

Scientific Research Report

Impact of the Brush Day & Night Programme on Well-Being, Plaque, and Dental Caries in Children

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ABSTRACT

Objectives: Poor oral hygiene can have an adverse effect on quality of life. School-based interventions can establish positive behaviours that reduce the likelihood of dental caries later in life. The Brush Day & Night programme aims to encourage good oral health behaviour and improve oral health and quality-of-life outcomes. In this article, we report the effect of the programme on well-being and oral hygiene measured by plaque levels at 3, 8, and 24 weeks and dental caries at 24 weeks after programme start date.

Methods: This was a superiority cluster randomised trial of children 6–12 years of age from Indonesia ($N = 2021$) and Nigeria ($N = 2104$). All children were provided with toothpaste and a toothbrush. Children in the intervention group received the 21-day Brush Day & Night programme, whereas those in the control group did not. Children completed a questionnaire addressing the objectives at all time points. Their oral hygiene was assessed using the Oral Hygiene Index-Simplified (OHI-S). Additionally, at baseline and 24 weeks their caries status was recorded using the decayed, missing, and filled teeth (DMFT) index.

Results: In Indonesia, after participation in the programme children demonstrated a 45% increased probability of no worsening in the occurrence of decayed, missing, or filled teeth. In Nigeria, children had a 71% higher probability of having confidence in their smile and the proportion of children with good oral hygiene doubled from 40% to 80% at 24 weeks.

Conclusions: The Brush Day & Night programme was successful in improving well-being and oral hygiene in children in Nigeria and reduced the likelihood of worsening in the occurrence of decayed, missing, or filled teeth in children in Indonesia.

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Introduction

Oral health has an impact on overall health and well-being of children.¹ Dental caries is the most prevalent oral disease and, despite decreases in caries prevalence over the last decades, it remains a significant problem in developing countries^{2–10} and disproportionately affects people of lower socioeconomic status.¹¹ Previous studies in both adults and children have demonstrated that the impact on quality of life (QoL) correlates with the severity of dental caries, with the greatest effect associated with the most severe dental caries.^{12,13}

Untreated, it can lead to pain and infection and result in the need for tooth extraction.¹⁴

From the patient's perspective, dental caries can significantly affect QoL by impacting social functioning, including chewing, appetite, sleep, and absenteeism.^{15,16} In children, dental caries is associated with significant pain, poor general health and well-being, and lower body weight and growth.¹⁵ It is estimated that children miss 50 million school hours per year due to oral health problems, which can ultimately affect a child's success later in life.¹⁷

Dental caries is almost entirely preventable. Prevention is achieved through inexpensive methods such as limiting sugar intake and brushing teeth twice daily with a fluoride toothpaste.^{14,18,19} The prevention of dental caries could also significantly reduce the financial burden on health services.²⁰ Establishing regular toothbrushing habits during childhood can help reduce the likelihood of caries in later life.²¹

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Microbial dental plaque is one of the most important aetiological factors for dental caries,²² and toothbrushing is considered the simplest individual preventive measure for plaque control, and it is effective in the long-term preservation of oral health.^{23,24} Considering that a healthy mouth and teeth can be achieved with education and properly acquired habits during childhood,²⁵ school-based interventions are ideal to establish these behaviours.¹⁷ Evidence suggests that informing children about the best behaviours leads to a better knowledge of the link between plaque removal and reduction in risk for dental caries, ultimately improving oral hygiene and well-being.^{1,5,20,26-29}

A 2013 Cochrane review of school-based interventions found that interventions that utilise behavioural theory in their design improved children's oral health knowledge and plaque outcomes.¹⁵ To this end, FDI World Dental Federation (FDI) and Unilever have developed a 21-day school-based educational programme called Brush Day & Night (BDN). The BDN programme was designed based on the theories of behaviour change³⁰ and aims to establish the habit of brushing day and night with a fluoride toothpaste. Participants are instructed on daily brushing and given free toothpaste and toothbrushes. In a previous study conducted in 10 countries with 7991 children aged 2-12 years, the 21-day BDN intervention led to a 25% increase in the number of schoolchildren brushing their teeth twice daily at the conclusion of the programme.³¹ However, as well-being and oral health status were not assessed in that study, it is not known whether the behaviour change prompted by the 21-day BDN intervention translates into health benefits.

The main aim of the present study (NCT04001296) is to determine the impact of the 21-day BDN intervention on children's well-being and oral hygiene in a randomised sample 3, 8, and 24 weeks after the start of the study, and decayed, missing and filled teeth after 24 weeks, compared with baseline and a control group in two countries, Nigeria and Indonesia.

Materials and methods

Study design

The methodology for this study has been described in detail previously.³⁰ In brief, this was a two-arm, superiority, randomised controlled trial involving infant and junior schoolchildren aged 6-12 years from Indonesia and Nigeria. A total of 2021 children from Indonesia were included, 914 in the control group and 1107 in the intervention group. From Nigeria, a total of 1947 children were included, 915 in the control group and 1032 in the intervention group. Schools were matched into pairs by location (rural vs urban) and socioeconomic status and randomised to intervention and control groups using a randomisation table. The Nigerian study recruited children from 20 schools (10 in the control group and 10 in the intervention group, of which five were from rural locations and five from urban locations). The Indonesian study recruited children from 22 schools (10 in the control group, of which six were from rural locations and four were from urban locations, and 12 in the intervention group, of which eight were

from rural locations and four from urban locations). Teachers were responsible for implementing the programme and were trained by local study coordinators. Schools in Indonesia were located in low- and middle-income areas, and schools in Nigeria were located in low- middle- and high-income settings.

Inclusion and exclusion criteria

The study included healthy children in grades 1, 2, and 3, in which most children are within the target age range of 6 to 12 years. Although the standard age range for these grades is 6-9 years, some children repeat school years, resulting in a broader age range being included in the study. Children needed to be willing and able to participate in the programme and planning to attend their school for the next 12 months. Children and families had no affiliation with FDI or Unilever.

The study excluded children who did not have a signed consent form, those scheduled for medical or dental procedures, those with allergies to toothpaste ingredients, those with obvious untreated caries or significant periodontal disease, and those whose well-being would be affected by the study.

Study endpoints

The primary endpoint of the study was to measure the impact of the 21-day school programme on oral hygiene via plaque levels and number of decayed, missing, and filled teeth in schoolchildren at different timepoints compared with baseline and with a control group. Plaque levels were measured by the short-form Oral Hygiene Index-Simplified (OHI-S) at all timepoints: baseline (T0), after 3 weeks (T0+21), 8 weeks (T1), and 24 weeks (T2). Decayed, missing and filled teeth were assessed by the Decayed Missing and Filled Teeth (DMFT) index at T0 and T2.

The secondary endpoint was to measure the impact of the 21-day BDN programme on well-being. This endpoint was measured using the percentage of positive change in answers to questions related to well-being in the children's questionnaire at all timepoints T0, T1, and T2. At baseline (T0), children answered a questionnaire consisting of eight main questions, of which three were related to well-being (Supplementary Figure 1, available online) and five were related to oral health knowledge and toothbrushing behaviour. The latter aspects are analysed and reported in a separate article in this supplement.³² Adverse events were also monitored.

Intervention

Children in the intervention schools took part in the structured 21-day Brush Day & Night programme and were each provided with toothpaste and a toothbrush at T0. Children were supervised when brushing and sang songs to facilitate learning the importance of brushing day and night, with stickers and calendars to track progress. A celebration was held at the end of the programme with certificates and rewards. The programme was supported by colourful materials with cartoon characters. Parents were provided with

educational leaflets. Children in the control schools were provided with free toothpaste and toothbrushes at T0 but did not receive the 21-day intervention.

Statistical analysis

Baseline (T0) characteristics in the control and intervention groups were compared. Proportions and continuous variables were compared using the χ^2 and Mann-Whitney tests, respectively. The frequency of each outcome (original and transformed variables) was estimated separately for the control and intervention groups and at each timepoint. The comparison of variables within the same group and across evaluation moments was performed for dependent groups, using McNemar's test for proportions and the Wilcoxon signed-rank test for continuous variables.

