

RHINOLOGY

# Validity and reliability of the Questionnaire of Olfactory Disorders for Italian-speaking patients with olfactory dysfunction

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## SUMMARY

**Objective.** To translate and validate an Italian version of the Questionnaire of Olfactory Disorders (IT-QOD).

**Materials and methods.** This is a prospective, multicentre study that involved patients with olfactory dysfunction (OD). Both cases and controls underwent administration of the IT-QOD, Sino-Nasal Outcome Test-22 (SNOT-22) and psychophysical evaluation of ortho-nasal and retronasal olfactory function.

**Results.** The IT-QOD was administered to 96 patients and 38 controls. The Cronbach's alpha exceeded 0.90, indicating satisfactory internal consistency. The test-retest reliability was found to be high for both parosmia ( $r_s = 0.944$ ) and life quality ( $r_s = 0.969$ ). Patients with OD had significantly higher IT-QOD scores compared to healthy individuals ( $p < 0.001$ ), indicating strong internal validity. The external validity was also satisfactory, as shown by the significant correlation with SNOT-22 ( $r_s = -0.54$ ) and the threshold, discrimination, and identification score ( $r_s = -0.63$ ).

**Conclusions.** The IT-QOD was demonstrated to be reliable and valid to assess the impact of OD on the quality of life of Italian-speaking patients.

**KEY WORDS:** olfactory dysfunction, parosmia, quality of life, anosmia, olfactory loss, rhinology, maxillo-facial surgery, otorhinolaryngology

## Introduction

Olfactory dysfunction (OD) is a common yet often overlooked condition that affects millions of people worldwide <sup>1</sup>. This complex sensory impairment can manifest in various forms, such as anosmia (complete loss of smell), hyposmia (reduced ability to smell), or parosmia (distorted perception of smell). These olfactory disturbances can arise from a multitude of causes, including head trauma, viral infections, neurodegenerative diseases, and aging <sup>2</sup>. More recently, the COVID-19 pandemic has brought OD into the spotlight, as it has emerged as a prevalent and sometimes persistent symptom of SARS-CoV-2 infection <sup>3</sup>. This increased attention has led to a greater understanding and recognition of the challenges faced by individuals with OD, whether it is due to COVID-19 or other causes <sup>4</sup>.

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In fact, the impact of OD on a patient's quality of life is frequently dramatic, as sense of smell plays a crucial role in our daily lives<sup>5,6</sup>. Smell influences our taste perception, food preferences, and eating habits, as well as our ability to detect potential environmental dangers. Additionally, olfactory cues are deeply intertwined with our emotional well-being, social interactions, and the formation of memories<sup>7</sup>. Despite the significant impact of OD on patients' quality of life, there is currently only one validated specific instrument available to assess it in individuals with olfactory dysfunction: the Questionnaire of Olfactory Disorders (QOD), which exists in both a full length<sup>8</sup> and a short version<sup>9</sup>. Proposed in 2005 by Frasnelli and Hummel<sup>8</sup>, QOD is a self-administered instrument designed specifically to assess the impact of OD on patients' quality of life. It evaluates various aspects of patients' experiences with olfactory disorders, addressing issues such as social and emotional well-being, food enjoyment, safety concerns, and daily activities. In recent years, the QOD has been validated in English<sup>10</sup>, Portuguese<sup>11</sup>, Spanish<sup>12</sup>, Korean<sup>13</sup>, Chinese<sup>14</sup> and French<sup>15</sup>. The short version of the QOD was recently validated in Italian<sup>16</sup>. Cross-cultural validation of quality-of-life assessment tools is essential, as it ensures the applicability and accuracy of these instruments across diverse populations. Cultural differences can influence the interpretation and perception of various aspects of quality of life, leading to potential discrepancies and misinterpretations when using non-validated instruments<sup>17</sup>. To date, the adaptation and validation of the Italian version of the QOD have not been performed. Therefore, the primary objective of this study is to adapt and validate the Italian version of the QOD (IT-QOD), in order to provide a reliable tool to assess Italian patients with olfactory dysfunction. This endeavour is of particular importance considering that, in recent years, Italy has ranked second among countries worldwide in terms of the number of research articles produced on olfactory disorders<sup>18</sup>.

