

# Assessing Dentists' knowledge and training needs in smoking cessation and Electronic Nicotine Delivery Systems: a cross-sectional study in Kosovo

Avaliação do conhecimento e das necessidades de treinamento de dentistas em cessação do tabagismo e Sistemas Eletrônicos de Liberação de Nicotina: um estudo transversal em Kosovo

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**How to cite:** Dalipi ZS, Krasniqi MS, Shabani DB, Dula L. Assessing Dentists' knowledge and training needs in smoking cessation and Electronic Nicotine Delivery Systems: a cross-sectional study in Kosovo. *Braz Dent Sci.* 2025;28(1):e4530. <https://doi.org/10.4322/bds.2025.e4530>

## ABSTRACT

**Background:** Electronic cigarettes (e-cigarettes) vaporize a liquid solution containing nicotine and are marketed as safer than traditional tobacco. However, they are linked to health issues, including cardiovascular, respiratory, and oral problems. Dental professionals play a key role in educating patients and supporting smoking cessation. **Objective:** This study evaluates dentists' knowledge of smoking cessation methods in Kosovo and identifies the need for further training. **Material and Methods:** The study involved 189 licensed dentists in Kosovo, using an 18-question questionnaire to assess their discussions about e-cigarettes, smoking cessation knowledge, and training participation. Data were analyzed using SPSS 22. **Results:** Among participants, 42.9% were male and 57.1% female. Most (63.0%) felt confident discussing e-cigarettes' harmful effects, while only 36.5% were knowledgeable about advanced cessation methods, and 11.6% were familiar with structured intervention models like the 5As and 5Rs. Participation in training was low (27.0%). Dentists showed confidence in discussing e-cigarettes but lacked knowledge of advanced cessation methods. This gap highlights the need for standardized educational programs to improve counseling effectiveness. **Conclusion:** While dentists in Kosovo recognize the risks of e-cigarettes, there is a clear need for enhanced training in smoking cessation methods to better support patients.

## KEYWORDS

Electronic nicotine delivery systems; Oral health; Professional education; Smoking; Tobacco use cessation.

## RESUMO

**Contexto:** Os cigarros eletrônicos (VAPE) vaporizam uma solução líquida contendo nicotina e são vendidos como mais seguros do que o cigarro convencional. No entanto, eles estão ligados a problemas de saúde, incluindo problemas cardiovasculares, respiratórios e bucais. Os profissionais de odontologia desempenham um papel fundamental na educação dos pacientes e no apoio à cessação do tabagismo. **Objetivo:** Este estudo avalia o conhecimento dos dentistas sobre os métodos de cessação do tabagismo em Kosovo e identifica a necessidade de treinamento adicional. **Material e Métodos:** O estudo envolveu 189 dentistas habilitados em Kosovo, usando um questionário de 18 perguntas para avaliar suas discussões sobre cigarros eletrônicos, conhecimento sobre cessação do tabagismo e participação no treinamento. Os dados foram analisados usando o SPSS-22. **Resultados:** Entre os participantes, 42,9% eram homens e 57,1% mulheres. A maioria (63,0%) se sentiu confiante em discutir os efeitos nocivos dos cigarros eletrônicos, enquanto apenas 36,5% tinham conhecimento sobre métodos avançados de cessação,

e 11,6% estavam familiarizados com modelos de intervenção estruturados como os 5As e 5Rs. A participação no treinamento foi baixa (27,0%). Os dentistas mostraram confiança em discutir os cigarros eletrônicos, mas não tinham conhecimento sobre métodos avançados de cessação. Essa lacuna destaca a necessidade de programas educacionais padronizados para melhorar a eficácia do aconselhamento. **Conclusão:** Embora os dentistas em Kosovo reconheçam os riscos dos cigarros eletrônicos, há uma necessidade clara de capacitação aprimorada em métodos de cessação do tabagismo para fornecimento de melhor suporte aos pacientes.

## PALAVRAS-CHAVE

Usos de cigarros eletrônicos; Saúde bucal; Educação Profissional em Saúde Pública; Tabagismo; Cessação tabágica.

