Statistical Analysis Plan

Title: Improving Uptake of Genetic Cancer Risk Assessment in African American Women – Video

Protocol # NCI-2019-0489

NCT# NCT 04476654

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Data Analysis. Statistical Design and Power. This study is designed to evaluate feasibility and to estimate effect sizes for a future planned confirmatory RCT. As such, the sample size calculation is based on practical considerations. van Belle and Julious have both recommended a minimum sample size of twelve per group for pilot studies.[1, 2] This is based on the fact that the precision of the estimate of the mean and variance greatly increases up to a sample size of twelve at which point the decrease becomes less dramatic. Although these recommendations were based on continuous outcomes, the same logic applies to binary outcomes as the square root of N also appears in the denominator for the test of proportions. With a sample size of 25 per group we will have an adequate sample to estimate the difference in the proportion of participants who obtain GT between groups. No attrition is expected for the primary outcome as patient records will be used to determine if participants seek GT.

References

1. Van Belle G. Statistical rules of thumb. New York: New York: Wiley-Interscience, 2002.
2. Julious SA. Sample size of 12 per group rule of thumb for a pilot study. Pharmaceutical Statistics. 2005;4: 287-291.