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Assessing the Italian version of the respiratory symptom experience scale (IT-RSES) in smokers and former smokers: a validation study

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Abstract

Background Smoking causes respiratory symptoms, and research suggests these improve with cessation or switching to less harmful nicotine products. The Respiratory Symptom Experience Scale (RSES) was developed and validated for the purpose of assessing these such symptoms online in an English-speaking American sample. This study aimed to develop and validate an Italian version, the IT-RSES, administered via telephone interview, and, further, to use it to assess symptoms in smokers who had switched to e-cigarettes or to heated tobacco products (HTPs).

Methods After translation into Italian, the IT-RSES was administered by phone interview to 750 Italian participants in 5 tobacco use groups (150 each never-smokers, former smokers not using alternative products, HTP users, e-cigarette users, and continuing smokers) who also reported any history of diagnoses with relevant medical conditions. Psychometric analyses examined scale factor structure, reliability, and convergent validity. Analyses controlling for age and for years smoking compared symptoms across tobacco use groups.

Results Factor analyses confirmed the IT-RSES' unidimensionality (factor one accounting for 74.2% of the variance; all factor loadings > 0.80). Internal-consistency reliability was high (Cronbach's alpha = 0.91). IT-RSES scores correlated significantly with years of smoking ($r = 0.51$, $p < 0.0001$), and were higher in individuals with respiratory conditions (2.02 vs. 1.36, SE = 0.05, significant by THSD). Discriminant validity was demonstrated by higher scores in smokers compared to never-smokers, even among those without respiratory conditions. After adjustment for years of smoking, former smokers, HTP users and e-cigarette users had lower scores than smokers (m = 2.17 vs. 1.49, SE = 0.06, $p < 0.05$, THSD; 1.63 vs. 2.16, SE = 0.06, THSD) and did not significantly differ from each other.

Conclusions The results support the reliability and validity of the IT-RSES, suggesting its utility for assessing respiratory symptoms in smokers, and former smoker who stopped smoking and were using e-cigarettes or HTPs. The scores of former smokers are similar to those not using these products, and lower than smokers', suggests that HTPs and e-cigarettes do not add materially to respiratory symptoms when smokers stop smoking.

Keywords Scale validation, Respiratory symptoms, Smoking, Italian, IT-RSES

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Background

Protracted exposure to the chemicals in cigarette smoke, which are inhaled and accumulate in the lungs, leads to impaired muco-ciliary clearance, oxidative damage, and airway inflammation [1, 2]. This persistent inflammation and subsequent remodeling of the airways can give rise to chronic respiratory diseases such as chronic obstructive pulmonary disease (COPD) [3, 4]. However, it is important to note that smokers often display respiratory symptoms such as coughing, wheezing, and sputum production even if they do not (yet) fulfill the diagnostic criteria for COPD [5–7] or any other formal respiratory diagnosis.

A method of measuring such symptoms would be useful, as it could be used to track their recovery when smokers stop smoking and to assess the impact of switching to alternative products such as e-cigarettes or heated tobacco products [8], which are inhaled but do not emit toxicants produced by combustion. Questionnaires developed and validated to assess clinical respiratory symptoms in COPD patients [9–12] are unlikely to be suitable, as they are calibrated to reflect a higher severity of symptoms typical of COPD, but not typical in non-COPD smokers. For example, questions about severe breathlessness or significant limitations in daily activities may not be relevant for smokers with milder symptoms, potentially leading to an underestimation of their actual respiratory problems.

The need for a scale that is appropriate for assessing smokers' and former smokers' symptoms is highlighted by the need to assess respiratory symptoms in smokers who switch away from smoking using to combustion-free alternative nicotine products like e-cigarettes, also known as ENDS, or Electronic Nicotine Delivery Systems) and heated tobacco products (HTPs). Cigarette smoke exposes smokers to toxic chemicals that are products of combustion and that contribute to pulmonary (and other) harms of smoking. The aerosol from non-combustible products do not contain these combustion products [13]. Biomarker data demonstrate that, compared to smoking, these products reduce users' exposure to many toxicants, including not only carcinogens and cardiovascular toxicants, but also respiratory toxicants [14, 15], suggesting that switching to such products would improve respiratory symptoms. Nevertheless, since these products are inhaled, it is important to assess their impact on respiratory symptoms. It is likely to take many years or decades to detect effects on pulmonary disease or mortality in epidemiological data. In the interim, assessing differences in respiratory symptoms might provide data that addresses the harm-reduction potential of non-combusting inhaled nicotine products.

Evidence to date suggests that smokers' respiratory symptoms are decreased when they switch to ENDS or HTPs [13], and one study demonstrated improvements in objectively-assessed pulmonary function when smokers switched to HTPs [16]. Conversely, a recent study of respiratory symptoms in non-smokers who used ENDS found increases in respiratory symptoms, suggesting adverse effects of ENDS [17].

Research in this field would be aided by a clinical assessment tool specifically developed and validated to assess respiratory symptoms in adult current and former smokers. The Respiratory Symptom Experience Scale (RSES) [18] was designed to meet this need. A validation study found that the scale was unidimensional, and had high internal and test-retest reliability. The scale strongly differentiated individuals with a diagnosis of respiratory disease or COPD, as well as differentiating smokers from former smokers. Smokers who had switched to e-cigarettes had scores lower than smokers' and similar to those of former smokers. A separate case-control study found that smokers who had switched to an ENDS for an average of three years had lower RSES scores than a group of matched smokers who had continued to smoke [15].

The RSES validation was conducted in English with American participants. One aim of the present study is to validate an Italian-language version of the RSES in an Italian population, particularly when administered by telephone interview rather than online. While online administration may reduce memory burden by allowing participants to see all the response options at once, it necessarily excludes people who do not have online access, making telephone administration advantageous.

The second aim of the present paper was to use the IT-RSES, if found to be valid, to assess differences in respiratory symptoms in smokers who stopped smoking and switched to non-combustible nicotine products, specifically HTPs or e-cigarettes. Comparisons to continuing smokers, on the one hand, and, on the other hand, to former smokers who were not using any inhaled nicotine products, and to never-smokers, would help address the health impact of HTPs and ENDS. Comparisons of respiratory symptoms between former smokers who are using HTPs or ENDS and former smokers who are not using such products can also address the impact of the non-combusting products on respiratory symptoms.