## INTRODUCTION

The most common and significant independent risk factor for periodontal disease that can affect the host's immune-inflammatory response is smoking [1]. Electronic cigarettes (e-cigarettes) are battery-operated devices that produce an aerosol by heating a liquid. They are commonly known as vapes, vape pens, e-cigs, and electronic nicotine delivery systems [2,3]. These devices typically use e-liquids, which are solutions made from glycerol and/or propylene glycol, and vary in nicotine concentration [4]. Nicotine, the primary addictive substance in traditional tobacco products, is also a prominent ingredient in e-cigarettes. Its presence in e-cigarettes contributes to their addictive potential, similar to conventional cigarettes, making it difficult for users to quit [5].

Originally designed as a less harmful alternative to traditional tobacco smoking, e-cigarettes have gained significant popularity. This increase is due to factors such as the wide range of appealing flavors, the absence of smoke and its odors, their sleek and modern appearance, and their ability to provide high nicotine levels [6].

The impact of electronic cigarettes (e-cigarettes) on various clinical outcomes remains unclear due to insufficient or missing evidence. This includes conditions such as cancer, cardiovascular diseases, respiratory disorders beyond lung injury, mental health issues, developmental and reproductive health concerns, sleep disturbances, neurological conditions excluding seizures, and various endocrine, olfactory, optical, allergic, and hematological conditions. However, there is substantial evidence indicating that e-cigarettes contribute to indoor air pollution, generate waste, and pose fire hazards. Additionally, while direct evidence is limited, there are indications that e-cigarette use may adversely affect cardiovascular

health markers, including blood pressure and heart rate, lung function, and adolescent brain development and function [7,8].

In vitro studies have shown that aldehydes and free radicals in e-cigarette aerosols cause oxidative stress, alterations in cellular antioxidant activity, and DNA damage—changes that are expected to ultimately lead to periodontal tissue destruction and alveolar bone loss, both characteristic of periodontal diseases [9]. The increased plaque accumulation and deeper periodontal pockets observed in e-cigarette users may be linked to the inflammatory effects of chemicals in e-cigarette aerosols, which can disrupt oral health and promote the development of periodontal disease [10].

Furthermore, clinical research indicates that vaping negatively affects gum health, with e-cigarette users demonstrating a less favorable response to periodontal treatments compared to non-smokers. The chemicals in e-cigarette vapor can induce inflammation and gum damage, increasing the risk of periodontal issues such as gingivitis and periodontitis. Additionally, the healing process after periodontal treatments may be impaired in individuals who vape [11].

Dental healthcare professionals, including dentists, play a crucial role in raising awareness about the adverse effects of electronic cigarettes. Beyond providing medical care, they are instrumental in educating patients about the potential health risks associated with e-cigarettes and vaping. Their efforts include informing patients about the impact of these products on various aspects of health, such as cardiovascular, respiratory, and oral health. By highlighting these risks, healthcare professionals help patients make informed decisions and take preventive measures to protect their well-being [12-15]. However, effective smoking cessation strategies

require adequate knowledge and training. In this context, structured models such as the 5As, 5Rs, and STAR method have been developed to help healthcare providers, including dentists, deliver comprehensive and effective smoking cessation interventions [16].

Despite their proven benefits, studies suggest that smoking cessation education is often underemphasized in dental training programs. Dental professionals who receive formal education in smoking cessation strategies are significantly more effective in supporting patients in quitting smoking compared to those without such training.

The aim of this study is to evaluate dentists' knowledge of smoking cessation methods and the importance of training for dentists to effectively provide patients with comprehensive information and support regarding smoking cessation strategies.

This study hypothesizes that although dentists in Kosovo have a basic understanding of smoking cessation techniques, there is a significant gap in their knowledge of structured intervention models and advanced cessation strategies, emphasizing the need for targeted training programs.

## MATERIAL AND METHODS

This cross-sectional study was conducted from May-September 2024 and adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines. The study aimed to assess dentists' knowledge and training needs in smoking cessation and electronic nicotine delivery systems in Kosovo. The 189 dentists were selected from those licensed by the Kosovo Dental Chamber and working in both public and private healthcare institutions across Kosovo. Dentists were randomly selected to participate in the study, with inclusion based on their availability and willingness to engage during the designated study period.

The participants were selected to provide a comprehensive evaluation of their knowledge and training concerning smoking cessation methods. The sample size of 189 dentists was determined based on a power analysis to achieve a confidence level of 95% and a margin of error of  $\pm 5\%$ . The final number ensured representativeness of active dental professionals in Kosovo.

