



**Comparison of Modified Circular and Natural Tooth Brushing Methods in  
Effectiveness of Dental Plaque Removal  
(Study Protocol, Statistical Analysis Plan, Informed Consent Form, and Results)**

**Istiyanti Hapsari**

**Faculty of Dentistry  
Prince of Songkla University  
2018**

### **1. Research Title**

Comparison of Modified Circular and Natural Tooth Brushing Methods in Effectiveness of Dental Plaque Removal

### **2. Researcher Name**

Istiyanti Hapsari

E-mail address: [istiyantihapsari@gmail.com](mailto:istiyantihapsari@gmail.com)

### **3. Background information/Significance of Research Project**

Dental caries, or commonly known as tooth decay, is worldwide disease that pursues people during their lifetime (1). Dental caries can affect the health and quality of life patients so that it is important to focus on caries prevention (2). Ministry of Health Republic of Indonesia in Basic Health Research 2013 (3) showed that DMF-T Index of Indonesia for population aged start from 12 years old was 4.6. While the DMF-T Index in Yogyakarta province was 5.9, higher than the national index of DMF-T. Not only dental caries, gingivitis also being a problem. In Jakarta, 68% children aged 12 years old have gingivitis. While, 92% of the children aged 12 years old have substantial amount of plaque (4).

Both of dental caries and gingivitis are caused by dental plaque or known as dental biofilm. Gingivitis is built by the accumulated dental plaque that infect soft tissue around the teeth (5). Dental caries is caused generally by acid production from bacterial fermentation in the dental plaque on the tooth surface (6).

Dental caries and gingivitis can be prevented by plaque control. Self-performed mechanical plaque removal with a manual toothbrush remains the primary method of maintaining good oral hygiene for a majority of the population (7). Good oral hygiene habit that is built especially in children age will protect permanent teeth that can make it lasts a lifetime (8). Oral hygiene instructions should be given to a child considering their age and associated with their manual dexterity. Tooth brushing instruction can be effectively given in the age start from 10 years old because they can be actively involved and have better manual dexterity than children in younger age (9).

Ideal tooth brushing method is the method that can work for the individual and can remove dental plaque without causing damage on the teeth, gingiva, or other tissue

(10, 11). The method should clean all tooth surfaces and must be systematically organized so that each parts of the dentition is brushed (12, 13). Horizontal motions of brushing and parallel positions of the brush with the teeth will cause abrasion (14). Brushing force is not specifically determined. If it is too much, it will cause gingival trauma (15). Tooth brushing method that is ideal also has to be simple and easy to learn (12).

Tooth brushing will be effective in removing the dental plaque if it is done with the sufficient duration at least 2 minutes (16). Frequency of tooth brushing is recommended to be done twice a day (17). Tooth brushing type that is used to brush is recommended using manual tooth brush with small-headed toothbrush, soft round-ended filaments and comfortable handle (18). There are several factors from individual that may cause the differences in effectiveness of tooth brushing in plaque removal such as age, education, and socioeconomic status (13, 19, 20).

People, without any training, naturally brush their teeth using horizontal scrub, a rotary motion, or simple up and down (21). Many people using natural motion of tooth brushing can produce good oral environment that inhospitable to biofilm without any damaging effect in their tissue (21, 22). Asadoorian (15) estimated that over 90% of people employ their natural tooth brushing method that is personally built. This method will remove plaque from smooth surfaces of the teeth, but this method have limitation that is considered detrimental because it can cause gingival recession and tooth abrasion (23). People will pay poor attention to the lingual areas of their teeth while practicing this method probably because these areas do not affect the aesthetics and tend to difficult to be accessed (24).

A systematic review by Muller-Bolla and Courson (25) showed that in early mixed dentition stage, the most effective tooth brushing technique is horizontal technique. McClure (26) comparing tooth brushing efficacy between horizontal Scrub and modified Bass method in children aged 10-12 years old reported there were no significant differences in plaque removal ( $P > 0.01$ ) between two methods. Robinson (27) evaluated plaque removal of Scrub and Bass methods in children aged 12-13 years old and found that there were no differences between two methods. Smutkeeree et al. (28) found that there were no significant differences in gingival condition (Gingivitis Index) between Horizontal Scrub and Modified Bass groups ( $P > 0.05$ ) in children aged

10-12 years old. However, the studies about tooth brushing method recommended for children in late mixed dentition aged are still limited.

