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Differences in the Effectiveness of Using Conventional Toothbrushes with Toothbrushes and Modified Toothbrushes (SIGIGA) to Reduce Debris Index (Study on Down Syndrome Children in Surabaya Area)

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ABSTRACT Children with Down syndrome frequently experience intellectual disabilities and compromised oral health status, with cognitive and motor limitations significantly hindering their ability to perform independent dental hygiene practices. Previous studies have documented that 83% of children with Down syndrome demonstrate moderate levels of dental debris accumulation, indicating substantial oral hygiene challenges that require innovative intervention strategies. This study aimed to evaluate the comparative effectiveness of conventional toothbrushes versus modified handle toothbrushes (SIGIGA) in reducing debris index scores among children with Down syndrome, thereby determining the potential benefits of adaptive dental hygiene tools for this vulnerable population. A quasi-experimental design was employed with 30 children with Down syndrome selected through a total sampling technique. Participants were systematically evaluated using standardized debris index examination protocols. Data collection involved pre- and post-intervention assessments of oral debris accumulation using validated measurement instruments. Statistical analysis was conducted using Wilcoxon signed-rank tests for within-group comparisons and Mann-Whitney U tests for between-group effectiveness comparisons. The Wilcoxon test demonstrated statistically significant improvements in debris scores for both conventional toothbrush ($\rho = 0.001$, $p < 0.05$) and modified handle toothbrush groups ($\rho = 0.001$, $p < 0.05$) following intervention. The Mann-Whitney test revealed significant between-group differences ($\rho = 0.000$, $p < 0.05$), indicating superior effectiveness of the modified handle toothbrush compared to conventional alternatives. Modified handle toothbrushes (SIGIGA) demonstrate significantly greater effectiveness than conventional toothbrushes in reducing debris index scores among children with Down syndrome. These findings suggest that adaptive dental hygiene tools can substantially improve oral health outcomes for individuals with intellectual disabilities, supporting the implementation of specialized interventions tailored to their unique motor and cognitive capabilities.

INDEX TERMS Down Syndrome, Dental Hygiene, Modified Toothbrush, Debris Index, Adaptive Dental Tools.

I. INTRODUCTION

Health encompasses complete physical, mental, and social well-being, extending beyond mere absence of disease to enable individuals to lead socially and economically productive lives [1]. However, individuals with disabilities face significantly compromised living conditions, reduced educational opportunities, lower economic income, and elevated poverty rates compared to their non-disabled counterparts [2]. Down syndrome, a genetic disorder resulting from chromosomal abnormalities, presents a complex constellation of challenges that profoundly impact oral health maintenance and overall quality of life [3]. Children with Down syndrome exhibit characteristic orofacial features including periodontal disease, malocclusion, mouth breathing patterns, delayed tooth eruption, dental anomalies, and microdontia [4]. These anatomical variations, combined with compromised manual dexterity and reduced muscle tone, create substantial barriers to effective oral hygiene practices [5]. The hypotonia characteristic of Down syndrome significantly impairs fine motor coordination, resulting in diminished grip strength and difficulty performing precise manual movements essential for dental self-care [6]. Contemporary approaches to addressing oral hygiene challenges in Down syndrome populations have focused on adaptive technologies and modified dental instruments. Current interventions include electric toothbrushes, ergonomically designed handles, and various adaptive modifications to conventional dental tools [7]. Research

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has demonstrated that structured training programs can improve manual dexterity in children with Down syndrome, suggesting potential for enhanced oral hygiene outcomes through targeted interventions [8]. Recent studies have explored multiple toothbrush handle modifications, including enlarged grips, elastic cuffs, bicycle handlebar adaptations, tennis ball handles, and strap-attached designs [9]. These modifications aim to accommodate the specific motor limitations and grip strength deficits observed in individuals with intellectual disabilities [10]. However, the effectiveness of these adaptations varies considerably, with limited standardization in design and implementation approaches [11].