The study employed an 18-question questionnaire, divided into six sections. The first section included three descriptive questions about dentists' approach to discussing e-cigarettes with patients based on gender. The second section addressed how dentists approach discussing e-cigarettes with patients based on their professional education/training. The third section focused on participants' knowledge of smoking cessation methods, categorized by gender. The fourth section assessed the level of dentists' knowledge on smoking cessation methods by their education/professional training. The fifth section involved questions on participation in, and the need for, smoking cessation training among respondents based on gender. The sixth section explored participation in, and the need for, smoking cessation training among respondents based on their education/professional training. Eligibility criteria included dentists licensed by the Kosovo Dental Chamber, actively practicing in public or private clinics. Exclusion criteria included retired professionals, administrative-only roles, and those with incomplete survey responses. Anonymity was ensured by making the questionnaire anonymous, with no personal identifiers collected from the participants. This means that respondents did not have to provide their names or any other personal information that could link their responses to their identities.

Participants received an 18-question self-administered questionnaire at professional dental meetings. The survey assessed knowledge of smoking cessation methods, electronic cigarette use, and participation in training. Responses were collected anonymously and securely stored to ensure confidentiality.

The study received ethical approval from the Kosovo Dental Chamber (Approval No: 48-1-30.05.2024.). Written informed consent was obtained from all participants before survey completion, ensuring voluntary participation and confidentiality in accordance with the Declaration of Helsinki.

Data analysis was performed using SPSS 22. Chi-squared and Fisher's exact tests were used to analyze categorical variables, as they are appropriate for assessing associations between independent groups. Missing data were handled using leastwise deletion to maintain data accuracy, and significance was set at  $P < 0.05$ .

## RESULTS

Our study included 189 dentists from Kosovo, all licensed by the Kosovo Dental Chamber, of which 81 (42.9%) were male and 108 (57.1%) were female (Table I). In response to the statement, "As professionals, we do not need to discuss the harmful effects of e-cigarettes with patients," 39.7% of the dentists agreed. However, more than half (63.0%) felt confident in discussing the harmful effects of e-cigarettes with patients, and 61.4% regularly spent a few minutes talking about the impact of e-cigarettes on oral health with their patients. No significant differences based on gender were found in these responses ( $P>0.05$ ) (Table II).

Of the total respondents, 54.5% (103) were dental specialists, while 45.5% (86) were general dentists without specialization. When examining

the responses related to discussing e-cigarettes with patients based on their level of professional education, no statistically significant differences were identified ( $P>0.05$ ) (Table III).

Only 36.5% of the dentists surveyed had knowledge of the recommended non-pharmacological and pharmacological methods for smoking cessation. Additionally, just 11.6% were aware of the structured models, such as the 5As and 5Rs, used to assist with brief smoking cessation interventions, and only 10.1% were familiar with the FDA-approved STAR method for creating individualized smoking cessation plans. The structured models "5As and 5Rs" indicate a framework intended to facilitate medical professionals in implementing smoking cessation treatments. The 5As model comprises Ask, Advise, Assess, Assist, and Arrange, providing doctors

**Table I** - General characteristics of the participants

Gender	Dentist		Specialist		Total	
	N	%	N	%	N	%
F	53	51.5	55	64.0	108	57.1
M	50	48.5	31	36.0	81	42.9
Total	103	100.0	86	100.0	189	100.0
Chi test, P-value		Chi=2.50, P=0.114				

**Table II** - Dentists' approach to discussing e-cigarettes with patients according to gender

	Female		Male		Total		
	N	%	N	%	N	%	p-value
Total N	108	100.0	81	100.0	189	100.0	
%	57.1	-	42.9	-	100.0	-	
As professionals, do we not need to discuss the harmful effects of e-cigarettes with patients?							
Yes	41	38.0	34	42.0	75	39.7	p=0.748
No	50	46.3	33	40.7	83	43.9	
I don't know	17	15.7	14	17.3	31	16.4	
As a professional, do I feel prepared in my ability to discuss the harmful effects of e-cigarettes with patients?							
Yes	68	63.0	51	63.0	119	63.0	p=0.663
No	19	17.6	11	13.6	30	15.9	
I don't know	21	19.4	19	23.5	40	21.2	
How much time do you spend discussing the impact of cigarettes on oral health with patients?							
A few minutes	70	64.8	46	56.8	116	61.4	p=0.508
I don't discuss it	27	25.0	26	32.1	53	28.0	
I don't know	11	10.2	9	11.1	20	10.6	