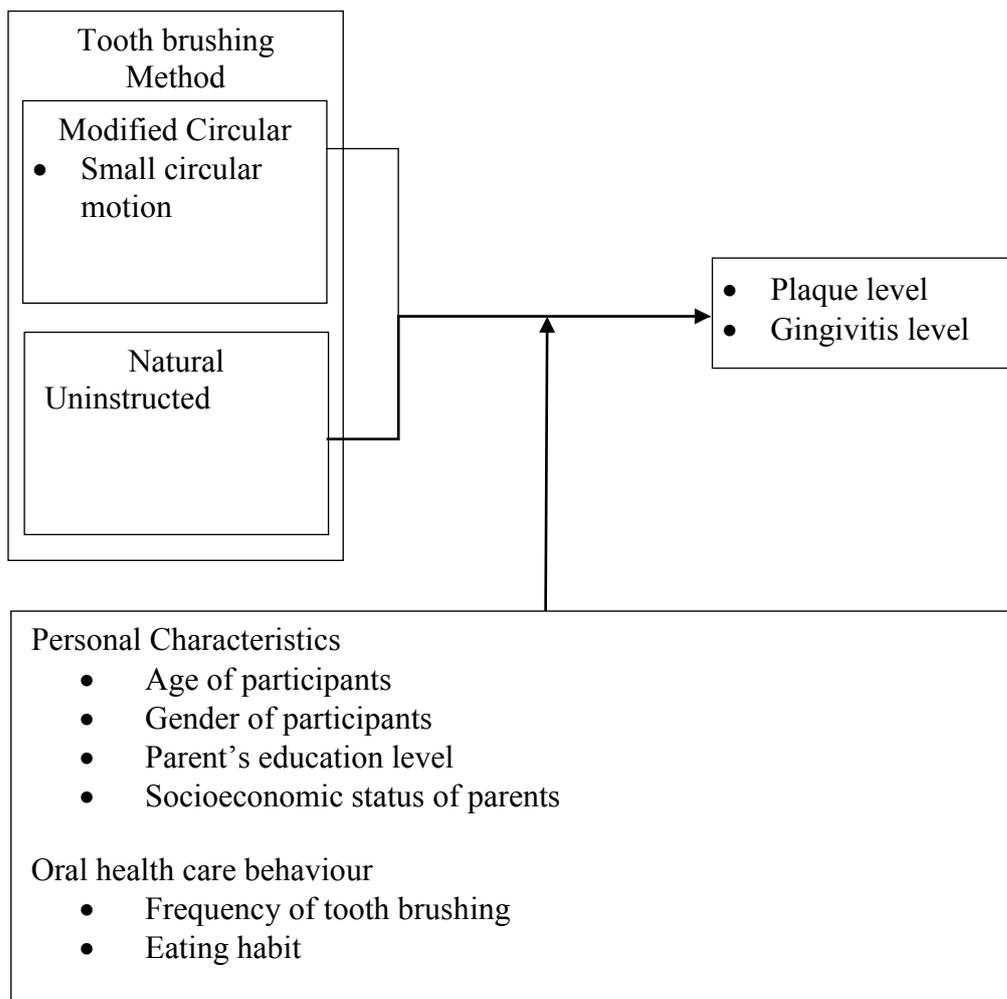
Children aged 10-12 years old are in late mixed dentition (29), a transitional period from children with milk teeth into adult with permanent teeth (30). Tooth brushing technique that is suitable for children should be simple to be performed so that it can be mastered by children and effectively remove dental plaque as well as prepare children for adult period and protect permanent teeth that can make it lasts a lifetime (8, 31). The review literature by Wainwright and Sheiham (32) showed that the Bass and modified Bass methods are the most frequently advocated method for adults. The Bass method showed a superiority in plaque removal ability compared with roll, circular, and horizontal method (33). The Bass method is good in cleaning the tooth tissue adjacent to the gingival tissue, the gingival margins and the gingiva sulcus (34). Nevertheless, this method is difficult to exercise (35). Katz et al. (36) recommended the Bass method to be combined with roll method to be the Modified Bass to ensure plaque removal from gingival margin and coronal surface. Modified Bass is effective in plaque removal of supragingival area (37). This method also can reduce chance of developing gingival recession and tooth abrasion (28). However, the Modified Bass method still have limitation that can cause difficulty in children to replace the brush in gingival sulcus position (5).

Combined tooth brushing technique can be considered as a good method for plaque removal (37). The combination should provide satisfactory method that should clean all tooth surfaces, the movement of the brush should not injure the soft and hard tissue, the technique should be simple and easy to learn, and it must be well organized so that each part of the dentition is brushed (12). In the Bass method originated by Bass (38), the brush need to be positioned at about a 45 degree to the long way of the teeth and then brush forced into crevices and moved short back and forth. Furthermore, most of people gradually switch from the correct Bass method with short stroke to be a horizontal scrubbing method as the interval since the instruction of the Bass method given (39). Eley et al. (12) in their book stated in different way that the Bass method should move with small circular motion and this combination can be recommended as the method of choice for general use. This method might be benefit for children in late mixed dentition because it does not need rolling motion like in the Modified Bass method that cause children difficult to replace in gingival sulcus position and the movement is not short

back and forth like in the original Bass method that children gradually switch from the correct Bass method with short stroke to be a horizontal.

