Study title: Does a Behavior Change Skills and Physical Activity Program Improve Self-regulation and Health Outcomes in Adolescents with Type 1 Diabetes?

Document Date: 12/06/2024

Statistical Analysis Plan:

To assess the preliminary efficacy of the Activate program we will examine changes in proximal primary outcomes of average daily active minutes compared between treatment and control groups at baseline and the 12-week follow-up assessment. We will conduct multilevel models with baseline- residualized gain scores for outcomes to identify the effect size for the treatment program on each on the primary outcome. All participants will be used in analyses, with missing data addressed using an intention-to-treat approach where missing data were included and given a zero. A power sensitivity function was generated wherein our pilot study analyses were used to determine expected effect sizes. Anticipated effect sizes based on our pilot work for between group differences in behavior-change skills and average daily active minutes are Cohen's d of 0.4 to 1.2. With 60 participants, we will have 80% power to detect a Cohen's d of .7, 60% power to detect a Cohen's d of .6, at 95% power to detect a Cohen's d of .8. Thus, we will be powered to detect all but the smallest of potentially meaningful effects found in our previous intervention pilot work.