

KIDNEY AND PERIODONTAL DISEASE (KAPD) STUDY

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Data analysis and sample size

We will calculate descriptive statistics as appropriate for each feasibility, process, and clinical outcomes at each visit. Generalized linear mixed models (GLMMs) for repeated continuous, binary, and count outcomes will be used to assess treatment effects on study outcomes at 4, 8, and 12 months; the baseline outcome will be included in the analysis to control for any between-group differences at baseline, with treatment effects captured using time-by-treatment interactions. Outcomes will be transformed as needed to meet model assumptions, and random effects will be used to account for within-participant correlation of the outcomes. GLMMs for tooth-specific periodontal outcomes including pocket depth (PD), clinical attachment loss (CAL), and bleeding on probing (BOP), will include tooth and site as fixed effects, and account for the nested correlation of teeth within participant within occasion. In addition, we will assess summary periodontal measures including the gingival and plaque indices. If treatment effects on the periodontal measures are detected, we will conduct exploratory analyses of mediation of treatment effects on kidney function outcomes by improvements in the periodontal measures. Specifically, we will assess the independent effects of the periodontal measures on each outcome, controlling for treatment, and also assess the attenuation of the treatment effect after adjustment for the periodontal measures. Results will be considered statistically significant at $p < 0.05$.

The accrual target of 51 participants assigned 2:1 to intensive ($n=34$) or rescue treatment ($n=17$) is typical for a pilot study and feasible given available resources. In the overall sample, we will be able to estimate the means of feasibility and process outcomes within margins of sampling error (MSEs) of ± 14 percentage points (ppts) for binary measures and 0.28 standard deviations (SDs) for continuous ones; within the treated group, corresponding MSEs will be 18 ppts and 0.35 SDs. In providing preliminary estimates to inform sample size calculations for a definitive trial, we will be able to estimate the net effect of intensive vs delayed intensive periodontal treatment on CKD biomarkers at 12 months within MSEs of 0.35-0.51 SDs, depending on the degree of within subject correlation, after accounting for loss to follow-up of 20% of participants by 12 months.