## Materials and methods

### *Setting*

This is a prospective, multicentre study conducted from July 2022 to April 2023 at the University Hospital of Trieste and at the University Hospital of Sassari in Italy.

### *Questionnaire adaptation*

The adaptation of the IT-QOD originates from the original German version provided by Prof. Hummel from the Centre for Olfactory Disorders in Dresden<sup>8</sup> (Supplementary I, available online). The translation process followed established guidelines for adapting questionnaires to different

languages<sup>17,19</sup>. Two independent, bilingual translators with Italian as their native language translated the questionnaire from German to Italian. One of the translators was an otolaryngologist with expertise in olfactory disorders, while the other was a layperson, unaware of the questionnaire's purpose. Any disagreements that arose were resolved between the two translators, with the involvement of a third independent translator, if necessary, who was not involved in the previous translations. This initial Italian translation was then back translated into German to ensure accuracy and to identify any potential misunderstandings. The back-translation was performed by two bilingual, German-native translators who were unaware of the questionnaire's content and purpose. The Italian version of the questionnaire, resulting from the translation and back-translation process, was subsequently evaluated by a panel of Italian-native experts in olfactory disorders. The panel reached a consensus on each individual item, refining the translation as needed. This prefinal version of the questionnaire was then administered to a sample of 10 respondents who were asked to complete the questionnaire and explain their understanding of each question-and-answer option.

The panel of experts analysed the responses to ensure that there were no misunderstandings or misinterpretations of the questions and answers. A new consensus was reached on each item, resulting in the definitive IT-QOD (Tab. I).

### *Enrolment*

The study included adult patients (> 18 years old) with self-reported OD of any aetiology, who were followed up at the Departments of Otorhinolaryngology, Rhinology, and Neurology of the participating centres. Enrolment was on a voluntary basis, and patients were excluded if they were not native Italian speakers, had severe systemic comorbidities that could predominantly affect their quality of life, had a prior psychiatric diagnosis before the onset of the olfactory disorder, or had neuropsychiatric comorbidities that could compromise their understanding of the questionnaire. Using the same exclusion criteria, a control group was established, consisting of adult individuals who did not self-report the presence of an olfactory disorder.

### *Data collection*

For all individuals included in the study, general data were collected including age, gender, and comorbidities. In the case group, the subjective assessment of olfactory loss was conducted using the olfaction item of the COVID-19 Severity Index<sup>20</sup>, which classifies olfactory function into three degrees: normal, reduced, and total loss of smell. The presence of parosmia, phantosmia and gustatory disturbances was assessed using a dichotomous assessment as either pre-

sent or absent. Additionally, the duration and aetiology of the olfactory disorder were recorded.

Both cases and controls were administered the Sino-Nasal Outcome Test-22 (SNOT-22) and underwent psychophysi-

**Table I.** Italian translation from the original German version of the 29-items QOD.

P1	Il cibo ha un sapore diverso da quello che dovrebbe avere a causa dei miei problemi con l'olfatto.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
P2	Avverto sempre un odore sgradevole nel naso, indipendentemente dalla presenza di una sostanza odorosa nelle vicinanze.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
P3	Gli odori che per altri sono gradevoli li avverto come sgradevoli.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
P5	Il problema più grande per me non è tanto quello di percepire gli odori in modo più debole (o di non percepirli affatto), quanto il fatto che hanno un odore diverso da quello che dovrebbero avere.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
1	A causa dei miei disturbi di olfatto vado meno spesso al ristorante con parenti o conoscenti.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
4	Ho sempre consapevolezza delle mie difficoltà nel sentire gli odori, dal risveglio all'andare a letto.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
11	Le mie difficoltà con l'olfatto limitano anche la mia capacità di sentire i gusti.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
13	Mi chiedo se sarò mai in grado di venire a capo di questo problema.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
14	Mantengo sempre una promessa, per quanto possa essere difficile fare ciò che ho detto.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
15	Mi sento più teso/a di prima a causa del cambiamento del mio olfatto.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
17	Di tanto in tanto ho pensieri e idee che non vorrei gli altri scoprissero.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
19	Quasi tutti i miei problemi dipendono dalle mie difficoltà con l'olfatto.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
22	La difficoltà nel sentire gli odori mi disturba quando mangio.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
23	Mi comporto sempre bene e in modo corretto.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>