Methods

Aim, design and setting

The aim of this study was to validate an Italian-language version of the Respiratory Symptom Experience Scale (IT-RSES) for use in Italian-speaking populations. The study was designed as a psychometric validation study to assess the scale's reliability, validity, and unidimensionality. Additionally, the study aimed to use the IT-RSES to compare respiratory symptoms among smokers, former

smokers, and users of alternative nicotine products, such as HTPs and e-cigarettes, in contrast to never-smokers.

Participants

With the aim of achieving a sample that was diverse with regard to tobacco and nicotine product use, participants were recruited, between January and December 2023, from medical records at the Smoking Prevention and Treatment Center of the Policlinico Hospital in Catania.

This center collaborated closely with the University of Catania's CoEHAR research center to promote smoking harm reduction through clinical and research initiatives. After being selected based on the inclusion criteria, participants were interviewed via telephone following a rigorous standardized protocol. Our team used several approaches these databases to identify eligible individuals from prior studies, including community outreach via the smoking cessation clinics and university student via social media platforms to increase the diversity and representativeness of our study samples. The recruitment strategy for healthy participants followed the same approach used for smokers and former smokers, leveraging community collaboration and social media outreach among college students. Participants were recruited from various community groups and university networks to ensure a diverse and representative sample. We established a quota of 150 participants per group and ceased recruitment upon reaching this number. This approach was implemented to maintain balance across groups. This sample was subdivided by age, gender, and smoking status. Participant had to be 18 to 75 years old, reside in Italy, speak Italian, and have access to a telephone. Those who had a first-degree relative who is a current or former employee of the tobacco or e-cigarette industry, had a household member in litigation with a tobacco or e-cigarette company, or had participated in marketing research pertaining to tobacco or e-cigarettes in the past month were excluded. All participants were screened to confirm their eligibility and provided informed consent in accordance with ethical standards approved by the Ethics Review Board. Participants were not compensated for their time.

Five groups were delineated: (1) Never Smokers, (2) Smokers, (3) Former Smokers not using any inhaled tobacco/nicotine product, (4) Former Smokers who had switched to e-cigarettes ("ENDS Users"), and (5) Former Smokers who had switched to using heated tobacco products ("HTP Users"). The tobacco use groups were defined by self-report as follows: (1) Never smokers had never smoked 100 cigarettes in their lifetime (including never having smoked at all). (2) Cigarette smokers were daily smokers of at least 5 cigarettes per day at the time of enrollment and had smoked at that rate for at least five years (so had smoked at least 100 cigarettes). There were three groups of former smokers who had stopped smoking from at least six months (3) Former Smokers had stopped smoking without switching to e-cigarettes of heated tobacco products. (4) HTP Users had fully switched from smoking to HTPs for at least 6 months. (5) ENDS Users had fully switched from smoking to ENDS for at least 6 months.

Measures

The published RSES (Supplemental Table 1) was translated into Italian using international recommendations for translation and cultural adaptation [19, 20], as follows: The original RSES instrument in English was initially distributed among the Italian-speaking research team, leading to a series of translations that were subsequently combined into a unified version. The resulting draft in Italian was then re-translated into English by an interpreter and reviewed by the research team to assess possible corrections. Finally, the translated items were pre-tested on a small convenience sample of 10 Italian participants. during the pre-test, participants were asked questions to ensure they fully understood the instrument. These included: 'Were there any words or phrases in the questions or response options that you found unclear or difficult to understand?' (clarity of language), 'Did you understand what each question was asking about your respiratory symptoms? If not, can you describe which part was unclear?' (intent of questions), and 'Were the response options clear, and did they make it easy for you to choose the answer that best fit your situation?' (ease of responding). All participants confirmed their understanding of the questions and response options, and no significant issues were identified. The resulting instrument, in Italian, is shown in Supplemental Table 2.

Participants reported demographic characteristics, and those with a history of smoking reported how long they had smoked (in years). This is relevant to respiratory symptoms, as chronic smoking progressively causes respiratory symptoms [21]. Participants also were asked whether their health status was "good." Those who indicated it was "not good" were asked the reason for this, and participants who reported respiratory conditions or diseases (COPD, lung cancer, asthma, and allergies) were identified.

Procedures

Prior to enrollment, subjects were fully informed about the study's objectives, procedures, and the confidential handling of data, ensuring that their participation was voluntary. They were assured that the information collected would be used exclusively for research purposes. The research adhered to the ethical standards outlined in the Declaration of Helsinki and received approval from the Ethics Review Board of the Department of

Educational Sciences, Section of Psychology at the University of Catania (03 January 2023). Informed consent was obtained from each participant before they joined the study, and strict measures were taken to safeguard their privacy and the confidentiality of their personal information.

Telephone interview

The IT-RSES was administered in a telephone-based survey between January and December 2023. At the beginning of the call, the interviewer explained the purpose of the scale and provided clear instructions to the respondent. The interviewer stated: "For the following questions, please think about your experiences in the past 30 days." The response options were then carefully explained to ensure the participant understood the frequency categories. The full set of response options was repeated for each item to maintain consistency and clarity throughout the interview and to avoid taxing participants' memory. The interviewer proceeded to ask about each of the five items, confirming the chosen response before moving to the next item. If a participant expressed uncertainty, the interviewer reread the item and response options.

Analysis

A first set of analyses focused on assessing the psychometric properties of the IT-RSES. An exploratory factor analysis was used to assess unidimensionality. Cronbach's alpha was used to assess internal-consistency reliability. IT-RSES scores were computed by averaging responses across the five items.

Several analyses were undertaken to assess validity. Using regression models, RSES scores were compared between those with and without respiratory diagnoses. As the Tobacco Use Groups differed in age, and pulmonary function declines with age [22], the models adjusted for participants' age. In the groups with a history of smoking, RSES scores were correlated with duration of smoking. Age-adjusted models compared RSES scores of Smokers versus Never Smokers. As RSES scores are meant to tap smoking-related respiratory symptoms even in the absence of respiratory diagnoses, Smokers' and Never Smokers' scores were compared among participants without a reported respiratory diagnosis.