The variables "Mouth Pain," "Smile Confidence," and "Bullying because of teeth" were related to well-being. Improvement in well-being was calculated based on the percentage of positive change. Positive change was considered when a child moved from selecting a negative or neutral answer (ie, inadequate) to selecting a positive answer (ie, adequate) in any of the variables.

Particular outcome variables observed before and after the intervention/control period were categorised as adequate or inadequate using binary responses, where "1" represents adequacy and "0" represents inadequacy, as follows: Mouth Pain experience, "No pain" (1) vs "any reported level of pain" (0); Smile Confidence "Yes" (1) vs "No" or "Do not know" (0); Bullying because of teeth "No" (1) vs "Yes" or "Do not know" (0).

The effect of the intervention was analysed comparing the effect at each timepoint against baseline, with changes from adequate to inadequate categorised as "worse," changes from inadequate to adequate categorised as "improved" and no change categorised as "equal."

The effect of the intervention was analysed based on a conditional logistic approach for each of the three evaluation timepoints: T0 + 21, T1, and T2 and reported as odds ratio (OR) with 95% CI.

OHI-S score before and after the intervention/control was categorised as "poor," "moderate," or "good," and change in plaque levels was categorised as "equal," "improved," or "worse." The effect of the intervention on the DMFT Index was assessed using a standard logistic regression, where the response variable stated "Not worse" (no change in the index treated as a continuous variable) or "Worse" from T0 to T2 evaluation.

Crude estimates of the effect of the intervention on particular outcomes were adjusted for variables showing relevant relation with both assignment group and given outcome. Significant variables identified through a univariate analysis (P value $\leq .05$) were selected from the grouped set of covariates: (i) basic children's data (age, grade, gender), (ii) children's other characteristics at baseline evaluation (their opinion on the importance of everyday brushing, usage of fluoride toothpaste, feeling of pain in mouth while eating), and (iii) location of school (rural or urban), and subsequently added to a model. As a result, each outcome was adjusted for a different combination of controlling variables.

Ethics

This study was conducted in accordance with the Declaration of Helsinki. Ethical approval was received from the Nigerian State Universal Basic Education Board and the Health Research Ethics Commission at the Faculty of Dental Teaching, Trisakti University, Indonesia. All parents or legal guardians of the participating children signed an informed consent form.

Results

Nigeria

Distribution of study participants

The recruitment of children is presented in [Figure 1](#). A total of 5436 observations were made on 2104 children. Of these, 157 children were excluded before randomisation to give a total of 1947 (1032 in the intervention group and 915 in the control group). During the study, a further 593 children were excluded from the intervention group and 604 children from the control group, leaving 439 and 311, respectively.

Baseline characteristics

Baseline characteristics are presented in [Table 1](#). Median (25th–75th percentiles) ages of children were similar across intervention and control groups (9.0 [8.0–10.0] vs 8.0 [7.0–10] years, respectively). The distribution of male and female children was likewise similar (approximately 50%). The intervention group included significantly more children from rural or semirural areas than the control group (61.7% vs 53.4%; $P = .027$). Smile confidence was significantly lower in the intervention group compared with the control group ($P = .005$). The intervention group showed significant differences in oral hygiene, with 39.6%, 52.4%, and 8.0% of children presenting good, moderate, or poor oral hygiene, respectively, compared with 50.8%, 40.1%, and 9.1% in the control group ($P = .01$). Almost all children (approximately 92%) across both groups presented with no decayed, missing, or filled teeth.

Effect of the BDN programme

Well-being. At Week 3 (T0 + 21), both control and intervention groups showed a significant decrease in mouth pain versus baseline ($P < .05$) ([Figure 2A](#)), but by Weeks 8 and 24 (T1 and T2), this was only seen in the intervention group. When adjusted for children and school characteristics, there were significantly more children reporting mouth pain in the intervention group at Week 3 (T0 + 21) compared with the control group ([Table 2](#), [Figure 3](#)). There were no differences between groups at Weeks 8 or 24 (T1 and T2). In children reporting pain or unsure of pain at baseline, similar levels of improvement were seen for both groups across all timepoints.

In children from the intervention group, the proportion reporting confidence in their smile significantly increased at all timepoints compared with baseline ([Figure 2B](#)) ($P < .05$). When adjusted for children and school characteristics, this increase was observed at Week 24 (T2) only when children had a 71% higher probability of having smile confidence

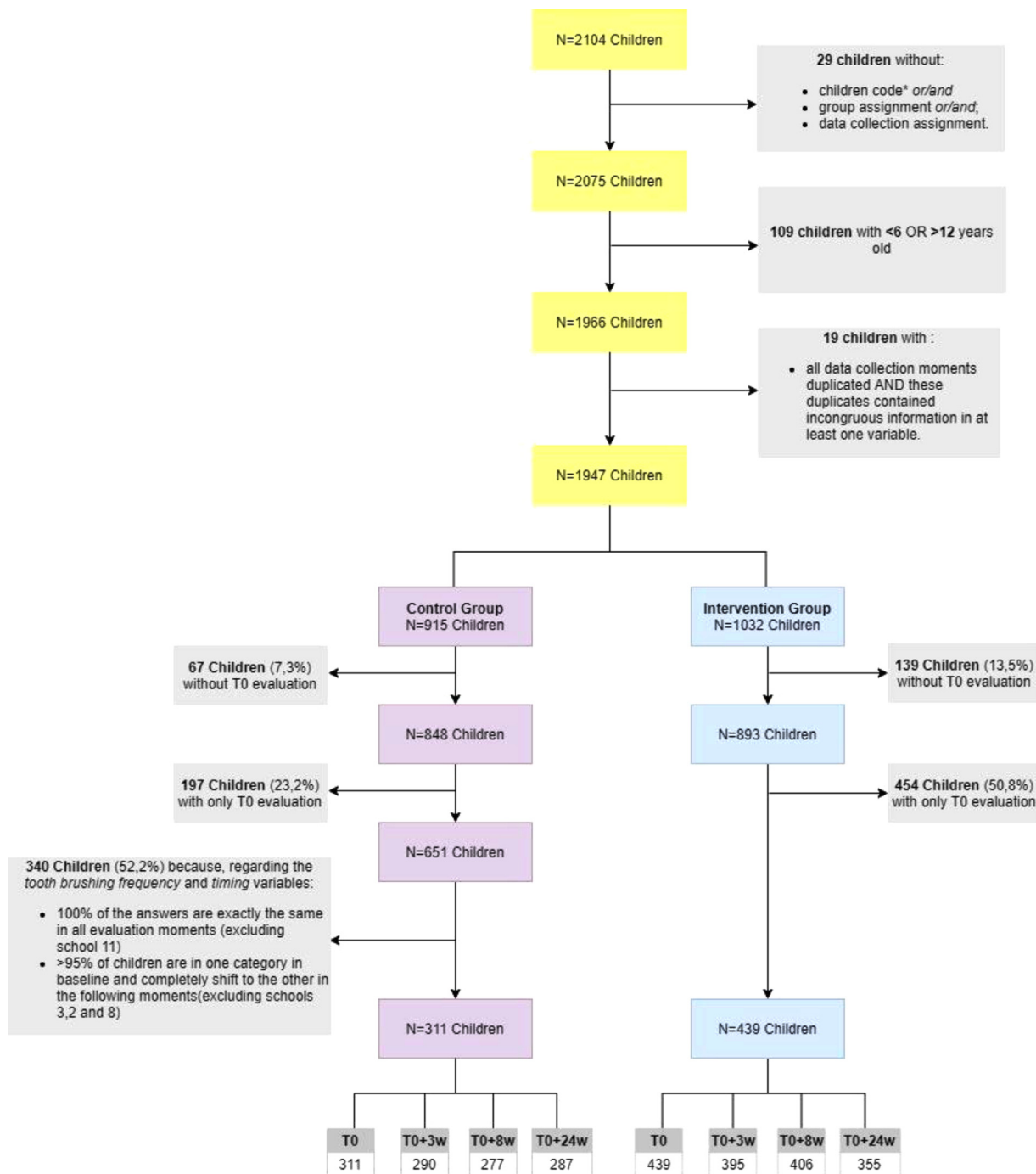


Fig. 1 – Study flowchart for the Nigeria study.