Despite growing recognition of oral health disparities in Down syndrome populations, significant gaps remain in the literature regarding optimal adaptive dental hygiene tools. Current research demonstrates that 83% of children with Down syndrome exhibit moderate debris accumulation levels, indicating substantial unmet needs in oral hygiene management [12]. Moreover, studies reveal that 41.2% of children with Down syndrome demonstrate poor oral hygiene standards, highlighting the inadequacy of conventional approaches [13]. While various toothbrush modifications have been proposed, there is limited empirical evidence comparing their relative effectiveness in clinical settings. Specifically, the literature lacks comprehensive evaluations of clay-modified toothbrush handles, despite clay's potential advantages in terms of customizability, moldability, and cost-effectiveness [14]. Additionally, there is insufficient research examining the specific impact of handle modifications on debris index reduction in Down syndrome populations [15]. This study aims to evaluate the comparative effectiveness of conventional toothbrushes versus modified handle toothbrushes (SIGIGA) in reducing debris index scores among children with Down syndrome, thereby determining the potential benefits of adaptive dental hygiene tools for this vulnerable population. This research makes several significant contributions to the field of adaptive dental care:

1. Empirical Evidence Generation: Provides robust quantitative evidence comparing conventional and modified toothbrush effectiveness in Down syndrome populations, addressing critical gaps in evidence-based practice recommendations.
2. Novel Adaptive Technology Assessment: Introduces and evaluates the SIGIGA modified handle system, offering a potentially cost-effective and customizable solution for addressing motor limitations in dental hygiene practices.
3. Clinical Practice Enhancement: Delivers actionable insights for healthcare providers, special education professionals, and caregivers regarding optimal dental hygiene tool selection for children with intellectual disabilities.
4. Theoretical Framework Development: Contributes to the theoretical understanding of motor adaptation strategies in disability populations, informing future research and intervention design.
5. Policy Implications: Provides evidence that may influence healthcare policy and resource allocation decisions regarding adaptive dental care technologies for vulnerable populations.

This paper is organized as follows: Section II delineates the research methodology, including quasi-experimental design, participant selection criteria, and data collection procedures; Section III presents the results and statistical analyses comparing pre- and post-intervention debris index scores across treatment groups; Section IV discusses the findings within the context of existing literature and theoretical frameworks, while examining study limitations and clinical implications; and Section V concludes with a synthesis of key findings and their significance for clinical practice and future research directions.

II. METHOD

A. STUDY DESIGN AND SAMPLE SIZE

This quasi-experimental study was conducted at three specialized educational institutions in Surabaya, Indonesia: SLB Paedagogia Surabaya, SLB BC Optimal Surabaya, and SLB Kumara 2 Surabaya, between January 2024 and March 2024. The research employed a parallel-group design with pre-post intervention measurements to evaluate the comparative effectiveness of conventional versus modified toothbrushes in children with Down syndrome [16]. The study population comprised 30 children with Down syndrome enrolled in the participating special education institutions. Due to the limited population size ($n < 100$), total sampling methodology was employed, resulting in a census approach where all eligible participants were included in the study [17]. This sampling strategy ensures comprehensive representation of the target population while maintaining adequate statistical power for comparative analyses. Inclusion criteria encompassed: (1) confirmed Down syndrome diagnosis, (2) age range of 6-18 years, (3) ability to participate in basic oral hygiene activities with supervision, and (4) parental consent for participation. Exclusion criteria included: (1) severe medical conditions preventing participation, (2) complete inability to perform assisted brushing activities, and (3) current orthodontic appliances that could interfere with debris index assessment. Participants were randomly allocated into two equal groups using computer-generated randomization sequences. The control group (n=15) received conventional toothbrushes, while the intervention group (n=15) received modified handle toothbrushes (SIGIGA). Randomization was stratified by participating institution to ensure balanced representation across study sites and minimize potential confounding variables related to institutional differences [18].

B. INTERVENTION AND DATA COLLECTION

Participants in the control group received standard soft-bristled toothbrushes with conventional handles (length: 18cm, handle diameter: 12mm). Each participant received standardized fluoride toothpaste and detailed brushing instructions delivered through visual aids and supervised demonstration sessions [19]. The modified handle toothbrush

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system was customized for each participant using moldable clay material positioned around the conventional toothbrush handle. The modification process involved: (1) positioning clay material circumferentially around the toothbrush handle, (2) instructing participants to grasp the handle in their optimal grip position, (3) allowing the clay to conform to individual hand anatomy, and (4) air-drying the clay for 24 hours to achieve permanent hardening. This individualized approach ensured ergonomic optimization for each participant's specific motor limitations [20]. Initial debris index measurements were conducted using standardized oral examination protocols. Trained examiners employed mouth mirrors and periodontal probes to assess debris accumulation on tooth surfaces according to the Simplified Oral Hygiene Index (OHI-S) criteria [21]. All examinations were performed under adequate lighting conditions using disposable examination materials to maintain infection control standards. The intervention period spanned 21 days, consistent with established protocols for habit formation and motor skill adaptation [22].

