomes in asthma. *J Allergy Clin Immunol Pract*. 2024;12(10):2562-72.

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This manuscript contains online supplementary material

SUPPLEMENTARY MATERIAL

Please choose the response below that best describes the severity of your sinonasal symptoms over the past week:

- ☐ No symptoms
- ☐ Mild
- ☐ Moderate
- ☐ Severe

Figure S1. PGAT.

Table S1a. Test-retest results for CCT scores.

Language	ICC (95% CI)	SEM	Bland-Altman Limits of Agreement	σ_B^2	σ_W^2
Dutch	0.914 (0.802, 0.964)	1.6	(-2.51, 2.51)	27.1	2.55
Italian	0.892 (0.756, 0.954)	1.8	(-2.86, 2.86)	27	3.27
Spanish	0.784 (0.550, 0.903)	2.05	(-3.30, 3.30)	15.27	4.22
Romanian	0.805 (0.589, 0.914)	1.82	(-4.16, 4.16)	13.64	3.3
English	0.794 (0.569, 0.909)	1.93	(-3.10, 3.10)	14.38	3.73
Greek	0.910 (0.794, 0.962)	1.01	(-1.64, 1.64)	10.29	1.02

ICC = intraclass correlation coefficient, 95% CI = 95% confidence intervals, SEM = standard error of measurement, σ_B^2 = between-subject variance, σ_W^2 = within-subject variance. ICC values were interpreted as follows: <0.5 poor, 0.5 - 0.75 moderate, 0.75 - 0.9 good, and >0.9 excellent reliability.

Table S1b. Test-retest results for CPCT scores.

Language	ICC (95% CI)	SEM	Bland-Altman Limits of Agreement	σ_B^2	σ_W^2
Dutch	0.886 (0.742, 0.951)	4.38	(-6.93, 6.93)	148.12	19.16
Italian	0.772 (0.531, 0.898)	6.08	(-9.91, 9.91)	125.45	36.97
Spanish	0.970 (0.928, 0.988)	2.17	(-3.54, 3.54)	153.19	4.72
Romanian	0.573 (0.235, 0.788)	7.53	(-15.88, 15.88)	76.26	56.76
English	0.788 (0.558, 0.906)	4.31	(-6.74, 6.74)	69.07	18.57
Greek	0.970 (0.928, 0.988)	1.54	(-2.42, 2.42)	48.19	2.39

ICC = intraclass correlation coefficient, 95% CI = 95% confidence intervals, SEM = standard error of measurement, σ_B^2 = between-subject variance, σ_W^2 = within-subject variance. ICC values were interpreted as follows: <0.5 poor, 0.5 - 0.75 moderate, 0.75 - 0.9 good, and >0.9 excellent reliability.

Table S2a. Assessment of predefined correlations for the CCT.

CCT – Estimated correlations with:	Correlation coefficient	Estimate (95% CI)	A priori hypothesis
VAS-Control by HCP	Pearson	0.518 (0.473, 0.560)	+M
VAS-Control by Patient	Pearson	0.586 (0.546, 0.624)	+H
VAS-Severity by HCP	Pearson	-0.568 (-0.607, -0.526)	-M
VAS-Severity by Patient	Pearson	-0.694 (-0.724, -0.662)	-H
EPOSCT by HCP	Spearman	0.644 (0.608, 0.678)	+H
EPOSCT by Patient	Spearman	0.687 (0.654, 0.718)	+H
PGAT	Spearman	-0.769 (-0.792, -0.743)	-H
SNOT-22 Total Score	Pearson	-0.778 (-0.800, -0.753)	-H

References: + = positive expected correlation, - = negative expected correlation. H = high correlation > 0.7, M = moderate correlation > 0.5, L = low correlation > 0.

Table S2b. Assessment of predefined correlations for the CPCT.