*Number of children code incomplete (without identification of school and grade).

(Table 2, Figure 3). In children with no confidence in their smile or no opinion at baseline, most declared an improvement at all timepoints compared with baseline in both the control and intervention groups (Supplementary Figure 2B, available online).

The proportion of children who were bullied due to their teeth decreased at all timepoints for all children but, particularly, for those in the intervention group. Significantly fewer

children in the intervention group reported not feeling bullied at Weeks 3 (T0 + 21) and 8 (T1) compared with baseline ($P < .05$) (Figure 2C). When adjusted for children and school characteristics, at Week 8 (T1), significantly fewer children felt bullied in the intervention group compared with the control group (Table 2, Figure 3). In children who felt they were bullied due to their teeth at baseline, there was an improvement in all severity categories at all timepoints in children in both

Table 1 – Childrens' baseline characteristics by assigned group in the Nigeria study.

	Control 311 N (%) [*]	Intervention 439 N (%) [*]	P value [†]
Age			
Median (P25, P75)	8.0 (7.0, 10.0)	9.0 (8.0, 10.0)	.453
Gender			
Male	161 (51.8)	212 (48.8)	.305
Female	143 (46.0)	222 (51.2)	
Schools			
Rural	166 (53.4)	271 (61.7)	.027
Urban	145 (46.6)	168 (38.3)	
Do not use	16 (5.2)	39 (8.9)	
Not sure	21 (6.8)	154 (35.2)	
Mouth Pain			
Do not hurt	244 (78.5)	347 (79.4)	.989
It hurts a little bit/ sometimes	29 (9.3)	45 (10.3)	
It hurts	15 (4.8)	24 (5.5)	
It makes me cry	8 (2.6)	13 (3.0)	
Do not know	6 (1.9)	8 (1.8)	
Smile Confidence			
Confident	290 (94.2)	393 (89.7)	.005
Not confident	13 (4.2)	43 (9.8)	
Do not know	3 (0.0)	2 (0.5)	
Bullying			
Do not feel bullied	266 (88.4)	373 (86.5)	.184
Feel bullied and it's okay	17 (5.6)	22 (5.1)	
Feel bullied and feel sad	13 (4.3)	19 (4.4)	
Feel bullied and makes me cry	4 (1.3)	5 (1.2)	
Do not know	1 (0.3)	12 (2.8)	
OHI-S Scores			
Good oral hygiene	123 (50.8)	158 (39.6)	.010
Moderate oral hygiene	67 (40.1)	209 (52.4)	
Poor oral hygiene	22 (9.1)	32 (8.0)	
DMFT			
0	238 (94.4)	364 (90.5)	.111
1	8 (3.2)	24 (6.0)	
2	5 (2.0)	9 (2.2)	
3-5	0 (0.0)	5 (1.2)	
>5	1 (0.4)	0 (0.0)	

DMFT = decayed, missing, or filled teeth; OHI-S = Oral Hygiene Index-Simplified.

^{*} Percentage of non-missing responses within the study group.

[†] Wilcoxon test for continuous variable; chi-square test for all other variables.

groups, although improvements appeared greater in children in the intervention groups (Supplementary Figure 2C, available online).

Oral hygiene. At baseline in Nigeria, 39.6% of children in the intervention group presented with good oral hygiene. There was an upward trend in oral hygiene over the duration of the programme, increasing to 65.7%, 64.5%, and 79.9% of children with good oral hygiene at 3, 8 and 24 weeks, respectively ($P < .05$ with respect to baseline) (Figure 4). In the control group, 50.8% of children presented with good oral hygiene at baseline. However, unlike the intervention group, there was a downward trend in oral hygiene over the 24-week period (44.8%, 38.8%, and 39.7% of children with good oral hygiene at 3, 8, and 24 weeks, respectively; $P < .05$ with respect to baseline). When assessed by baseline status (Figure 5), oral hygiene did not improve in either the intervention or control group in

children presenting good oral hygiene at baseline over the 24-week period. However, in children with moderate oral hygiene at baseline, improvement was observed over time in the intervention group compared with the control group (50%, 57%, and 75% of children with good oral hygiene at 3, 8, and 24 weeks, respectively, compared with 35%, 13%, and 16%, respectively; $P < .001$ for all timepoints). In children with poor oral hygiene at baseline, except for the 8-week timepoint, improvement was observed in the intervention group compared with the control group, but with no pattern over time (74%, 50%, and 65% of children with good oral hygiene at 3, 8, and 24 weeks, respectively, compared with 56%, 53%, and 50%, respectively; $P < .001$ for all timepoints). Covariate analysis revealed an odds ratio (OR) (95% CI), independent of age and school location, for change of OHI-S category to "good" at 3 weeks of 10.9 (4.631-25.685), which decreased over time to 3.8 (2.675-5.311) at 24 weeks (Table 2, Figure 3).

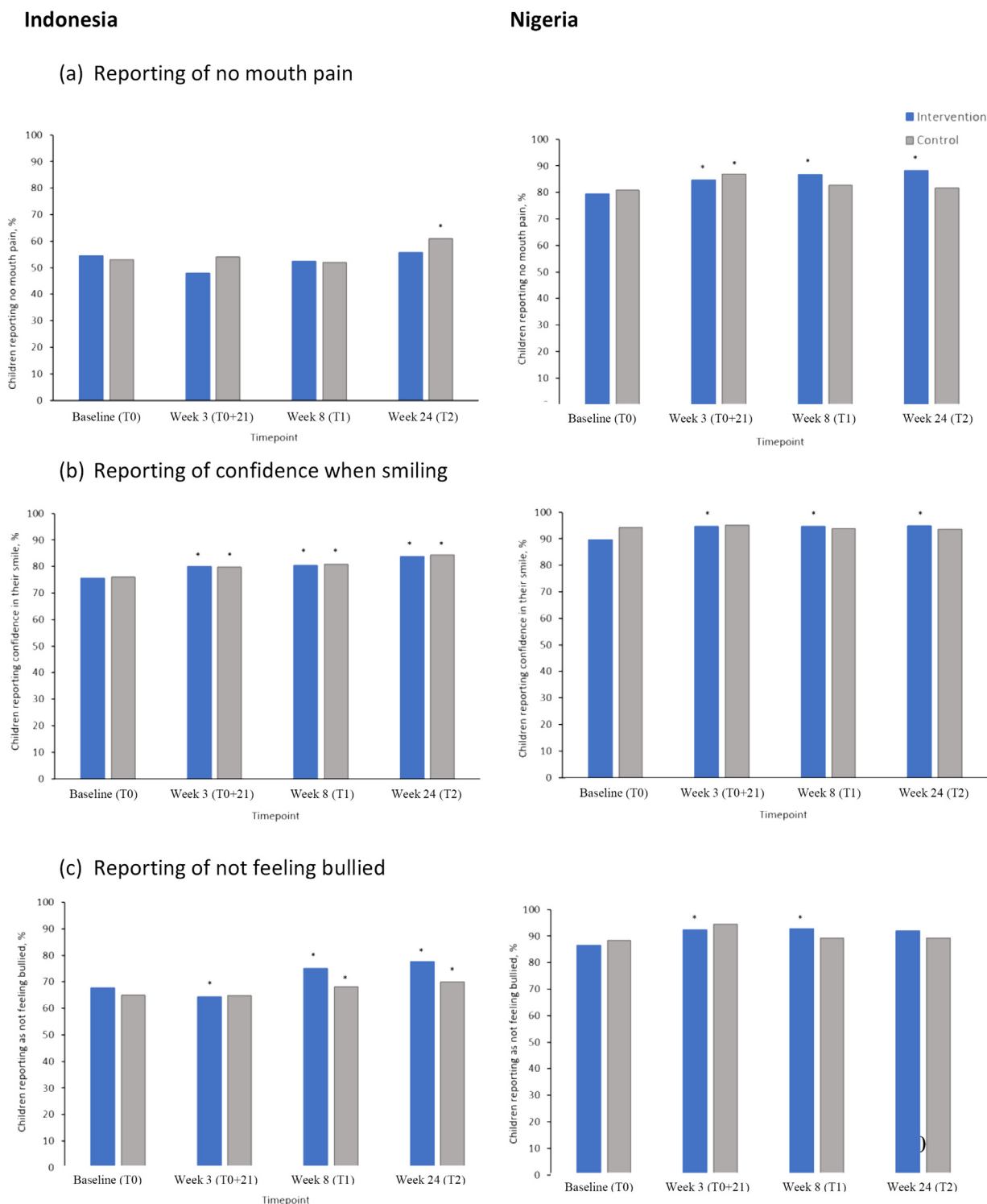


Fig. 2 – Effect of Brush Day & Night programme or control on change in quality of life, well-being, and social measures of schoolchildren from Indonesia and Nigeria at Weeks 3, 8, and 24 compared with baseline (FAS). (A) Reporting of confidence when smiling. (B) Reporting of not feeling bullied. BDN = Brush Day & Night FAS = full analysis set; QoL = quality of life.