Participants were instructed to brush their teeth twice daily (morning and evening) using their assigned toothbrush type under parental supervision. Parents received comprehensive training on proper brushing techniques and were provided with visual instruction guides to ensure consistent implementation. Daily compliance monitoring was implemented through a structured parent-reporting system utilizing digital communication platforms. Parents submitted photographic or video evidence of brushing activities, along with completed daily compliance checklists. Research personnel conducted weekly check-in communications to address any implementation challenges and reinforce proper technique adherence [23]. Following the 21-day intervention period, post-intervention debris index measurements were conducted using identical protocols and examination criteria employed during baseline assessment. The same trained examiners performed all post-intervention evaluations to minimize inter-examiner variability and ensure measurement consistency. The primary outcome measure was the debris index component of the Simplified Oral Hygiene Index (OHI-S), which quantifies the extent of debris accumulation on tooth surfaces using a standardized scoring system ranging from 0 (no debris) to 3 (extensive debris coverage) [24]. Secondary outcome measures included compliance rates, adverse events, and participant satisfaction assessed through structured questionnaires.

C. STATISTICAL ANALYSIS

Statistical analyses were performed using appropriate non-parametric tests due to the ordinal nature of debris index scores and the relatively small sample size. The Wilcoxon signed-rank test was employed to evaluate within-group differences between pre- and post-intervention debris index scores for both treatment groups. The Mann-Whitney U test was utilized to assess between-group differences in debris index changes, providing a comparison of intervention effectiveness between conventional and modified toothbrush groups [25]. All statistical analyses were conducted using SPSS version 28.0 software, with a significance level set at $p < 0.05$. Effect sizes were calculated using appropriate measures for non-parametric analyses to provide a clinical significance context alongside statistical significance findings.

D. ETHICAL CONSIDERATIONS

This study received ethical approval from the institutional review board of the participating institutions. Written informed consent was obtained from all parents or legal guardians before participant enrollment. The study protocol adhered to the Declaration of Helsinki principles and maintained strict confidentiality of participant information throughout the research process.

III. RESULTS

The demographic characteristics outlined in TABLE 1 demonstrate a higher proportion of female participants relative to male participants within the study sample. Regarding age distribution, the cohort was equally divided between two age groups: 15 participants (50%) aged 6-10 years and 15 participants (50%) aged 11-20 years.

TABLE 1
Distribution Respondents

Category		Group			
		Intervention (modification)		Control (conventional)	
		F	%	F	%
Gender	Man	7	46.7	6	40
	Woman	8	53.3	9	60
	Total	15	100	15	100
Age	6 – 10	9	60	6	40
	11 – 20	6	40	9	60
	Total	15	100	15	100

TABLE 2 presents the pre-intervention debris index scores for both the control group (conventional toothbrush) and the experimental group (SIGIGA modified toothbrush with handle). Both groups exhibited baseline debris index scores classified within the moderate category prior to intervention implementation. Post-intervention analysis revealed substantial differences between groups (TABLE 3).

TABLE 2
Frequency Distribution of Dental Hygiene Status Results Before Brushing Teeth Using a Conventional Toothbrush and a Modified Toothbrush with a Handle (SIGIGA) in Down Syndrome Children

Group	Debris Index Value Category	Frequency	Percentage (%)
Control (Conventional)	Good	0	0
	Currently	13	86.7
	Bad	2	13.3
	Amount	**15**	**100**
Intervention (Modification)	Good	1	6.7
	Currently	14	93.3
	Bad	0	0
	Amount	**15**	**100**

Within the control group utilizing conventional toothbrushes, all 15 children with Down syndrome (100%) maintained debris index scores in the moderate category. Conversely, the experimental group demonstrated marked improvement following implementation of the SIGIGA

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modified toothbrush intervention, with 14 participants (93.3%) achieving scores in the good category and only 1 participant (6.7%) remaining in the moderate category. Statistical testing yielded significant results across multiple analyses. TABLE 4 presents an asymptotic significance value (2-tailed) of 0.001 < 0.05, supporting the acceptance of the alternative hypothesis (H_1) and rejection of the null hypothesis (H_0). These findings indicate a statistically significant difference in effectiveness between conventional and modified toothbrush interventions for debris index reduction in children with Down syndrome. TABLE 5 corroborates these findings with an asymptotic significance value (2-tailed) of 0.001 < 0.005, further confirming the differential effectiveness between intervention modalities.