*Delivering better oral health* (18) stated that there is no tooth brushing that is superior to another and people's existing method may need to be modified to clean all tooth surfaces. A study showed that different surface of the teeth need different technique to produce effective plaque removal (24). This study will apply the Modified Circular to be used in most of tooth surfaces areas as all labial areas, and posterior lingual/palatal areas and combine with vertical technique to be used in anterior lingual areas, and horizontal to be used in occlusal areas. To show the possibility that the Modified Circular method that can effectively remove plaque in late mixed dentition children, it is needed to comparing the Modified Circular method with the natural tooth brushing method.

#### 4. Conceptual Framework



## 5. Objectives

### General objectives

- a. To compare level of plaque of children aged 10-12 years old that use the Modified Circular method and natural tooth brushing method.
- b. To compare level of gingivitis of children aged 10-12 years old that use the Modified Circular method and natural tooth brushing method.

### Specific objectives

- a. To compare level of plaque before and after using the Modified Circular tooth brushing method.
- b. To compare level of gingivitis before and after using the Modified Circular tooth brushing method.

## 6. Research Procedures

### Participants and setting

One hundred and twenty four students from two state elementary school in Yogyakarta, Indonesia participated in this study. The age of the participants were between 10 and 12 years old including males and females students. All of the participants were fifth graders from Caturtunggal IV State Elementary School and Babarsari State Elementary School. To be eligible to participate in this study, each participants met the criteria including: students with age 10 to 12 years old and willing as well as permitted by the parents/guardian to join thorough the study. The exclusion criterias were not being discovered from them, that were being diagnosed having developmental disorder, using orthodontic appliances, and using antiseptic mouthwash for daily use.

Caturtunggal IV State Elementary School and Babarsari State Elementary School are the government's schools that are placed in the same cluster in one sub-district. These two schools have the similar characteristics in social-economy, number of students, and

the type of school based on the data and recommendation from Education and Culture Office of Sleman District, Yogyakarta, Indonesia. The examinations were done in the terrace in front of the classes to get the sufficient lighting. The training session was done in the class and the schoolyard. Examination and training each lasted approximately 15 minutes and 60 minutes. The examinations were done two times; before and after training with a distance of one month. While the training session were given one time each group after baseline examination. The reinforcement sessions were given to the intervention group once a week in a month after the training session. The reinforcement sessions lasted approximately 20 minutes for each session.

#### Materials and Equipment

The materials being used in training session were posters, dental model, tooth brush, rinsing glass, and water bucket. The examiner collected the data using probe, mouth-mirror, microbrush, disclosing solution, kidney-basin, cotton roll, mask, gloves, rinsing glass, bucket, table, and chairs. The data of the examination and interview was collected using examination forms, questionnaire, and a pen, while the tooth brushing video was recorded using smartphone and the data was written in observational sheet. The materials for reinforcement sessions were dental model, tooth brush, rinsing glass, bucket, and mirror. Additionally, child size tooth brush and tooth paste were given for each participant.

#### Dependent Variables and Data Collection

The dependent variables in this study were Plaque Index (PI) and Gingival Index (GI). The hypotheses of this study were the plaque level and gingivitis level in subjects using the Modified Circular method is different from that in subjects using natural tooth brushing method and the level of plaque after using the Modified Circular method is different from that before using the method.

*Plaque Index Examination.* Participants' plaque level was measured using Turesky Modification of Quigley Hein (83). Data were collected during baseline and follow-up to track the changing of the plaque level before and after intervention. The tools used in this examination were micro-brush, mouth mirror and probe under the natural light. The procedure was painting all of the exposed tooth surfaces with disclosing solution and the participants were asked to rinse one time. Facial and lingual surfaces of the teeth were examined except third molars. A score between 0 and 5 was given based on the criteria. The plaque scores were recorded on the plaque index examination sheet containing the diagram of the teeth with the separated boxes of facial and lingual/palatal areas. The index was determined by calculating the total score divided by the numbers of the surfaces examined.

Table 1 Scoring criteria of Turesky Modification of Quigley-Hein Index (83)

Score	Criteria
0	No plaque.
1	Separate flecks of plaque at the cervical margin of the tooth.
2	A thin continuous band of plaque (up to one mm) at the cervical margin of the tooth.
3	A band of plaque wider than one mm but covering less than one-third of the crown of the tooth.
4	Plaque covering at least one third but less than two thirds of the crown of the tooth.
5	Plaque covering two-thirds or more of the crown of the tooth.

*Gingival Index Examination.* The examination of gingival condition was using the Gingival Index (88). Data were collected during baseline and follow-up to track the changing of the gingival condition before and after intervention. The tools used in this examination were mouth mirror under the natural light. The procedure was examining all of the gingiva on the buccal, lingual/palatal, mesial, and distal areas of the teeth. A score between 0 and 3 was given based on the criteria. The Gingival Index were recorded on the gingival index examination sheet containing the diagram of the teeth with the separated boxes of buccal, lingual/palatal, mesial, and distal areas. The index was determined by calculating the total score divided by the numbers of the areas examined.