CPCT – Estimated correlations with:	Correlation coefficient	Estimate (95% CI)	A priori hypothesis
VAS-Control by HCP	Pearson	-0.563 (-0.602, -0.521)	-H
VAS-Control by Patient	Pearson	-0.583 (-0.621, -0.543)	-H
VAS-Severity by HCP	Pearson	0.630 (0.592, 0.665)	+H
VAS-Severity by Patient	Pearson	0.739 (0.711, 0.765)	+H
EPOSCT by HCP	Spearman	-0.673 (-0.705, -0.639)	-H
EPOSCT by Patient	Spearman	-0.739 (-0.765, -0.710)	-H
PGAT	Spearman	0.836 (0.817, 0.853)	+H
SNOT-22	Pearson	0.834 (0.815, 0.852)	+H

References: + = positive expected correlation, - = negative expected correlation. H = high correlation > 0.7, M = moderate correlation > 0.5, L = low correlation > 0.

Details of the statistical analysis

Qualitative data were described using frequency and percentage. Quantitative data were summarised using mean and standard deviation, or median and interquartile range if serious deviations from the normal distribution were noted.

Test-retest reliability was evaluated using an intraclass correlation coefficient (ICC) estimated from a linear mixed model including patient as a random and time as a fixed effect. In addition, agreement was assessed by providing the Bland-Altman limits of agreement (39).

To determine construct validity for CCT and CPCT first convergent validity was evaluated by assessing correlation statistics between the CCT/CPCT and the other tools against a list of 'a priori' defined expected correlations. The full list of expected correlations can be found in supplementary tables S2a and S2b. Correlations with the VAS and with the SNOT-22 scores were estimated using Pearson/Spearman (for categorical data) correlation statistics. The associated 95% confidence intervals were calculated using Fisher's transformation. Second, discriminative validity was evaluated by comparing CCT and CPCT scores between a priori defined groups using analysis of variance (ANOVA). For ease of interpretation, correlations were classified as high (H) if their size was >0.7 , moderate (M) when >0.5 and low (L) otherwise. Analysis was performed for the full CRS group and CRSwNP and CRSsNP separately.

Internal consistency of CCT/CPCT was assessed using Cronbach's alpha whereby a coefficient > 0.7 will be deemed acceptable for both tests.

For the evaluation of cross-cultural validity, differential item functioning (DIF) was assessed for each item in the CCT/CPCT questionnaires using a multinomial logistic regression analysis on the item scores with the total score and country as independent variables in the model. The model also included the interaction between the total score and country to allow any differential effect between countries to vary according to total score. Plots of predicted average item scores by country and total score were examined to assess the size and shape of the differences between countries. All above analyses were done using SAS 9.4 for Windows. All tests and confidence intervals are two-sided and assessed at a significance level of 5%.

Item response theory post-hoc analysis supplement for CCT

Statistical methodology

Unidimensional model

To evaluate the item-level psychometric properties of the 6-item Patient-Reported Outcome Measure (PROM), an Item Response Theory (IRT) analysis was performed. Given the ordinal nature of the response scales, a unidimensional Graded Response Model (GRM) was initially fitted to the data. Model fit was evaluated

using the Root Mean Square Error of Approximation (RMSEA; threshold ≤ 0.06), Standardized Root Mean Square Residual (SRMSR; threshold ≤ 0.08), Comparative Fit Index (CFI; threshold ≥ 0.95), and Tucker-Lewis Index (TLI; threshold ≥ 0.95). Local independence was formally evaluated using Yen's Q3 residual correlation matrix, where residual correlations exceeding a magnitude of 0.20 indicate potential local dependence violations. Item performance was visualized using Item Characteristic Curves (ICCs) and Item Information Curves (IICs).

The analysis was performed using R Statistical Software (version 4.6.0; R Core Team, 2026) via the mirt (Multidimensional Item Response Theory) package (version 1.46.1). Parameter estimation was executed using the Full-Information Maximum Likelihood (FIML) algorithm via the Expectation-Maximization (EM) architecture.

Bifactorial model extension

To resolve localized misfit and structural dependencies identified during the unidimensional phase, a multidimensional bifactor Graded Response Model (bifactor-GRM) was subsequently specified. The bifactor model defined:

1. One General Factor F1 capturing the overarching latent construct of "General CRS Disease Control" across all 6 items.
2. One Specific Group Factor F2 dedicated exclusively to the medical treatment items (Q4a and Q4b) to model the variance that is associated with treatment rather than symptom control.

