

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

Background

- **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.
- **Patient navigation** is an evidence-based strategy for increasing rates of colonoscopy completion.
- Partnering with “real-world” primary care practices may present challenges for clinical trial implementation

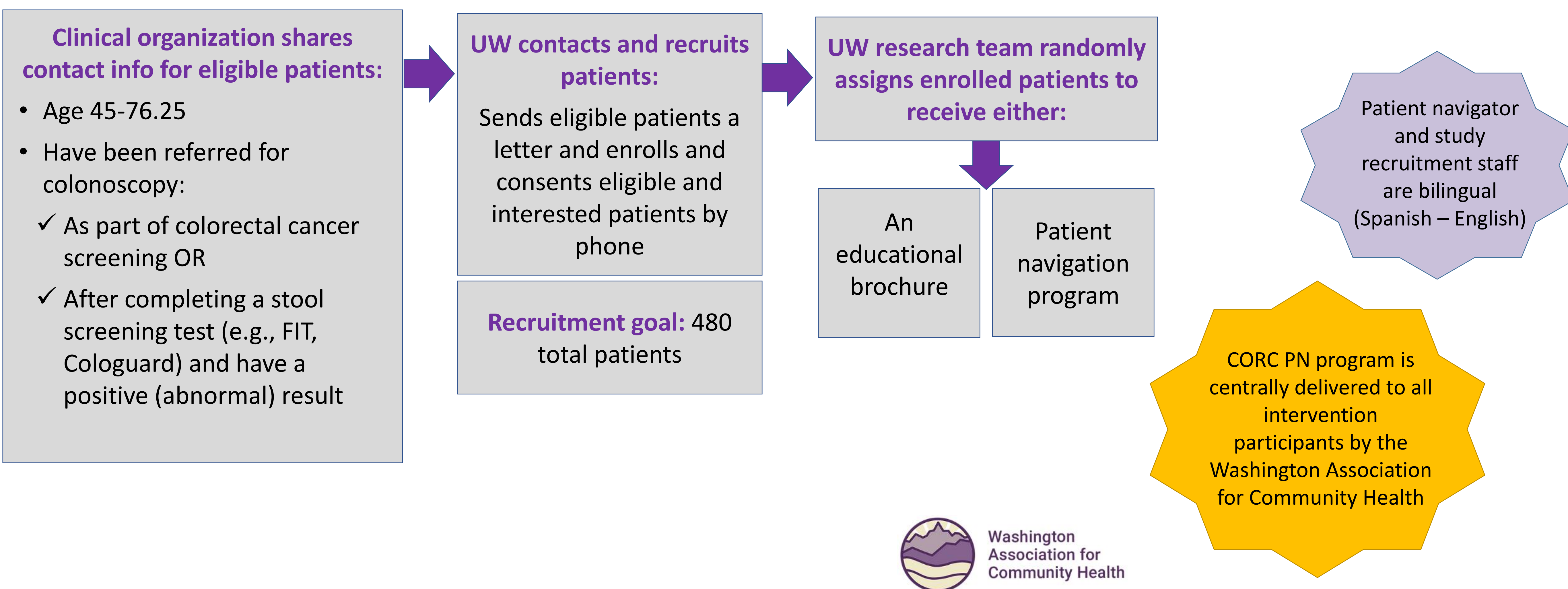
The CORC Study

- Colonoscopy Outreach for Rural Communities (CORC) is a pragmatic study to:
 - **Aim 1: Conduct a stakeholder needs assessment** and coadaptation process to design delivery of a remote patient navigation (PN) program.
 - **Aim 2: Test the effectiveness of the CORC PN program** to increase colonoscopy completion for CRC screening among patients at six rural-serving primary care clinical organizations through a randomized controlled trial.
 - **Aim 3: Evaluate the PN program and its implementation.**

The final CORC protocol reflects real-world design adaptations to address known challenges and ensure CORC can meet both recruitment targets and the needs of rural communities and patients.

Challenges	Protocol Adaptation or Study Process to Address Challenge
Original CORC protocol doesn't reach all patients who need colonoscopy for CRC screening (only included patients with positive stool screening)	Expanded patient eligibility criteria to include patients referred for colonoscopy: <ul style="list-style-type: none"> ✓ As part of colorectal cancer screening OR ✓ After an abnormal stool screening test
Some partner organizations do not allow sharing patient contact information with the CORC research team	Accepted variation in methods across clinical partners for initial patient outreach. <u>4 clinical partners:</u> <ul style="list-style-type: none"> • Share contact information for all identified patients directly with CORC research team. <u>2 clinical partners:</u> <ul style="list-style-type: none"> • Reach out to patients and obtain permission for CORC research team to contact them; • Share contact information of patients who gave permission, with the research team.
CORC PN program is delivered remotely to six different primary care clinical organizations, by a community-based organization	Adapted and tailored the study intervention to align with clinical partner settings <ul style="list-style-type: none"> • Conducted a stakeholder needs assessment and used a co-design process with our clinical partners and community advisory board to adapt the PN program. • Worked with each clinical partner to tailor the PN program for successful implementation. This included tailored communication protocols and resource lists.

Overview of Final CORC Protocol



Discussion

- By remaining flexible and open to adapting the CORC protocol to address challenges to implementing the study protocol, the CORC team was able to recruit and build relationships with partner primary care clinical organizations and match the study implementation with the setting to ensure the best possibility of study success.
- Expanding patient eligibility criteria provided a large enough pool of patients for recruitment that we anticipate hitting 50% of our recruitment goal within 1 year from starting the study, which is ahead of schedule.
- CORC demonstrates that building a collaborative process into study design can support a successful roadmap for partnerships to address barriers to cancer screening.