A second set of analyses compared IT-RSES scores of HTP Users and ENDS Users to each of the other groups, and to each other, to address the effect of smokers switching to use of these non-combusted products. Since years of smoking is related to respiratory symptoms, manifesting residual effects even after the person stops smoking, and years of smoking differed significantly between groups, these analyses adjusted for years smoked as well as for age. Tukey's Honestly Significant Difference (THSD) test [23] was used for all group comparisons, at a significance level of 0.05.

Results

750 adults (150 per tobacco-use group) participated at this research (Fig. 1).

Table 1 shows the demographics of the sample, along with their diagnostic history, and health status measure, by tobacco use group. The sample was uniformly Caucasian, and roughly equally balanced by gender. Most participants did not have a university education. Average age was approximately 35, with variation among tobacco history groups, with group means ranging from 25 (Never Smokers) to 40 (ENDS Users and Former Smokers). Those with a history of smoking had smoked for an average of 17 years, with variation among Tobacco Use groups from 13 years (HTP Users) to 20 years (Smokers and ENDS Users). As shown in Table 1, these variables showed significant differences between groups.

Psychometric analyses

Table 2 shows the mean response on each item, and the overall average IT-RSES score. Notably, for each item, at least half the participants indicated never experiencing the symptom, but at least some reported experiencing it daily. The scale scores were right-skewed. (However, using log-transformed IT-RSES scores to reduce skewness did not change any of the results reported.)

Dimensionality and internal consistency reliability

An Exploratory Factor Analysis (EFA) using Principal Component Analysis (PCA) was used to extract factors. A dominant first factor emerged (eigenvalue = 3.71), accounting for 74.2% of the total variance. The remaining factors all had eigenvalues < 1. Table 3 shows the items' loadings on the factor, i.e., the correlations between the items and the underlying latent factor. All loadings were high (> 0.80). This indicated that the scale was unidimensional.

The average inter-item correlation was $r = 0.68$. Cronbach's alpha was 0.91, indicating high internal consistency.

Validity

The IT-RSES demonstrated discriminant validity in several ways. As expected, IT-RSES scores were higher in those who reported their health was not good (2.46 ± 1.18 vs. 1.47 ± 0.59, $p < 0.0001$ by unequal-variances t-test). Participants with respiratory diagnoses had considerably higher IT-RSES scores than those without such diagnoses (2.75 ± 1.32 vs. 1.58 ± 0.74, $p < 0.0001$ by unequal-variances t-test).

Respiratory function declines with age [22]. Consistent with this, IT-RSES scores were correlated with age

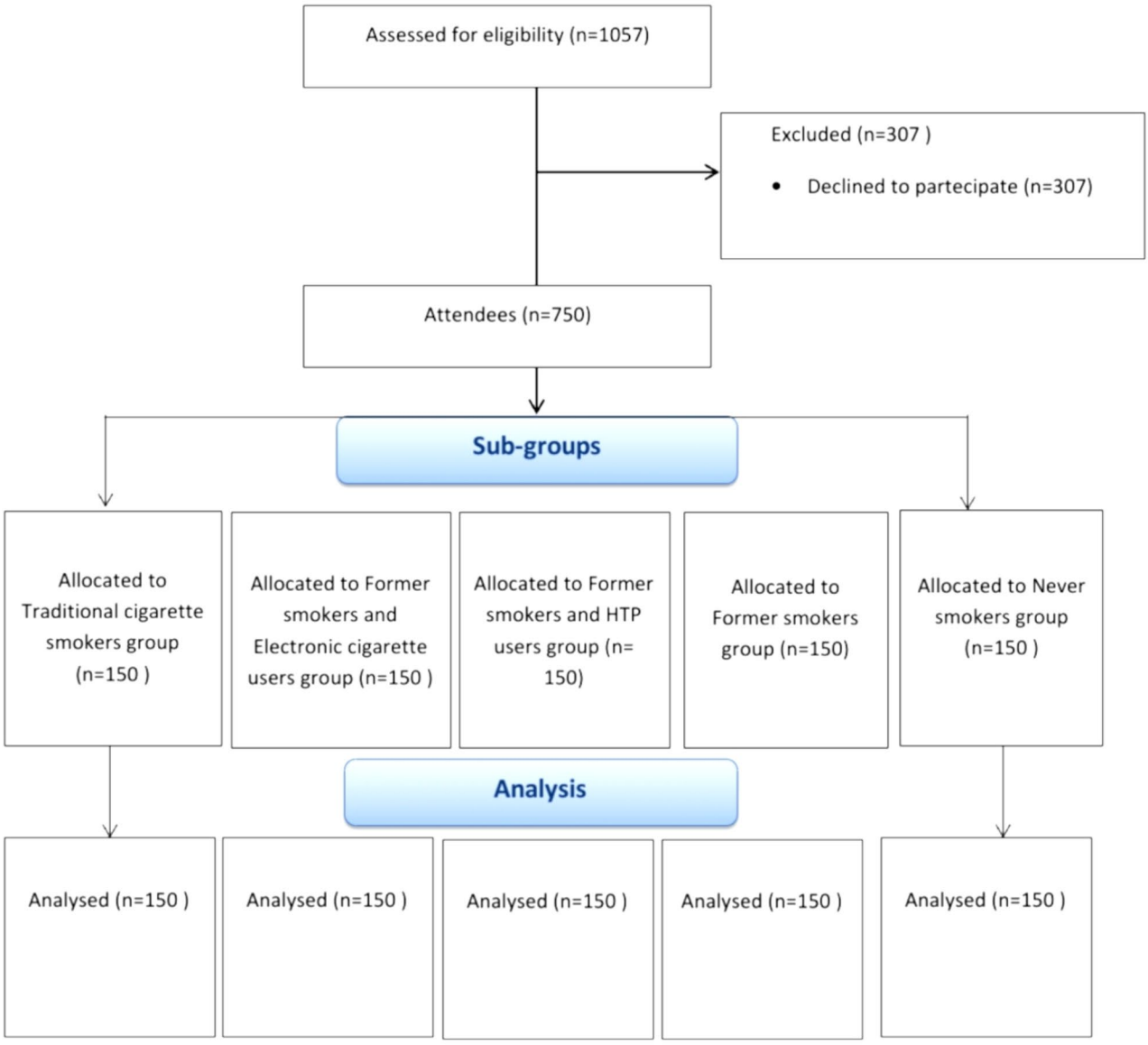

Fig. 1 Flow of participants. *After screening, a total of 750 subjects consented to participate and were included in the study. Participants were allocated into five separate study groups

($r = 0.51$, $p < 0.0001$), even independent of tobacco use status (standardized beta = 0.48, $p < 0.0001$). As expected, because chronic smoking leads to respiratory symptoms, in the groups with a history of smoking, there was a high correlation between IT-RSES scores and the number of years the participant had smoked ($r = 0.61$, $p < 0.0001$), even independent of current tobacco use status (standardized beta = 0.70, $p < 0.0001$). The relationship was linear, with no significant curvilinearity (Table 1).