Decayed, missing, and filled teeth. At baseline, approximately 92% of children presented with a DMFT index of 0, indicating no decayed, missing, or filled teeth. At 24 weeks, 3% of children in the intervention group presented with a worse (increased) DMFT score, whereas all children in the control

group continued to present with a DMFT score of 0 (Figure 6). However, covariate analysis revealed no impact of the programme on the OR of no worsening in the DMFT index at 24 weeks, either crude or adjusted for children's age and school location (Table 2, Figure 3).

Table 2 – Effect of intervention on oral health, covariate analysis in the Nigeria study.

	T0+3W			T0+8W			T0+24W		
	n	OR	95% CI	N	OR	95% CI	n	OR	95% CI
Change to no pain in the mouth when eating									
Crude effect of the intervention	662	0.764	0.365-1.600	656	1.246	0.880-1.765	622	1.360	1.063-1.739
+ children's age and grade	275/387	0.646	0.293-1.425	263/393	1.311	0.908-1.893	277/345	1.387	1.066-1.803
+ children's other characteristics ^{*,†}		0.367	0.145-0.926		1.058	0.709-1.577		1.229	0.921-1.640
+ school location (rural vs urban)		0.318	0.123-0.823		0.941	0.619-1.432		1.205	0.896-1.619
Change to being confident with the smile									
Crude effect of the intervention	662	1.948	0.671-5.655	662	1.433	0.886-2.317	621	1.471	1.059-2.043
+ children's other characteristics ^{*,‡}	275/387	1.587	0.511-4.932	266/396	1.205	0.719-2.020	276/345	1.521	1.059-2.184
+ school location (rural vs urban)		2.938	0.743-11.616		1.308	0.764-2.238		1.709	1.132-2.581
Change to not being bullied due to teeth									
Crude effect of the intervention	660	0.640	0.241-1.700	651	1.451	0.948-2.221	620	1.088	0.919-1.454
+ children's grade	276/384	0.599	0.206-1.742	260/391	1.868	1.129-3.092	277/343	1.100	0.789-1.533
+ children's other characteristics ^{‡,§}		0.640	0.208-1.966		2.222	1.275-3.875		1.114	0.788-1.573
+ school location (rural vs urban)		0.633	0.206-1.942		2.381	1.340-4.231		1.147	0.802-1.642
Change to "Good" OHI-S category									
Crude effect of the intervention	507	9.707	4.270-22.670	537	5.066	3.230-7.947	479	3.515	2.594-4.843
+ children's age	169/338	10.451	4.502-24.264	186/351	5.738	3.503-9.399	194/285	3.504	2.561-4.793
+ school location (rural vs urban)		10.906	4.631-25.685		5.741	3.504-9.406		3.769	2.675-5.311
No worsening in DMFT Index									
Crude effect of the intervention							519	0.143	0.018-1.126
+ children's age							210/309	0.139	0.017-1.102
+ school location (rural vs urban)								0.120	0.014-0.932

CI = confidence intervals; DMFT = decayed, missing, or filled teeth; n, number of children (control/intervention); OHI-S = Oral Hygiene Index-Simplified; OR = odds ratio.

* Usage of fluoride toothpaste at baseline child's adequacy of brushing timing at baseline.

† Child's adequacy of brushing frequency at baseline.

‡ Experience of being laughed at because of teeth.

§ Confidence when smiling.

Indonesia

Distribution of study participants

The recruitment of children is presented in Figure 7. A total of 8084 observations were made in 2021 children (1107 in the intervention group and 914 in the control group). All evaluation timepoints were available for all children and none were excluded.

Baseline characteristics

Baseline characteristics are presented in Table 3. Children in the intervention group were older by 1 year compared with the control group (median [25th–75th percentiles] 10 [9–10] vs 9 [7–10], respectively). The distribution of male and female children was similar across intervention and control groups (approximately 50%). The intervention group included more children from rural or semirural areas than the control (67.4% vs 60.5%). There was a significant difference in mouth pain between the intervention and control groups. Approximately 66% of children across both groups presented with good oral hygiene, and approximately 32% presented with moderate oral hygiene. However, only approximately 10% of children presented with no decayed, missing, or filled teeth, with a median DMFT score of 6.

Effect of the BDN programme

Well-being. At baseline, more than 40% of children from both groups in Indonesia reported mouth pain when eating. There

were no significant differences in the proportion of children from either the intervention or control group reporting mouth pain at baseline or Weeks 3 and 8 (T0, T0+21, and T1) (Figure 2A). At Week 24 (T2), there were significantly fewer children reporting mouth pain in the control group compared with baseline ($P < .05$), but there was no significant difference from baseline in children in the intervention group.

When adjusted for children and school characteristics, there were significantly fewer children reporting mouth pain in the control group at Week 3 (T0+21) compared with the intervention group ($P < .05$) (Table 4, Figure 8). In children who reported pain at baseline, there was a similar improvement in reduction in pain severity at all timepoints in both the control and intervention group (Supplementary Figure 2A, available online).

The proportion of children reporting confidence in their smile significantly increased in both the intervention and control group at all timepoints compared with baseline (Figure 2B). When adjusted for children and school characteristics, there was no significant difference between the intervention and control groups in the proportion of children reporting confidence in their smile (Table 4, Figure 8). In children with no confidence in their smile or no opinion at baseline, except for the control group at Week 3, most declared an improvement at all timepoints compared with baseline in both the control and intervention groups (Supplementary Figure 2B, available online).

The proportion of children who were bullied due to their teeth decreased significantly at Weeks 8 and 24 (T1 and T2)

