Supplemental File 3

Power for Effectiveness Outcomes

All adult (age ≥18 years), English-speaking (directed or non-directed) LD candidates with African ancestry who attend clinic evaluation will be recruited for study participation. In 2019, the number of AA LDs who attended the clinic visit was ~40 at NU and ~60 at GU. While the estimated participation rate based on prior research is 86%(1), we anticipate being able to enroll at a slightly higher rate (~90%) given community engagement and culturally competent recruitment approaches(2-5). Power estimations were based on assuming enrollment of 56 participants in the 10-month pre-implementation period and 240 in the post-implementation period for a total of 296. Our proposed sample size will provide 80-90% power, with a two-sided type I error rate of 0.05, to detect differences in the mean decisional conflict scale (DCS) between arms ranging from 5.0 to 7.7, assuming standard deviations ranging from 12 to 16 (Table S1)(6). Thus, our proposed sample size will provide adequate power to detect small to medium Cohen's D effect sizes(7). As similar studies have observed even larger effects(8-10), we anticipate seeing differences of at least this magnitude in our study. Power considerations were based on a simplified two-sample t-test; however, sample sizes were inflated upward by a factor of 1/(1-R²) for planned multivariable models, resulting in a necessary sample size of 370. We have assumed an R² of 0.2, as an estimate of the square of the multiple correlation coefficient of the predictor of interest regressed on all other variables likely to be included in the model. Finally, we inflated our sample size to account for 5% attrition(11-13); thus, we plan to enroll a total of 74 participants in the control period and 316 in the intervention period. Of note, for H₃ the proposed sample size will also allow for construction of a confidence interval around the difference in the mean willingness to donate score with adequate precision to claim non-inferiority if the lower limit of the confidence interval does not intersect with the NI margin. We have assumed a confidence interval centered between 0 and -0.2, 90% power, a one-sided type 1 error rate of 0.025, standard deviations of 2.6(14) in both groups, and an NI margin of 1.5 units.

References Cited