**Participant flow**

Consented: 65

Screen Failure/Disqualified: 5

Randomized to treatment: 60

Withdrawal/Dropped: 2

Completed: 58

**Baseline characteristics**

| **Demographics Summary**  **Treated Subjects** | | | | |
| --- | --- | --- | --- | --- |
| **Demographic/ Statistic or Category** | **Regular Manual Brush (n=30)** | **Electrical Toothbrush Kit (n=30)** | **Overall (n=60)** | **p-value** |
| **Age (Years)** | | | | |
| Mean (SD) | 14.9 (1.69) | 14.8 (1.77) | 14.8 (1.72) | 0.767 |
| Min.-Max. | 13 - 18 | 13 - 18 | 13 - 18 |  |
| **Sex** | | | | |
| Female | 19 (63.3%) | 12 (40.0%) | 31 (51.7%) | 0.121 |
| Male | 11 (36.7%) | 18 (60.0%) | 29 (48.3%) |  |
| **Race** | | | | |
| Asian Occidental | 8 (26.7%) | 5 (16.7%) | 13 (21.7%) | 0.448 |
| Asian Oriental | 2 (6.7%) | 1 (3.3%) | 3 (5.0%) |  |
| Black | 1 (3.3%) | 0 (0.0%) | 1 (1.7%) |  |
| Caucasian | 19 (63.3%) | 24 (80.0%) | 43 (71.7%) |  |

**Outcome measures**

| **Change from Baseline Efficacy Results Analysis of Covariance Summary**  **Loe Silness Gingival Index - Whole Mouth  Evaluable Subjects** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Treatment** | **N** | **Adjusted Mean (SE)** | **% Change from Baseline** | **Treatment Difference (SE)** | **Trt Comparison 2-sided p-value (95% CI)** | **% Trt Difference Relative to Regular Manual Brush** |
| **Week 6 (Overall Baseline=1.282, Error Variance=0.0728)** | | | | | | |
| Regular Manual Brush | 29 | 0.242 (0.0501) | 18.8% | 0.050 (0.0704) | 0.481 (-0.091, 0.191) |  |
| Electrical Toothbrush Kit | 30 | 0.192 (0.0493) | 14.9% |  |  | -20.7% |
| **Week 12 (Overall Baseline=1.282, Error Variance=0.0191)** | | | | | | |
| Regular Manual Brush | 29 | 0.127 (0.0257) | 9.9% | -0.036 (0.0363) | 0.332 (-0.108, 0.037) |  |
| Electrical Toothbrush Kit | 29 | 0.163 (0.0257) | 12.7% |  |  | 27.9% |

| **Change from Baseline Efficacy Results Analysis of Covariance Summary**  **Loe Silness** **Number of Bleeding Sites - Whole Mouth  Evaluable Subjects** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Treatment** | **N** | **Adjusted Mean (SE)** | **% Change from Baseline** | **Treatment Difference (SE)** | **Trt Comparison 2-sided p-value (95% CI)** | **% Trt Difference Relative to Regular Manual Brush** |
| **Week 6 (Overall Baseline=37.15, Error Variance=225.115)** | | | | | | |
| Regular Manual Brush | 29 | 11.79 (2.789) | 31.7% | 1.62 (3.915) | 0.681 (-6.22, 9.46) |  |
| Electrical Toothbrush Kit | 30 | 10.17 (2.742) | 27.4% |  |  | -13.7% |
| **Week 12 (Overall Baseline=37.09, Error Variance=146.251)** | | | | | | |
| Regular Manual Brush | 29 | 10.56 (2.249) | 28.5% | -4.60 (3.184) | 0.154 (-10.98, 1.78) |  |
| Electrical Toothbrush Kit | 29 | 15.16 (2.249) | 40.9% |  |  | 43.5% |

| **Change from Baseline Efficacy Results Analysis of Covariance Summary**  **Pre-Brushing TQHPI - Whole Mouth  Evaluable Subjects** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Treatment** | **N** | **Adjusted Mean (SE)** | **% Change from Baseline** | **Treatment Difference (SE)** | **Trt Comparison 2-sided p-value (95% CI)** | **% Trt Difference Relative to Regular Manual Brush** |
| **Week 6 (Overall Baseline=4.105, Error Variance=0.1411)** | | | | | | |
| Regular Manual Brush | 29 | 1.161 (0.0698) | 28.3% | 0.080 (0.0981) | 0.419 (-0.117, 0.276) |  |
| Electrical Toothbrush Kit | 30 | 1.081 (0.0687) | 26.3% |  |  | -6.9% |
| **Week 12 (Overall Baseline=4.102, Error Variance=0.0942)** | | | | | | |
| Regular Manual Brush | 29 | 1.460 (0.0571) | 35.6% | -0.116 (0.0809) | 0.156 (-0.278, 0.046) |  |
| Electrical Toothbrush Kit | 29 | 1.577 (0.0571) | 38.4% |  |  | 8.0% |

| **Change from Baseline Efficacy Results Analysis of Covariance Summary**  **Post-Brushing TQHPI - Whole Mouth  Evaluable Subjects** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Treatment** | **N** | **Adjusted Mean (SE)** | **% Change from Baseline** | **Treatment Difference (SE)** | **Trt Comparison 2-sided p-value (95% CI)** | **% Trt Difference Relative to Regular Manual Brush** |
| **Baseline (Overall Baseline=4.101, Error Variance=0.0456)** | | | | | | |
| Regular Manual Brush | 30 | 0.707 (0.0390) | 17.2% | -0.141 (0.0552) | 0.014 (-0.251, -0.030) |  |
| Electrical Toothbrush Kit | 30 | 0.847 (0.0390) | 20.7% |  |  | 19.9% |

**Adverse events**

There were no AEs/ADEs neither observed nor reported in this study.