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Title

The Benefits of Flexibility in Designing the Colonoscopy Outreach for Rural Communities Study Protocol

Priority 1 (Research Category)

Clinical trial

Presenters

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Abstract

Context: Colorectal cancer (CRC) is a leading cause of cancer death in the United States and its burden is greater in rural communities. Colonoscopy is a critical step in the CRC screening pathway and a key opportunity to reduce CRC mortality. Colonoscopy Outreach for Rural Communities (CORC) is a pragmatic study involving a stakeholder needs assessment and coadaptation process to design delivery of a patient navigation (PN) program and test the effectiveness of the program to increase colonoscopy completion for CRC screening among patients at rural-serving primary care clinical organizations (PCCOs).

Objective: Share the final CORC study protocol design and highlight key learnings and subsequent protocol adaptations resulting from the co-adaptation development process.

Study Design and Analysis: Type 1 hybrid implementation-effectiveness study.

Setting: Six diverse rural and rural-serving PCCOs across three states.

Population Studied: Patients from PCCOs aged 45-76 and referred for colonoscopy for CRC screening.

Intervention: A 4-topic, virtual PN program.

Outcome Measures: Completion of colonoscopy within 6 and 12 months of referral.

Results: The CORC protocol reflects real-world design adaptations to address known challenges and ensure the study can both meet recruitment targets and meet the needs of rural communities and patients. The original CORC protocol only included patients referred to colonoscopy for follow-up after an abnormal stool screening test. Based on input from partner PCCOs, where the majority of CRC screening is performed through colonoscopy, we expanded the scope of the study to include any patients referred for colonoscopy for CRC screening. In addition, the original CORC protocol consisted of PCCOs sharing contact information for potentially eligible patients with the research team for recruitment outreach. Multiple PCCOs required the clinics to obtain patient permission before sharing

patient information with the CORC research team; in order to be responsive to partner needs and maintain our collaborative partnerships, we modified the protocol to accommodate this recruitment option.

Conclusions: By remaining flexible and open to adapting the CORC protocol to address challenges and barriers to implementing the study protocol, the CORC team was able to recruit and build relationships with partner PCCOs and match the study implementation design with the setting to ensure the best possibility for successful patient recruitment.