

Title: A Pilot Study on the Use of Real-Time Continuous Glucose Monitoring (RT-CGM) as a Tool for Weight Loss/Behavior Modification in Patients with Prediabetes and Diabetes

NCT #: 03805412

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## Initial statistical analysis

Sample Size Justification and data analysis: In order to establish stable estimates of effect sizes, we anticipate using a total sample size of N=30 patients (15 prediabetes, 15 Type 2 diabetes). Data will be analyzed using mixed model regression, which accounts for within subject correlation. The relevant effect size for each outcome will be the time main effect. As a secondary analysis, we plan to examine predictors of change using general linear models. This will help us determine the type of patient for whom the CGM intervention is most effective, which can inform the patient selection process in later studies. Predictors of interest include diagnosis (diabetes vs prediabetes), comorbidities, demographics (age, sex, race, type of insurance), BMI, and pre-intervention attitudes (toward diet, activity, and exercise changes)