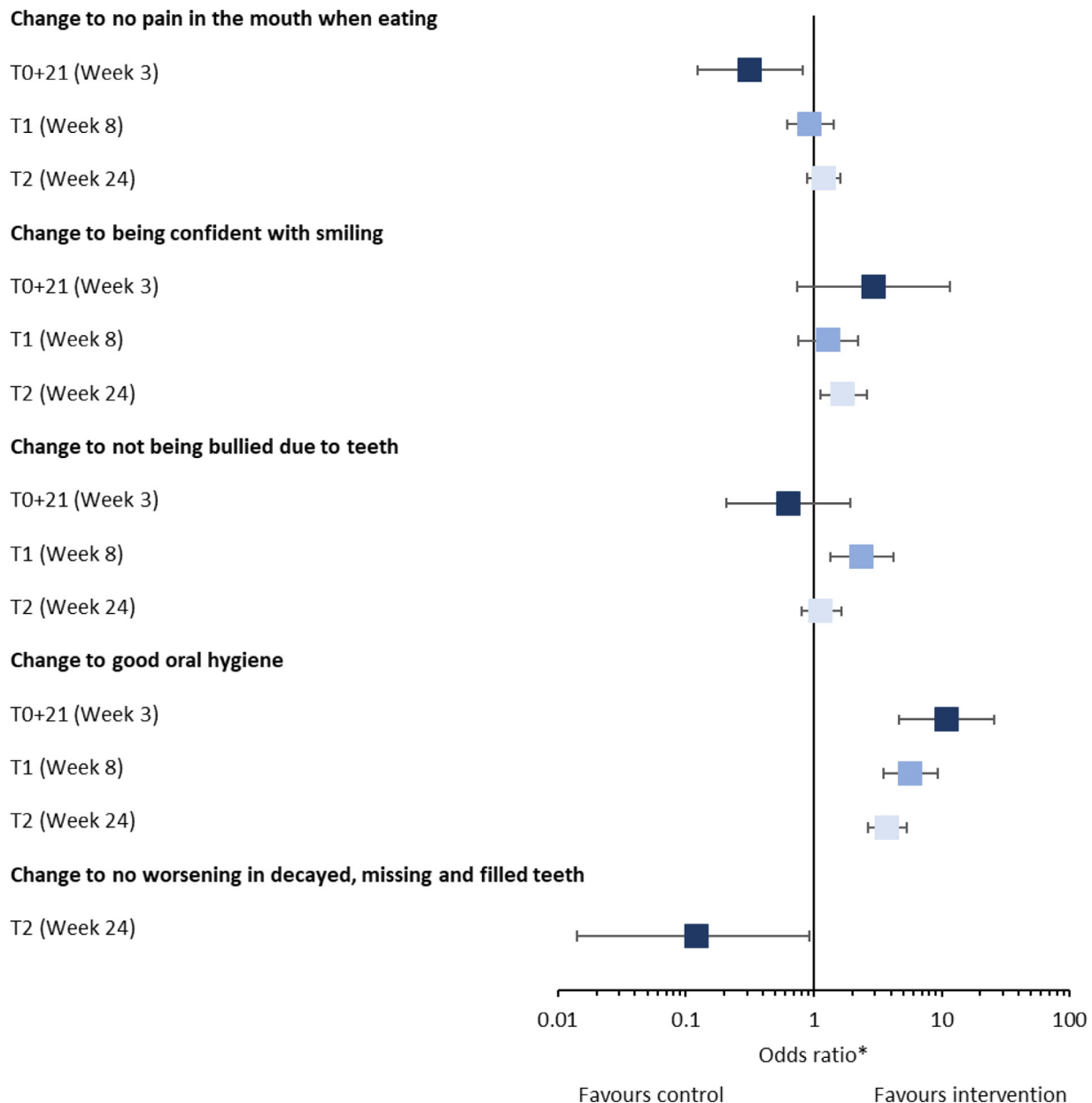


Fig. 3 – Effect of Brush Day & Night programme on well-being and oral health in schoolchildren from Nigeria at Weeks 3, 8, and 24 compared with control (FAS). BDN = Brush Day & Night; FAS = full analysis set.
*Adjusted for child's age and school location.

for all children, but particularly for those in the intervention group ($P < .05$) (Figure 2C). When adjusted for children and school characteristics, there was no significant difference between groups at all timepoints, apart from Week 3, when there was a significant increase in the number of children in the intervention group who felt they were bullied due to their teeth compared with those in the control group (Table 4, Figure 8). In children who felt they were bullied due to their teeth at baseline, there was an improvement in all severity categories at all timepoints in both groups, although improvements appeared greater in children in the intervention group (Supplementary Figure 2C, available online).

Oral hygiene. At baseline in Indonesia, 65.4% of children in the intervention group presented with good oral hygiene. There was a slight upwards trend in oral hygiene over 3, 8 and 24 weeks, increasing to 70.6%, 69.2%, and 70.1% of children with good oral hygiene, respectively ($P < .05$ with respect to baseline) (Figure 9). In the control group, 66.4% of children presented with good oral hygiene at baseline. As with the intervention group, there was a slight upwards trend in oral hygiene over the 24-week period (70.0%, 65.4%, and 70.9% of children with good oral hygiene, $P < .05$ with respect to baseline). When assessed by baseline status (Figure 10), oral hygiene did not improve in either the intervention or control

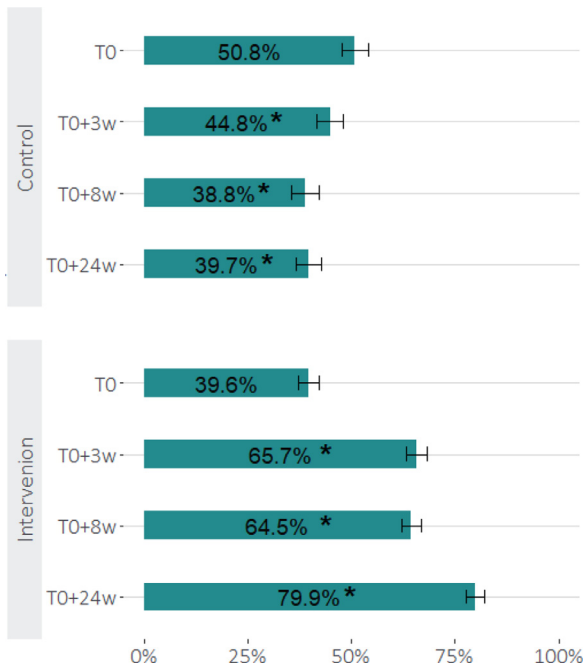


Fig. 4 – Proportion of children with good oral hygiene by OHI-S score in the Nigeria study. OHI-S = Oral Hygiene Index-Simplified.
*Statistically significant difference in proportions relative to baseline (P value < .05 from McNemar’s test).

group in children presenting with good oral hygiene at baseline over the 24-week period. However, in children with moderate oral hygiene at baseline, improvement was observed in the intervention group compared with the control group (55%, 55%, and 59% of children with good oral hygiene at 3, 8, and

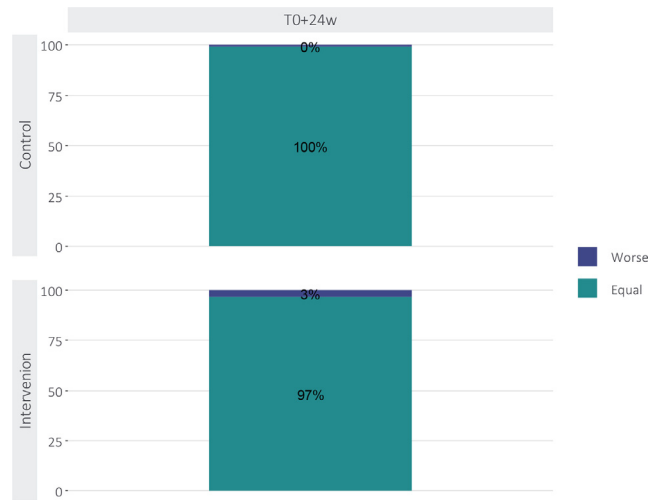


Fig. 6 – Change in DMFT score by assigned group in the Nigeria study. DMFT = decayed, missing, or filled teeth.

and 24 weeks, respectively, compared with 48%, 32%, and 40%, respectively; $P < .001$). In children with poor oral hygiene at baseline, except for the 3-week time point, a marked improvement in oral hygiene was observed in the intervention group compared with the control group (73%, 100%, and 100% of children with good oral hygiene at 3, 8, and 24 weeks, respectively, compared with 91%, 74%, and 74%, respectively; $P < .001$). Covariate analysis revealed no increased likelihood of changing category to “good” at any time point over 24 weeks (Table 4, Figure 8).

Decayed, missing and filled teeth . At baseline, only approximately 10% of children presented with a DMFT index of 0,

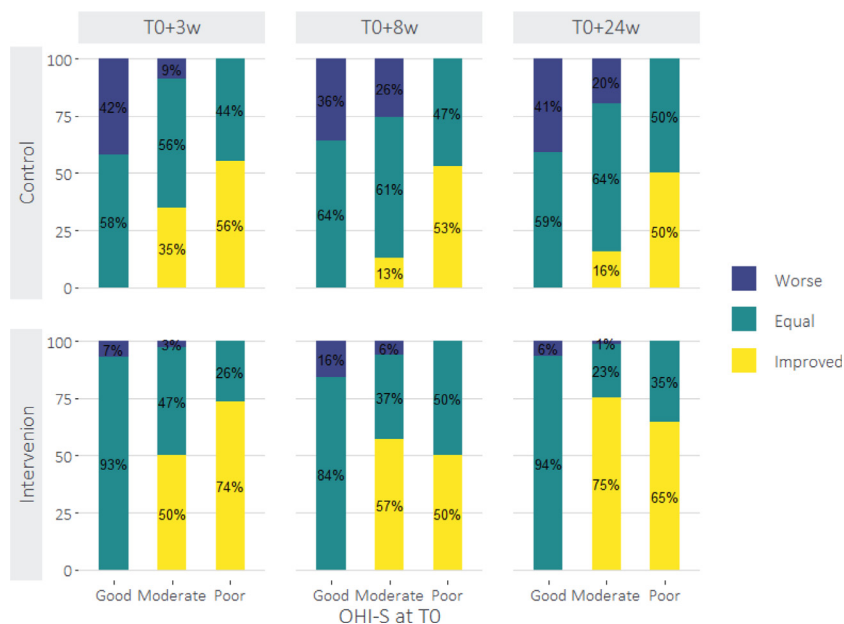


Fig. 5 – Change in OHI-S score category according to baseline status in the Nigeria study. OHI-S = Oral Hygiene Index-Simplified.

