

Assessment of Efficacy Of Four Different Types Of Bristle Designs Of Tooth Brush On Plaque And Gingival Status: A Cross Over Randomized Control Trial.

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ABSTRACT

Backgrounds: Improper maintenance of oral hygiene can result in accumulation of dental plaque which can lead to gingivitis and periodontitis. Study aimed to compare the effect of four different bristle designs of tooth brush on plaque and gingival status.

Methods: A cross over randomized clinical trial was carried out to evaluate the efficacy of four different types of toothbrush. The toothbrushes used were flat trim, Bi-level, Zig Zag and Wavy. The study was carried out over a period of four months. A total of 160 volunteers were taken as the study subjects. These subjects were randomly allocated into 4 groups. Each group comprised of 40 study subjects. All the subjects were assessed for gingival and plaque status using gingival and plaque index at the end of week 1, week 2 and week 3 from baseline score. A wash out period of seven days was allowed between the study periods and then cross over among the study groups were performed. Student's paired t-test was applied to see the change in variables with respect to time and one way ANOVA followed by post-hoc test were used for multiple group comparison. Statistical significance was defined at $P < 0.05$.

Results: Statistically significant difference was found in both plaque and gingival score from baseline to 4 months in all the groups. Zigzag toothbrush design was found to be superior in reduction of plaque and gingival score followed by wavy, bi-level and flat trim tooth brush design.

Conclusion: Zigzag and wavy tooth brush designs found to be most effective than other tooth brush designs and can be recommended at the community level.

Keywords: Dental Plaque, Gingivitis, Periodontitis, Volunteers

1. INTRODUCTION

Oral hygiene has been widely used and endorsed as an effective preventive practice which assures better dental health.

Improper maintenance of oral hygiene can result in greater accumulation of dental plaque which can lead to gingivitis and periodontitis [1]. There is a direct relation between the degree of plaque accumulation and gingival disease. Plaque is one of the etiological factors in the development of chronic inflammatory disease which is well known [2]. Thus, plaque control is an effective way of preventing and treating gingivitis and periodontal diseases [3]. There are two methods of plaque control, one is mechanical and the other one is chemical plaque control. Till date, the effective way of plaque control is mechanical cleaning with a toothbrush for maintaining oral hygiene. Therefore it is the most widely used method if performed correctly for an appropriate duration. The design of toothbrush has undergone a various degree of refinement and is by far the most commonly adopted and accepted tooth cleaning aid. Numerous designs of toothbrush have been evolved and individual brands keep claiming superiority over others by generous media [4]. It has been well documented that the accumulation of microbial plaque can lead gingival inflammation and regular removal of plaque results in resolution of the gingival inflammation in few days [5]. Various factors influence the design and the fabrication of toothbrushes. These designs include bristle length, shape, material, diameter, and number of bristles, size, design of brush head, angulations of brush head to the handle, arrangement of tufts and handle design. Emphasis should be given to the toothbrush design that provides accessibility to all the areas of oral cavity and should not traumatize the tissues and also be able to remove plaque efficiently. Numerous designs of toothbrushes are available in the market causes dilemma in an individual's mind thus they usually choose tooth brushes based on availability, cost, family tradition, advertising claims or habit. Person should seek professional advice regarding the type of tooth brush to be used for cleaning. Various bristle designs include Zigzag, flat trim, wavy design, bi-level design and many more are available in the market but there is no evidence which bristle design is superior over the other, has been documented yet. The new advancement of tooth brush designs and numerous varieties available, the oral health professionals must have high level of knowledge to advise them appropriately [6].

In 2003, a survey was conducted by oral health survey and fluoride mapping; the findings of the survey revealed that nearly 2/3rd of the population both urban and rural uses toothbrushes. There is a need to aware them about constant development of new tooth brushes which are cost effective, easily available and effectively remove plaque; therefore it is necessary to compare the efficacy of different tooth brush designs in plaque removal that are available in the market [6]. There are very few studies on efficacy of manual toothbrushes in plaque removal in India and their results found to be contradictory and no similar study has been conducted till date in Jodhpur city hence this study had been undertaken to compare the efficacy of four different designs of toothbrushes on plaque and gingival status to recommend for an individual's requirement.