*continues ►*

Table I. *follows.*

26	Frequento conoscenti, parenti o vicini di casa meno spesso di prima a causa delle mie difficoltà nel sentire gli odori.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
27	A causa delle mie difficoltà con l'olfatto mi è più difficile rilassarmi.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
28	Ho problemi di peso a causa delle mie difficoltà con l'olfatto.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
31	Tra tutti quelli che conosco ce ne sono alcuni che proprio non sopporto.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
32	Posso solo immaginare di imparare a convivere con il disturbo dell'olfatto.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
33	Le mie difficoltà con l'olfatto mi fanno sentire come escluso.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
34	Evito i gruppi di persone a causa delle mie difficoltà con l'olfatto.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
35	Le difficoltà con l'olfatto sono uno dei problemi della vita con i quali devo convivere.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
36	Non sono mai arrivato tardi a un appuntamento o a lavoro.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
37	A causa dei miei disturbi di olfatto mangio meno/più di prima.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
39	Ho paura di essere esposto a certi pericoli (p. es. gas domestico, cibo andato a male) a causa delle mie difficoltà nel sentire gli odori.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
42	Sorgono problemi nelle attività quotidiane a causa delle mie difficoltà con l'olfatto.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
48	A volte parlo di cose delle quali non capisco nulla.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
49	Le mie difficoltà con gli odori mi rendono nervoso.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>
50	A causa delle difficoltà con l'olfatto la mia relazione con il partner è danneggiata.	Vero <input type="checkbox"/>
		In gran parte vero <input type="checkbox"/>
		In gran parte non vero <input type="checkbox"/>
		Non vero <input type="checkbox"/>

cal evaluation of the olfactory function using the extended version of the Sniffin' Sticks test (Medisense, Groningen, Netherlands), according to validated protocols and as previously described<sup>21</sup>. The test allowed for the assessment of three domains of olfactory function: threshold (T), discrimination (D), and identification (I), providing a TDI score that enables classification of olfactory function into three categories: normosmia (TDI score  $\geq 31$ ), hyposmia (TDI score 17-30.75), and anosmia (TDI score  $< 17$ )<sup>22</sup>. All individuals included in the study were also subjected to the evaluation of retronasal olfactory function using 20 tasteless powders (Givaudan Schweiz AG, Dubendorf, Switzerland), as previously described<sup>23</sup>. Approximately 0.05 grams of powder were placed on the dorsal surface of the patient's tongue while blindfolded and with nostrils closed. Once the powder was positioned, the patients were asked to inhale deeply through their nose and attempt to identify the perceived odour from four possible choices. The total score could range from 0 to 20, with 14 representing the cut-off to define normal retronasal olfactory function.

