# Effectiveness of a Dentist-based Anti-Smoking Intervention Among Malaysian Adolescents: A Randomized Controlled Field Trial

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# Abstract

**Background:** The KOTAK program is a national public health initiative in Malaysian primary and secondary schools aimed at reducing youth smoking through school dental services. This study evaluated its effectiveness in Seremban, Negeri Sembilan, Malaysia. **Objectives:** 1) To determine the percentage of schoolchildren who quit smoking through the KOTAK program; 2) To identify factors associated with quitting smoking in the program. **Methods:** A clustered, randomized controlled trial was conducted in schools. Self-reported smokers meeting inclusion criteria were enrolled. Data on demographics, self-reported smoking abstinence, and nicotine addiction levels were collected at baseline, three months, and six months post-intervention. Exhaled carbon monoxide was measured at all time points, and salivary cotinine was collected at three- and six-month follow-ups. **Results:** Six months post-intervention, 29.8% of students in intervention schools and 14.6% in control schools reported quitting smoking. The odds of quitting were higher with the KOTAK program (aOR = 2.25, 95% CI = 1.11-4.57). Factors such as age, maternal education, and baseline nicotine addiction level were protective for smoking abstinence. **Conclusion:** The intervention group showed a higher self-reported smoking cessation rate, indicating the potential efficacy of the KOTAK program.

Keywords: Adolescents smoking- schoolchildren smoking- Hooked on Nicotine- nicotine addiction

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# Introduction

Tobacco use among Malaysian adolescents remains a significant public health concern despite concerted government efforts. Adolescents comprise 20% of Malaysia's estimated 5 million smokers [1], and demonstrate significantly higher susceptibility to nicotine addiction than adults, even at lower consumption levels. This heightened vulnerability contributes to poorer cessation success rates and increased mortality risk later in life [2].

While determinants of adolescent smoking show similarities across developed and developing nations [1], research has identified several key factors influencing initiation among young smokers. These include sociodemographic, environmental, behavioural, and personal factors [1, 3]. Crucially, adolescents are a primary target of the tobacco industry, which views them as essential for its long-term viability [4].

Malaysia's concerning adolescent smoking rates have prompted various government-led public health initiatives. These include nationwide smoke-free city implementations, health promotion programs, mass media campaigns, Quitline services, quit-smoking clinics, and online training for healthcare personnel [5]. However, existing research on tobacco control in schools largely focuses on smoking prevalence, intrapersonal and interpersonal motivations for initiation, the effectiveness of mass media campaigns, and exposure to second-hand smoke [6]. Despite these initiatives, compliance with Malaysia's anti-tobacco policies remains low, hindering their effectiveness [7].

The KOTAK program, launched in 2016 by the Malaysian Ministry of Health, aims to prevent smoking and encourage cessation among schoolchildren through integration with the annual School Dental Service (SDS). The SDS utilizes an Incremental Dental Approach to provide dental care in Malaysian schools, facilitated by a collaboration between the Ministries of Health and Education, and delivered via the Ministry of Health's Mobile Dental Team at school dental clinics. Limited evidence exists on the KOTAK program's effectiveness. This study therefore aimed to determine the quit smoking success rate of schoolchildren participating in the KOTAK program and to identify factors associated with smoking abstinence.

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# **Materials and Methods**

# Study design

This study employed a cluster-randomized controlled field trial design. Clusters consisted of public coeducational secondary schools in the Seremban district of Negeri Sembilan, Malaysia. The study population comprised secondary school students in this district. Inclusion criteria were: current smoking status, age 13-17 years, and written parental consent.

## Sampling

Sample size was calculated using an effect size of 0.10, based on the mean outcome difference between intervention and control groups reported in a school-based smoking prevention program [8]. An alpha ( $\alpha$ ) level of 0.05 and power of 0.80 yielded an initial sample size of n = 164. This was increased by 30% to account for attrition [9], resulting in a sample size of 214. Using G\*Power Statistical Analysis software version 3.1.9.3, and incorporating a design effect as recommended by Killip et al. [10], the final sample size was increased to 327.

## Randomization

The Seremban District encompasses 43 secondary schools; 13 were excluded due to being private, boarding schools, single-sex schools, or vernacular schools, leaving a final sample frame of 30 schools. A two-stage stratified sampling approach was employed. Eligible schools, with assistance from the District Education Office, were matched into 15 pairs based on location (urban/rural) and academic performance. At the second stage, each matched pair was randomly allocated to either the intervention or control group using an online computerized list generator. This resulted in 15 schools assigned to the intervention group and 15 to the control group. The intervention group received the KOTAK program, while the control group received generic anti-tobacco lectures delivered by dentists in the school hall to all students.