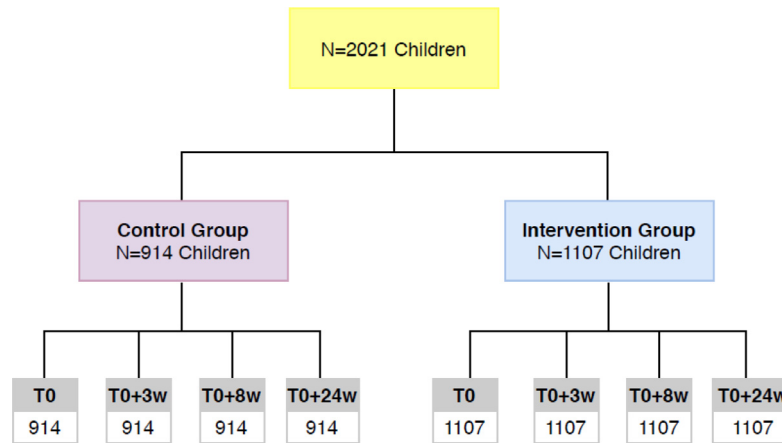


Fig. 7 – Study flowchart for the Indonesia study.

Table 3 – Childrens' baseline characteristics by assigned group in the Indonesia study.

	Control 914 N (%) [*]	Intervention 1107 N (%) [*]	P value [†]
<i>Age</i>			
Median (P25, P75)	9 (7, 10)	10 (9, 10)	.008
<i>Gender</i>			
Male	449 (49.1)	559 (50.5)	.569
Female	465 (50.9)	548 (49.5)	
<i>Schools</i>			
Rural	553 (60.5)	746 (67.4)	.001
Urban	361 (39.5)	361 (32.6)	
<i>Mouth Pain</i>			
Do not hurt	484 (53.1)	603 (54.6)	.001
It hurts a little bit/ sometimes	212 (23.2)	225 (20.4)	
It hurts	88 (9.6)	163 (14.8)	
It makes me cry	84 (9.2)	77 (7.0)	
Do not know	44 (4.8)	37 (3.2)	
<i>Smile Confidence</i>			
Confident	693 (76.0)	834 (75.6)	.978
Not confident	190 (20.8)	234 (21.2)	
Do not know	29 (3.2)	35 (3.2)	
<i>Bullying</i>			
Do not feel bullied	593 (65.0)	741 (67.7)	.120
Feel bullied and it's okay	228 (25.0)	222 (20.3)	
Feel bullied and feel sad	51 (5.6)	74 (6.8)	
Feel bullied and makes me cry	10 (1.1)	13 (1.2)	
Do not know	30 (3.3)	44 (4.0)	
<i>OHI-S scores</i>			
Good oral hygiene	606 (66.4)	724 (65.4)	.112
Moderate oral hygiene	284 (31.1)	368 (33.2)	
Poor oral hygiene	23 (2.5)	15 (1.4)	
<i>DMFT</i>			
Median (P25, P75)	6 (3, 10)	6 (3, 9)	.086
Categories			
0	81 (8,9)	113 (10,2)	.625
1	52 (5,7)	58 (5,2)	
2	63 (6,9)	90 (8,1)	
3-5	217 (23,8)	265 (23,9)	
>5	500 (54,8)	581 (52,5)	

DMFT = decayed, missing, or filled teeth; OHI-S = Oral Hygiene Index-Simplified.

^{*} Percentage of non-missing responses within the study group.

[†] Wilcoxon test for continuous variable; chi-square test for all other variables.

Table 4 – Effect of intervention on oral health, covariate analysis in the Indonesia study.

	T0+3W			T0+8W			T0+24W		
	n	OR	95% CI	n	OR	95% CI	n	OR	95% CI
Change to no pain in the mouth when eating									
Crude effect of the intervention	2010	0.516	0.358-0.743	2001	0.974	0.826-1.147	1998	0.855	0.766-0.956
+ children's sex and grade	2010	0.521	0.361-0.753	2001	0.973	0.830-1.156	1998	0.859	0.767-0.961
+ children's other characteristics*	2010	0.492	0.333-0.726	2001	0.959	0.811-1.134	1998	0.852	0.760-0.955
+ school location (rural vs urban)	2010	0.445	0.286-0.694	2001	1.010	0.841-1.213	1998	0.902	0.793-1.065
Change to being confident with the smile									
Crude effect of the intervention	1997	1.018	0.693-1.496	2007	0.918	0.763-1.106	2000	1.005	0.884-1.142
+ children's sex and grade	1997	1.024	0.696-1.507	2007	0.917	0.761-1.104	2000	1.001	0.880-1.138
+ children's other characteristics*	1997	1.069	0.711-1.607	2007	0.918	0.760-1.110	2000	0.995	0.871-1.137
+ school location (rural vs urban)	1997	0.690	0.434-1.095	2007	0.874	0.718-1.064	2000	0.935	0.806-1.084
Change to not being bullied due to teeth									
Crude effect of the intervention	2001	0.752	0.508-1.130	1998	1.080	0.879-1.326	1997	1.107	0.969-1.265
+ children's sex and grade	2001	0.749	0.489-1.126	1998	1.081	0.879-1.330	1997	1.114	0.974-1.273
+ children's other characteristics*	2001	0.847	0.550-1.304	1998	1.029	0.822-1.289	1997	1.076	0.933-1.242
+ school location (rural vs urban)	2001	0.475	0.281-0.803	1998	1.014	0.799-1.286	1997	1.047	0.892-1.228
Change to "Good" OHI-S category									
Crude effect of the intervention	2015	1.054	0.765-1.453	2015	1.169	0.981-1.392	2015	0.950	0.848-1.065
+ children's sex and grade	2015	1.044	0.756-1.442	2015	1.173	0.853-1.398	2015	0.942	0.840-1.057
+ children's other characteristics*	2015	1.136	0.812-1.590	2015	1.182	0.988-1.415	2015	0.940	0.834-1.058
+ school location (rural vs urban)	2015	1.191	0.835-1.702	2015	1.131	0.933-1.372	2015	1.027	0.902-1.170
No worsening in DMFT Index									
Crude effect of the intervention							2015	0.786	0.624-0.990
+ baseline DMFT Index							2015	0.801	0.635-1.011
+ children's sex and grade							2015	0.805	0.638-1.016
+ children's other characteristics ^a							2015	0.794	0.628-1.004
+ school location (rural vs urban)							2015	1.454	1.115-1.891

CI = confidence interval; DMFT = decayed, missing, or filled teeth; n, number of children; OHI-S = Oral Hygiene Index- Simplified; OR, odds ratio.

* Child's opinion on the importance of everyday brushing (at baseline), usage of fluoride toothpaste (at baseline), feeling of pain in the mouth while eating (at baseline).

indicating the presence of decayed, missing, or filled teeth in approximately 90% of children, with a mean DMFT index of 6 (Table 3). At 24 weeks, the score remained unchanged (Figure 11), and approximately 22% of children in both groups showed worsening (Figure 12). However, covariate analysis revealed an OR (95% CI) of no worsening in DMFT index at 24 weeks of 1.45 (1.115-1.891) and 0.79 (0.624-0.990) when adjusted for baseline DMFT Index, sex, school grade, baseline opinion on importance of everyday brushing, use of fluoride toothpaste, and feeling of pain in the mouth while eating [Table 4, Figure 8]).

