

Statistical Analysis Plan

Official Title:

Effectiveness of visual pedagogy-assisted tooth-brushing training among preschoolers with special needs for oral health promotion

Date: 2015.11.22

All the data will be analysed using IBM SPSS. Variables from the questionnaires will be analysed by t test for independent samples or its non-parametric equivalent for continuous data and Chi-square tests for categorical data. Descriptive statistics of cooperation with tooth brushing in each group will be determined and variations in cooperation with tooth-brushing and developmental level of special needs will be determined by Chi-square statistics. McNemar's test will be used to analyse whether children's oral-health related behaviours will be changed before and after intervention. Then regression analyses will be conducted to determine developmental factors associated with children's oral health status or cooperation in conducting tooth brushing, accounting for child's age and gender in the model. Variations in simplified oral hygiene index, modified gingival index, caries incidence, number of completed tooth brushing tasks and time taken to complete the overall task will be determined using repeated measures ANOVA (or Friedmann ANOVA for nonparametric data). Inter-group comparisons of the above outcome variables with respect to baseline will be determined using paired t-test (or Wilcoxon signed rank for nonparametric data). Intra-group comparisons of at baseline, 6-month, 12-month, and 24-month will be conducted using student's t-test (or Mann Whitney U test for nonparametric data). Magnitude of change will be derived through effect size calculation (mean change/ SD of baseline values) to provide an indication of clinical significance of the results. The significance levels will be set to be $P < 0.05$.