

Official Title:

Project Wellness: A Pilot Feasibility Randomized Controlled Trial

ClinicalTrials.gov Identifier:

NCT04209348

Statistical Analysis Plan date:

8/8/2023

Analyses will be intention to treat. Mean daily minutes spent in walk/run activity and MVPA (i.e., device-based measures), as well as mean MET hours per week in the sports and exercise domain overall and just walking and jogging (i.e., questionnaire-based measures) will be compared between groups with Proc Mixed in SAS 9.4. All models will be adjusted for GGI vs. GDM status. Models of the device-based measures will include repeated statements for observation day number, by study visit. The model for total MVPA will include additional adjustment for device wear-time (i.e., by day and study visit). Models for the questionnaire-based measures will include repeated statements for study visit. For the neonatal outcomes, PA intervention verse control group differences will be examined in Proc Mixed, adjusting for GGI vs. GDM status.