OBJECTIVES: This project will determine the efficacy of a program of periodontal screening and therapy in improving the level of glycemic control in poorly controlled diabetics.

RESEARCH PLAN: This is a randomized clinical trial in diabetics receiving medical care in 4 VHA outpatient clinics in the Boston area.

METHODS: We enrolled 193 diabetic patients with HbA1c levels of >8.5% and > 8 teeth. A 2X2 design was used. Patients were randomly assigned initially to one of two groups: 1. experimental group- immediate periodontal evaluation and therapy; and 2. control group- periodontal evaluation and treatment 4 months after enrollment. After initial treatment, 1/2 of the participants in each group continue treatment for one year and the other half will be referred to their regular providers. The primary measure for the efficacy of periodontal screening and therapy will be the comparison of the change in HbA1c levels at 4 months between the experimental and control groups. A secondary measure of will be change in HbA1c over a 1-year period.

This report describes comparisons of the sample frame to those randomized, and between study groups in characteristics that might affect the study outcomes. We used administrative (baseline HbA1c, comorbid conditions, age), survey (SES, use of dental care, self-reported general and oral health, stress, limitations in physical activity, duration of diabetes, BMI, smoking and alcohol use) and clinical examination (number of teeth, root tips, CPITN, exudate on probing and palpation, Gingival Index, Plaque Index, periodontal probing, gingival recession, tooth mobility) data. We examined means for continuous variables, frequencies for categorical variables, compared treatment groups (group A versus B) using t-tests and chi square tests (alpha=0.05 for both).

FINDINGS: The 193 randomized participants were younger (58 years) and had slightly higher HbA1c (10.2) than the 2534 not randomized (64 years, HbA1c=9.8). Participants were also more likely to be depressed, drug dependent, and obese. Among the randomized, group A was more likely than group B to have a history of kidney disease (7% vs 1 %) and transient ischemic attacks (5.3% vs. 0%), higher self-reported stress (mean=5.8 [out of 10] vs. 4.9), and less likely to be male (95% vs. 100%), current smokers (20% vs. 32%) or former smokers (50% vs. 55%). The 63 other parameters examined showed no significant differences between study groups. These data suggest that while the mechanism for randomization was successful in this study, several covariates (stress, smoking, gender) may be important in the analysis of efficacy in this study. A manuscript is preparation and four abstracts were submitted for presentation at national meetings.