Patient and Provider Engagement and Empowerment Through Technology Program to Improve Health in Diabetes

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Analytical and Statistical approaches

We will use Stata v15.0 (Stata Corp, College Stations Tx 2017) for all statistical analyses. Descriptive analysis will yield means/standard deviations for continuous variables and frequencies for categorical variables. We will examine distributions to determine whether data meets assumptions for planned statistical analyses. We will compare patient demographic and health-related characteristics between the individuals in the intervention group and the usual care group. We will compare continuous variables using a Student's t test or the Wilcoxon Signed-Rank test, and will compare categorical variables using the chi-squared test and Fisher's exact test, as appropriate. We will compare number of steps per week at baseline (Week 2) versus 3 months (Week 13), baseline versus 9 months (Week 37) and 3 months versus 9 months, using a paired t-test to evaluate the change in physical activity over time.

We will calculate change in outcomes over time as the difference between baseline and 3 months, and baseline and 9 months for diabetes self-efficacy scores, depression severity (PHQ-9), patient stress score, and PROMIS measures (Emotional distress anxiety, and physical functioning). We will use Student's t test to compare the change in outcome between usual care and intervention groups (Significance level: $p \leq .05$).

In the primary analysis, we will estimate the difference over time in the effects of the intervention over usual care in the study participants. This is an intent to treat analysis, with the assumption that any dropouts are missing at random. We will also use an analytical method (Mixed model) which accounts for the missing data contributed by participants who dropped out from the study. Lastly, we will conduct a sensitivity analysis to determine whether there is a difference with regards to the significance of our findings when we exclude participants who drop out from the analysis. All participants, regardless of intervention completion, will be included in the intent to treat analysis.

We will use multivariate regression modeling for all hypotheses testing to estimate within-groups and across group effects of the intervention on the outcome (significance level: $p \leq 0.05$). The mixed effects models will evaluate the impact of the intervention over time in the outcomes of Diabetes Self-Efficacy, depressive symptoms, and Perceived Stress Score (PSS). We

will include a binary indicator for intervention group assignment, and a group- by-time interaction term in the models to compare improvement over time between the intervention group and usual care group. We will assess all variables for collinearity before including in the model. We will evaluate model fit using deviance tests for nested models, the Akaike Information Criterion, and the Bayesian Information Criterion for non-nested models. We will assess the estimates for the fixed effects using a pre-determined significance level ($p < 0.05$) on two sided tests and 95% confidence intervals. We will use the same approach for analyzing primary and secondary outcomes analyzing the effect of the intervention at baseline, 3 and 9 months.

We will conduct a post-hoc analysis examining the relationship between stage of change at baseline and intervention outcomes. We hypothesize that there might be differences in who the intervention benefits most – and will explores whether readiness to change status might be a tool for screening potential participants for inclusion in future trials or interventions.