School participation required collaboration with teachers acting as liaisons for the KOTAK program. Smokers were identified during annual dental checkups conducted by the dental team. Following individual screening, eligible students were invited to participate, with anonymity assured. Written parental/guardian consent was obtained using a provided consent form. Only students with completed consent forms were included in the study.

#### Intervention

The KOTAK program comprised a dentist-led screening process followed by three smoking cessation counselling sessions. After screening, smokers participated in at least three group briefings over one academic year. The program modules covered the dangers of smoking, benefits of a smoke-free lifestyle, nicotine addiction, cessation techniques, and nicotine withdrawal symptoms. Sessions were conducted in groups of five, lasting ten minutes each, and scheduled at four-week intervals. Content was based on the eight-module KOTAK guidebook. Participating government dentists received

#### prior training from the district Oral Health office.

#### Data Collection Procedure

Baseline data were collected prior to the KOTAK program intervention, with 3-month and 6-month followup data collected post-intervention (Figure 1). Selfadministered questionnaires, capturing demographic data and self-reported nicotine dependence using the Hookedon Nicotine Checklist (HONC), were administered at all three time points, in accordance with CONSORT guidelines. A research assistant assisted with questionnaire administration, exhaled carbon monoxide testing, and saliva collection. Both researchers were trained in questionnaire administration, breath analyser operation, and saliva collection procedures before commencing data collection. This study employed a single-blind design, with only the researchers aware of school group allocation (intervention/control).

#### **Outcome Measures**

Self-reported nicotine dependence was assessed using HONC, a 10-item questionnaire measuring loss of autonomy over tobacco use in adolescent smokers [11]. DiFranza's model posits that nicotine dependence (addiction) begins with the loss of autonomy [11]; each endorsed item represents a loss of autonomy, with the total score reflecting the degree of autonomy loss. Higher HONC scores indicate greater self-reported nicotine addiction; scores above zero indicate nicotine dependence [11]. In addition to the HONC, exhaled carbon monoxide (CO) and salivary cotinine levels were measured in both intervention and control schools. Exhaled CO was measured using a Bedfont Breath Analyzer; levels above 5 ppm were considered indicative of smoking in youth. Salivary cotinine was measured using the NicAlert<sup>TM</sup> strip, a semi-quantitative immunochromatographic assay. A coloured band of at least Code 1 (10-30 ng/mL cotinine concentration) indicated tobacco use.

#### Data Analysis

Data were analysed using SPSS version 22 for Windows. A chi-square test assessed the association between smoking status, smoking behaviour, and socio-demographics. Multivariate analysis controlled for confounders of smoking abstinence at the 6-month follow-up. Dropouts were included as intention-to-treat (ITT) subjects.

# Results

#### Demographic characteristics of the study participants

Table 1 shows the baseline demographic characteristics of the participants. Most were male and Malay. Both intervention and control schools had similar distributions across variables, except for ethnicity, which was statistically significant. Over half (76.2%) came from families with an average household income below USD 834 (MYR 3900), placing them in the bottom 40% income bracket in Malaysia in 2017 (DOSM, 2019). Most participants began smoking between ages 12 and 13. In terms of motivation to smoke, a significantly higher



Figure 1. CONSORT Flow Diagram of the Randomized Control Field Trial

percentage in control schools (57.4% vs. 43.2%) cited peer influence as a reason (p=0.039).

#### Smoking abstinence prevalence

Smoking abstinence was measured through self-reports and salivary cotinine levels.

Table 2 shows a significantly higher percentage of self-reported smoking cessation in the Intervention group (29.8%) compared to the Control group (14.6%) (p=0.002). However, the percentage of participants confirmed to be smoke-free based on salivary cotinine was similar between the intervention group (11.3%) and the control group (10.4%). Table 3 indicates an overall reduction in the mean of all outcome variables except for salivary cotinine at the 6-month follow-up.

## Relationship between demographic data and the selfreported smoking abstinence

The relationship between demographic data and self-reported smoking abstinence among adolescents six months post-intervention was analysed using logistic regression. Variables such as demographic data, type of school (intervention or control), self-reported nicotine addiction level at baseline, age of smoking initiation, factors influencing smoking uptake, and presence of family members who smoke were examined in relation to self-reported smoking abstinence at six months postintervention (Table 4).