**Table III** - Dentists' approach to discussing e-cigarettes with patients, based on professional preparation/education

	Dentist		Specialist		
	N	%	N	%	p-value
Total N	103	100.0	86	100.0	
%	54.5	-	45.5	-	
As professionals, is it not necessary for us to talk about the harmful effects of e-cigarettes with patients?					
Yes	40	38.8	35	40.7	p=0.862
No	47	45.6	36	41.9	
I don't know	16	15.5	15	17.4	
As a professional, do I feel well-prepared to address the harmful effects of e-cigarettes with patients?					
Yes	64	62.1	55	64.0	p=0.911
No	16	15.5	14	16.3	
I don't know	23	22.3	17	19.8	
How much time do you dedicate to discussing the impact of cigarettes on oral health with patients?					
A few minutes	64	62.1	52	60.5	p=0.959
I don't discuss it	28	27.2	25	29.1	
I don't know	11	10.7	9	10.5	

with an organized structure for supporting patients in cessation of smoking. The 5Rs model indicates Relevance, Risks, Rewards, Roadblocks, and Repetition, with the objective of enhancing patient motivation. The FDA-approved “STAR method” is a systematic framework for creating personalized smoking cessation strategies, which includes setting a quit date, informing family and friends, anticipating problems, and removing tobacco items to improve adherence to cessation initiatives. The questionnaire incorporated these models to evaluate dentists' awareness of evidence-based smoking cessation techniques. Nevertheless, the data revealed a limited awareness, underscoring the necessity for enhanced educational initiatives. None of these findings showed significant differences based on gender (Table IV). When evaluating the level of knowledge about smoking cessation methods by education or professional training, no statistically significant differences were found in any of the questions (Table V).

In response to the question “Have you attended any training or educational programs on smoking cessation methods as a healthcare professional?”, 27.0% of the participants answered “Yes.” Moreover, 69.3% reported learning about the effects of smoking on oral

health through professional lectures, with no significant difference between genders ( $P > 0.05$ ). When asked if ongoing professional education through lectures and awareness programs on the impact of e-cigarettes is essential for dental professionals, 86.2% of respondents agreed, again with no significant gender differences ( $P > 0.05$ ) (Table VI). The questions concerning participation in and the need for smoking cessation training were also analyzed based on professional background (dental specialists vs. general dentists), and no significant statistical differences were found ( $P > 0.05$ ) (Table VII).

## DISCUSSION

Smoking has a well-documented adverse impact on oral health, including increased risks for periodontal disease, oral cancers, and delayed healing. Given this, dentists are in a unique position to play a pivotal role in smoking cessation efforts.

Our study revealed significant gaps in dentists' knowledge regarding the latest smoking cessation methods. While most dentists were familiar with basic cessation techniques, advanced methods such as pharmacological aids and behavioral counseling were less well understood.



**Table IV** - Knowledge level of participants on smoking cessation methods, categorized by gender

	Femal		Male		Total		
	N	%	N	%	N	%	p-value
Total	108	100.0	81	100.0	189	100.0	
Are you knowledgeable about the recommended non-pharmacological and pharmacological methods for quitting smoking?							
Yes	40	37.0	29	35.8	69	36.5	p=0.213
No	41	38.0	23	28.4	64	33.9	
I don't know	27	25.0	29	35.8	56	29.6	
Do you have information on structured models available to support the implementation of brief interventions for smoking cessation (such as the 5As and 5Rs)?							
Yes	14	13.0	8	9.9	22	11.6	p=0.779
No	56	51.9	42	51.9	98	51.9	
I don't know	38	35.2	31	38.3	69	36.5	
Do you know about the STAR method for developing a personalized smoking cessation plan, which has been approved by the FDA?							
Yes	10	9.3	9	11.1	19	10.1	p=0.894
No	61	56.5	46	56.8	107	56.6	
I don't know	37	34.3	26	32.1	63	33.3	

**Table V** - Level of dentist knowledge on smoking cessation methods by education/Professional training

	Dentist		Specialist		p-value
	N	%	N	%	
Total	103	100.0	86	100.0	
Do you have information on the recommended non-pharmacological and pharmacological methods for smoking cessation?					
Yes	38	36.9	31	36.0	p=0.963
No	34	33.0	30	34.9	
I don't know	31	30.1	25	29.1	
Do you have information on structured models available to assist with the implementation of brief interventions for smoking cessation (such as the 5As and 5Rs)?					
Yes	8	7.8	14	16.3	p=0.191
No	56	54.4	42	48.8	
I don't know	39	37.9	30	34.9	
Are you familiar with the STAR method for developing an individualized smoking cessation plan, which is approved by the FDA?					
Yes	7	6.8	12	14.0	p=0.138
No	64	62.1	43	50.0	
I don't know	32	31.1	31	36.0	

