STUDY PROTOCOL

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A Randomized Controlled Trial on Shared Decision-Making for Colorectal Cancer Screening Among High-Risk First-Degree Relatives Aged 40–49

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1. Background

Colorectal cancer (CRC) remains a major global health challenge. According to GLOBOCAN 2020, CRC is the third most commonly diagnosed cancer worldwide and the second leading cause of cancer‑related death, with more than 1.9 million new cases and over 900,000 deaths annually.

Most CRC develops through a gradual progression from benign adenomatous polyps to invasive carcinoma over several years. Screening programs are effective because they detect and remove precancerous lesions or detect cancer at an earlier stage when treatment is more effective.

Individuals with a first‑degree relative (FDR) diagnosed with CRC—defined as a biological parent, sibling, or child—have significantly increased risk of developing CRC. International evidence shows that individuals with an affected FDR have approximately 2.25 times the risk of CRC compared with those without family history. If the relative was diagnosed before age 45, the risk increases to approximately 3.87 times, and if more than two FDRs are affected, the risk increases to approximately 4.25 times.

Guidelines from the US Multi‑Society Task Force and the American College of Gastroenterology recommend that individuals with a first‑degree relative diagnosed with CRC before age 60 begin screening at age 40 or 10 years earlier than the youngest diagnosis in the family.

Despite these recommendations, screening uptake among high‑risk individuals aged 40–49 remains low. Studies suggest screening rates in this population are only around 31–40%. At the same time, the incidence of CRC in individuals younger than 50 has been increasing in recent years, highlighting an urgent public health concern.

Shared decision‑making (SDM) is a patient‑centered approach in which clinicians and patients collaborate to make healthcare decisions based on clinical evidence and patient preferences. SDM may reduce barriers to CRC screening by improving knowledge, addressing misconceptions, and aligning screening options with patient values.

Decision aids are commonly used tools in SDM. These materials present balanced information about screening options, including colonoscopy and fecal immunochemical testing (FIT), allowing patients to compare benefits, risks, and procedures.

This trial proposes that a structured SDM intervention that explicitly offers both colonoscopy and FIT as screening options may increase screening uptake among high‑risk individuals compared with the standard approach of direct colonoscopy referral.

2. Study Objectives and Hypotheses

Primary Objective
The primary objective of this study is to evaluate whether a structured shared decision‑making intervention improves colorectal cancer screening uptake among individuals aged 40–49 with a first‑degree relative diagnosed with CRC compared with standard care.

Primary Hypothesis
Participants assigned to the SDM intervention will have a higher screening completion rate within three months after randomization compared with those assigned to standard care.

Secondary Objectives
• Evaluate participant satisfaction with the decision‑making process and care received.
• Assess the quality of the SDM process using validated questionnaires.
• Examine screening modality choices (colonoscopy vs FIT).
• Evaluate detection rates of colorectal neoplasia, including adenoma, advanced adenoma, and colorectal cancer.

3. Study Design and Methodology

Overall Design
This study is a two‑arm parallel randomized controlled trial. Participants will be randomized in a 1:1 ratio to either the SDM intervention group or the standard care group.

Study Setting
Participants will be recruited from multiple medical centers in Taiwan including hospitals in northern, central, and southern regions.

Participant Eligibility
Inclusion Criteria:
• Age 40–49 years
• At least one first‑degree relative diagnosed with CRC
• Ability to understand study procedures and provide written informed consent

Exclusion Criteria:
• Personal history of CRC or inflammatory bowel disease

- Symptoms requiring diagnostic evaluation rather than screening
- Medical conditions contraindicating colonoscopy
- Colonoscopy within the past three years

4. Outcome Measures

Primary Outcome
Colonoscopy uptake within three months after randomization.

Secondary Outcomes
- Patient satisfaction measured using the Shared Decision Making Questionnaire (SDM-Q-9)
- Screening modality selection among participants in the SDM group
- Detection rates of colorectal neoplasia

5. Data Collection and Management

All study data will be collected and managed using REDCap (Research Electronic Data Capture), a secure web-based platform designed for research data management. Data will be entered into electronic case report forms by trained research staff.

6. Study Duration and Coordination

The study is expected to run from September 1, 2025 to December 31, 2026. The coordinating center will be National Taiwan University Hospital. Collaboration will involve multiple hospitals across Taiwan, with principal investigators at each participating center responsible for local coordination.

7. Ethical Considerations

This study will follow the ethical principles outlined in the Declaration of Helsinki and Good Clinical Practice guidelines. Approval will be obtained from the Institutional Review Boards of all participating institutions prior to study initiation.

Informed consent will be obtained from all participants before any study procedures are performed. Participant confidentiality will be strictly maintained through the use of unique study identification numbers and secure data storage systems.

8. Potential Risks and Benefits

Risks associated with participation are minimal and primarily related to time commitment. Risks associated with colonoscopy include bleeding, perforation, and sedation-related complications. FIT screening may produce false-positive or false-negative results.

Potential benefits include increased knowledge about CRC screening and the opportunity to participate in informed decision‐making regarding screening options.

9. Expected Outcomes

This study aims to generate evidence regarding the effectiveness of shared decision‐making strategies in increasing CRC screening uptake among high‐risk populations. If effective, the intervention may inform future screening policies and clinical guidelines and contribute to improved CRC prevention strategies.