Simple Logistic Regression (SLR) provided preliminary results on potential factors with p < 0.25. The initial SLR analysis indicated a significant difference in the odds of quitting smoking between intervention and control schools. Seven variables were identified as potentially significant (p < 0.25): age, gender, type of school, ethnicity, mother's education, father's education, and nicotine dependency status. These variables were included in multiple logistic regression analysis, which found four variables to be statistically significant.

The odds of smoking abstinence were higher among participants from the intervention school (aOR = 2.25, 95% CI = 1.11–4.57). Conversely, factors associated with lower odds of smoking abstinence (i.e., protective factors against smoking cessation) included age (aOR = 0.69, 95% CI = 0.53–0.91), having a mother with a degree-level education (aOR = 0.15, 95% CI = 0.04–0.55), and not being nicotine-dependent as measured by the Hooked-on Nicotine Checklist (HONC) (aOR = 0.18, 95% CI = 0.09–0.37).

## Discussion

The current study found that most participants who were smokers were male, which aligns with national statistics indicating that a quarter of Malaysian male Nawwal Alwani Mohd Radzi and Zamros Yuzadi Mohd Yusof

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Characteristic	Intervention (n=172)	Control (n=177)	Overall (N=349)	p-value
	n (%)	n (%)	N (%)	
Age (years)				
Mean ±SD	$14.48{\pm}~1.29$	14.50±1.35	14.49±1.32	0.823ª
Gender				
Male	162 (94.2)	164 (92.7)	326 (93.4)	0.564 <sup>b</sup>
Female	10 (5.8)	13 (7.3)	23 (6.6)	
Ethnicity				
Malay	110 (64.0)	163 (92.1)	237 (78.2)	$< 0.001^{b}$
Chinese	8 (4.7)	0 (0)	8 (2.3)	
Indian	52 (30.2)	11 (6.2)	63 (18.1)	
Others	2 (1.2)	3 (1.7)	5 (1.4)	
Father's Education				
Up to the secondary level	132 (79.5)	137 (79.2)	269 (79.4)	0.941 <sup>b</sup>
University	34 (20.5)	36 (20.8)	70 (20.6)	
Mother's Education				
Up to the secondary level	143 (85.6)	142 (82.1)	285 (83.8)	0.374 <sup>b</sup>
University	24 (14.4)	31 (17.9)	55 (16.2)	
Household Income Malaysian Ringgit (M	/IYR) / USD			
≤ 3900 (830) (B40)	128 (74.7)	138 (78.7)	266 (76.2)	0.517 <sup>b</sup>
3900 (830) to 8300 (1770) (M40)	34 (19.3)	33 (18.6)	67 (19.2)	
≥ 8300 (1771) (T20)	10 (5.8)	6 (3.4)	16 (4.6)	
Smoking inhiation age (years)				
<7	9 (5.3)	5 (2.9)	14 (4.1)	
8 to 9	10 (5.9)	10 (5.8)	20 (5.9)	
10 to 11	23 (13.5)	33 (19.3)	56 (16.4)	
12 to 13	69 (40.6)	76 (44.4)	145 (42.5)	0.464 <sup>b</sup>
14 to 15	49 (28.8)	39 (22.8)	88 (25.8)	
>16	10 (5.9)	8 (4.7)	18 (5.3)	
Reasons for smoking cigarettes				
Peers	73 (43.2)	101 (57.4)	174(50.4)	
Family	17 (10.1)	14 (8)	31 (9)	
Stress	23 (13.6)	21 (11.9)	44 (12.8)	
Curiosity	45 (6.6)	37(21)	82 (23.8)	0.039 <sup>b</sup>
Others	11 (6.5)	3 (1.7)	14 (4.1)	

<sup>a</sup>Man-Whitney U test; <sup>b</sup>Pearson Chi-Square; B40, median income representing bottom 40% of income earner in Malaysia; M40, median income representing middle 40% of income earner in Malaysia; T20, median income representing top 20% of income earner in Malaysia

secondary school children (aged 13 to 15 years) were current smokers in 2017, compared to only 6.7% of female secondary school children who smoked .[12] The high rate of participation among male adolescent smokers might also reflect cultural perceptions, as a comparative study of Malaysian and Thai adolescents reported that Malaysian boys were more likely to view smoking as an appealing and modern activity [13]. This suggests that male adolescents may perceive smoking as socially acceptable and are less inclined to conceal their smoking behavior [14]. Additionally, baseline data from the present study indicated that nearly half of the participants (42.5%) started smoking between the ages of 12 and 13, which is consistent with findings from

