

Study Title: Technology Intensified Diabetes Education Study in African Americans With Type 2 Diabetes
NCT02088658

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Sample Size and Power. With 80 subjects randomized to each of the two intervention groups, we will have 85% power to detect at least a 0.4 standardized effect size (difference in comparison group means in sd units) for continuous outcome measures.

Analysis Plan

We will use a generalized linear models (GLMM) approach as the general analytic framework for inferential analyses for the Primary/Secondary efficacy aims. In addition to accommodating a wide range of distributional assumptions [dichotomous/categorical (e.g., binomial), continuous (e.g., normal), ordinal, count (e.g., Poisson). GLMM is equivalent to a linear mixed effect model (MEM) approach. MEM analyses estimate individual change in outcome for each subject in addition to estimating average change in outcome within each of the individual a, b, c, d intervention groups. The basic modeling procedure will involve using the longitudinal measurements of HbA1c (primary) separately as the dependent (outcome) variable, with intervention group (fixed effect), time (random effect), and time by intervention as the primary independent variables.