In a test of "known-groups validity," we compared IT-RSES scores of Smokers and Never Smokers, adjusting for age. Smokers' scores were significantly higher (Adjusted means 2.17 vs. 1.49, SEs 0.06, significant by THSD). The difference held when the sample was limited to those without respiratory conditions (2.02 vs. 1.36, SEs 0.05, significant by THSD).

Former smokers were also compared to Smokers, adjusting for years smoked, as a test of ability to detect presumed changes in respiratory symptoms due to stopping smoking (Fig. 2).

Former Smokers had significantly lower IT-RSES scores than did smokers (1.63 vs. 2.16, SEs 0.06, significant by THSD).

Table 1 Participants' characteristics

	Tobacco Use Group											
	Traditional cigarettes		Former smokers		HTP		E-cigarettes		Never smokers		All	
	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev
Age	38.88a	15.22	40.15a	14.56	32.52b	11.29	40.38a	13.66	24.67c	5.60	35.32	13.91
Years of smoking cigarettes	19.99a	15.01	15.77b	12.95	12.67b	11.85	20.67a	14.23	--	--	17.28	13.92
Gender												
Male	48%		57%		41%		59%		31%		47%	
Female	52%		43%		59%		41%		69%		53%	
Educational level												
Elementary	8%		5%		3%		7%		1%		5%	
High school	16%		19%		10%		21%		1%		13%	
Secondary school	41%		51%		42%		51%		32%		43%	
University	35%		26%		45%		21%		67%		39%	
Health status												
Not Good	23%		24%		20%		27%		13%		20%	
Any respiratory condition												
Yes	12%		5%		5%		3%		9%		7%	

*Means with different letter superscrips differ significantly from each other

Respiratory symptoms among HTP users and ENDS users

As seen in Fig. 2, in comparisons adjusted for age, both HTP Users and ENDS Users had IT-RSES scores significantly lower than those seen in Smokers, and not significantly different from those in Never Smokers (Comparisons with Former Smokers are compromised by the fact that Former Smokers scored (non-significantly) lower than Never Smokers and that the analyses are not adjusted for years smoked).

As also seen in Fig. 2, when additionally adjusting for years of smoking (and thus precluding comparisons to the Never-Smokers), Former Smokers, HTP users, and ENDS Users all had scores significantly lower than Smokers' scores (all $p < 0.05$), and not significantly different from each other.

Supplementary Table 3 reports the tobacco use groups' scores on the scale and on each component item without adjustment, with adjustment for age, and with adjustment for age and years of smoking (for the groups with smoking history).

Discussion

Assessment of respiratory symptoms in smokers and former smokers is of clinical and research relevance. However, there is currently a dearth of specific tools available for this purpose, and none in languages other than English. While many instruments are available for assessing clinically significant symptoms in those already diagnosed with various diseases [24–27], it is useful to have a tool for assessing respiratory symptoms in more general samples of smokers and former smokers. Such tools could be used to help assess positive or negative changes in symptoms attending smokers' switching to other products such as ENDS or HTPs.

Thus, validated tools for assessing respiratory health in smokers could improve our ability to detect subtle respiratory changes in smokers before they manifest as clinically diagnosable disease, helping enhance early diagnosis, clinical management, and intervention to reduce the risk of tobacco-related lung disease [28]. Appropriate respiratory symptom assessments for smokers could also provide a more nuanced understanding of the risk profiles associated with different tobacco products, which could inform action by clinicians and regulators [29, 30] and could be useful in clinical trials [31, 32].

Comparison with other respiratory symptom scales

The RSES has several similarities and differences compared to other validated respiratory symptom scales used in previous studies. One notable point of comparison is the measure of functionally important respiratory symptoms developed in the Population Assessment of Tobacco and Health (PATH) study, which was validated in a large, nationally representative U.S. sample

Table 2 Item and scale statistics: factor loadings, score distributions, and means and standard deviations

Item #	Content	Factor Loading	1	2	3	4	5	Mean	Std Dev
Item 1	Morning cough	0.81	50%	24%	14%	8%	4%	1.92	1.15
Item 2	Cough freq	0.86	59%	20%	12%	7%	2%	1.72	1.04
Item 3	Short breath	0.87	63%	19%	11%	5%	2%	1.62	0.96
Item 4	Winded	0.88	64%	21%	10%	4%	2%	1.60	0.95
Item 5	Wheeze	0.89	72%	15%	8%	3%	1%	1.46	0.85
IT-RSES*	--	--	34%	43%	14%	7%	2%	1.66	0.85

* For IT-RSES scale scores, which can take decimal values, column values represent scores of 1, <=2, <=3, <=4, >4

Table 3 Exploratory factor analysis (EFA)

	Factor 1
ITEM 1	0.880
ITEM 2	0.862
ITEM 3	0.842
ITEM 4	0.801
ITEM 5	0.705

[33]. The PATH-based respiratory symptom index was designed to assess the presence of functionally limiting respiratory symptoms, such as shortness of breath and activity-related dyspnea, and has been used to examine associations between tobacco use and long-term respiratory health outcomes.