Table 2. Percentages of Schoolchildren v	vho Quit Smoking at 6-Months	Follow up According to Group
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Method of Abstinence selection criteria	Intervention School (n=151) n (%)	Control School (n=144) n (%)	Overall (N=295) N (%)	p-value
Self-reported	45 (29.8)	21 (14.6)	66 (22.3)	0.002
Salivary cotinine	17 (11.3)	15 (10.4)	32 (10.8)	0.816
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\*Not 349 because the attrition rate at the end; \* chi-square

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Variable	Intervention School Mean (SD)	Control School Mean (SD)	Overall Mean (SD)	Ν
Mean Hooked on Nicotine Checklist Score				
Baseline	2.85(2.9)	2.43 (2.3)	2.65 (2.7)	263
3-Months	2.68 (2.7)	2.46 (2.3)	2.57 (2.5)	263
6-Months	2.24 (2.6)	1.87 (2.2)	2.06 (2.5)	263
The mean score of Exhaled CO				
Baseline	4.60 (3.1)	4.11 (1.9)	4.35 (2.6)	325
3-Months	2.32 (1.6)	2.15 (1.7)	2.23 (2.0)	325
6-Months	2.44 (2.0)	2.20 (1.4)	2.32 (1.8)	325
Mean Level of Salivary Cotinine				
3- Months	2.14 (1.5)	2.07 (1.5)	2.10 (1.5)	303
6- Months	2.17 (1.7)	2.28 (1.6)	2.23 (1.7)	303

Table 3. The Mean Score of Hooked on Nicotine Checklis	st, mean carbon monoxide reading and mean salivary cotining
level of the schoolchildren during baseline, 3-months and	d 6-months post Intervention according to Group.

Table 4. Logistic Regression Analysis of Factors influencing Smoking Abstinence [Quit=1, Not Quit=0]

Variables	Simple Logistic Regression Crude Odds Ratio (95% CI)	p-value	Multiple Logistic Regression Adjusted Odds Ratio (95%CI)	p-value
Age	0.75 (0.61,0.93)	0.008	0.69 (0.53,0.91)	0.008
Gender				
Male*	1		1	
Female	0.40 (0.16,1.03)	0.057	0.43 (0.14,1.35)	0.147
Control Schools/Intervention Sch	ools			
Control*	1		1	
Intervention	2.48 (1.39,4.43)	0.002	2.25 (1.11,4.57)	0.025
Ethnicity				
Malay*	1		1	
Chinese	2.45 (0.57,10.64)	0.231	0.23 (0.03,1.56)	0.133
Indian	1.86 (0.93,3.71)	0.079	0.55 (0.47,6.57)	0.64
Education (Mother)				
Primary/Secondary*	1		1	
Degree	3.94 (1.36,11.4)	0.011	0.15 (0.04,0.55)	0.004
Education (Father)				
Primary/Secondary*	1		1	
Degree	1.77 (0.84, 3.71)	0.131	1.16 (0.46,2.92)	0.762
Monthly Household income (MY	(USD)			
≤ 8299 (1770) <b>*</b>	1		1	
≥ 8300 (1771)	0.55 (0.12,2.52)	0.441	1.38 (0.20,9.77)	0.746
Nicotine dependency status based	l on Hooked on Nicotine Checklist scor	e (HONC) at	baseline	
Nicotine Addicted *	1	< 0.001	1	< 0.001
Not Addicted	0.23 (0.13,0.41)		0.18 (0.09,0.37)	
Age of first trying to smoke				
Before age 10*	1		1	
After age 10	0.92 (0.37,2.26)	0.852	1.48 (0.46,4.80)	0.516
What are the factors that cause yo	ou to smoke?			
Friends*	1		1	
Family	0.97 (0.36,2.61)	0.953	1.21 (0.38,3.85)	0.746
Stress	0.65 (0.25,1.69)	0.373	1.18 (0.39,3.58)	0.769
Curiosity	1.02 (0.53,1.97)	0.949	0.88 (0.38,2.01)	0.756
Do you have a family who smoke	es?			
Yes *	1		1	
No	1.06 (0.57,1.97)	0.854	1.03 (0.50,2.14)	0.931

#### Nawwal Alwani Mohd Radzi and Zamros Yuzadi Mohd Yusof

the National Health and Morbidity Survey (NHMS) in 2017, where the majority (68.9%) of adolescent smokers reported initiating smoking before the age of 14 [12]. The mean age of smoking initiation among adolescents in Asia ranged from 10 to 14 years [15].