Table 2 Scoring criteria of Gingival Index (88)

Score	Criteria
0	Normal gingiva.
1	Mild inflammation - slight change in color, slight edema. No bleeding on probing.
2	Moderate inflammation - redness, edema and glazing. Bleeding on probing.
3	Severe inflammation - marked redness and edema. Ulceration. Tendency to spontaneous bleeding.

*Questionnaire.* Personal information; oral health knowledge, attitudes, practices; and eating habits of the participants were recorded using questionnaire. The questionnaire were questioned by interview. Data were collected during baseline and follow-up to check the changing of tooth brushing practice and eating habit that may influence the plaque and gingival index. The back-translation technique had been used to ensure the quality between the English and Indonesian language versions. The interviewer marked

X on the box of questionnaire choice of answers in accordance with the answers of participants.

### Validity and Reliability

*Validity.* Questionnaire had been evaluated for the content, scoring criteria, and language compatibility by three experts from Faculty of Dentistry, Prince of Songkla University using the face validity.

Standardization of oral examination (Plaque Index and Gingival Index) had been evaluated between the examiner and the expert using Cohen's Kappa index. For the Gingival Index, the value of inter-rater calibration was 0.73. The value of intra-rater calibration of Plaque Index was 0.77. All of the values were exceeding 0.7 and categorized as good by Altman (1999).

*Reliability.* The reliability of intra-examiner had been evaluated using Cohen's Kappa Index. The value were 0.76 for the Gingival Index and 0.79 for the Plaque Index. The values were exceeding 0.7 and categorized as good by Altman (1999).

### Experimental Design

The research was using a quasi-experimental study design. Data were gathered from two groups of subjects. This research was a single-blind study which the examiner will be blinded to the allocation of subjects.

This study began with selecting two elementary schools in the same district in Yogyakarta, Indonesia, that have similarity in socio-economic status and the number of the students based on the data and recommendation of Technical Education Service Unit of Yogyakarta. The schools met the criteria that was not under any plans of getting other interventions of dental health program during one month intervention period of this study. All of the fifth graders of the selected schools participated the study. With the coin flipping method, a school was allocated to be intervention group and the other was being the control group. The participants had been informed about the purpose of the study, the procedure, and the right to continue or withdrawn without any penalties. The participants had given consent to follow the study.

The study began with the baseline data collection. Then it continued with the training for the participants about improving the oral hygiene. In this stage, the intervention group was demonstrated and instructed to brush their teeth using Modified Circular method, while the control group was not given any instruction to brush their teeth using a specific tooth brushing method and asked to brush their teeth using the way they brushed every day. The period of intervention was started after training and lasted for one month. In intervention period, intervention group was observed once a week to ensure that they brushed their teeth correctly using Modified Circular method. Finally the evaluation was implemented after 1 month of intervention.

#### Data collection procedure

- 1) The researchers well informed the teachers, parents or guardians, and the children about the purpose of the study, the procedure, and the right to continue or withdrawn without any penalties. The parents or guardians of the children who meet the inclusion criteria were asked by the researcher and teachers the permission to their children to participate in this study. Their consent were shown by signing of the consent form.
- 2) The appointment were made with the teachers to set the time to perform examination and intervention to the children.
- 3) Baseline data collection were done to all of the student participating of the study. The children were interviewed by interviewee using structured-questionnaire inside of the class. The oral examinations were done after completing the interview. The oral examination began with the examination of gingival condition and then continued with plaque level examination. Examination area was set outside of the class to get enough light. The children were examined on a chair in sitting position using natural sun light. The examiner was blind to the allocation of the group, the examiner will not know whether the group examined was intervention group or control group. After the oral examination was done, the video recording was taken to the children to record the way the children brush their teeth. The area recorded was only around their mouth and not showing their face.
- 4) In the other day, children in each group were given 2 hours for tooth brushing training course in small groups containing 4-5 children per group. The instructor motivated the children about how to improve oral hygiene for both groups. The

children were instructed to brush their teeth two times per day in two minutes. The control group were instructed to brush the teeth as how they brushed every day. The intervention group were demonstrated about how to brush the teeth using Modified Circular method. After the training in the class was completed, the activity then continued with practiced brushing together in schoolyard. Intervention group were observed once a week to make sure that they did Modified Circular method well without any repetition or addition of intervention. The researcher provided toothbrush and toothpaste to be used by the children during the one-month intervention period.

- 5) Follow up examination were done one month after the training by collecting the same data as baseline.

## **7. Statistical analysis**

All of the data were analyzed using IBM SPSS Statistics 21. The data gathered from the control and the groups were compared using t-test for the mean and standard deviation. A chi-square statistic were used to investigate whether distributions of categorical variables differ from one another. The significance level used in this study was 0.05 for all of the statistical test.

## **8. Results**

At the beginning of the study, participants who participated in this study amounted to 62 children for control group and 62 children in experimental group. There was no number of excluded participants. The schools was not under any plans of getting other interventions of dental health program during one month intervention period of this study. After random assignment of the groups, all of the participants received the intervention. Lost to follow-up were found with the number of 2 in control group and 4 in intervention group. The participants did not come in the day of follow-up data collection with the reason of sick and family occasion. Using the intention-to-treat method, the number of data analyzed were following the original number allocated, that were 62 for each group. The missing value in follow-up were replaced using the last value obtained, in this case the baseline value was used.