One of the key differences between RSES and the PATH-based respiratory symptom index lies in their respective designs and applications. The RSES was developed specifically to assess symptom burden across different tobacco user categories, with a focus on frequency of respiratory symptoms, and an emphasis on symptoms that may not reach the level of functional or clinical significance, but can be sensitive to changes in tobacco product use behavior. In contrast, the PATH respiratory symptom index has been used to assessing functionally important respiratory symptoms, indicative of airway obstruction, in a large nationally representative sample of U.S. adults without COPD [33]. Additionally, possible thresholds for determining "functionally important respiratory symptoms" were used to assess the relationship between exposures, such as tobacco product use, and respiratory illness [34, 35].

A major advantage of the RSES is its ability to capture a broader range of symptom experiences across different user groups, including conventional smokers, former smokers, and users of alternative nicotine products such as heated tobacco products (HTPs) and e-cigarettes. This is particularly relevant given that findings from PATH indicate that former smokers have a significantly lower

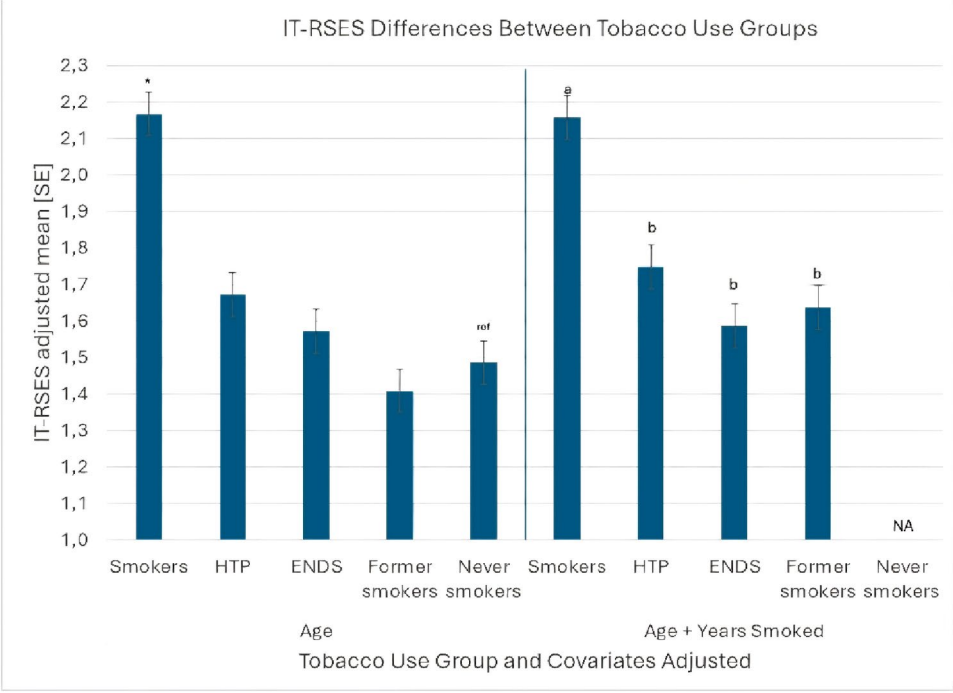

Fig. 2 IT-RSES differences between Tobacco Use Groups. *In the left panel, asterisks indicate significant differences vs. Never Smokers. In the right panel, bars that share a letter do not differ significantly from each other, by Turkey's Honestly Significant Difference test

prevalence of functionally limiting respiratory symptoms compared to current smokers [34]. Moreover, in an analysis of adolescent and young adult tobacco users, Tanski et al. (2022) found that cigarette smoking and secondhand smoke exposure were cross-sectionally associated with functionally important respiratory symptoms. The risk increased with increasing frequency of cigarette use but not with electronic cigarette use [35]. This makes it a valuable tool for evaluating respiratory symptom burden in populations with varying levels of tobacco exposure. On the other hand, the PATH-based index, by focusing on functionally limiting symptoms, provides insights into more severe respiratory health outcomes, which may be particularly relevant for clinical assessments [36].

The findings of the present study align with previous PATH-based research showing that smoking is strongly associated with respiratory symptoms, and that former smokers generally report fewer symptoms over time [34]. However, our results add to this body of literature by providing further evidence on how alternative nicotine products, such as e-cigarettes and HTPs, may be associated with lower symptom burden compared to continued smoking.

Our findings in this Italian population were also consistent with those of Shiffman et al.'s study in the US [18]. While detailed quantitative comparisons are difficult because of differences in sampling and other factors (notably, the US sample was much older [average age in the 60s] and almost half had respiratory-relevant medical conditions), broad comparative conclusions emerge. Despite cultural and other differences in the populations, both studies found that former smokers have less respiratory symptoms than current smokers, suggesting that smoking cessation is associated with remission of some symptoms. Both studies also showed that smokers who switched completely to ENDS had fewer symptoms than those who continued smoking, with symptom levels comparable to those who stopped smoking without taking up ENDS. Replication across these two diverse samples lends confidence in these findings.

The Italian version of RSES

The RSES has potential to fill the gap in assessment of respiratory symptoms, but its utility is potentially limited by being English-only and online-only. The present study showed that a carefully-crafted Italian translation, the IT-RSES, is, like the original RSES, unidimensional and highly reliable. The IT-RSES also demonstrated validity with respect to distinguishing smokers from never-smokers, and this distinction held even when participants with diagnoses of respiratory conditions were excluded. This shows the instrument met its stated goal of assessing smokers' symptoms at levels below those attending diagnoses of respiratory disease. Former smokers also showed lower IT-RSES symptoms than smokers did, suggesting that the IT-RSES likely can detect changes in symptoms attending smoking cessation for six months or more. As the duration of former smokers' abstinence was not known, these data do not address how rapidly such changes may occur. Longitudinal studies of smokers who are quitting would shed light on this. The demonstrated associations with smoking status confirm the IT-RSES' validity.

The RSES' ability to capture smokers' respiratory symptoms, and its sensitivity to changes with smoking cessation made it a good candidate for assessing the impact on respiratory symptoms of inhaled non-combusting tobacco / nicotine products such as HTPs and ENDS. Analyses adjusting for age and years of smoking showed that users of HTPs or ENDS had symptom scores lower than those of current smokers, which is suggestive of their potential to reduce harm. This is consistent with several other studies that have reported lower respiratory symptoms in smokers who switched to HTPs or ENDS [37–39].