Regarding factors that encouraged smoking, half of the participants (50.4%) reported that peer influence was the primary reason for initiating smoking. This aligns with well-established evidence showing that peers significantly influence risky behaviors in adolescents [16]. Moreover, the odds of being a smoker are higher among those who had a best friend who smoked [6]. Although adolescent smokers are generally more vulnerable to nicotine addiction [17], less than a quarter of this study's participants (22%) scored zero on the HONC, indicating no nicotine addiction. Previous studies have established disparities in nicotine addiction across different socioeconomic backgrounds [1].

The overall mean HONC score for participants at baseline was 2.65, which decreased to 2.06 at the 6-month follow-up. These findings were lower than those reported in a Greek study, which had a mean HONC score of 4.13 [18]. However, the results were comparable to intervention studies conducted in Florida and Kuala Lumpur, which reported mean HONC scores of 2.7; the latter study also included users of electronic cigarettes [6]. In this study, the percentage of participants who quit smoking (self-reported) in intervention schools at the 6-month follow-up was 22.3%, comparable to the 30.2% quit rate observed among Korean adolescents [19]. However, the structure of the Korean program (Project EX) involved eight clinic-based sessions, each lasting 60 minutes [19]. Despite the shorter sessions in the KOTAK program, the group lecture format with no more than five participants may have contributed to its effectiveness, as group behavioural interventions have been shown to be a successful method for smoking cessation [20]. This finding is supported by a local Malaysian study that found group counselling improved both smoking knowledge and quit rates among adolescent smokers [21].

Regarding biochemical validation, salivary cotinine levels in the intervention schools did not show a significant improvement, with only a slight increase in smoke-free adolescents (11.3% vs. 10.4%). This aligns with findings from a local study conducted in Negeri Sembilan and Kuala Lumpur, which reported high salivary cotinine levels due to second-hand smoke exposure and inadequate enforcement of smoke-free laws in Malaysia [7]. Additionally, Ab Manan et al. [22] suggested that smokers tend to deny or underestimate their cigarette consumption, leading to discrepancies between selfreported abstinence and biochemical measures like urine cotinine levels in Malaysian adolescents. This phenomenon could also result from the use of other nicotine-containing devices, such as Electronic Nicotine Delivery Systems (ENDS) [23]. The significant reduction in self-reported smoking abstinence compared to salivary cotinine levels in the intervention group may also be influenced by the Hawthorne effect, where participants alter their behavior because they know they are being observed [24].

In this study, the overall mean CO levels decreased to 2.32, 2.44, and 2.20 ppm, respectively. This reduction is similar to findings from a Spanish study, which reported a significant decrease in CO levels after a two-year classroom-based smoking prevention program [25].

The odds of self-reported smoking cessation at 6 months post-intervention were higher in the intervention schools, with an Odds Ratio of 2.48 (95% CI = 1.39-4.43, p = 0.002). Even after controlling for variables such as age, gender, school type (intervention or control), ethnicity, parental education, and baseline nicotine addiction status, the Adjusted Odds Ratio (AOR) decreased slightly to 2.25 but remained statistically significant (95% CI = 1.11-4.57, p = 0.025). Significant factors influencing smoking abstinence at 6 months post-intervention included age, school type, maternal education, and baseline nicotine addiction status.

The AOR in this study was comparable to a French study, which reported an AOR of 2.1 for smoking abstinence in the intervention group, though the follow-up duration was longer (12 months post-intervention) [26]. Logistic regression identified age as a protective factor against smoking abstinence (AOR = 0.69, 95% CI = 0.53-0.91, p = 0.008), indicating that younger adolescents are more likely to quit smoking. A study by Mertens et al. [27] also found higher quit rates among younger smokers (58% among 12-year-olds) compared to older smokers (40.3% among 17-year-olds). This trend may be due to prolonged nicotine addiction, which hampers quit attempts [16].