The age of the participants and the percentage of male and female participants between control and intervention group were not significantly different ( $P < 0.05$ ). The

tooth brushing habit of the participants seen from the frequency and the duration of brushing were not significantly different ( $P < 0.05$ ). Snacking and eating frequency that reflected the eating habit of the participants were also not different ( $P < 0.05$ ).

In this study, all of the participants (100%) in the control group can follow the protocol to brush their teeth using natural method. In intervention group, 79% of the participants followed the protocol to brush their teeth using Modified Brush tooth brushing method systematically.

### ***Plaque index***

Mean of plaque index for all surfaces in baseline were not different ( $P > 0.05$ ). Analyzed from each surface of each sextant, right and left upper lingual posterior surfaces had statistically different mean plaque index ( $P < 0.05$ ) with the higher number of dental plaque in intervention group. However, the anterior upper labial surface of control group had approximately 0.4 points higher number of plaque index than the control group ( $P < 0.05$ ). In follow up mean of plaque index for all surfaces were significantly different ( $P < 0.05$ ) between groups. All of the mean plaque index in intervention group analyzed from every sextant had lower score than the control group and almost all of them were statistically significant ( $P < 0.05$ ).

### ***Gingival Index***

In baseline, there was no differences in mean of plaque index between groups ( $P > 0.05$ ). The intervention group had significant lower mean of gingival index than the control group ( $P < 0.05$ ).

## References

1. Selwitz RH, Ismail AI, Pitts NB. Dental caries. *Lancet* (London, England). 2007;369(9555):51-9.
2. Veiga N, Aires D, Douglas F, Pereira M, Vaz A, Rama L, et al. Dental Caries: A Review. *J Dent Oral Health*. 2016;2(5):1-3.
3. National report on basic health research (RISKESDAS 2013). Jakarta: Ministry of Health Republic of Indonesia; 2013.
4. Adiatman M, Yuvana AL, Nasia AA, Rahardjo A, Maharani DA, Zhang S. Dental and Periodontal Status of 5 and 12 year old Children in Jakarta and it's Satellite Cities. *Journal of Dentistry Indonesia*. 2016;23(1):5-9.
5. Wilkins EM. *Clinical Practice of The Dental Hygienist*. 12 ed. Philadelphia: Wolters Kluwer; 2017.
6. Vos T, Flaxman AD, Naghavi M, Lozano R, Michaud C, Ezzati M, et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet* (London, England). 2012;380(9859):2163-96.
7. George J, John J. The Significance of Brushing Time In Removing Dental Plaque. *Int J Dentistry Oral Sci*. 2016;3(8):315-7.
8. Lynch RJ. The primary and mixed dentition, post-eruptive enamel maturation and dental caries: a review. *International dental journal*. 2013;63 Suppl 2:3-13.
9. Pujar P, Subbareddy VV. Evaluation of the tooth brushing skills in children aged 6-12 years. *European archives of paediatric dentistry : official journal of the European Academy of Paediatric Dentistry*. 2013;14(4):213-9.
10. Da Silva JD. *Oxford American Handbook of Clinical Dentistry*. Oxford: Oxford University Press; 2008.
11. Miller M, Scully C. *Mosby's Textbook of Dental Nursing*. 2 ed. China: Mosby Elsevier; 2015.
12. Eley BM, Soory M, Manson JD. *Periodontics*. 6 ed: Wright; 2010.
13. Sandstrom A, Cressey J, Steckslen-Blicks C. Tooth-brushing behaviour in 6-12 year olds. *International journal of paediatric dentistry*. 2011;21(1):43-9.
14. Bergstrom J, Lavstedt S. An epidemiologic approach to toothbrushing and dental abrasion. *Community dentistry and oral epidemiology*. 1979;7(1):57-64.
15. Asadoorian J. CDHA Position Paper on Tooth Brushing. *CJDH*. 2006;40(5):232-48.
16. Darby ML. *Mosby's comprehensive review of dental hygiene: Elsevier Health Sciences*; 2013.
17. American Dental Association Statement on Regular Brushing and Flossing to Help Prevent Oral Infections: American Dental Association; 2013 [cited 12 Dec 2016]. Available from: <http://www.ada.org/en/press-room/news-releases/2013-archive/august/american-dental-association-statement-on-regular-brushing-and-flossing-to-help-prevent-oral>.
18. *Delivering Better Oral Health: An evidence-based toolkit for prevention*: British Association for the Study of Community Dentistry; 2009.
19. Amalia R, Schaub RM, Widyanti N, Stewart R, Groothoff JW. The role of school-based dental programme on dental caries experience in Yogyakarta Province, Indonesia. *International journal of paediatric dentistry*. 2012;22(3):203-10.
20. Casanova-Rosado AJ, Medina-Solís CE, Casanova-Rosado JF, Vallejos-Sánchez AA, Minaya-Sánchez M, Mendoza-Rodríguez M, et al. Tooth brushing frequency in