Discussion

Childhood is a good time to introduce new toothbrushing habits because children seem to be receptive, and it is when their personality starts to develop together with mental maturation, increasing the likelihood for these habits to be maintained for life.^{25,33} The BDN programme developed by FDI and Unilever aims to instigate behavioural change leading to twice-daily brushing with a fluoride toothpaste in countries of low socioeconomic status. A previous study showed that the 21-day BDN intervention led to a 25% increase in the number of schoolchildren brushing their teeth twice daily and a further 8% improvement after 6-12 months.³¹ The main aim of the present study is to determine the impact of the

21-day BDN intervention on the well-being and oral health of children in Nigeria and Indonesia.

This study focuses on three key areas that may be burdensome to schoolchildren in terms of well-being: mouth pain, confidence in their smile, and feeling bullied because of their teeth. Oral health-related QoL is an outcome that has garnered increasing interest due to the growing focus on patient-centered care, and the recognition that health extends beyond disease, encompassing a state of physical, mental, and social well-being.¹⁶ In this study, we attempted to measure well-being through three questions addressing symptomatic, psychological, and social interaction domains. The oral health-related to quality of life (OHIP-14) questionnaire could have been introduced, but children at this age require either a simpler format or an interviewer to supervise/administer the questionnaire,³⁴ which would have made the questionnaire too time-consuming to implement.

In the Nigerian study, baseline characteristics showed some significant differences in terms of happiness with smile and good oral hygiene being more prevalent in the control group.

After participation in the BDN programme, when adjusted for children's and school characteristics, the intervention group children showed a 71% higher probability of smile confidence after 24 weeks.

This is one of the expected outcomes of an intervention because children feel that they are taking care of their teeth, making them cleaner and brighter.³⁵ On the other

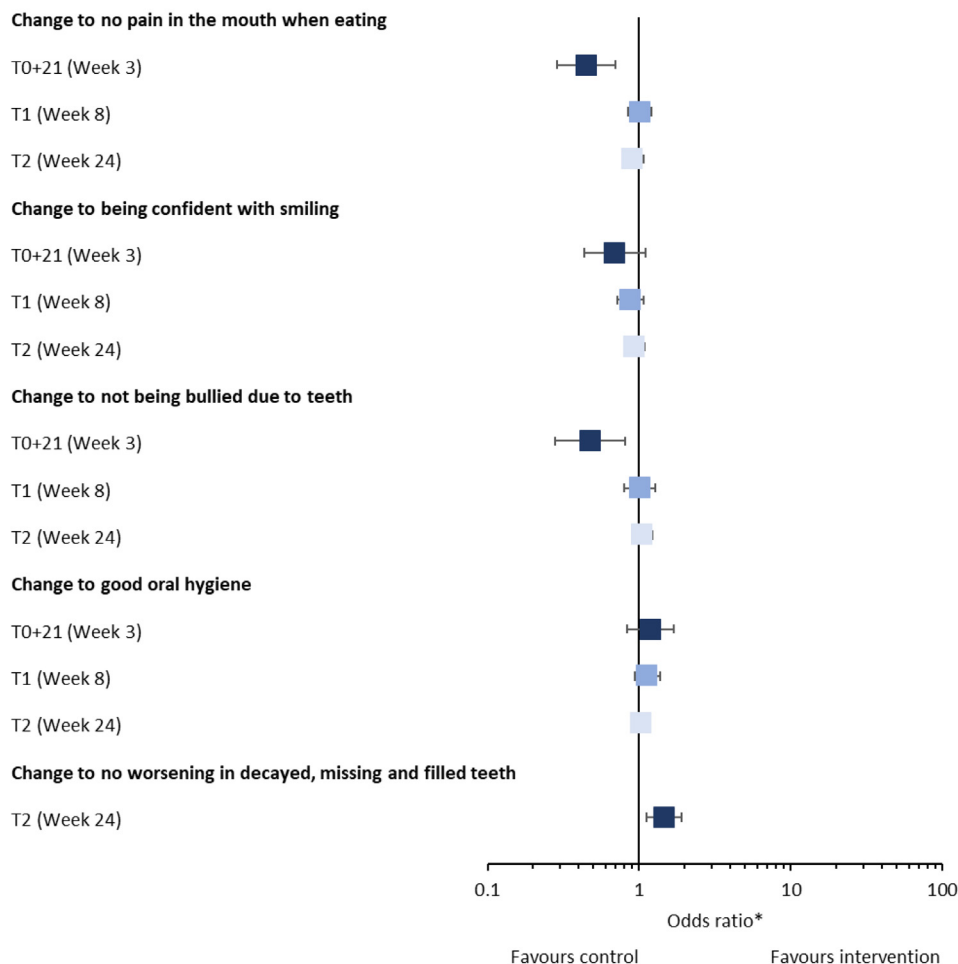


Fig. 8 – Effect of BDN programme on well-being and oral health in schoolchildren from Indonesia at Weeks 3, 8, and 24 compared with control (FAS). BDN = Brush Day & Night; FAS = full analysis set. *Adjusted for child’s age and school location.

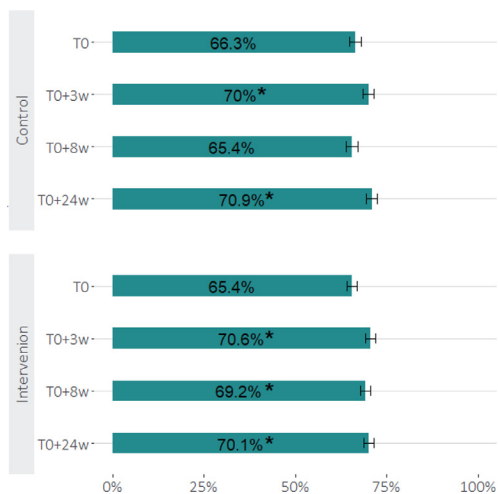


Fig. 9 – Proportion of children with good oral hygiene by OHI-S score in the Indonesia study. OHI-S = Oral Hygiene Index-Simplified. *Statistically significant difference in proportions relative to baseline (P value < .05 from McNemar’s test).

hand, six months may not be a long enough period to observe if this intervention can modify mouth pain and bullying, although an overall improvement in both groups was measured.

In the Nigerian study, poor oral hygiene was rare, and prevalence was similar across both groups, as was occurrence of dental caries. After 24 weeks, the proportion of children achieving good oral hygiene doubled in the intervention group and decreased in the control group. Analysis of baseline oral hygiene revealed that this effect of the programme was seen in children presenting with moderate or poor oral hygiene. Covariate analysis revealed that children in the intervention group were almost 11 times more likely to change OHI-S category to “good” at 3 weeks, independently of age and school location, but this effect declined to 3.8 times more likely at 24 weeks. These findings are in accordance with studies that include regularly conducted interactive education^{25,36,37} and where significant reduction in plaque index scores was reported after intervention.^{38,39} This study shows that the 21-day programme can maintain good oral hygiene in children for 6 months without the need of any additional intervention during this period.

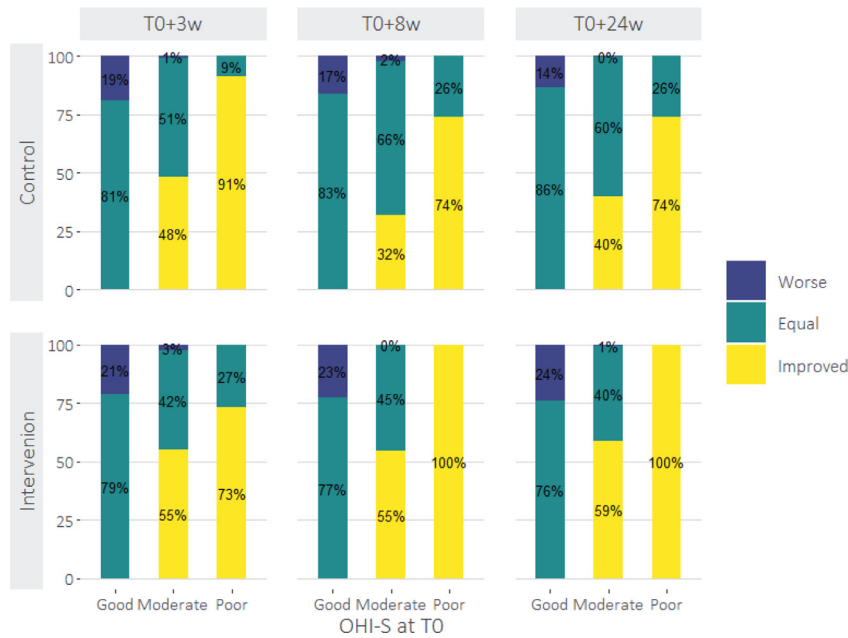


Fig. 10 – Change in OHI-S score category according to baseline status in the Indonesia study. OHI-S = Oral Hygiene Index-Simplified.