**Table VI** - Participation in and need for smoking cessation training among researchers by gender

	Female		Male		Total		
	N	%	N	%	N	%	P-value
Total	108	100.0	81	100.0	189	100.0	
Have you participated in any training or educational programs on smoking cessation methods as a healthcare professional?							
Yes	25	23.1	26	32.1	51	27.0	P=0.315
No	76	70.4	52	64.2	128	67.7	
I don't know	7	6.5	3	3.7	10	5.3	
Are you familiar with the effects of smoking on oral health through professional lectures?							
Yes	76	70.4	55	67.9	131	69.3	P=0.884
No	26	24.1	22	27.2	48	25.4	
I don't know	6	5.6	4	4.9	10	5.3	
Is it essential for dental professionals to receive continuing education through lectures and awareness programs on the effects of e-cigarettes?							
Yes	96	88.9	67	82.7	163	86.2	P=0.466
No	3	2.8	4	4.9	7	3.7	
I don't know	9	8.3	10	12.3	19	10.1	

**Table VII** - Participation in and need for smoking cessation training among researchers by education/Professional training

	Dentist		Specialist		p-value
	N	%	N	%	
Total	103	100.0	86	100.0	
Have you participated in any training or educational programs on smoking cessation methods as a healthcare professional?					
Yes	27	26.2	24	27.9	p=0.246
No	73	70.9	55	64.0	
I don't know	3	2.9	7	8.1	
Are you familiar with the effects of smoking on oral health through professional lectures?					
Yes	68	66.0	63	73.3	p=0.433
No	30	29.1	18	20.9	
I don't know	5	4.9	5	5.8	
Are you aware of the effects of smoking on oral health through professional lectures?					
Yes	88	85.4	75	87.2	p=0.614
No	3	2.9	4	4.7	
I don't know	12	11.7	7	8.1	

Furthermore, the training programs currently available were often insufficient in equipping dentists with practical skills for effective smoking cessation interventions. Effective smoking cessation programs incorporate behavioral

counseling, pharmacotherapy, and continuous patient monitoring. Motivational interviewing and structured therapies such as the 5As and 5Rs enhance the personalization of the cessation process. Pharmacological interventions, such

as nicotine replacement therapy (NRT) and prescription medications are crucial for enhancing cessation rates. Our data indicate that many dentists utilize these structured intervention methods, emphasizing the need for specialized continuing education programs that incorporate behavioral and pharmacological therapies.

More than half (63.0%) felt confident in discussing the harmful effects of e-cigarettes with patients. Unlike the research of Parkar et al, where most of the dentists strongly believed that it is their responsibility to educate the patients regarding tobacco cessation counselling, but the lack of proper training was found to be the major barrier for tobacco cessation counselling [17].

Only 36.5% of the dentists surveyed had knowledge of the recommended non-pharmacological and pharmacological methods for smoking cessation. Additionally, just 11.6% were aware of the structured models, such as the 5As and 5Rs, and only 10.1% were familiar with the FDA-approved STAR method. A study conducted by Surrati et al, found that 60% of physicians demonstrated a solid understanding of smoking cessation counseling, with satisfactory practice reported in certain areas [18]. The discrepancy between dentists' and physicians' knowledge levels in smoking cessation counseling could be attributed to differences in medical and dental education. Physicians often receive formal training in patient lifestyle interventions, whereas dental curricula focus primarily on clinical procedures rather than behavioral counseling. Additionally, medical professionals may have greater exposure to smoking cessation programs as part of primary healthcare services, whereas dental professionals typically focus on oral health without the same level of preventive care training.

A study conducted in the Netherlands compared 14 groups of healthcare providers and found that dentists had the lowest rates of giving advice and making referrals, compared with the other groups [19]. This highlights the need to address barriers and enhance smoking cessation practices within dental care, as oral health professionals play a crucial role in disease prevention. In our study, only 27.0% of participants reported attending any training or educational programs on smoking cessation techniques. This suggests that professional lectures and ongoing education are essential to raise awareness about the dangers of smoking

and the benefits of quitting. Dentists should, therefore, be more actively involved in counseling patients to stop smoking.