In addition to favorable comparisons to continuing smokers, in the adjusted analyses, HTP and ENDS users had symptom scores that were not significantly different from those of former smokers who stopped smoking without using HTPs or ENDS, suggesting that such products may not themselves produce symptoms of the kind measured by the RSES. This seems at odds with a study suggesting increased symptoms in never-smokers using e-cigarettes [40]. It may be that such impacts on symptoms are not seen in former smokers who already have residual symptoms from their years of smoking. Of course, further research with larger samples is needed to confirm the suggestive conclusions of this study.

Overall, these findings add to accumulating evidence of the potential for switching to HTPs and ENDS to reduce smokers' disease risks. This includes not only favorable findings on respiratory symptoms [41], but also documentation of lowered exposure to cigarette-smoking-related toxicants [42], and lowered biomarkers of potential harm [43], including those associated with the development of respiratory disease. Because it is difficult to observe effects on disease and mortality until products have been used by large populations for many years, further research focusing on symptoms (respiratory and otherwise) as leading clinical indicators can be important, and the RSES is a useful tool in that endeavor.

The present study had limitations. The sample, though diverse with respect to tobacco/nicotine product use, was not necessarily representative of the adult population of Italy, though that does not invalidate the analyses reported here. Further psychometric work on reliability over time and longitudinal data can help establish the

IT-RSES' sensitivity to change, which will be important for studying changes when smokers stop smoking.

The relatively young sample skew and lack of data on dual use or product-specific exposure levels could be considered as other limitations. Our understanding of the dynamics of respiratory symptoms might have been advanced with data on the amount and duration of HTP and ENDS use to assess dose-response for respiratory symptoms, and also to have relevant biomarkers to compare against reported symptoms. Those remain tasks for future research.

Comparison of RSES scores between US and Italian studies

The IT-RSES validation demonstrates construct validity through the observed patterns of respiratory symptom reporting across different tobacco use categories. Similar to the original US validation study, our Italian data showed that active smokers consistently reported the highest symptom scores, followed by alternative product users and former smokers, with never smokers reporting the lowest symptom burden. This consistent pattern suggests that the IT-RSES effectively captures the expected relationship between tobacco product use and respiratory symptoms, regardless of cultural context. However, direct comparisons between the two studies should be interpreted with caution due to several important methodological differences. These include: different recruitment strategies, with the US study including participants with relevant medical conditions; potential variations in definitions of user categories; differences in types and duration of alternative product use; varying demographic characteristics; and potential cultural differences in symptom reporting behavior. Rather than focusing on specific score comparisons, the similar pattern of results across tobacco use categories in both populations provides stronger evidence for the cross-cultural applicability of the RSES conceptual framework. The IT-RSES thus represents a validated tool for measuring self-reported respiratory symptoms that maintains the underlying construct validity of the original measure while being culturally appropriate for the Italian context.

Conclusion

This translation and psychometric testing of the IT-RSES indicates that it is a reliable and valid method of assessing respiratory symptoms in smokers, even among those who have not (yet) been diagnosed with respiratory disease. Use of the IT-RSES enabled the study to show that smokers who switch completely to HTPs or ENDS have levels of respiratory symptoms close to those in people who never smoked and those who stopped smoking without ENDS or HTPs, and lower than those in continuing smokers. This adds to the evidence for the harm-reduction potential of ENDS and HTPs for adult smokers. Future research will focus on longitudinal predictive validation of the IT-RSES. Our research group is currently designing a prospective study to assess how IT-RSES scores predict subsequent respiratory health outcomes and changes in tobacco use behaviors over time in an Italian population.

Abbreviations

CoEHAR	Center of Excellence for the Acceleration of Harm Reduction
COPD	Chronic Obstructive Pulmonary Disease
EFA	Exploratory Factor Analysis
ENDS	Electronic Nicotine Delivery Systems
HTP	Heated Tobacco Product
IT-RSES	Italian Version of the Respiratory Symptom Experience Scale
PATH	Population Assessment of Tobacco and Health
PCA	Principal Component Analysis
RSES	Respiratory Symptom Experience Scale
THSD	Tukey's Honestly Significant Difference

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12889-025-22824-y.

Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

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Author contributions

P.C. contributed to the conceptualization, project administration, methodology, formal analysis, supervision, and writing of the original draft and review and editing of the manuscript. S.S. contributed to methodology, formal analysis, study design, data curation, supervision, and writing of the original draft and review and editing of the manuscript. G.C.P. contributed to methodology, formal analysis, data curation, and writing of both the original draft and the review and editing. R.P. contributed to methodology, formal analysis, study design, data curation, supervision, and writing of the original draft and review and editing of the manuscript.

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Data availability

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study adhered to the ethical principles outlined in the Declaration of Helsinki. Ethics approval was obtained from the Ethics Review Board of the Department of Educational Sciences, Section of Psychology at the University of Catania (Approval Date: January 3, 2023). All participants provided informed consent before enrollment, including consent for the collection and analysis of their data for research purposes.

Consent for publication

Not applicable. This manuscript does not include identifiable individual data requiring consent for publication.

Competing interests

SS through PinneyAssociates, provides consulting on tobacco harm reduction exclusively to JUUL Labs, Inc. RP is a full-time employee of the University of Catania, Italy. In relation to his work in the area of tobacco control and respiratory diseases, RP has received lecture fees and research funding from Pfzer, GlaxoSmithKline, CV Therapeutics, NeuroSearch A/S, Sandoz, MSD, Boehringer Ingelheim, Novartis, Duska Therapeutics, and Forest Laboratories. He has also served as a consultant for Pfzer, Global Health Alliance for treatment of tobacco dependence, CV Therapeutics, NeuroSearch A/S, Boehringer Ingelheim, Duska Therapeutics, Forest Laboratories, ECITA (Electronic Cigarette Industry Trade Association, in the UK) and Health Diplomat (a consulting company that delivers solutions to global health problems with special emphasis on harm minimization). Lecture fees from a number of European electronic cigarette industry and trade associations (including FIVAPE in France and FIESEL in Italy) were directly donated to vaper advocacy non-profit organizations. He is currently a scientific advisor for LIAF, Lega Italiana Anti Fumo (Italian acronym for Italian Anti-Smoking League) and Head of the European Technical Committee for standardization on "Requirements and test methods for emissions of electronic cigarettes" (CEN/TC 437; WG4). PC and GCP have no conflicts of interest to declare.