Results

Unidimensional model

The unidimensional GRM yielded acceptable global fit-indices: CFI = 0.984, TLI = 0.973, SRMR = 0.043. However, the RMSEA was 0.072 (95% CI: 0.056 – 0.090), which exceeded the preferred 0.06 threshold for excellent fit, indicating localized strains.

This strain was further examined using Yen's Q3 residual correlation matrix. Substantial negative residual correlations were observed among several symptom/control items (e.g., Q3 = -0.347 between Q1 and Q5). These are consistent with model misfit or multidimensionality, where the unidimensional model over-accounts for shared variance among items. In addition, the Q3 values indicated distinct residual behaviour of the medical treatment items (Q4a and Q4b). These items showed relatively weak residual associations with the symptom/control items, indicating that they are not well represented by the same latent trait. This pattern supports the presence of a separate underlying construct related to treatment use, which is not captured within a strictly unidimensional framework.

The item discrimination a , and location/difficulty b parameters from the unidimensional model are presented in Table S3a.

Table S3a. Item parameter estimates from the unidimensional graded response model.

Item	Description / Construct	a	b1	b2	b3	b4
Q1	CRS kept from getting much done	2.521	-2.045	-1.171	-0.334	0.489
Q2	Bothersome CRS symptoms	2.735	-1.237	-0.479	0.362	1.200
Q3	CRS symptoms affect sleep	2.251	-1.409	-0.575	-0.173	0.504
Q4a	Treatment with Corticosteroids	1.014	-2.677	-1.225	NA	NA
Q4b	Treatment with Antibiotics	0.983	-3.856	-1.459	NA	NA
Q5	Rating of Disease Control	3.016	-1.573	-0.762	0.110	1.253

Note: a represents item discrimination. b1 to b4 represent category threshold locations on the latent trait scale (θ). Items Q4a and Q4b contain three response options, yielding exactly two thresholds (hence thresholds 3 and 4 are Not Applicable).

The four symptom and control items (Q1, Q2, Q3, Q5) displayed very high discrimination values, ranging from $a = 2.251$ to $a = 3.016$. This indicates an exceptional capacity to differentiate varying levels of patient disease control. Their threshold parameters (b1 to b4) were well-distributed across the latent spectrum (spanning from approximately -2.0 to $+1.25$), ensuring high measurement precision across a broad range of patient severity.

In contrast, the medical treatment items (Q4a and Q4b) exhibited substantially lower discrimination ($a = 1.014$ and $a = 0.983$, respectively) and thresholds concentrated in the extreme lower range of the scale. This indicates limited ability to discriminate among patients with mild-to-moderate disease and suggests that these items primarily capture information at the most severe end of the spectrum.

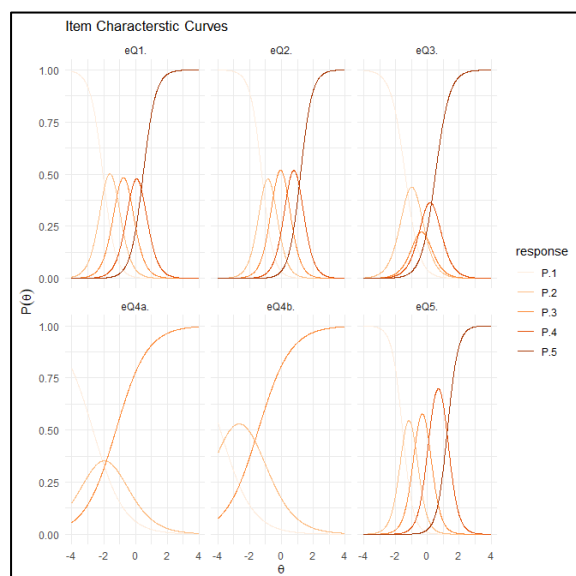


Figure S2. Item Visualization (ICCs and IICs).

The Item Characteristic Curves (ICCs) and Item Information Curves (IICs) corroborated these findings. The IICs for Q1, Q2, Q3, and Q5 formed high, broad peaks centered around the middle of the latent trait scale (θ between -1.5 and $+1.0$), demonstrating that these items provide substantial statistical information for the vast majority of the patient population. In contrast, the IICs for Q4a and Q4b produced flat curves positioned entirely on the far-left of the graph ($\theta < -1.5$), indicating minimal measurement precision for patients with moderate-to-good disease control and limited contribution outside of the

most severe cases.