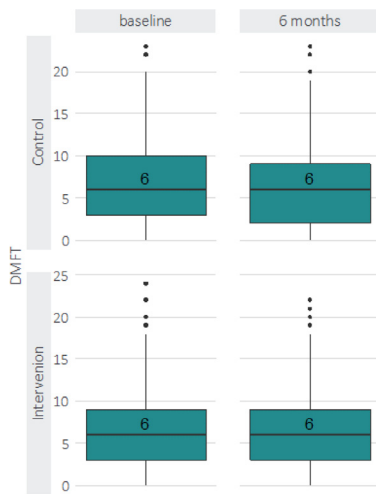


Fig. 11 – Distribution of DMFT by evaluation moment and assigned group in the Indonesia study. DMFT = decayed, missing, or filled teeth.



Fig. 12 – Change in DMFT by assigned group in the Indonesia study. DMFT = decayed, missing, or filled teeth.

Almost all children in Nigeria presented no decayed, missing, or filled teeth at baseline. However, after 24 weeks, 3% of the children in the intervention group had a worse DMFT score, whereas those in the control group maintained a DMFT score of 0. Covariate analysis revealed a likelihood of DMFT worsening by more than 8-fold. It is challenging to explain this because there is no reason for worsening of the DMFT score, mainly because in a low-caries-prevalence population one would not expect to observe a significant change in this short period of time.

In the Indonesia study, the intervention group had significantly more mouth pain at baseline. Baseline caries were

similar across groups with the majority having good oral hygiene, but with high caries prevalence and severity. However, unlike what was seen in Nigeria, there seems to be a negative correlation between good oral hygiene and high incidence of dental caries. In Indonesian children, the high caries prevalence cannot be due to bad oral hygiene habits, as reported in a separate article in this supplement.³² This negative correlation might be explained by the fact that dental caries is a multifactorial disease where different factors may play a role in the disease manifestation and not only oral hygiene.^{40,41} Behavioural factors such as regular toothbrushing, use of dental floss and mouthwashes, a balanced diet,

and regular visits to oral-health professionals are all associated with a decreased risk of dental caries.^{16,17}

After the BDN programme, changes in mouth pain, smile confidence, and bullying were similar in both the intervention and control groups, in both the crude and adjusted analyses. As with the Nigerian study, six months may be too short a period to observe changes to the bully experience and pain. The high level of caries experienced at baseline may explain the lack of effect on smiling confidence as decay of anterior teeth can cause embarrassment that would not be negated by the positive feeling of participating in the programme and taking care of one's own oral health. However, children who were bullied at baseline showed a greater improvement in severity in the intervention group than the control group. As children in the control group were also supplied with a toothbrush and toothpaste and were aware of their participation in the study, this could suggest that a greater awareness of oral health and hygiene at baseline is associated with a greater improvement in well-being outcomes. After the BDN programme, a moderate upwards trend of similar magnitude (~5%) in oral hygiene in both the intervention and control groups was observed.

When comparing oral hygiene measured at T0 with later timepoints, the improvement observed in the intervention group was limited to children presenting moderate to poor oral hygiene, and the improvement was more pronounced than in the control group in these populations. In addition, covariate analysis revealed no increased likelihood of changing category to "good" at any timepoint of the programme, which is in line with the results of other studies.^{42,43} This may be because the control group became self-motivated to improve their oral hygiene habits due to their participation in the study and the frequent oral examinations, known as the Hawthorne effect.⁴³

Only 10% of children presented no decayed, missing, or filled teeth at baseline, with a high DMFT index. This remained unchanged after 24 weeks, while overall decayed, missing, or filled teeth worsened in approximately 22% of children. However, covariate analysis adjusting for baseline DMFT Index, gender, school grade, baseline opinion on importance of everyday brushing, use of fluoride toothpaste, and feeling of pain in the mouth while eating revealed a 45% increase in the likelihood of no further worsening of DMFT score. Other school-based oral health studies have found no changes in the DMFT scores after 6 months⁴³⁻⁴⁵ and some found DMFT scores to be higher in control group but not significantly different.^{42,43,46}

Although it is not possible to statistically compare both countries' results due to the sample differences, it is interesting to analyse the common outcomes and the differences found. The improvement in well-being of children from both countries is an important outcome because it is related to less absenteeism at school, better learning and better productivity.⁴⁷ The children in Nigeria and Indonesia showed some important differences at baseline that can be explained by differing habits and knowledge. The high percentage of Indonesian children with good oral hygiene habits and dental caries contrasts with Nigerian children at baseline.

Indonesian children seem to be affected by other factors that lead to high dental caries prevalence and severity. Oral

hygiene improvement could not be seen within the intervention group in Indonesia, mostly due to the high percentage of children with good oral hygiene at baseline, making an improvement difficult. Dietary habits may play an important role with regard to caries experience because good oral hygiene is not enough to offset other cariogenic factors.⁴⁸

However, the BDN programme proved effective in preventing additional caries over 24 weeks. This finding makes a strong case for implementing the programme to achieve sustained oral hygiene habits, while trying to reduce aetiologic factors for dental caries.

On the other hand, Nigerian children showed a very low caries prevalence, and it was expected that good oral hygiene habits would help maintain these levels. Given the significant improvement in oral hygiene at 24 weeks compared to baseline in Nigeria, the BDN programme can play an important role in caries prevention.

Certain results from the present study are consistent with previous research. Significant reduction in intervention children's plaque levels versus control groups were reported in a 2017 meta-analysis⁴⁹ and in all four studies included in the 2013 Cochrane Review.¹⁵ Short follow-up periods highlight the need for further research into the sustainability of programme outcomes. Previous research results related to caries incidence show mixed results, with some studies reporting reduced DMFT or decayed, missing, or filled surfaces (DMFS) scores following school-based education programmes,^{20,50} while others have found no effect.^{44,51-53} Short evaluation periods in certain studies may hinder the detection of programme effects on caries incidence.^{49,52,53}

This study has some limitations. Many exclusions in the Nigeria study resulted in a small study population, reducing the interpretability of the results. In addition, the socioeconomic status of the children was not comparable. Parent's educational level was used as a proxy measure for children's socioeconomic status; however, limited responses to the questionnaire administered to parents meant that this variable was not included in the data analysis. The data obtained did show socioeconomic differences between the two countries, with children in Nigeria overall having a higher socioeconomic status than those in Indonesia. As mentioned, schools were paired according to the socioeconomic status of the area in which they were located and divided between intervention and control groups.

Another limitation is that the effect of the interventions beyond 24 weeks on oral hygiene and caries is unknown. It would therefore be of interest to extend the observation period to determine whether, and when, the programme should be repeated.

Conclusion

The BDN programme proved successful in improving the well-being of the children taking part in both Indonesia and Nigeria. In Indonesia, the BDN programme increased the likelihood of no further worsening in decayed, missing, or filled teeth by 45%. In Nigeria, the programme led to a 71% higher probability of having confidence in their smile and doubled the proportion of children presenting with good oral hygiene.

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Conflict of interest

P.M., C.F., and S.T. report no conflicts of interest regarding the work under consideration for publication, no relevant financial activities outside the submitted work, and no patents or copyrights. S.M. is an employee of Unilever Oral Care.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.identj.2021.01.018.

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