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References

1. U.S. Department of Health and Human Services. How Tobacco Smoke Causes Disease. The biology and behavioral basis for Smoking-Attributable disease: A report of the surgeon general. Atlanta, GA: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2010. Accessed September 2017.
2. Morjaria JB, Malerba M, Polosa R. Biologic and Pharmacologic therapies in clinical development for the inflammatory response in COPD. Drug Discov Today. 2010;15(9–10):396–405.
3. MacNee W. Pathogenesis of chronic obstructive pulmonary disease. Proc Am Thorac Soc. 2005;2:258–66. discussion 290– 251.
4. Qaseem A, Wilt TJ, Weinberger SE, Hanania NA, Criner G, van der Molen T, Marciniuk DD, Denberg T, Schünemann H, Wedzicha W, MacDonald R, Shekelle P, American College of Physicians; American College of Chest Physicians; American Thoracic Society; European Respiratory Society. Diagnosis and management of stable chronic obstructive pulmonary disease: a clinical practice guideline update from the American college of physicians, American college of chest physicians, American thoracic society, and European respiratory society. Ann Intern Med. 2011;155(3):179–91.
5. Woodruff PG, Barr RG, Bleecker E, Christenson SA, Couper D, Curtis JL, Gouskova NA, Hansel NN, Hoffman EA, Kanner RE, Kleerup E, Lazarus SC, Martinez FJ, Paine R 3rd, Rennard S, Tashkin DP, Han MK, SPIROMICS Research Group. Clinical significance of symptoms in smokers with preserved pulmonary function. N Engl J Med. 2016;374(19):1811–21. https://doi.org/10.1056/NEJMoa1505971.
6. Bazzan E, Semenzato U, Turato G, Biondini D, Cubero P, Marin-Oto M, Forner M, Tinè M, Casara A, Baraldo S, Spagnolo P, Marin JM, Saetta M, Cosio MG. Symptomatic smokers without COPD have physiological changes heralding the development of COPD. ERJ Open Res. 2022;8(2):00202–2022. https://doi.org/10.1183/23120541.00202-2022.
7. McKleroy W, Shing T, Anderson WH, Arjomandi M, Awan HA, Barjaktarevic I, Barr RG, Bleecker ER, Boscardin J, Bowler RP, Buhr RG, Criner GJ, Comellas AP, Curtis JL, Dransfield M, Doerschuk CM, Dolezal BA, Drummond MB, Han MK, Hansel NN, Helton K, Hoffman EA, Kaner RJ, Kanner RE, Krishnan JA, Lazarus SC, Martinez FJ, Ohar J, Ortega VE, Paine R 3rd, Peters SP, Reinhardt JM, Rennard S, Smith BM, Tashkin DP, Couper D, Cooper CB, Woodruff PG. Longitudinal Follow-Up of participants with tobacco exposure and preserved spirometry. JAMA. 2023;330(5):442–53. https://doi.org/10.1001/jama.2023.11676.
8. Goniewicz ML, Miller CR, Sutanto E, Li D. How effective are electronic cigarettes for reducing respiratory and cardiovascular risk in smokers? A systematic review. Harm Reduct J. 2020;17(1):91. https://doi.org/10.1186/s12954-020-00440-w. Published 2020 Nov 23.
9. Jones PW, Quirk FH, Baveystock CM. The St George's respiratory questionnaire. Respir Med. 1991. https://doi.org/10.1016/s0954-6111(06)80166-6. 85 Suppl B:25–31; discussion 33– 7.
10. Williams JE, Singh SJ, Sewell L, Guyatt GH, Morgan MD. Development of a self-reported chronic respiratory questionnaire (CRQ-SR). Thorax. 2001;56(12):954–9. https://doi.org/10.1136/thorax.56.12.954.
11. 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. https://doi.org/10.1186/1477-7525-1-13.
12. 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.
13. Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. Ther Adv Drug Saf. 2014;5(2):67–86. https://doi.org/10.1177/2042098614524430.
14. Goniewicz ML, Knysak J, Gawron M, et al. Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. Tob Control. 2014;23(2):133–9. https://doi.org/10.1136/tobaccocontrol-2012-050859.
15. Shiffman S, Oliveri DR, Goldenson NI, Liang Q, Black RA, Mishra S. Comparing adult smokers who switched to JUUL versus continuing smokers: biomarkers of exposure and of potential harm and respiratory symptoms. Nicotine Tob Res. 2024;26(4):494–502. https://doi.org/10.1093/ntr/ntad197.
16. Polosa R, Morjaria JB, Prosperini U et al. Health outcomes in COPD smokers using heated tobacco products: a 3-year follow-up [published correction appears in Intern Emerg Med. 2022;17(6):1849. doi: 10.1007/s11739-022-03043-4]. Intern Emerg Med. 2021;16(3):687–696. https://doi.org/10.1007/s11739-021-02674-3
17. Chaiton M, Pienkowski M, Musani I, et al. Smoking, e-cigarettes and the effect on respiratory symptoms among a population sample of youth: retrospective cohort study. Tob Induc Dis. 2023;21:08. https://doi.org/10.18332/tid/156839. Published 2023 Jan 21.
18. Shiffman S, McCaffrey SA, Hannon MJ, et al. A new questionnaire to assess respiratory symptoms (The respiratory symptom experience Scale): quantitative psychometric assessment and validation study. JMIR Form Res. 2023;7:e44036. https://doi.org/10.2196/44036.
19. Evers A, Muñiz J, Hagemeister C, et al. Assessing the quality of tests: revision of the EFPA review model. Psicothema. 2013;25(3):283–91. https://doi.org/10.7334/psicothema2013.97.
20. Wild D, Grove A, Martin M, et al. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR task force for translation and cultural adaptation. Value Health. 2005;8(2):94–104.
21. Liu Y, Pleasants RA, Croft JB, et al. Smoking duration, respiratory symptoms, and COPD in adults aged ≥ 45 years with a smoking history. Int J Chron Obstruct Pulmon Dis. 2015;10:1409–16. https://doi.org/10.2147/COPD.S82259. Published 2015 Jul 21.
22. Roman MA, Rossiter HB, Casaburi R. Exercise, ageing and the lung. Eur Respir J. 2016;48(5):1471–86. https://doi.org/10.1183/13993003.00347-2016.
23. Abdi H, Williams LJ. Turkey's honestly significant difference (HSD) test. Encyclopedia of research design. Thousand Oaks: Sage; 2010. pp. 1–5.
24. McCaffrey S, Shiffman S, Hannon MJ, Goldenson NI, Black RA. Development and validation of a new questionnaire appropriate to assess respiratory symptoms in current and former smokers without chronic obstructive pulmonary disease: the respiratory symptom questionnaire (RSQ). Published Online January. 2022;28. https://doi.org/10.21203/rs.3.rs-1297115/v1.
25. Karlsson N, Atkinson MJ, Müllerová H, et al. Validation of a diagnosis-agnostic symptom questionnaire for asthma and/or COPD. ERJ Open Res. 2021;7(1):00828–2020. https://doi.org/10.1183/23120541.00828-2020.
26. Tosca MA, Schiavetti I, Ciprandi G, et al. The challenge of asthma control grading in clinical practice. Respiratory Invest. 2021;59(5):683–5. https://doi.org/10.1016/j.resinv.2021.06.001.

