



**Evaluation of the Effectiveness of Customized Handle Toothbrush in
Dental Plaque Control in Healthy Children and Children with Down
Syndrome (Randomized Controlled Trial)**

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1-Study design:

This study design as a randomized controlled double-blinded clinical trial for Evaluation of the Effectiveness of Customized Handle Toothbrush in Dental Plaque Control in Healthy Children and Children with Down Syndrome.

2-Sample description:

The required sample size was estimated using Program Gpower 3.0.10. By approval Confidence Interval 95% and $\alpha=5\%$ the sample have been consisted of 48 children.

Children will be randomly assigned to four groups each one according to his group:

1. A group of healthy children using conventional toothbrush (12 children).
2. A group of healthy children using toothbrush with Customized Handle (12 children).
3. A group of children with Down syndrome using conventional toothbrush (12 children).
4. A group of children with Down syndrome using toothbrush with Customized Handle (12 children).

3-Randomization:

Randomization will be done by using the website www.randomizer.org in order to aid in allocating children into groups randomly.

4-Inclusion criteria:

Inclusion criteria:

- Ages between 6-9 years old.
- Participant must have at least 10 teeth free from dental caries on both buccal and lingual surfaces of the teeth.
- TQHPI is at least 2.

- Cooperative participant (Positive according to Frankel's behavioral rating scale).
- Parents' consent.
- Participant with down syndrome must have been diagnosed by specialist.

5-Exclusion criteria:

- Children undergoing orthodontic treatment.
- Allergic to any of the toothpaste ingredient used the study.
- Participant used any toothbrush other than the conventional brush before.
- Healthy children Participant with systemic diseases
- Excluding children with Down syndrome who suffer from chronic weakness such as epilepsy or taking medications continuously.

6-Method of work:

1. Children will be examined to ensure that they have met the sample entry criteria, then they will be randomly assigned to four groups each one according to his group:
 - 1- A group of healthy children using conventional toothbrush (12 children).
 - 2- A group of healthy children using toothbrush with Customized Handle (12 children).
 - 3- A group of children with Down syndrome using conventional toothbrush (12 children).
 - 4- A group of children with Down syndrome using toothbrush with Customized Handle (12 children).
2. Customized handle will be prepared for the groups that will be using customized handle toothbrush.
3. Brushing instructions:
 1. The researcher will teach the patients how to brush using (tell-show -do) technique.
 2. The brushing method that will be used is the modified Stillman technique.
 3. The duration of the brushing must be at least 3 minutes.
 4. The brushing must be twice a day.
 5. The amount of toothpaste is pea size.

4. Mechanism of examination and follow up:

After apply the plaque disclosing solution on the teeth with a bond brush, the plaque will be evaluated with Turesky Modification Quigley-Hein Plaque Index(TQHPI), checking on the buccal and lingual surfaces of all the teeth existing in the patient's mouth. The patients will be observed in baseline, before and after brushing, and after one week and after three weeks.

Scoring criteria for plaque index TQHPI:

0 = no plaque/debris

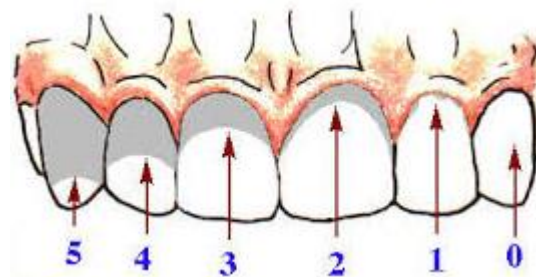
1 = separate flecks of plaque at the cervical margin of the tooth.

2 = a thin continuous band of plaque (up to 1mm) at the cervical margin of the tooth.

3 = a band of plaque wider than 1 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.



7. Statistical Analysis:

Statistical Analysis will be performed using the SPSS program version (23) (SPSS Inc, Chicago, Ill). Kolmogorov-Smirnov test will determine the data distribution: If data is nonparametric then Kruskal-Wallis, Mann-Whitney U, Friedman and Wilcoxon tests will be applied to evaluate the differences in (TMQHPI) in each studied time point. Significance level was set at (0.05).

8. Informed Consent:

Ethical approval was obtained from the Ethic Committee at the Ministry of Higher Education in Syria (1674/SM).