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A hybrid patient decision aid integrating a large language model-powered chatbot to improve colorectal cancer diagnostic uptake

Submission date 15/01/2026	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/02/2026	**Overall study status** Ongoing	
Last Edited 22/09/2026	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

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Study information

Scientific Title
Design and effectiveness evaluation of a hybrid patient decision support system integrating an integrated large language model chatbot for improving the compliance of community residents with colorectal cancer diagnosis: A study based in Shanghai, China

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/01/2026, Ethics Committee of the School of Public Health (Fudan University, Shanghai, 200032, China; +86 (0)21 5423 7148; gwkyb@fudan.edu.cn), ref: H2026009

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Diagnostic, Health services research

Study type(s)

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions
Current interventions as of 22/09/2026:

Participants allocated to the intervention group will receive the multicomponent PDAs intervention when they attend the Community Healthcare Center (CHC) to collect their CRC

screening results. Trained investigators will introduce the printed desk calendar, explain its content, demonstrate how to use the LLM-based interactive consultation module on a smartphone, and assist participants in subscribing to the WeChat Official Account. Following enrollment, the WeChat Official Account will serve as the digital platform for continuous intervention. In addition to providing access to the LLM-based interactive consultation module, the platform will deliver CRC-related health education and diagnostic guidance every two weeks, thereby providing ongoing behavioral support and reinforcing participants' motivation to undergo timely diagnostic evaluation.
Participants allocated to the control group will receive routine care according to the existing CRC screening program. When collecting their screening results at the CHC, they will receive the standard recommendation from their GP to undergo further diagnostic evaluation. No additional intervention beyond routine care will be provided to the control group. All participants obtained informed consent from their GP teams before being enrolled in the study.

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Previous interventions:

Study sites were randomly assigned to either a digital decision aid intervention group or a usual care control group. The intervention consisted of two components:
1. Training for Healthcare Providers: Medical staff in the intervention group received a 4–5 hour training session on using the decision aid and related clinician-patient communication skills prior to implementation.
2. Digital Decision Aid Implementation: The digital tool was used during outpatient colorectal cancer screening consultations to support the pre-colonoscopy decision-making process. Its primary content involved educating residents about colorectal cancer and colonoscopy screening.

Intervention Type
Behavioural

Primary outcome(s)
1. CRC diagnostic uptake measured using telephone follow-up survey at 3 months post-intervention

2. CRC diagnostic uptake measured using telephone follow-up survey at 6 months post-intervention

3. Quality-adjusted life years (QALYs) measured using patient records at 3 months post-intervention

4. Intervention costs measured using patient records at 3 months post-intervention

Previous primary outcome(s):

1. Decision whether to undergo colonoscopy screening measured using telephone follow-up survey at 3 months post-intervention

Key secondary outcome(s)
Current key secondary outcome(s) as of 22/09/2026:

1. Residents' knowledge and cognitive level, using a question-and-answer scale designed by the research team at baseline, immediately post-intervention, and 3 months post-intervention. Residents need to judge whether 10 descriptions about colorectal cancer and cancer screening diagnosis are correct, and their knowledge level will be determined based on the accuracy rate.
2. Decision conflict level, measured using the Chinese version of the Decisional Conflict Scale at baseline, immediately post-intervention, and 3 months post-intervention
3. Decision self-confidence, measured using the Chinese version of the Decision Self-Efficacy scale at baseline, immediately post-intervention, and 3 months post-intervention
4. Decision regret degree, measured using the Chinese version of the Decision Regret Scale at at 3 months post-intervention
5. Residents' satisfaction with the intervention tools, measured using the Chinese version of the Decision Preparation scale at 3 months post-intervention
6. Residents' expectations regarding shared decision-making measured using the Chinese version of the shared decision-making scale 9-item Shared Decision Making Questionnaire (SDM-Q-9) at baseline and 3 months post-intervention

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Previous key secondary outcome(s):

1. Residents' knowledge and cognitive level, using a question-and-answer scale designed by the research team at baseline, immediately post-intervention, and 3 months post-intervention. Residents need to judge whether 10 descriptions about colorectal cancer and cancer screening diagnosis are correct, and their knowledge level will be determined based on the accuracy rate.
2. Decision conflict level, measured using the Chinese version of the Decisional Conflict Scale at baseline, immediately post-intervention, and 3 months post-intervention
3. Decision self-confidence, measured using the Chinese version of the Decision Self-Efficacy scale at baseline, immediately post-intervention, and 3 months post-intervention
4. Decision regret degree, measured using the Chinese version of the Decision Regret Scale at at 3 months post-intervention
5. Residents' satisfaction with the intervention tools, measured using the Chinese version of the Decision Preparation scale at 3 months post-intervention
6. Diagnostic preference, measured using a self-designed scale at baseline, immediately post-intervention, and 3 months post-intervention
7. Residents' expectations regarding shared decision-making measured using the Chinese version of the shared decision-making scale 9-item Shared Decision Making Questionnaire (SDM-Q-9) at baseline and 3 months post-intervention

Completion date
31/03/2027

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 22/09/2026:

1. Aged 50–100 years and registered as local participants
2. Have a positive result from the most recent CRC screening
3. Have not undergone diagnostic evaluation following their most recent positive CRC screening result
4. Own a smartphone and have a personal WeChat account

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Previous key inclusion criteria:

1. Permanent residents of Shanghai (including individuals with local household registration and non-local residents who have lived in Shanghai for over 6 months).
2. Individuals eligible according to the Shanghai Community Colorectal Cancer Screening Implementation Plan.
3. Individuals enrolled in any of Shanghai's basic medical insurance or healthcare security schemes.

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
50 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 22/09/2026:

1. Have already been diagnosed with colorectal cancer
2. Cannot be contacted during the follow-up period
3. Have life-threatening illnesses or other serious medical conditions that may preclude study participation
4. Have cognitive impairment that prevents them from completing the study questionnaire

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Previous key exclusion criteria:

1. Individuals who have previously undergone colonoscopy and were confirmed to be at no risk for colorectal cancer.
2. Individuals whose health status is unsuitable for colonoscopy.
3. Individuals with cognitive impairment that prevents participation in follow-up and questionnaire surveys.
4. Individuals with a confirmed diagnosis of colorectal cancer.
5. Individuals with a confirmed diagnosis of other high-risk diseases where the mortality risk is too high for them to be suitable for colonoscopy screening.

Date of first enrolment
01/03/2026

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
China

Sponsor information

Organisation
National Health Commission of the People's Republic of China

Funder(s)

Funder type

Funder Name
National Health Commission of the People's Republic of China

Alternative Name(s)
National Health Commission of the PRC, National Health Commission, , , , NHC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available