Interestingly, this study found that adolescent smokers whose mothers had a degree or higher education were less likely to quit smoking (AOR = 0.15, 95% CI = 0.04-0.55). This contradicts other studies suggesting that the risk of adolescent smoking increases as parental education decreases [28]. However, the findings of this study may be explained by the financial advantages associated with higher parental education, leading to higher household incomes [29]. A higher household income provides adolescents with a larger allowance, increasing their ability to purchase cigarettes [30]. Notably, household income was not a significant factor influencing smoking abstinence at the 6-month follow-up in this study.

Participants who were not nicotine-dependent at baseline had lower odds of achieving smoking abstinence (AOR = 0.18, 95% CI = 0.09-0.37). This contrasts with findings by Csibi et al., who reported that baseline HONC scores significantly predicted smoking cessation among adolescents, suggesting that a higher HONC score could serve as a protective factor against nicotine addiction [31]. The discrepancy in this study may be attributed to adolescents' misperception of their addiction levels [31]. The finding in this study could be explained by the tendency of adolescents who may find themselves addicted but perceive it differently [32]. Adolescents might not fully grasp the severity of addiction items on the HONC scale [32]. A recent systematic review by Vallata found that, unlike adults, adolescents are generally unaware of their nicotine addiction levels, often attempting to quit without counseling despite already being dependent [33].

#### Study Limitations

This study only included secondary school children from government schools, limiting the interpretation of the findings to students with characteristics similar to those in the Seremban district. Additionally, the use of self-reported questionnaires as the primary data collection method may introduce some degree of response bias. The timing of saliva sample collection varied throughout the week, reflecting the sporadic and irregular smoking patterns of adolescents. Participants' awareness of upcoming saliva tests may have led them to temporarily abstain from nicotine use, potentially skewing the results. Samples collected on Mondays may also have been influenced by participants' social activities over the weekend. Similarly, for breath carbon monoxide measurements, the timing of school recess breaks could have impacted results, depending on students' access to cigarettes between classes.

#### Implication for Future Studies and Recommendation

To enhance the generalizability of future research, studies should include a wider range of geographical areas and school types. A comprehensive analysis of local socioeconomic factors and parental influence is recommended to identify potential confounders. Future research could also benefit from an extended follow-up period to assess the long-term impact of the intervention.

The control group in this study received only general advice about the negative effects of smoking, which may not be directly comparable to the structured and repetitive intervention provided to the KOTAK program group. Future studies should consider implementing a control intervention that is more equivalent to the experimental condition. Additionally, the inconsistent timing of saliva sample collection throughout the week suggests that standardizing sample collection times could improve the reliability of the results.

In conclusion, the KOTAK program demonstrated a higher self-reported smoking cessation rate compared to control schools, suggesting its potential effectiveness. School-based smoking cessation programs typically use a combination of strategies to achieve positive outcomes. Therefore, a direct comparison of the KOTAK program with other school-based interventions was not feasible. It is also important to interpret these findings with caution, as external factors like the tobacco retail environment or prevailing social norms around smoking at the school level were beyond the researchers' control and could act as confounders, potentially overestimating or underestimating the observed relationships [27].

#### Ethical Clearance

The study was approved by the Medical Ethics Committee of the Faculty of Dentistry, University of Malaya (Reference number: DFCO1811/0080[1]0). Permissions to conduct the research were obtained from the Oral Health Programme, Ministry of Health; Ministry of Education; Negeri Sembilan State Education Department; and the Negeri Sembilan Oral Health State Director. The study was registered with the National Medical Research Ethics Committee (NMRR) (Registration number: NMRR-18-3415-44030) and the ClinicalTrials.gov Protocol Registration System (ID NCT04378725). Written informed consent was obtained from the parents of the participating schoolchildren before the research commenced.

# **Author Contribution Statement**

Conceptualization: Z.Y.M.Y, N.A.M.R, Formal Analysis: N.A.M.R. Original Draft Preparation: N.A.M.R, Review and Editing: Z.Y.M.Y, N.A.M.R

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## Data Availability

The data supporting this study are available upon request, subject to restrictions imposed by the funding agency.

### Study Registration

This study was registered with the National Medical Research Ethics Committee (NMRR) (Registration number: NMRR-18-3415-44030) and the ClinicalTrials. gov Protocol Registration System (ID NCT04378725).

#### Approval

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# Ethical Declaration

Ethical approval for this study was granted by the Medical Ethics Committee of the Faculty of Dentistry, University of Malaya (Reference number: DFCO1811/0080[1]0).

# Conflict of Interest

None.

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