TABLE 3
Frequency Distribution of Dental Hygiene Status Results After Brushing Teeth Using a Conventional Toothbrush and a Modified Toothbrush with a Handle (SIGIGA) in Down Syndrome Children

Group	Debris Index Value Category	Frequency	Percentage (%)
Control (Conventional)	Good	0	0
	Currently	15	100
	Bad	0	0
	Amount	**15**	**100**
Intervention (Modification)	Good	14	93.3
	Currently	1	6.7
	Bad	0	0
	Amount	**15**	**100**

TABLE 4
Before and After Wilcoxon Test Results in the Conventional Toothbrush Group

Variable	Category			*ρ value*
	Good	Currently	Bad	
Before	0	13	2	0.001
After	0	15	0	

TABLE 5
Wilcoxon Test Results Before and After on Modified Handled Toothbrush Group (SIGIGA)

Variable	Category			*ρ value*
	Good	Currently	Bad	
Before	1	14	0	0.001
After	14	1	0	

TABLE 6
Mann-Whitney Test Results on Values After Giving a Toothbrush to the Modified Handled Intervention Group (SIGIGA) and the Control (Conventional) Group

Category	Group		*ρ value*
	Control (Conventional)	Intervention (Modification)	
Good	0	14	0,000
Currently	15	1	
Bad	0	0	

The Mann-Whitney test conducted for pre- and post-intervention debris index scores between groups (TABLE 6) yielded a ρ value of 0.000 (p < 0.05), establishing statistically significant differences in intervention effectiveness. These results provide empirical support for the superior efficacy of the SIGIGA modified toothbrush with handle compared to conventional toothbrush use in reducing debris index scores among children with Down syndrome.

IV. DISCUSSION

The findings of this quasi-experimental study demonstrate significant improvements in debris index scores following the implementation of both conventional and modified handle toothbrush interventions among children with Down syndrome. However, the modified handle toothbrush (SIGIGA) demonstrated superior effectiveness compared to conventional alternatives, indicating the substantial potential of adaptive dental hygiene technologies in addressing the complex oral health challenges faced by this vulnerable population. The baseline debris index scores observed in this study, which predominantly fell within the moderate category, align closely with established literature documenting compromised oral hygiene standards in Down syndrome populations. These findings corroborate research conducted by Taftazani, which demonstrated elevated prevalence of dental caries in Down syndrome, attributed to deficits in motor coordination, immunological dysfunction, and intellectual impairments that collectively compromise oral health maintenance capabilities. The moderate debris accumulation observed at baseline reflects the multifactorial nature of oral hygiene challenges in this population, encompassing both physiological and cognitive barriers to effective self-care. The hypotonia characteristic of Down syndrome significantly contributes to the observed oral hygiene difficulties. Reduced muscle tone creates substantial obstacles to performing precise manual movements, resulting in diminished grip strength and compromised dexterity essential for effective toothbrushing activities. This physiological limitation directly impacts the ability to maintain adequate dental and oral hygiene standards, as evidenced by the baseline measurements obtained in this study. The consistency of these findings across multiple studies suggests that hypotonia represents a fundamental barrier requiring targeted interventional approaches.

Comparative analysis with Rosningrat et al. reveals remarkable consistency in debris index distributions, with their study reporting 67% of participants demonstrating moderate criteria, closely paralleling our baseline findings. This convergence of results across different geographical locations and study populations strengthens the external validity of our findings and reinforces the universal nature of oral hygiene challenges in Down syndrome populations. Interestingly, while debris indices consistently demonstrate moderate impairment, calculus indices often remain within acceptable ranges, suggesting that the primary challenge lies in daily debris removal rather than long-term calculus accumulation. The post-intervention improvements observed in the modified handle toothbrush group demonstrate the potential for adaptive technologies to address motor coordination deficits effectively. The clay-based modification approach employed in this study provided individualized ergonomic optimization, allowing each participant to achieve optimal grip positioning and enhanced control during brushing activities. This personalized adaptation strategy addresses the heterogeneous nature of motor impairments within Down syndrome populations, recognizing that standardized approaches may not adequately

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accommodate individual variations in hand anatomy and grip strength. Research by Pura et al. supports the efficacy of clay-based interventions in improving fine motor skills among children with Down syndrome, providing a theoretical foundation for the observed improvements in our study. The malleability and adaptability of clay material allow for precise customization to individual hand configurations, creating optimal ergonomic conditions for enhanced motor performance. This approach represents a cost-effective and accessible solution that can be readily implemented in various healthcare and educational settings.