27. Zampogna E, Ambrosino N, Centis R, et al. Minimal clinically important difference of the 6-min walking test in patients with asthma. Int J Tuberc Lung Dis. 2021;25(3):215–21. https://doi.org/10.5588/ijtld.20.0928.
28. Sahin H, Naz I. Comparing the effect of pulmonary rehabilitation in patients with uncontrolled and partially controlled asthma. J Asthma. 2019;56(1):87–94. https://doi.org/10.1080/02770903.2018.1443468.
29. Global Initiative for Asthma: Global Strategy for Asthma Management and Prevention. 2018. Available at: http://ginasthma.org/wpcontent/uploads/2018/04/wms-GINA-2018-report-V1.3-002.pdf
30. Polosa R, Rodu B, Caponnetto P, Maglia M, Raciti C. A fresh look at tobacco harm reduction: the case for the electronic cigarette. Harm Reduct J. 2013;10(1):19. https://doi.org/10.1186/1477-7517-10-19.
31. Gotts JE, Jordt SE, McConnell R, Tarran R. What are the respiratory effects of e-cigarettes? BMJ. Published Online September. 2019;30:l5275. https://doi.org/10.1136/bmj.l5275.
32. Schraufnagel DE. Electronic cigarettes: vulnerability of youth. Pediatric allergy. Immunol Pulmonol. 2015;28(1):2–6. https://doi.org/10.1089/ped.2015.0490.
33. Halenar MJ, Sargent JD, Edwards KC, Woloshin S, et al. Validation of an index for functionally important respiratory symptoms among adults in the nationally representative population assessment of tobacco and health study, 2014–2016. Int J Environ Res Public Health. 2021;18(18):9688. https://doi.org/10.3390/ijerph18189688.
34. Sargent JD, Halenar MJ, Edwards KC, Woloshin S et al. Tobacco Use and Respiratory Symptoms Among Adults: Findings From the Longitudinal Population Assessment of Tobacco and Health (PATH) Study 2014–2016. Nicotine Tob Res. 2022;24(10):1607–1618. https://doi.org/10.1093/ntr/ntac080. Erratum in: Nicotine Tob Res. 2024;27(1):164. doi: 10.1093/ntr/ntae235.
35. Tanski S, Halenar MJ, Edwards KC, Emond J, et al. Tobacco product use and functionally important respiratory symptoms among US adolescents/young adults. Acad Pediatr. 2022;22(6):1006–16. https://doi.org/10.1016/j.acap.2022.03.001.
36. Sargent JD, Lauten K, Edwards KC, Tanski SE, et al. Functionally important respiratory symptoms and continued cigarette use versus e-cigarette switching: population assessment of tobacco and health study waves 2–6. EClinicalMedicine. 2024;79:102951. https://doi.org/10.1016/j.eclinm.2024.102951.
37. Znyk M, Jurewicz J, Kaleta D. Exposure to heated tobacco products and adverse health effects, a systematic review. Int J Environ Res Public Health. 2021;18(12):6651. https://doi.org/10.3390/ijerph18126651. Published 2021 Jun 21.
38. Edmiston JS, Webb KM, Wang J, Oliveri D, Liang Q, Sarkar M. Biomarkers of exposure and biomarkers of potential harm in adult smokers who switch to e-Vapor products relative to cigarette smoking in a 24-week, randomized, clinical trial. Nicotine Tob Res. 2022;24(7):1047–54. https://doi.org/10.1093/ntr/ntac029.
39. Oliveri D, Liang Q, Sarkar M. Real-World evidence of differences in biomarkers of exposure to select harmful and potentially harmful constituents and biomarkers of potential harm between adult E-Vapor users and adult cigarette smokers. Nicotine Tob Res. 2020;22(7):1114–22. https://doi.org/10.1093/ntr/ntz185.
40. Polosa R, Morjaria JB, O'Leary R, et al. Respiratory symptoms among e-cigarette users without an established history of combustible cigarette smoking. Sci Rep. 2024;14:80221. https://doi.org/10.1038/s41598-024-80221-8.
41. Gale N, McEwan M, Eldridge AC, et al. Changes in biomarkers of exposure on switching from a conventional cigarette to tobacco heating products: A randomized, controlled study in healthy Japanese subjects. Nicotine Tob Res. 2019;21(9):1220–7. https://doi.org/10.1093/ntr/nty104.
42. Goodall S, Gale N, Thorne D, et al. Evaluation of behavioural, chemical, toxicological and clinical studies of a tobacco heated product glo™ and the potential for bridging from a foundational dataset to new product iterations. Toxicol Rep. 2022;9:1426–42. https://doi.org/10.1016/j.toxrep.2022.06.014. Published 2022 Jun 25.
43. Shahab L, Goniewicz ML, Blount BC, et al. Nicotine, carcinogen, and toxin exposure in Long-Term E-Cigarette and nicotine replacement therapy users: A Cross-sectional study. Ann Intern Med. 2017;166(6):390. https://doi.org/10.7326/M16-1107.

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