- Mexican schoolchildren and associated socio-demographic, socioeconomic, and dental variables. *Medical science monitor: international medical journal of experimental and clinical research*. 2014;20:938.
21. Hiremath SS. *Textbook of Preventive and Community Dentistry*: Elsevier; 2007.
  22. Limeback H. *Comprehensive Preventive Dentistry*. Oxford: Wiley-Blackwell; 2012.
  23. Piotrowski BT, Gillette WB, Hancock EB. Examining the prevalence and characteristics of abfractionlike cervical lesions in a population of US veterans. *The Journal of the American Dental Association*. 2001;132(12):1694-701.
  24. Rugg-Gunn A, MacGregor I. A survey of toothbrushing behaviour in children and young adults. *Journal of Periodontal Research*. 1978;13(4):382-9.
  25. Muller-Bolla M, Courson F. Toothbrushing methods to use in children: a systematic review. *Oral health & preventive dentistry*. 2013;11(4):341-7.
  26. McClure DB. A comparison of toothbrushing technics for the preschool child. *Journal of dentistry for children*. 1966;33(3):205-10.
  27. Robinson E. A comparative evaluation of the Scrub and Bass Methods of toothbrushing with flossing as an adjunct (in fifth and sixth graders). *American journal of public health*. 1976;66(11):1078-81.
  28. Smutkeeree A, Rojlakkanawong N, Yimcharoen V. A 6-month comparison of toothbrushing efficacy between the horizontal Scrub and modified Bass methods in visually impaired students. *International journal of paediatric dentistry*. 2011;21(4):278-83.
  29. Tausche E, Luck O, Harzer W. Prevalence of malocclusions in the early mixed dentition and orthodontic treatment need. *European journal of orthodontics*. 2004;26(3):237-44.
  30. Schour I, Massler M. *The development of the human dentition*: publisher not identified; 1941.
  31. Mescher KD, Brine P, Biller I. Ability of elementary school children to perform sulcular toothbrushing as related to their hand function ability. *Pediatric dentistry*. 1980;2:31-6.
  32. Wainwright J, Sheiham A. An analysis of methods of toothbrushing recommended by dental associations, toothpaste and toothbrush companies and in dental texts. *British dental journal*. 2014;217(3):E5.
  33. Bergenholtz A, Gustafsson LB, Segerlund N, Hagberg C, Ostby N. Role of brushing technique and toothbrush design in plaque removal. *Scandinavian journal of dental research*. 1984;92(4):344-51.
  34. Gibson JA, Wade AB. Plaque removal by the Bass and Roll brushing techniques. *Journal of periodontology*. 1977;48(8):456-9.
  35. Xuedong Z. *Dental Caries: Principles and Management*: Springer Berlin Heidelberg; 2015.
  36. Katz S, McDonald JL, Stookey GK. *Odontología preventiva en acción*: Ed. Medica Panamericana; 1975.
  37. Poyato-Ferrera M, Segura-Egea JJ, Bullon-Fernandez P. Comparison of modified Bass technique with normal toothbrushing practices for efficacy in supragingival plaque removal. *International journal of dental hygiene*. 2003;1(2):110-4.
  38. Bass CC. An effective method of personal oral hygiene. *The Journal of the Louisiana State Medical Society : official organ of the Louisiana State Medical Society*. 1954;106(2):57-73; contd.
  39. Axelsson P, Odont D. Concept and practice of plaque control. *Pediatric dentistry*. 1981;3(Special Issue):101-13.

## Appendix

## Appendix A

### Research Information Sheet/Invitation Letter

Invitation to participate in research project entitled “Comparison of Modified Circular and Natural Tooth Brushing Methods in Effectiveness of Dental Plaque Removal in Children Aged 10-12 Years Old”

#### Dear Participants,

My name is Istiyanti Hapsari. I am from Faculty of Dentistry, Prince of Songkla University, Prince of Songkla University, Thailand. I would like to explain about research project and invite you join this research project as describe below.

#### 1. Description of the study

Dental caries and gingivitis prevalences in schoolchildren in Indonesia is high. Dental diseases can potentially caused missed school, concentrace disturbance, impaired speech, poor self-esteem, and systemic illness. Caries and gingivitis can be prevented by maintaining oral hygiene. Toothbrushing is one of oral hygiene method to remove and prevent dental plaque that can cause dental caries and gingivitis. The present study aims to evaluate the effectiveness plaque removal of two brushing methods, Modified Circular and natural tooth brushing methods.

The result will give the benefit to determine the toothbrushing method that suitable and appropriate to be taught to children in Indonesia to prevent dental caries.

