

COOP Trial Study Summary

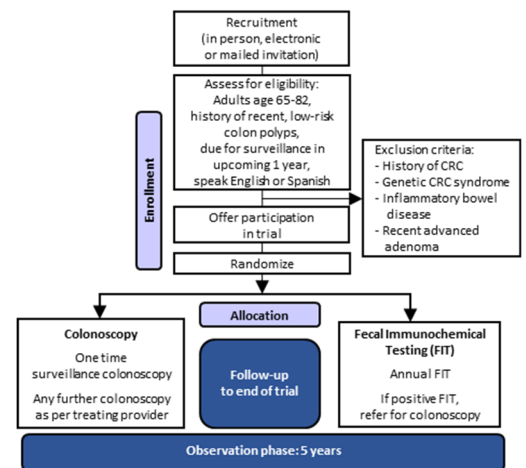
What is COOP? Colonoscopy vs. Stool-based Testing for Older Adults with a History of Colon Polyps

This is a large research trial comparing yearly fecal immunochemical testing (FIT) and colonoscopy for surveillance among adults aged 65-82 with a history of colorectal polyps.

Why is this study being done? Colon polyps are extremely common among adults 50 years and older, occurring in over 40% of individuals who undergo screening colonoscopy. People with colon polyps are commonly recommended to undergo regular follow-up colonoscopy (surveillance) in hopes of preventing subsequent colorectal cancer (CRC). Of note, most people with polyps will never get CRC. Older adults, particularly those who are age ≥ 70 years, most of whom have a history of only small colon polyps, may benefit little from repeated colonoscopies because of the increased risks of colonoscopy due to age and co-morbidities and potentially limited life expectancy due to other competing medical problems - CRC may never be a problem for them. In addition, older adults may be hesitant to get repeated colonoscopy because of the risk of complications (e.g., bleeding, perforation, etc.) and inconvenience that becomes increasingly challenging with age. More surveillance options are needed to help address the concerns and challenges with repeated colonoscopies in older adults with a history of low-risk polyps.

FIT is a noninvasive, stool-based test that is recommended and widely used globally for CRC screening in average-risk adults 45 to 75 years of age. FIT is already used as a surveillance option for patients with a history of low-risk adenomas in Canada and has been shown to be equivalent to colonoscopy for screening of certain high-risk populations (e.g., those with a low-risk family history of CRC). However, FIT's role for surveillance among adults who have a history of low-risk adenomas has not been studied.

By comparing FIT to surveillance colonoscopy in this study, the researchers hope to learn more about patients' preferences for surveillance and how well FIT works compared to colonoscopy for surveillance in people who've had polyps.



Study design: We will randomly assign by chance 8,946 adults age 65-82 with a history of low risk polyps to surveillance colonoscopy or annual FIT across 14 different sites in the US and 3 in Canada. All participants will be asked to complete an annual survey including information on health, mediations, and opinions on surveillance testing. Our primary outcome is detection of colorectal cancer and advanced polyps. Other outcomes include patient satisfaction, cancer worry and cumulative risk of harms. We have already enrolled over 1500 patients.

Study advisory panel: A panel of diverse research partners including patients, PCPs, specialists, advocacy groups, medical system and population health administrators, and insurers will advise us throughout the study's lifespan.

Impact: We believe the results of this study will bring meaningful change in the delivery of CRC prevention for older adults with a history of low-risk colon polyps and be readily adoptable into clinical practice. Healthcare providers and health systems can use the findings from this study to help patients make an informed patient-centered choice about managing surveillance of polyps.

Timeline: Full trial phase 4/1/2024 to 12/30/2030

Funding: Patient Centered Outcomes Research Institute (PCORI) Phased Large Award for Comparative Effectiveness Research: [Colonoscopy vs. Stool-Based Testing for Older Adults With a History of Colon Polyps | PCORI](#)