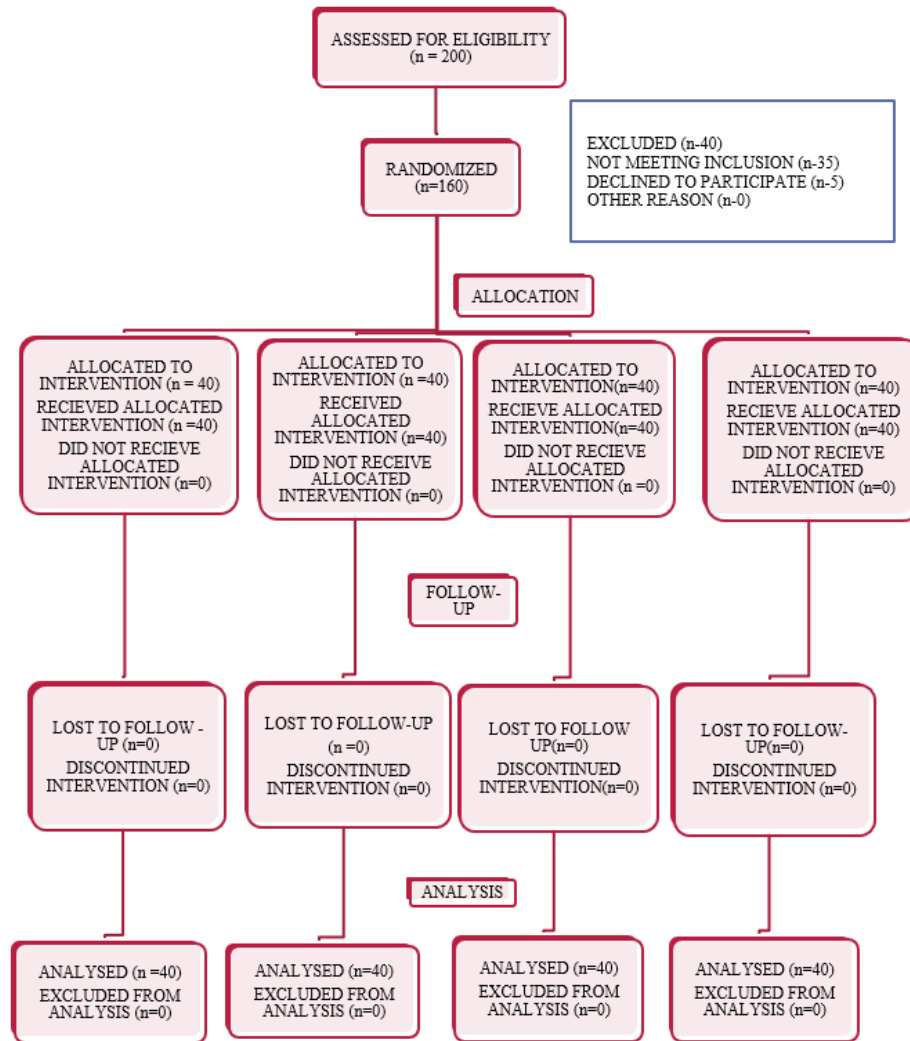


Figure -1 Consort flow chart

2. ATERIAL AND METHODS

A randomized clinical trial was carried out to evaluate the efficacy of four different types of toothbrush designs on plaque and gingival status that are available in the market of Jodhpur. The study was carried out over a period of four months.

Consent and Ethical Approval – All the study subjects were informed about the nature and purpose of the study and written consent was obtained from each subject before the start of the study. The study was ethically approved by Ethical clearance committee of Vyas Dental College and Hospital, Jodhpur, Rajasthan, India.

Pilot study – The pilot study was conducted to assess feasibility, practicability and methodology of procedure of data collection before commencement of the main study. A Pilot study was carried out on 40 volunteers. These subjects were randomly allocated into 4 groups. Each group comprised of 10 study subjects but they were not part of the main study and problems that were encountered during the pilot study were later corrected in the main study.

Study Subjects –Both male and female subjects were included for the study having age group of 18-44 years. The study was a randomized 4 cell, examiner blind cross-over clinical research to assess the efficacy of four designs of toothbrushes. The study subjects were allocated toothbrushes based on the random list prepared. The randomization process was asked to be completed by a dentist who was not participating. Every toothbrush was assigned a code. The codes were decoded only at the end of the study.