The recruited children will be 10-12 years old. Children will be interviewed about their oral hygiene practice and eating habit. Every children also will be given examination to record level of plaque and gingivitis. This examination will be conducted around 15 minutes. The children then will be given a training about “how to improve oral hygiene”. Children will be instructed to brush their teeth two times a day as in the morning and before bedtime with the duration of 2 minutes each time. The project will provide one toothpaste and one toothbrush. After training course, they will be asked to show how they brush their teeth. After one month, children will be evaluated again about their levels of plaque and gingivitis.

**2. Risks and Discomfort**

This study will not use any invasive treatment due to oral examination. No drugs or chemical materials will be used except nontoxic disclosing agent that will be used only 2-3 drops for staining the dental plaque. The colors of disclosing agent will gradually disappear and easily removed by brushing. The examination will be done 2 times (in the beginning and after 1 month later) and it does not cost you.

**3. Benefits**

This study will help teachers, parents, and students to know the level of oral cleanliness and the effective method of toothbrushing to remove plaque in schoolchildren.

**4. Confidentiality**

All information in the present study will be confidential and anonymous. Only the researcher is eligible to access the data. Your name, your children name and identifying information will not be used in the report of the study. After completing the study, all data will be destroyed.

**5. Contact Information**

If you have any question or suggestion, you can directly contact the researcher by phone 087737639177 or email to [istiyantihapsari@gmail.com](mailto:istiyantihapsari@gmail.com).

You have the right to participate or not to participate in this study. You also have the right to withdraw from your participation at any time without any cost, impact on your receiving service, or impact in any dental treatment or routine care.

If you have a doubt or any questions in this research, please ask researcher for more understanding.

Sincerely yours,

Signature.....  
(Istiyanti Hapsari)

**Note: Please read carefully before signing and participating this research project**

## Appendix B

### Consent Form For Caretaker

I am, \_\_\_\_\_, as a parent of Mr./Ms. \_\_\_\_\_ is invited to join research carried out by Istiyanti Hapsari, Faculty of Dentistry, Prince of Songkla University who is the researcher of the reearch entitled “Comparison of Modified Circular and Natural Tooth Brushing Methods in Effectiveness of Dental Plaque Removal in Children Aged 10-12 Years Old”.

The objective of the study is to evaluate the effectiveness plaque removal of two brushing methods, Modified Circular and natural tooth brushing methods, in a sample of 10-12 years old schoolchildren. It will give benefit to know the effective method of tooth brushing to remove plaque in schoolchildren. This study will help teachers, parents, and students to know the level of oral cleanliness and the effective method of toothbrushing in order to maintain oral hygiene and prevent dental caries and gingivitis. The recruited children will be 10-12 years old. Children will be interviewed about their oral hygiene practice and eating habit. Every children also will be given examination to record level of plaque and gingivitis. This examination will be conducted around 15 minutes. The children then will be given a training about “how to improve oral hygiene”. Children will be instructed to brush their teeth two times a day as in the morning and before bedtime with the duration of 2 minutes each time. The project will provide one toothpaste and one toothbrush. After training course, they will be asked to show how they brush their teeth. After one month, children will be evaluated again about their levels of plaque and gingivitis.

This study will not hurt my child and the oral examination will not use invasive treatment or chemical materials except disclosing agent to see the dental plaque in the tooth surfaces. The examination will be done twice (in the beginning and after 1 month later).

The information will be kept confidential and anonymus by the researcher. If I have any queastion or suggestion, I can directly contact the researcher by phone 087737639177 or email to [istiyantihapsari@gmail.com](mailto:istiyantihapsari@gmail.com).

I have read and understand the information about this research study and its risks and benefits. I have had the opportunity to ask question and to have my questions answered to my satisfaction. I freely give my consent to participate in this research.

Date .....

Signature.....(Participant)

Signature.....(Researcher)

(Istiyanti Hapsari)

Signature..... (Witness)

Signature..... (Witness)

## Appendix C

### Assent Form

You are given the opportunity to be a participant in this study. This project is conducted by Istiyanti Hapsari, Faculty of Dentistry, Prince of Songkla University who is the researcher of this project.

The present study aims to evaluate the effectiveness plaque removal of tooth brushing methods in children. This study will help teachers, parents, and students to know the level of oral cleanliness and the effective method of toothbrushing in order to maintain oral hygiene and prevent dental caries and gingivitis.

The recruited children will be 10-12 years old. Children will be interviewed about their oral hygiene practice and eating habit. Every children also will be given examination to record level of plaque and swollen gums. This examination will be conducted around 15 minutes. The children then will be given a training about “how to improve oral hygiene”. Children will be instructed to brush their teeth two times a day as in the morning and before bedtime with the duration of 2 minutes each time. The project will provide one toothpaste and one toothbrush. After training course, they will be asked to show how they brush their teeth. After one month, children will be evaluated again about their levels of plaque and gingivitis.

This study will not use any invasive treatment due to oral examination. This study uses disclosing agent made from a safe food dyes only 2-3 drops for staining the dental plaque. The colors of disclosing agent will gradually dissappear and easily removed by brushing. The examination will be done 2 times (in the beginning and after 1 month later) and it is does not cost you.