Bifactorial model fit

The bifactor-GRM yielded good Q3 values and demonstrated good global fit-statistics, significantly outperforming the unidimensional solution, with CFI = 0.990, TLI = 0.979, SRMSR = 0.030, and RMSEA = 0.064 (95% CI: 0.045 - 0.084), indicating good model fit.

Item parameter estimates from the finalized bifactor model are reported in Table S1.

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Item parameter estimates from the finalized bifactor model are reported in Table S1.

Table S3b. Item parameter estimates from the bifactor graded response model.

Item	Description / Construct	a_1 (F1)	a_2 (F2)	b_1 / d_1	b_2 / d_2	b_3	b_4
Q1	CRS kept from getting much done	2.509	0.000	-2.049	-1.171	-0.332	0.491
Q2	Bothersome CRS symptoms	2.746	0.000	-1.236	-0.477	0.363	1.199
Q3	CRS symptoms affect sleep	2.249	0.000	-1.410	-0.574	-0.172	0.505
Q4a	Treatment with Corticosteroids	1.051	0.649	2.890*	1.335*	NA	NA
Q4b	Treatment with Antibiotics	1.338	1.774	5.254*	2.091*	NA	NA
Q5	Rating of Disease Control	3.046	0.000	-1.569	-0.759	0.111	1.250

Note: a_1 = item discrimination on the General Factor (Disease Control); a_2 = item discrimination on the Specific Group Factor (Medical Treatment). For items Q1, Q2, Q3, and Q5, b_1 to b_4 represent category threshold locations. For items Q4a and Q4b, asterisked values (*) represent logistic intercept parameters (d_1, d_2) due to their 3-category ordinal constraint.

The symptom and control items (Q1, Q2, Q3, Q5) have exceptionally high discrimination parameters on the General Factor (a_1 = 2.249 to 3.046), serving as the primary drivers of general disease control measurement. Crucially, the treatment items (Q4a and e/Q4b) demonstrated significant dual-loading properties. They

successfully tied into the General Factor (a_1 = 1.051 and 1.338), while simultaneously exhibiting strong standalone discrimination on the Specific Treatment Factor (a_2 = 0.649 and 1.774, respectively).

Item Response Theory Post-Hoc Analysis Supplement for CPCT

Statistical methodology

To evaluate the item-level psychometric properties of the 14-item chronic rhinosinusitis (CRS) questionnaire, an Item Response Theory (IRT) analysis was performed. Prior to model estimation, local independence was evaluated. Five frequency items (Q04, Q06, Q08, Q10, and Q14) violated the assumption of local independence (Yen's $Q3 > 0.2$) due to severe redundancy with their respective severity paired items and were subsequently removed. A unidimensional Graded Response Model (GRM) for the remaining 9 items initially yielded poor goodness-of-fit. Therefore, an exploratory bifactorial Graded Response Model (bifactor-GRM) was applied to accommodate the remaining multidimensional structure, resulting in one General Factor (F_1)

capturing overall CRS symptom burden and one Specific Group Factor (F_2) capturing Disease Burden & Quality of Life. Model fit was evaluated using the Root Mean Square Error of Approximation (RMSEA; threshold ≤ 0.06), Standardized Root Mean Square Residual (SRMSR; threshold ≤ 0.08), Comparative Fit Index (CFI; threshold ≥ 0.95), and Tucker-Lewis Index (TLI; threshold ≥ 0.95). Structural reliability and factor strength were assessed using Explained Common Variance (ECV), Omega (ω), Omega Hierarchical Omega (ω_H), the H-Index, and Factor Determinacy (FD). The analysis was performed using R Statistical Software (version 4.6.0; R Core Team, 2026) via the mirt (Multidimensional Item Response Theory) package (version 1.46.1). Parameter estimation was executed using the Full-Information Maximum Likelihood (FIML) algorithm via the Expectation-Maximization (EM) architecture.