The QOD is a validated tool related to the assessment of olfaction quality of life, originally comprised of 52 statements<sup>8</sup>. The most recent original German version<sup>24</sup> included 29 statements that can be categorised into three subscales: 19 negative and positive statements on quality of life (QOD-QOL); 6 items on social desirability (QOD-DS); 4 items on parosmia (QOD-P). Negative statements describe the extent to which patients suffer from olfactory impairment, while positive statements highlight how well patients cope with their olfactory impairment. "Socially desired" statements – similar to the "lie scale" of the Eysenck Personality Inventory (EPI) – reflect whether patients give answers that they believe they are expected to give. This domain was crafted to gauge the authenticity of an individual's or to discern if they were trying to convey a specific impression by providing socially agreeable responses. Patients could agree (2 points), partly agree (1 point) or disagree (0 point) with each statement<sup>8</sup>. The aggregate scores for QOD-QOL and QOD-P ranged between 0-57 and 0-12, respectively. A higher score represents greater impairment. The total score for QOD-DS ranged between 0-18. A higher score means a tendency toward giving a socially desired answer, implying that the results might lack credibility. Total and sub-scale scores were finally converted in a 0-100% scale according to QOD manual.

The entire evaluation procedure was conducted twice, with a 7-day interval between the two assessments, to ascertain the test-retest reliability of the IT-QOD.

#### *Statistical analysis*

The required sample size was determined according to the

rule of thumb of four patients per QOD item<sup>25</sup>. Considering a total of 29 items, the study planned to enrol at least 116 patients.

An explorative factor analysis was conducted to identify latent subscales, enhancing item loadings by means of oblique rotation. A minimum factor loading of 0.35 was used as the criterion for associating an item with a specific factor. Reliability (i.e. internal consistency) was evaluated within each subscale by calculating Cronbach's alpha coefficient. Items with reliabilities of 0.70 or greater were considered as adequate, while a reliability criterion of 0.90 is recommended for analysing individual patient items<sup>25</sup>. Criterion-related validity (i.e. external validity) was evaluated for parosmia and quality of life subscales by correlating them with TDI score, retronasal olfactory score, and SNOT-22 through the Spearman correlation coefficient. Discriminant validity was conducted by comparing subscales score in three groups of patients with different olfactory impairment (i.e. controls, COVID-19 patients, and patients with sinonasal dysfunction); differences across groups were evaluated through Kruskal-Wallis test. Finally, test-retest reliability was analysed by Spearman's correlation coefficient.

## **Results**

Ninety-six patients with OD and 38 healthy individuals completed the study. The characteristics of patients are reported in Table II. The most prevalent comorbidities included allergic rhinitis and asthma. The causes of OD mainly consisted of post-viral (34.3%) and sinonasal (27.6%) disorders. The explorative factor analysis identified three subscales (Tab. III), in agreement with the original German version of QOD; only item P1 loaded on two different factors, i.e. life quality and parosmia. Internal consistency was evaluated for each subscale, reporting adequate consistency (i.e. Cronbach's alpha coefficient  $> 0.90$ ) for life quality statements (Tab. IV). Internal consistency was quite poor for sincerity statements. Discriminant validity of the IT-QOD was evaluated by comparing median subscale values according to aetiology of OD (Fig. 1). As expected, the median score for parosmia and life quality was lower in controls than in patients with olfactory impairment ( $p < 0.001$ ), considered overall and according to the aetiology of olfactory dysfunction; these results confirm the capability of the IT-QOD to discriminate between groups with different olfactory impairment.

Satisfactory criterion validity emerged for life quality statement, resulting in absolute value of the Spearman's correlation coefficient  $> 0.50$  with TDI score and SNOT-22 (Tab. V). Mild correlation also emerged for parosmia score,