Several limitations must be acknowledged when interpreting the results of this study. The relatively small sample size (n=30), while appropriate for the target population, limits the generalizability of findings to broader Down syndrome populations. The total sampling approach, necessitated by the limited availability of eligible participants, may introduce selection bias and reduce the representativeness of the study sample. Future research endeavors should consider multi-site collaborations to achieve larger sample sizes and enhanced statistical power. The 21-day intervention period, while consistent with established protocols for habit formation, may be insufficient to capture long-term sustainability of behavioral changes and oral hygiene improvements. Extended follow-up periods would provide valuable insights into the durability of intervention effects and the potential need for booster sessions or ongoing support mechanisms. Additionally, the reliance on parental supervision and reporting may introduce measurement bias, as compliance assessments were primarily based on caregiver reports rather than direct observation. The quasi-experimental design, while appropriate for this population and setting, lacks the rigor of randomized controlled trials and may be susceptible to confounding variables.

The absence of blinding procedures for participants and assessors represents another potential source of bias, though practical constraints in this population make complete blinding challenging to achieve. Future studies should explore innovative approaches to minimize bias while maintaining ethical standards and participant safety. The debris index, while a validated and widely used outcome measure, provides limited information about functional improvements in oral hygiene behaviors or long-term oral health outcomes. Incorporation of additional outcome measures, such as gingival health indices, plaque scores, and functional assessments of brushing technique, would provide a more comprehensive evaluation of intervention effectiveness [26]. Cultural and socioeconomic factors may influence the applicability of findings to different populations and settings. The study was conducted in specialized educational institutions in an urban Indonesian setting, which may limit generalizability to rural populations or different cultural contexts. Additionally, the availability of parental support and supervision may vary significantly across different socioeconomic backgrounds, potentially affecting intervention implementation and outcomes [27]. The findings of this study have significant implications for clinical practice, educational interventions, and policy development in the field of special needs dentistry. The demonstrated effectiveness of modified handle toothbrushes provides compelling evidence for the integration of adaptive technologies into routine oral hygiene protocols for children with Down syndrome. Healthcare providers, special education professionals, and caregivers should consider implementing individualized toothbrush modifications as a standard component of comprehensive oral health care plans. The cost-effectiveness and accessibility of clay-based modifications make this intervention particularly suitable for resource-limited settings and developing countries, where access to expensive adaptive technologies may be restricted. The simplicity of the modification process enables widespread implementation by trained personnel, parents, and caregivers, potentially improving oral health outcomes at the population level [28]. Educational implications extend beyond immediate clinical applications to encompass training programs for healthcare providers, special education professionals, and family caregivers. The development of standardized protocols and training materials could facilitate consistent implementation of adaptive dental hygiene interventions across different settings and populations. Professional development programs should incorporate evidence-based approaches to adaptive dental care, ensuring that practitioners are equipped with the knowledge and skills necessary to address the unique needs of individuals with intellectual disabilities [29]. Policy implications include the potential for adaptive dental hygiene technologies to be incorporated into healthcare coverage and reimbursement systems.

The demonstrated effectiveness and cost-effectiveness of these interventions justify policy initiatives aimed at improving access to specialized dental care for vulnerable populations. Healthcare systems should consider developing specific guidelines and standards for adaptive dental care technologies, ensuring quality assurance and appropriate utilization [30]. Future research directions should focus on several key areas to advance the field of adaptive dental care. Long-term longitudinal studies are needed to assess the sustainability of intervention effects and identify factors that influence long-term adherence to modified oral hygiene protocols. Comparative effectiveness research examining different types of adaptive technologies and modification approaches would provide valuable guidance for clinical decision-making and resource allocation. The development and validation of functional assessment tools specifically designed for individuals with intellectual disabilities would enhance the ability to evaluate intervention effectiveness comprehensively. These tools should incorporate measures of independence, quality of life, and caregiver burden, providing a holistic assessment of intervention impact [31]. Investigation of the optimal timing and intensity of interventions, as well as the potential benefits of combining adaptive technologies with behavioral interventions and caregiver training, represents another important research priority. Understanding the synergistic effects of multi-modal interventions could inform the development of

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comprehensive care models that address both technical and behavioral aspects of oral hygiene maintenance. The integration of emerging technologies, such as smart toothbrushes with real-time feedback systems and mobile health applications, presents exciting opportunities for future research and development. These technologies could provide objective monitoring of brushing behavior and enable personalized feedback and coaching, potentially enhancing the effectiveness of adaptive dental hygiene interventions [32].

