



STOP CRC Program (NIH R01) Statistical Analysis Plan

Official Trial Title: Culturally Adapted Multilevel Decision Support Navigation Trial To Reduce Colorectal Cancer Disparity Among At-Risk Asian American Primary Care Patients

Unique Protocol ID: R01MD012778

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Statistical Analysis Plan

Determine overall screening adherence in the culturally adapted decision support navigation intervention vs. the advanced control. The two study groups will be compared in terms of the fraction of participants who undergo colorectal cancer screening (through stool blood test or colonoscopy) within 12 months of the randomization date. Screening status will be determined using the 6-month survey, 12-month self-report of screening, and medical record review data at 6 and 12 months. We hypothesize that participants in the culturally adapted decision support navigation intervention group will have higher overall colorectal cancer screening rate than participants in the advanced control group. Generalized Estimating Equation (GEE) models with a logit link will be used to adjust for nesting of participants within primary care physicians. Specifically, the dependent variable is the screening status (yes vs. no) and the main predictor is the intervention groups (culturally adapted decision support navigation intervention versus advanced control). As mentioned above, we expect the two study groups to be comparable at baseline due to randomization. So, the model will control only for participant gender, age, and ethnicity (Chinese or Korean) (these three variables will be included to allow addition of interaction between study group and gender, age, or ethnicity in secondary analyses). If, however, substantial baseline imbalances occur, the model will control for additional variables.

Measure change in colorectal cancer screening decision stage in the culturally adapted decision support navigation intervention vs. the advanced control. We will elicit colorectal cancer screening decision stage separately for stool blood test and colonoscopy (decided against, not considering, undecided, decided to do), and compute an overall colorectal cancer screening decision stage as the higher of the two test-specific decision stages. We will elicit decision stage both at the baseline survey and at the 6-month survey. Forward change (between baseline and 6-month) will encompass any movement from a lower to a higher decision stage. We hypothesize that participants in the culturally adapted decision support navigation intervention group will have a greater likelihood of forward movement in screening decision stage than participants in the advanced group. We will analyze forward change in screening decision stage (yes vs. no (no change or backward movement between baseline and 6 months)) via a logit link to control for participants nested within primary care physicians. The model will adjust for participant baseline characteristics if necessary.