Sample size – Sample size was estimated after a pilot study. Based on the standard deviation for the response measures of 0.52, a significance level of $\alpha = 0.05$ and 80% level of power, the sample size calculated was 37 individuals per group were considered. A 10% possible attrition rate was added. Thus, each group comprised of 40 study subjects. A total of 160 volunteers were taken as the study subjects. These subjects were randomly allocated into 4 groups according to the type of tooth brush received like T1- Flat trim, T2-Zigzag T3- Wavy and T4 - Bi-bevel.

Inclusion Criteria-

1. Volunteers having age group of 18-44 years.
2. Absence of systemic diseases and underwent any treatment or medication
3. Study subjects who were willing to give written consent.
4. Study subjects having minimum of 20 functional teeth.
5. Subjects having baseline gingival index score of more than 1 and baseline plaque index score of more than or equal to 1.5.
6. No history of allergy to personal care consumer products, or their ingredients, relevant to any ingredient in the test products as determined by the dental/medical professional monitoring the study.

Exclusion Criteria-

1. Medical condition which requires pre-medication prior to dental visits/procedures.
2. Moderate or advanced periodontal disease.
3. Use of antibiotics or antimicrobial drugs within 30 days prior to study visit or current use of antibiotics for any purpose.
4. Pregnant or nursing women.
5. Participation in any other clinical study within 1 week prior to enrolment into this study.
6. Subjects who were going to receive dental treatment during the study dates.
7. Presence of an orthodontic appliance.
8. Immune compromised individuals (HIV, AIDS, immuno suppressive drug therapy).
9. Use of tobacco products

Study design – A randomized controlled trial was carried out. Study was done at satellite centres (primary health centre of GudaBishnoiya and community health centre of Salawas), Department of Public Health Dentistry of Vyas Dental College and Hospital in Jodhpur city, Rajasthan, India.

At the first visit, subjects were asked to refrain from all oral hygiene practice 24 hours before recording the score and also from the other unassigned forms of oral hygiene including non-study toothbrushes interdental brushes, dental floss, chewing gum, or oral rinses during the study. On day two, baseline score was recorded. The data was collected including demographic characteristics and plaque and gingival scores of the study subjects. The plaque scores were assessed using plaque index (PI) (Tureskey *et al.* modification of Quigley Hein Index, 1970) [7, 8] and the gingival scores using gingival index (GI) (Loe H and Silness J, 1963) [9]. All the subjects received oral hygiene instructions followed by the demonstration of uniform method of brushing (modified bass technique) and they were asked to perform the same in the presence of the instructor on a dentate model with a toothbrush. Modified bass technique was used as it is an effective method for removing plaque, has excellent sulcus cleaning, good interproximal and gingival cleaning and also provides good gingival stimulation. The subjects were advised to brush the teeth twice daily with pea size amount of toothpaste. Nylon soft bristled toothbrushes were used. The toothbrushes used were flat trim, bi-level, wavy and zigzag which of standardized brand and was according to American dental association specification. Toothbrushes were allocated to the study subjects. Standardized toothpaste was distributed to all the participants, as using different types of toothpaste during study could also affect plaque removal efficacy.

The baseline plaque scores and gingival scores were recorded on the second day after that score was recorded at the end of every week and final score was recorded after every month before changing the design of the tooth brush.

Follow up and assessment – All the subjects were assessed for gingival status and plaque status using gingival index and plaque index scores at the end of week 1, week 2 and week 3 from baseline score and a wash out period of seven days was allowed between the study period. After 3 weeks of data collection cross over among the study subjects groups were performed. Then, again the scores were recorded as done previously.

Oral examination - A trained and calibrated examiner accompanied by a recorder examined all the study subjects. The oral examination was carried out on a chair using mouth mirror, explorer No. 5, WHO periodontal probe (CPITN probe/ TRS 621-1978) and disclosing agent using Type III clinical examination. The Turesky *et al* Modified Plaque index (1970) and Gingival index (Loe H and Silness J - 1963) was used for evaluation of plaque and gingival status.

Statistical analysis – Variables were presented as mean and standard deviation. Student's paired t-test was applied to see the change in variables with respect to time and one way ANOVA followed by post-hoc test were used for multiple group comparison. P-value less than 0.05 considered as significant at 95% confidence level. The statistical software SPSS version

20.0 was used in analysis.

