

Study title: Efficacy of a Novel Brushing Device

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Document Name: Statistical Analysis Plan

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Please find the attached statistical analysis used for this study.

Statistical Analysis Plan

The proposed clinical study is a Single-blinded, randomized controlled clinical trial in humans designed to assess compare the effects the test brushing device versus a manual toothbrush.

Primary outcome analysis plan: Oral health status and plaque accumulation was measured and obtained through clinical examination. The Turesky modification of the Quigley-Hein Index was used to quantify the amount of dental plaque on six assigned index tooth sites in children (ages 5-17; N =40) prior to and after use of the assigned oral hygiene device. Individual tooth plaque scores were then averaged within device group pre and post brushing and reported (mean \pm sd). Data was assessed for normality using the *rnorm()* function within the “stats” package within R Statistical Software. Difference in mean plaque data within and between device groups pre and post brushing was then evaluated using the parametric *t.test()* function and adjusted for multiple testing by False Discovery Rate (FDR) with an *alpha* of 0.05 (95% CI) using the “rstatix” package within R Statistical Software.

Secondary outcome analysis plan: Dentition status (primary, mixed, permanent) was recorded through clinical examination. Data from the primary outcome (Plaque score using the Turesky modification of the Quigley-Hein Index) was then stratified to determine the impact of dentition status on outcomes between device groups. Individual tooth plaque scores were stratified by Dentition status (primary: N = 2; mixed: N = 27; permanent: N = 11) and then averaged within device group pre and post brushing and reported (mean \pm sd). Difference in mean plaque data within and between device groups and by dentition status pre and post brushing was then evaluated using the parametric *t.test()* function and adjusted for multiple testing by False Discovery Rate (FDR) with an *alpha* of 0.05 (95% CI) using the “rstatix” package within R Statistical Software.