Among respondents, 61.4% routinely spent a few minutes discussing the effects of e-cigarettes on oral health with their patients. There were no significant gender-based differences in these responses ( $P > 0.05$ ). In contrast, the study by B.W. Chaffee et al. found that dental professionals in California frequently asked about smoking but were less consistent in offering cessation support and asking about non-cigarette products [20].

A study by Alsiwat and Alayadi [21], highlights the importance of revising the undergraduate curriculum to incorporate smoking cessation counseling. The study also emphasizes the value of continuing education in enhancing dental hygiene practitioners' knowledge in this area. Despite a positive attitude, dentists lacked confidence in providing tobacco cessation counseling. Similarly, in our study, when participants were asked if ongoing professional education through lectures and awareness programs on the effects of e-cigarettes is crucial for dental professionals, 86.2% agreed, with no significant differences observed based on gender ( $P > 0.05$ ). Also, dentists believe that creating a curriculum focused on interdisciplinary collaboration and coordinating scientific activities with medical associations will be crucial for raising awareness about oral-systemic health [22].

While the study offers important insights into assessing dentists' understanding of smoking cessation techniques and underscores the need for training to effectively assist patients, additional research may be warranted. This could involve simulating training sessions for dentists in collaboration with the Kosovar Dental Chamber. Future studies should evaluate the impact of structured smoking cessation training programs within dental education. A key strategy could involve pilot studies implementing structured training modules—such as role-playing, patient simulations, or online courses—followed by assessments of knowledge retention and application in clinical practice. Collaborations with dental associations and public health organizations could further strengthen these initiatives by ensuring that smoking cessation training is standardized and accessible to all dental professionals. This research assessed the level of dentists' knowledge regarding smoking cessation techniques and identified their requirements for



additional training, with a particular emphasis on structured intervention models. While 63.0% of participants expressed confidence in their ability to discuss the harmful effects of e-cigarettes, only 36.5% exhibited knowledge of evidence-based smoking cessation strategies, and merely 11.6% were acquainted with structured intervention frameworks, including the 5As and 5Rs. The findings underscore a significant deficiency in smoking cessation education within the dental profession, emphasizing the importance for the development of specialized training programs focused on improving practitioners' ability to support patients in quitting smoking.

Numerous limitations must be addressed. The reliance on self-reported data heightens the possibility of recall bias, while the utilization of convenience sampling may have introduced selection bias by disproportionately representing dentists with a prior interest in smoking cessation. The study's cross-sectional design restricts the capacity to determine causal correlations between training participation and knowledge levels. Future study utilizing randomized or stratified sampling methods may provide a more thorough evaluation of these knowledge deficiencies. Deficiencies in smoking cessation education have been documented, underscoring the need for further research on the integration of structured cessation training within dental curricula and continuing education programs across diverse healthcare systems in Kosovo. Comparative studies could offer valuable insights into optimizing the role of dental professionals in tobacco cessation counseling.

## CONCLUSIONS

This study indicates that while a significant proportion of dentists in Kosovo are confident in discussing the risks associated with e-cigarette use, there is a notable deficiency in their knowledge of advanced smoking cessation techniques and structured intervention models. Dentists generally exhibit a positive attitude toward tobacco cessation counseling; however, a lack of formal training significantly impedes their ability to effectively implement such interventions.

## Acknowledgements

We would like to express our sincere gratitude to the Kosovar Dental Chamber for

their invaluable cooperation in facilitating the inclusion of dentists in our survey. Their support was crucial in ensuring the successful completion of this study and we deeply appreciate their collaboration and dedication to advancing research in dental care.

## Author's Contributions

ZSD: Conceptualization, Formal Analysis, Writing – Original Draft Preparation. MSK: Data Curation, Investigation, Writing – Review & Editing. DSH: Methodology, Supervision, Writing – Review & Editing. LD: Data Curation, Project Administration, Writing – Original Draft Preparation.

## Conflict of Interest

None

## Funding

None

## Regulatory Statement

This study protocol was reviewed and approved by the Ethics Committee of the Kosovo Dental Chamber (Approval No: 48-1-30.05.2024). The study adhered to ethical guidelines, ensuring voluntary participation, anonymity, and informed consent. Participants signed informed consent forms before completing the questionnaire, following ethical principles outlined in the Declaration of Helsinki.

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Date submitted: 2024 Sept 26  
Accept submission: 2025 Feb 17