CASE WESTERN RESERVE UNIVERSITY
Frances Payne Bolton School of Nursing

Stephanie Griggs, PhD, RN, FAAN
Associate Professor
Agnes Stahlin Baun Scholar

Nursing Research Building
2120 Cornell Road
Office NO304F
Health Education Campus
10900 Euclid Avenue
Cleveland, Ohio 44106-0000
Office 459T

phone 216.368.5518
fax 216.368.3542
stephanie.griggs@case.edu

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Title of Study: Self-Management in Young Adults with Type 1 Diabetes

ClinicalTrials.gov ID: NCT04975230

Please find the statistical analysis plan for this study.

Sincerely,

Stephanie Griggs

Stephanie Griggs, PhD, RN

Statistical analyses. Descriptive statistics will summarize each of the variables over the monitoring period, post-intervention (3-months), and 6-months for the intervention and control groups. The general estimating equation (GEE) will be used to estimate the difference in changes from baseline to post-intervention (3 months), and at a 6-month follow-up for primary and secondary outcomes, including each baseline outcome as a covariate. The hypothesis will guide the analyses that the intervention will improve total sleep time, interdaily stability, intradaily variability, and glycemia. However, our objective is not statistical significance but the determination of preliminary effect sizes. GEE will be used to estimate the statistical power necessary to conduct a larger clinical trial.

Sample size justification. We plan to enroll 48 participants to attain a final sample of 40 participants (20 per group) accounting for an estimated attrition of 20%. This sample size is based on previous studies on sleep and glycemia in young adults and adolescents with T1D[69] and pilot sleep intervention studies in young adults.[68] **A power calculation for sample size was not conducted due to the pilot nature of the study and our sample is in line with several research papers on an appropriate pilot sample size. A sample of** 40 participants (20 per group) will allow us to determine a Cohen's eta effect size with 95% CI for group differences at post-intervention (3 months) with bias-corrected limits of [.00 -.14], [.00 -.24], and [.01 -.34] for small (n^2 = .01), medium (n^2 = .06), and large (n^2 = .14) effect sizes respectively.