

Statistical Analysis Plan

Community Collaboration to Advance Racial/Ethnic Equity in CRC Screening

NCT Number: NCT05714644

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All sociodemographic, clinical, and outcome data were obtained from electronic health record EHR. Patient characteristics will be presented as means with standard deviations (continuous) or frequencies and proportions (categorical). For the RCT, the primary intent-to-treat analysis included all study participants who did not opt-out from the Boston and LA CHCs. A secondary analysis used a propensity score matched sample to ensure balance between the two groups on age, gender, race/ethnicity and insurance status. We also conducted a sensitivity analysis excluding participants who might have completed screening before receiving the mailed screening kit, defined as within 7 days after the kit was sent. A final analysis included participants from SD in the FIT-DNA arm.

We compared the proportions of eligible individuals who participated in screening within 90 days or 180 days between study arms using logistic regression models with the generalized estimating equations to account for the correlated nature of data within CHCs, adjusting for age and race/ethnicity, which were unbalanced between the two arms. We compared time to screening participation between the two arms using a log-rank test. We also explored the heterogeneity of treatment effect by conducting subgroup analyses for pre-specified subgroups of interest (region, race/ethnicity, age, and language) and added insurance subgroups as a post hoc comparison. Among participants who returned stool tests within 180 days, we compared the distribution of test results between study arms using Fisher's exact tests. Among those with an abnormal stool test result, we compared the rate of colonoscopy completion within 180 days by arm and region using Fisher's exact tests and compared time to colonoscopy completion between the two arms using a log-rank test. All analyses were conducted using SAS version 9.4 (Cary, NC).