All information in the present study will be confidential and anonymus. Only the researcher is eligible to access the data. Your name and identifying information will not be used in the report of the study. After completing the study, all data will be destroyed.

If you have any question or suggestion, you can directly contact the researcher by phone +6287737639177 or email to [istiyantihapsari@gmail.com](mailto:istiyantihapsari@gmail.com).

If you decide to participate in the project, please sign this form. You have the right to participate or not to participate and to withdraw from your participation at any time without any cost, impact on your receiving service, or impact in any dental treatment or routine care.

-----  
I am, Mr./Ms. \_\_\_\_\_ have been given information about this research study and its risks and benefits and have had the opportunity to ask questions and to have my questions answered to my satisfaction. I freely give my consent to participate in this research project.

Date .....

Signature.....(Participant)

Signature.....(Researcher)

(Istiyanti Hapsari)

Signature..... (Witness)

Signature..... (Witness)

## Appendix D - Ethical Clearance Document 1

RESEARCH ETHICS COMMITTEE (REC)  
BUILDING 1 5<sup>TH</sup> FLOOR ROOM 504  
TEL. 66-74-287533, 66-74-287504  
FAX. 66-74-287533



FACULTY OF DENTISTRY  
PRINCE OF SONGKLA UNIVERSITY  
HADYAI, SONGKHLA 90112, THAILAND  
TEL. 66-74-212914, 66-74-429871, 66-74-287500  
FAX. 66-74-429871, 66-74-212922

### Documentary Proof of Ethical Clearance

#### Research Ethics Committee (REC)

#### Faculty of Dentistry, Prince of Songkla University

The Project Entitled Comparison of Modified Circular and Natural Tooth Brushing Methods in Effectiveness of Dental Plaque Removal in Children Aged 10-12 Years Old

REC Project No. : EC6004-12-P-LR

Principal Investigator : Asst. Prof. Dr. Jaranya Hunsrisakhun

Co-Principal Investigator : Miss Istiyanti Hapsari

Approved by Research Ethics Committee (REC), Faculty of Dentistry, Prince of Songkla University.

This is to certify that REC is in full Compliance with International Guidelines for Human Research Protection such as the Declaration of Helsinki, the Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP).

Date of Approval : 15 May 2017 No. of Approval : MOE 0521.1.03/ 492

(Assoc. Prof. Dr. Chairat Charoemratrote)  
Chairman of Research Ethics Committee

(Asst. Prof. Surapong Vongvatcharanon)

(Asst. Prof. Dr. Nuttawut Thuaksuban)

(Assoc. Prof. Pornchai Sathirapanya)

(Asst. Prof. Wasin Suwannarat)

(Asst. Prof. Dr. Angkana Thearmontree)

(Dr. Supitcha Talungchit)

(Asst. Prof. Dr. Suwanna Jitpukdeebodintra)

(Mr. Boonsit Buaban)

(Asst. Prof. Dr. Supatcharin Piwat)

(Mr. Kemarajt Kemavongse)

## Appendix E - Ethical Clearance Document 2



MEDICAL AND HEALTH RESEARCH ETHICS COMMITTEE (MHREC)  
FACULTY OF MEDICINE GADJAH MADA UNIVERSITY  
- DR. SARDJITO GENERAL HOSPITAL



### ETHICS COMMITTEE APPROVAL

Ref : KE/FK/0773 /EC/2017

Title of the Research Protocol : Comparison of Modified Circular and Natural Tooth Brushing Methods in Effectiveness of Dental Plaque Removal in Children Aged 10-12 Years Old

Documents Approved : 1. Study Protocol versi 01 2017  
2. Information for Subjects versi 02 2017  
3. Informed consent form versi 02 2017

Principle Investigator : Istiyanti Hapsari

Name of supervisor : Asst. Prof. Dr. Jaranya Hunsrisakhun

Date of Approval : **17 JUL 2017**  
(Valid for one year beginning from the date of approval)

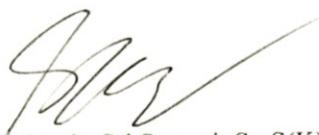
Institution(s)/place(s) of research : Elementary Schools in Yogyakarta Province, Indonesia

The Medical and Health Research Ethics Committee (MHREC) states that the above protocol meets the ethical principle outlined in the Declaration of Helsinki 2008 and therefore can be carried out.

The Medical and Health Research Ethics Committee (MHREC) has the right to monitor the research activities at any time.

The investigator(s) is/are obliged to submit:

- Progress report as a continuing review : Annually
- Report of any serious adverse events (SAE)
- Final report upon the completion of the study

  
Prof. Dr. dr. Sri Sutarni, Sp.S(K)  
Chairperson

  
dr. Ahmad Hamim Sadewa, Ph.D  
Secretary

Attachments:

- Continuing review submission form (AF 4.3.01-014.2013-03)
- Serious adverse events (SAE) report form (AF 6.1.01- 019.2013-03)