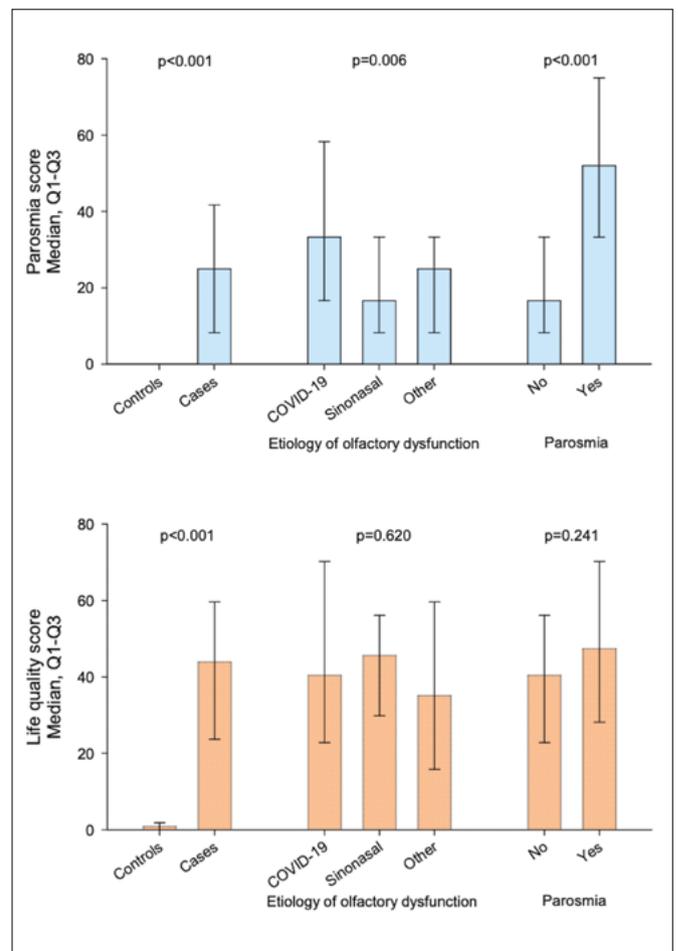
with absolute Spearman's correlation coefficient between 0.35 and 0.48. Finally, both parosmia and life quality subscales were successfully tested for reproducibility, with a Spearman's correlation coefficient  $> 0.90$  in the test-retest procedure (Tab. VI).

## Discussion

Questionnaires currently represent the gold standard to assess the effects of olfactory disorders on quality of life. Among the various available tools, the QOD is the most widely utilised, due to its comprehensive nature and reliable methodology. The QOD was designed to provide a robust measure of the impact of olfactory disorders on several aspects of life. It allows clinicians to better understand the depth and breadth of their patients' experiences and provides a standardised mean of quantifying and comparing the effects of different disorders and treatments. However, despite

**Table II.** Clinical and sociodemographic characteristics of enrolled patients.

Characteristics	n	(%)
<b>Gender</b>		
Female	68	(50.7)
Male	66	(49.3)
<b>Age (years)</b>		
Median (Q1-Q3)	52 (29-44)	
<b>Tobacco smoking</b>		
No	109	(81.3)
Yes	25	(18.7)
<b>Comorbidities</b>		
Allergic rhinitis	31	(23.1)
Asthma	31	(23.1)
Cardiovascular disease	19	(14.2)
Arthrosis	14	(10.5)
Depression	11	(8.2)
Active or former cancer	6	(4.5)
Psoriasis	4	(3.0)
Rheumatological diseases	4	(3.0)
Renal failure	1	(0.8)
Liver failure	0	(0.0)
Respiratory failure	0	(0.0)
<b>Aetiology of the olfactory disorder</b>		
Post-viral	46	(34.3)
Sinonasal	37	(27.6)
Post-traumatic	8	(6.0)
Neurological	3	(2.2)
Idiopathic	2	(1.5)
Control	38	(28.4)



**Figure 1.** Subgroup analysis of the differences in parosmia and quality of life scores.

its widespread international use, there is currently no Italian version of the QOD. This gap presents a significant hurdle for Italian-speaking researchers and clinicians who aim to assess quality of life in patients with olfactory disorders. The process of cross-cultural adaptation of a questionnaire into another language is a complex endeavour, encompassing all the steps undertaken in this study. These steps aim to produce a tool that measures outcomes consistently with the original instrument, ensuring data continuity and comparability across different linguistic and cultural backgrounds. Consistent with the original version, the questionnaire items can be grouped into three subscales evaluating: parosmia, quality of life, and sincerity. The items aligned with the same factors as in the original questionnaire, showcasing the reliability of the questionnaire's construct. Only one parosmia item spanned two subscales (quality of life and parosmia), while an item originally included in the sincerity statements instead fell into the quality of life subscale.