Results

The bifactor-GRM demonstrated good to excellent fit overall, with RMSEA indicating acceptable fit (RMSEA = 0.061, SRMSR = 0.022, TLI = 0.989, and CFI = 0.994). Item parameter estimates revealed that Nasal Congestion (Q01: $a_1 = 5.004$; Q02: $a_1 = 4.368$) and Interference with Daily Activities (Q11: $a_1 = 3.206$; Q12: $a_1 = 3.007$) exhibited the highest discrimination on the General Factor (F_1), indicating they are the strongest indicators of overall CRS burden. Conversely, items assessing Interference with Daily Activities also showed very high discrimination on the Specific Factor (F_2 ; $a_2 = 5.642$ for Q11 and 5.511 for Q12), showing sub-

stantial unique variance. Communalities (h^2) were high across most items, particularly for Q11 (0.936), Q12 (0.932), and Q01 (0.907), though lower for Loss of Smell (Q07: $h^2 = 0.284$). Factor indices confirmed a robust structure: the General Factor accounted for 53.3% of the explained common variance (ECV_SS = 0.533, $\omega_H = 0.525$, H-Index = 0.913, FD = 0.954), while the Specific Factor captured a substantial and unique 46.7% (ECV_SS = 0.467, $\omega_H = 0.428$, H-Index = 0.883, FD = 0.958). Total scale reliability was exceptionally high ($\omega = 0.953$).

Table S4a. Item parameters and communalities.

Item	Symptom / Dimension	a1	a2	d1	d2	d3	d4	h2
Q01	Nasal Congestion (Severity)	5.004	1.793	5.609	0.827	-3.464	-7.427	0.907
Q02	Nasal Congestion (Frequency)	4.368	1.534	4.908	1.306	-1.734	-6.097	0.881
Q03	Runny Nose (Severity)	1.958	1.093	1.971	-0.494	-2.336	-4.428	0.634
Q05	Facial Pressure (Severity)	1.204	1.477	0.802	-0.748	-2.555	-4.535	0.556
Q07	Loss of Smell (Severity)	0.941	0.511	1.117	-0.067	-0.941	-1.915	0.284
Q09	Postnasal Drip (Severity)	1.356	1.436	2.258	0.065	-2.033	-3.899	0.574
Q11	Interference with Daily Activities (Severity)	3.206	5.642	2.340	-2.303	-6.830	-11.686	0.936
Q12	Interference with Daily Activities (Frequency)	3.007	5.511	2.598	-1.320	-5.781	-10.867	0.932
Q13	Effect on Mood (Severity)	1.638	2.574	1.269	-1.352	-3.438	-5.541	0.763

a_1 = item discrimination slope for the General Factor F_1 ; a_2 = item discrimination slope for the Specific Group Factor F_2 ; d_1 to d_4 = category intercept thresholds for the 5-point Likert scale; h_2 = item communality (total explained variance by the model).

Table S4b. Structural bifactor indices.

Factor Indices	ECV_SS	Omega	OmegaH	H-Index	FD
General Factor (F_1)	0.533	0.953	0.525	0.913	0.954
Specific Factor (F_2)	0.467	0.953	0.428	0.883	0.958

ECV_SS = Explained Common Variance at the subscale/dimension level; Omega = total categorical scale reliability; OmegaH = McDonald's Omega Hierarchical (computed via Green & Yang, 2009); H-Index = construct replicability index; FD = Factor Determinacy score. Total scale Explained Common Variance (ECV) for the entire model is distributed as 38.3% for F_1 and 33.6% F_2 .

Discussion

This post hoc IRT analysis was conducted in response to assess item redundancy and scale structure. Substantial local dependence was identified between paired severity and frequency items, supporting the removal of five frequency items to reduce redundancy and improve adherence to model assumptions. The resulting 9-item bifactor graded response model demonstrated good overall fit and supported a structure comprising both a general CRS burden factor and a specific factor reflecting disease impact and quality of life. The general factor showed moderate strength, while the specific factor accounted for a

comparable proportion of variance, indicating that the instrument is not strictly unidimensional.

Item-level analyses identified nasal congestion and interference with daily activities as the most informative indicators, whereas loss of smell showed weaker alignment with the latent structure. Overall reliability remained high following item reduction. These findings support a more efficient and user-friendly 9-item version of the instrument, while highlighting the presence of multidimensionality that should be considered when interpreting total scores.