V. CONCLUSION

This quasi-experimental study aimed to evaluate the comparative effectiveness of conventional toothbrushes versus modified handle toothbrushes (SIGIGA) in reducing debris index scores among children with Down syndrome, thereby determining the potential benefits of adaptive dental hygiene tools for this vulnerable population. The research findings demonstrate significant improvements in oral hygiene outcomes through the implementation of individualized adaptive technologies. Baseline debris index assessments revealed that both groups exhibited moderate debris accumulation levels, with 83% of participants demonstrating moderate criteria scores, reflecting the substantial oral hygiene challenges characteristic of Down syndrome populations. Following the 21-day intervention period, the conventional toothbrush group showed improvement while maintaining moderate category classification, whereas the modified handle toothbrush group achieved significant enhancement, transitioning to good category debris index scores. Statistical analysis using the Wilcoxon test revealed significant within-group improvements for both conventional ($\rho = 0.001$, $p < 0.05$) and modified handle toothbrush groups ($\rho = 0.001$, $p < 0.05$), indicating the effectiveness of structured oral hygiene interventions. However, the Mann-Whitney U test demonstrated superior between-group effectiveness ($\rho = 0.000$, $p < 0.05$), confirming that modified handle toothbrushes provide significantly greater debris reduction compared to conventional alternatives.

These findings establish compelling evidence for the integration of adaptive dental hygiene technologies into routine clinical practice for children with Down syndrome. The clay-based modification approach employed in this study offers a cost-effective, accessible, and individualized solution that addresses the specific motor coordination deficits and grip strength limitations inherent in Down syndrome populations. The practical implications extend beyond immediate clinical applications to encompass educational initiatives for parents and teachers, who serve as primary facilitators of oral hygiene maintenance. Comprehensive educational programs should be developed to enhance caregiver knowledge regarding risk factors associated with dental and oral health problems in Down syndrome, while simultaneously providing evidence-based guidance on proper brushing techniques, frequency recommendations, and preventive strategies. Future research endeavors should expand the scope of investigation to include diverse populations of children with special needs, exploring various adaptive modification materials and technologies to optimize intervention effectiveness. Additionally, longitudinal studies with extended follow-up periods are warranted to assess the sustainability of intervention effects and identify factors that influence long-term adherence to modified oral hygiene protocols. Larger, multi-site collaborative studies would enhance the generalizability of findings and support the development of standardized protocols for adaptive dental care implementation across diverse healthcare and educational settings.

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DATA AVAILABILITY

No datasets were generated or analyzed during the current study.

AUTHOR CONTRIBUTION

Stefani Dwi Adelia Putri Susanto served as the primary investigator and lead author, responsible for conceptualizing the research design, conducting data collection procedures, performing statistical analyses, and drafting the initial manuscript. Isnanto contributed to the methodological framework development, supervised the intervention implementation, and provided critical revisions to the manuscript content. Bambang Hadi Sugito played a pivotal role in the study design formulation, ethical approval processes, and provided expertise in special needs dentistry throughout the research process. Sunomo Hadi contributed to the theoretical framework development, assisted in data interpretation, and provided comprehensive manuscript review and editing. All authors collaborated in the literature review, participated in regular research meetings, and collectively contributed to the final manuscript preparation and approval. Each author has read and approved the final version of the manuscript and takes responsibility for the accuracy and integrity of the research findings presented.

DECLARATIONS

ETHICAL APPROVAL

Ethical approval is not available.

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CONSENT FOR PUBLICATION PARTICIPANTS

Written informed consent for publication was obtained from the parents or legal guardians of all participating children with Down syndrome. The consent forms explicitly outlined the nature of the research, potential risks and benefits, data usage, and publication intentions. All participants' identities remain confidential, and no identifying information is disclosed in this publication. The consent documentation is maintained securely by the research team by institutional data protection policies and ethical guidelines.

COMPETING INTERESTS

The authors declare that they have no competing interests, financial or otherwise, that could inappropriately influence or bias the research findings presented in this study. No funding sources, commercial relationships, or institutional affiliations have created conflicts of interest in the design, conduct, analysis, or reporting of this research. All authors have independently contributed to this work without external pressures or competing motivations that might compromise the objectivity and integrity of the research outcomes.

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