**Table III.** Item factor loading.

#	Item	Factor 1 Life quality	Factor 2 Parosmia	Factor 3 Sincerity
P1	Food tastes different from what used to.	<b>0.58</b>	<b>0.36</b>	-0.31
P2	Often I perceive a bad smell, regardless whether a potential odour source is present.	0.25	<b>0.74</b>	-0.02
P3	Other people find odours pleasant which are unpleasant to me.	0.26	<b>0.86</b>	0.18
P5	My biggest problem is not that odours are less intense (or absent), but that things smell different from what they used to.	0.17	<b>0.87</b>	0.00
1	Because of the changes in my sense of smell, I go to restaurants less often than I used to.	<b>0.72</b>	-0.03	-0.15
4	I am always aware of the changes in my sense of smell.	<b>0.73</b>	0.03	-0.42
11	Because of the changes in my sense of smell, I don't enjoy drinks or food as much as I used to.	<b>0.66</b>	0.29	-0.26
13	I am worried that I will never get used to the changes in my sense of smell.	<b>0.64</b>	0.37	-0.36
S14	I always keep my promises, no matter what the cost.	0.02	<b>0.35</b>	-0.25
15	Because of the changes in my sense of smell, I feel more anxious than I used to feel.	<b>0.85</b>	0.15	-0.11
S17	Sometimes I have thoughts and ideas I would not want other people to know of.	-0.03	0.03	<b>0.80</b>
19	The changes in my sense of smell cause most of my problems.	<b>0.77</b>	0.18	0.04
22	The changes in my sense of smell annoy me when I am eating.	<b>0.70</b>	0.17	-0.25
S23	I always behave well and properly.	-0.05	0.12	<b>-0.36</b>
26	Because of the changes in my sense of smell I visit friends, relatives, or neighbours less often.	<b>0.76</b>	0.08	0.16
27	Because of the changes in my sense of smell, I try harder to relax.	<b>0.82</b>	0.19	0.05
28	Because of the changes in my sense of smell I have weight problems.	<b>0.73</b>	0.14	0.09
S31	Among all people I know, there is someone I can't stand.	0.03	0.10	<b>0.51</b>
32	I am wondering if I will ever be able to live with this problem.	<b>0.61</b>	0.16	-0.27
33	The changes in my sense of smell make me feel isolated.	<b>0.74</b>	0.03	0.07
34	Because of the changes in my sense of smell I avoid groups of people.	<b>0.68</b>	0.14	0.20
35	This problem is just one of the many problems in life one has to live with.	<b>0.48</b>	0.19	-0.25
S36	I have never been late for an appointment or work.	0.14	-0.02	<b>-0.53</b>
37	Because of the changes in my sense of smell I eat less than I used to or more than I used to.	<b>0.84</b>	0.12	0.02
39	Because of the difficulties with smelling, I am scared of getting exposed to certain dangers (e.g., gas, rotten food).	<b>0.75</b>	0.16	0.25
42	Because of the changes in my sense of smell I have problems with taking part in activities of daily life.	<b>0.85</b>	0.11	-0.26
S48	Sometimes I talk about things I don't know.	-0.05	-0.06	<b>0.58</b>
49	The changes in my sense of smell make me feel angry.	<b>0.87</b>	0.14	0.05
50	Because of the changes in my sense of smell, my relationship with my wife / husband / partner is affected.	<b>0.55</b>	0.02	0.15

Loadings  $\geq 0.35$  are in bold.

The enrolment of patients in the present study respected the same inclusion and exclusion criteria as the original study in which the German version of the questionnaire was validated. The original population consisted of 84 males and 121 females, with a mean age of 53.6 years, which is quite similar to ours in terms of age (median age, 52), while we had a less marked proportion of women (68 women and 66 men in our study). It is not possible to compare the two populations by aetiology of OD because this was not reported by Frasnelli and Hummel<sup>8</sup>.