3. RESULTS

Table 1 shows randomization of study subjects in four groups at every month allocated with four different designs of tooth brushes like T1- Flat trim, T2-Zigzag T3- Wavy and T4 - Bi-bevel.

Table 1: Randomization of the study subjects in four groups allocated with different designs of tooth brushes

Groups	1 st month	2 nd month	3 rd month	4 th month
Group 1	T1	T2	T3	T4
Group 2	T2	T3	T4	T1
Group 3	T3	T4	T1	T2
Group 4	T4	T1	T2	T3

T1- Flat trim, T2-Zigzag T3- Wavy and T4 - Bi-bevel.

Table 2 shows distribution of all the study participants according to age, gender and education status. Maximum number of study subjects were 48 (30%) from the age group of 21-25 years and minimum were 8 (5%) from 41-45 years of age group. Among 160 study subjects, 90 (56.3%) were male and 70 (43.7%) were female and with respect to educational status, 93 (58.1%) were graduates whereas only 4 (2.5%) study subjects were post graduates.

Table 2: Distribution of study participants according to age, gender, education status

Demographics	Characteristics	No. of study participants (n)	Percentage (%)
Age	Below 20 Years	24	15%
	21-25 Years	48	30%
	26-30 Years	34	21.2%
	31-35 Years	32	20%
	36-40 Years	14	8.8%
	41-44 Years	8	5%
Gender	Male	90	56.3%
	Female	70	43.7%
Education	Illiterate	16	10%
	Undergraduate	35	21.9%
	Graduate	93	58.1%
	Post Graduate	4	2.5%
	Others	12	7.5%

n- Number of patients in a particular category

Table 3 shows the Plaque and gingival levels of experimental groups at different times of evaluation. Significant reductions in plaque and gingival accumulation from baseline to 1 month were observed in the group 2 followed by group 1, 3 and 4. Additionally, at the end of 4 month the maximum plaque and gingival reduction was seen in group 3 (zigzag) followed by group 4 (wavy), group 1 (bi-bevel), and group 2 (flat trim).

Table 3: Mean value of

Index	Groups	Baseline	Score after 1 month	Score after 2 months	Score after 3 months	Score after 4 months
Plaque score	Group1	2.46±0.231	1.9±0.160	2.55±0.122	1.12±0.121	1.68±0.503

	Group 2	2.47±0.158	1.51±0.095	2.11±0.141	1.51±0.168	2.15±0.176
	Group 3	2.83±0.152	2.32±0.157	1.73±0.093	2.38±0.160	0.85±0.213
	Group 4	2.84±0.115	2.73±0.127	1.32±0.142	1.92±0.160	1.26±0.119
-Gingival score	Group 1	2.48±0.341	1.47±0.158	2.17±0.176	0.78±0.213	1.19±0.124
	Group 2	2.50±0.112	1.17±0.124	1.66±0.135	1.16±0.063	1.74±0.232
	Group 3	2.78±0.171	1.83±0.149	1.33±0.070	2±0.214	0.53±0.097
	Group 4	2.79±0.162	2.35±0.188	0.98±0.121	1.44±0.119	0.9±0.098

Plaque Index and Gingival Index at different intervals.

Mean±SD Standard deviation

Table 4 shows the mean value of plaque reduction at different intervals by using different toothbrushes. Significant reduction in plaque accumulation and gingival inflammation was observed from baseline to 4th month among the study subjects and maximum reduction in plaque and gingival scores were found in T2 toothbrush (zigzag) followed by T3 toothbrush (wavy), T4 toothbrush (bi-bevel) and T1 toothbrush (flat trim).

Table 4: Mean value of plaque and gingival inflammation reduction at different intervals by using different toothbrushes.

