Title: Quantitative Activity Levels and Gestational Age at Delivery: A Prospective Cohort Study among Nulliparous Women

Sample size and statistical power

The primary exposure and outcome will be the mean number of steps/day and the risk of spontaneous preterm delivery (<37 weeks), respectively. We will assess if the mean number of steps/day will differ between women that spontaneously deliver preterm versus those that deliver at term. Since data on the average number of steps/day among nulliparous women that spontaneously deliver preterm or at term remains unknown, we simulated the number of subjects required in this prospective cohort study to detect a difference in the number of steps/day between spontaneous preterm cases and term births based on the following assumptions: types I and II error rates of 5% and 10% (power of 90%), respectively, and the average number of steps/day among term births will be 5,000. Since the standard deviation (SD) of the number of steps/day remains unknown among term births, we calculated the sample size for 2 estimates of SD of 500 and 750. We allowed the possibility of loss to follow-up and to compensate for the reduced power due to statistical adjustment for potential confounders, we inflated the sample size by 25%. To detect a difference of 500 steps/day (about 0.25 mile) between spontaneous preterm births and women that deliver at term and with a SD=750, we will require a total of 126 subjects in the cohort (figure). With this recruitment, we anticipate that approximately 10-12 women will delivery preterm spontaneously.