The Italian version demonstrated high internal consistency for the quality of life and parosmia subscales, comparable

to that reported for the French version (Cronbach's alpha 0.827)<sup>15</sup>, English version (Cronbach's alpha 0.90)<sup>10</sup>, and the original German version (Cronbach's alpha 0.93)<sup>8</sup>. Like the French version, the consistency of the sincerity statements was found to be weaker. This suggests that, while these sections translated well and provided consistent results across different languages and cultures, the sincerity statements might require further adaptation to fit cultural nuances better or may inherently have more variability across different populations.

The discriminant validity was high, and the Italian version of the QOD detected significantly worse quality of life and

**Table IV.** Subscale internal consistency of the IT-QOD. Item-to-total correlation and Cronbach's alpha for questionnaire items.

#	Item	Item-to-total correlation	Cronbach's alpha if item is deleted
<b>Parosmia statements</b>			
P1	Food tastes different from what used to.	0.317	0.849
P2	Often I perceive a bad smell, regardless whether a potential odour source is present.	0.576	0.671
P3	Other people find odours pleasant which are unpleasant to me.	0.679	0.614
P5	My biggest problem is not that odours are less intense (or absent), but that things smell different from what they used to.	0.696	0.585
<b>Life quality statements</b>			
1	Because of the changes in my sense of smell, I go to restaurants less often than I used to.	0.680	0.952
4	I am always aware of the changes in my sense of smell.	0.747	0.951
11	Because of the changes in my sense of smell, I don't enjoy drinks or food as much as I used to.	0.700	0.952
13	I am worried that I will never get used to the changes in my sense of smell.	0.724	0.951
15	Because of the changes in my sense of smell, I feel more anxious than I used to feel.	0.846	0.949
19	The changes in my sense of smell cause most of my problems.	0.742	0.951
22	The changes in my sense of smell annoy me when I am eating.	0.722	0.951
26	Because of the changes in my sense of smell I visit friends, relatives, or neighbours less often.	0.682	0.952
27	Because of the changes in my sense of smell, I try harder to relax.	0.792	0.950
28	Because of the changes in my sense of smell I have weight problems.	0.676	0.952
32	I am wondering if I will ever be able to live with this problem.	0.634	0.952
33	The changes in my sense of smell make me feel isolated.	0.680	0.952
34	Because of the changes in my sense of smell I avoid groups of people.	0.623	0.953
35	This problem is just one of the many problems in life one has to live with.	0.508	0.955
37	Because of the changes in my sense of smell I eat less than I used to or more than I used to.	0.800	0.950
39	Because of the difficulties with smelling, I am scared of getting exposed to certain dangers (e.g., gas, rotten food).	0.764	0.951
42	Because of the changes in my sense of smell I have problems with taking part in activities of daily life.	0.853	0.949
49	The changes in my sense of smell make me feel angry.	0.841	0.949
50	Because of the changes in my sense of smell, my relationship with my wife / husband / partner is affected.	0.477	0.954
<b>Sincerity statements</b>			
S14	I always keep my promises, as hard as it is.	0.051	0.182
S17	Sometimes I have thoughts and ideas I would not want other people to know of.	0.197	0.031
S23	I always behave well and properly.	0.04	0.189
S31	Among all people I know, there is someone I can't stand.	0.230	0.008
S36	I have never been late to an appointment or work.	-0.166	0.374
S48	Sometimes I talk about things I don't know.	0.148	0.093

**Table V.** Criterion validity of the IT-QOD. Spearman correlation coefficient with TDI, retronasal olfactory score, and SNOT-22 for parosmia and life quality statement outcome.

Score	Spearman correlation coefficient	
	Parosmia	Life quality
TDI	-0.48	-0.63
Retronasal olfactory score	-0.35	-0.47
SNOT-22	0.44	0.54

**Table VI.** Reliability of the IT-QOD. Spearman correlation coefficient between first and second test administration for subscales.