Index	Type of tooth brush	Baseline	Score after 1 month	Score after 2 months	Score after 3 months	Score after 4 months
Plaque score	T1	2.84±0.115	2.73±0.127	2.32±0.157	2.15±0.160	1.83±0.634
	T2	2.83±0.152	2.38±0.160	2.32±0.157	1.73±0.093	0.85±0.213
	T3	2.73±0.127	2.48±0.341	1.92±0.344	1.32±0.095	1.26±0.095
	T4	2.47±0.158	1.92±0.160	1.32±0.157	1.26±0.095	1.68±0.135
Gingival score	T1	2.50±0.112	2.74±0.203	2.66±0.233	1.96±0.503	1.87±0.344
	T2	2.78±0.162	2.35±0.188	1.44±0.119	0.98±0.121	0.53±0.097
	T3	2.79±0.171	1.83±0.149	1.73±0.093	1.33±0.070	0.93±0.098
	T4	2.49±0.120	1.78±0.232	1.66±0.135	1.56±0.168	1.18±0.124

Mean±SD Standard deviation

Table 5 shows the difference between plaque scores at different interval periods using four different toothbrushes in different groups, statistically significant difference was observed between the mean scores of plaque accumulation from baseline to 4 months in all the groups. Zigzag toothbrush design was found to be superior in plaque reduction followed by wavy, bi-bevel and flat trim tooth brush design.

Table 5: Comparison between Plaque scores using different toothbrushes in four different groups.

Group	Time period	Mean±SD	t-value	P value
Group I	T1(baseline-1month)	0.11±0.026	25.488	0.000
	T2(1month-2 nd month)	1.41±0.064	137.867	0.000
	T3(2 nd month-3 rd month)	0.59±0.073	51.529	0.000
	T4(3 rd month-4 th month)	0.66±0.059	70.687	0.000
Group II	T2(baseline-1month)	0.59±0.164	19.602	0.000
	T3(1month-2 nd month)	0.65±0.084	44.357	0.000
	T4(2 nd month-3 rd month)	0.51±0.084	48.517	0.000
	T1(3 rd month-4 th month)	1.52±0.102	93.942	0.000
Group III	T3(baseline-1month)	0.62±0.09	36.738	0.000
	T4(1month-2 nd month)	0.53±0.085	45.951	0.000
	T1(2 nd month-3 rd month)	1.43±0.082	105.925	0.000
	T2(3 rd month-4 th month)	0.54±0.105	38.203	0.000
Group IV	T4(baseline-1month)	0.96±0.083	72.658	0.000
	T1(1month-2 nd month)	0.61±0.067	56.480	0.000
	T2(2 nd month-3 rd month)	0.60±0.059	63.336	0.000
	T3(3 rd month-4 th month)	0.56±0.076	46.968	0.000

p value ≤0.05 , significant

Table 6 shows the difference between gingival scores at different interval periods using four different toothbrushes in different groups, it was found that there was a statistically significant difference between the mean scores of gingival inflammation from baseline to 4 months in all the groups .Zigzag toothbrush design was considered to be superior in gingival score followed by wavy, bi-bevel and flat trim tooth brush design

Table 6: Comparison between Gingival scores using different toothbrushes in four different groups.

Group	Time period	Mean±SD	T value	P value
Group I	T1(baseline-1month)	0.44±0.067	41.425	0.000
	T2(1month-2 nd month)	1.37±0.093	92.258	0.000
	T3(2 nd month-3 rd month)	0.46±0.048	60.883	0.000
	T4(3 rd month-4 th month)	0.54±0.055	62.490	0.000

Group II	T2(baseline-1month)	0.66±0.153	34.219	0.000
	T3(1month-2 nd month)	0.94±0.091	39.022	0.000
	T4(2 nd month-3 rd month)	0.49±0.156	26.794	0.000
	T1(3 rd month-4 th month)	1.46±0.139	66.534	0.000
Group III	T3(baseline-1month)	1.01±0.084	75.933	0.000
	T4(1month-2 nd month)	0.41±0.087	29.765	0.000
	T1(2 nd month-3 rd month)	1.38±0.113	77.213	0.000
	T2(3 rd month-4 th month)	0.69±0.129	33.815	0.000
Group IV	T4(baseline-1month)	0.96±0.083	72.658	0.000
	T1(1month-2 nd month)	0.61±0.067	56.480	0.000
	T2(2 nd month-3 rd month)	0.64±0.059	63.336	0.000
	T3(3 rd month-4 th month)	0.60±0.105	38.203	0.000