Score	Spearman correlation coefficient
Parosmia	0.915
Life quality	0.969
Sincerity	0.791

parosmia scores in patients with OD compared to controls. Moreover, different score patterns were detected based on the aetiology of the OD. Patients with COVID-19 related OD had significantly worse parosmia scores compared to patients with OD from sinonasal disease. In patients with post-viral olfactory disorders, the higher prevalence of parosmia is evident. Specifically, when comparing patients with qualitative disorders to those with isolated quantitative disorders, the analysis shows significantly worse parosmia scores and a non-significant decline in quality of life in the former group compared to the latter. The impact of qualitative disorders on quality of life, which is even more pronounced than that of quantitative disorders, has been extensively documented and appears to be supported by this study, although statistical significance was not reached. Criterion validity was also satisfactory with moderate and significant correlations between the QOD scores and all analysed parameters (i.e. TDI, retronasal olfactory score, and SNOT-22). The correlations were in all cases stronger with the quality of life subscale than with the parosmia score. This is not surprising because the severity of parosmia is not directly proportional to olfactory loss, and patients with qualitative disorders, even severe ones, can present normal psychophysical olfactory scores. The strength of the correlations is similar to that reported for the French version, for which the SNOT-22 was used for criterion validation ( $r_s = 0.498$ ;  $p = 0.001$ ). Unlike in this study, where the correlation with TDI was found to be moderate and significant, the correlation between psychophysical test results and QOD scores was found to be weak and significant in the German version ( $r_s = -0.015$ ;  $p = 0.034$ ) and not significant in the English version. Finally, in line with previous findings, the reproducibility of QOD was demonstrated to be reliable, as evidenced by strong and significant correlations observed between the two evaluations performed for each patient. This study has the strength of proposing and validating, through a rigorous and comprehensive process, the IT-QOD. This is of substantial value as it provides researchers with a reliable tool to evaluate the quality of life in Italian-speaking patients with olfactory disorders.

As for the limitations of the study, it should be acknowledged that the majority of patients in the study had post-viral OD or OD related to chronic rhinosinusitis. This may restrict the generalisability of the findings and the applicability of the QOD instrument in assessing the quality of life in patients with OD of other causes. Finally, the study did not include children or adolescents and the IT-QOD, like the original, is to be considered reliable and validated only in adult patients.

## Conclusions

In conclusion, the Italian translation of the original German version of the olfactory disorder's questionnaire is a valid, reliable, and context-based scale. It will facilitate cross-cultural comparisons and allow for more comprehensive understanding of olfactory disorders and their impact on adult individuals. Moreover, in clinical practice, the questionnaire can serve as a valuable tool for Italian healthcare professionals in assessing and monitoring the severity and quality of life impact of olfactory disorders in their patients. This can aid in treatment planning, evaluating therapeutic interventions, and tracking patients' progress over time.

### *Conflict of interest statement*

The authors declare no conflict of interest.

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### *Author contributions*

LAV and PBR have full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. LAV, GT, GDR, PBR: conceptualization and methodology. DR, FU, FA, DR, NR, LC, PS: acquisition, analysis and interpretation of the data. PBR, LAV: statistical analysis. JRL, MM: critical revision of the literature. FB, PS: provision of resources. LAV, PBR: original draft preparation. JRL, MM, GT, GDR, DR, FU, FA, FT, DR, NR, LC, PS: critical revision of the manuscript for important intellectual content. GT, GDR: supervision. All the authors read and approved the final version of the manuscript.

### *Ethical consideration*

This study was approved by the University of Trieste Ethics Committee (approval N. CEUR-2020-Os-156) and University of Cagliari Ethics Committee (approval N. PG/2021/7118). The research was conducted ethically, with all study procedures being performed in accordance with the requirements of the World Medical Association's Declaration of Helsinki.

Written informed consent was obtained from each participant/patient for study participation and data publication.

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