p value ≤0.05 , significant

4. DISCUSSION

It is a proven fact that there is a direct relation between the degree of plaque accumulation and gingival disease. The mechanical plaque control method is considered to be an effective way to control plaque accumulation and further preventing gingival and periodontal diseases. Among all the mechanical methods, manual toothbrushes are the most widely used method [10,11]. Oral hygiene performed with a manual toothbrush is the most commonly used method to control plaque accumulation, maintaining good gingival health and for cleaning the teeth. Optimization of the technology and the design of brush have focused on improving elimination of plaque from inaccessible areas. Significant advances incorporated in the tooth brush design by the manufacturer are based on extensive ergonomic and scientific research^[12]. However, effectiveness depends not only on toothbrush design but also on brushing technique and the frequency and time spent during brushing [13,14,15,16]. Frandsen and Brothwell et al found that toothbrushing efficiency is constrained by a number of factors such as time devoted to brushing, patient motivation and brushing technique [17, 18]. There is a strong relationship between manual brushing technique, frequency and plaque removal efficacy concluded by Van der Weijden GA Van der Weijden GA et al [19, 20]. However these constraints were managed in the present study as the brushing procedure was well demonstrated and subjects were advised to brush the teeth twice daily.

The researchers in their studies have consistently concluded that there is no superior design of manual toothbrush yet different companies are coming out with different designs, each claiming superiority, backed by the results of their own clinical research teams [13, 21, 22]. Therefore, a cross over clinical study was undertaken to find out if any significant differences exist in plaque removal efficacy and improvement in gingival inflammation between different bristle designs of toothbrush. Cross over plaque removal studies are considered to be as accurate as conventional plaque removal studies in assessing the efficacy of brushes [23].

The selection of the index in the present study was based on the fact that with this index all natural teeth (except third molars) can be assessed for plaque accumulation and gingival inflammation and it also provides more sensitive and accurate evaluation of brushing effectiveness compared to other indices used in other studies [23] where only certain designated teeth are assessed. The results of the study showed that lingual surfaces showed greater plaque accumulation as well as gingival inflammation when compared to their counterparts. This is in agreement with most of the previous studies [24]. The results of the study also showed statistically significant differences in the plaque removal efficacy and improvement in the gingival inflammation between the four manual toothbrushes. This is in contrast with the previous studies conducted by Bergenholz and Keiser [24,25].

Zigzag tooth brush showed greater plaque removal efficiency and gingival inflammation improvement than the other types of toothbrushes and which is in accordance with the previous studies by Turner et al.[27] and Kakaret al [28]. Moreover, after zig zag toothbrush, wavy and bibevel tooth brushes showed slightly greater plaque removal efficiency as well as gingival improvement over the flat trim toothbrush which is similar to study by Andrew et al [29] that showed similar results by comparing them over a period of six months. The results of the present clinical study shows that toothbrushes with different bristle designs reduced plaque as well as gingival scores significantly compared to the baseline scores and significant differences were observed between the four toothbrushes. Similar results were found by Kieser and Groeneveld [26] where all brushes reduced plaque to a similar degree. In the Present Study significant difference was found in the decrease of dental plaque score and gingival score. A similar result was found by Camila Tirapelliet al.[30] Present study results contradicts to the study by Claydon et al.(2002)[10]. However, this study is in contradiction to the study by Sripriya N et al.(2007)[4],Bergenholtzet al. (1984)[31] and Staudt et al. (2001)[32] who conducted a study to compare the efficacy of three toothbrushes namely, convex bristle, multilevel bristle and flat-trim bristle. In our study, Zigzag toothbrush design was found

to be superior in plaque and gingival score followed by wavy, bi-bevel and flat trim tooth brush design. Further studies have to be conducted to verify our assumptions. The small sample size is one of the study's limitations. Although the study's findings suggest that zigzag toothbrushes are more effective than flat toothbrushes, they still require confirmation using a larger sample size. When a toothbrush's bristles start to flare up, we urge people to replace it.

5. CONCLUSION

Bristle designs of toothbrush plays an important role in plaque control and gingival inflammation reduction. In our study, Zigzag toothbrush design was found to be superior in plaque and gingival score followed by wavy, bi-bevel and flat trim tooth brush design. Thus, Zigzag and wavy tooth brushes can be recommended at the community level as these are not only quite inexpensive and affordable for the average person but also because the usage of toothpaste and toothbrush are the most common oral hygiene practices in modern society and should be practiced twice daily. Oral health education programme should also be conducted in the community to increase the awareness and improve oral health related behaviour and practices.

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