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Financial incentives and motivational intervention to improve gastric cancer screening in China: a randomized controlled trial study protocol

Quan Wang ,[1] Chao Gong,[1] Yumeng Lv,[1] Yiyang Tan,[1] Siqi Liu,[2] Li Yang[1]

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[1]School of Public Health, Peking University, Beijing, China
[2]Center of Health System and Policy, Institute of Medical Information & Library, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China

Correspondence to
Professor Li Yang;
lyang@bjmu.edu.cn

ABSTRACT

Gastric cancer (GC) remains a significant global health challenge, with high mortality rates, particularly in low- and middle-income countries, like China. Early detection through screening is crucial for improving prognosis and reducing mortality. However, uptake of GC screening remains suboptimal, highlighting the need for effective interventions to promote screening participation. This study employs an experimental design to evaluate the effectiveness of two interventions, financial incentives and motivational interventions, in promoting GC screening uptake at the individual level. A large sample size will be recruited from high GC-burden provinces in China, and participants will be randomly assigned to intervention and control groups. Statistical analyses, including the χ^2 test and interrupted time series analysis, will be used to assess the impact of interventions on screening uptake and adherence. The research protocol was reviewed by the ethical review committee of the Peking University Health Science Center (2024097) and registered at the ClinicalTrials.gov. Findings from this study will be disseminated through peer-reviewed publications, conference presentations, and engagement with stakeholders to inform evidence-based strategies for improving GC screening and reducing GC-related morbidity and mortality.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Gastric cancer (GC) is one of the most prevalent cancers in China, accounting for approximately half of the global deaths related to this disease.
⇒ Early detection and treatment can significantly reduce the mortality of GC.

WHAT THIS STUDY ADDS

⇒ This study assesses the effectiveness of financial incentives and motivational interventions in increasing individual participation in GC screening.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ By identifying effective strategies for promoting screening, this study can contribute to the development of evidence-based interventions to improve GC outcomes in China and other low- and middle-income countries.

INTRODUCTION

As one of the most prevalent malignancies globally, gastric cancer (GC) accounts for over 1 million new cases annually, positioning it as the fifth most diagnosed cancer worldwide. Its grim prognosis is underscored by its tendency for advanced-stage diagnosis, contributing to its ranking as the third leading cause of cancer-related deaths, with 784,000 fatalities reported globally in 2018.[1] Despite a declining global incidence over time, GC remains particularly prevalent in East Asia, especially in countries such as China, Japan, and Korea.[2]

GC ranks among the most prevalent cancers in China, with GC-related deaths in the country constituting approximately half of the global total.[3] Estimates suggest that the pooled 5-year survival rates for tumor node metastasis (TNM) stage I patients with GC stand at around 83.9%, contrasting sharply with the lower figures for TNM III/IV patients, at 31.9% and 9.1%, respectively.[4] Early detection and treatment can significantly reduce the mortality of GC.[5] Despite China's national screening guideline recommending initiation of screening at age 40 for individuals at risk,[6] the absence of comprehensive national screening programs, akin to those in Japan and Korea,[7 8] results in reliance on opportunistic screening methods alone.[9 10] However, for various reasons, many individuals remain hesitant to undergo gastroscopy, even when identified as high risk through screening. It is estimated that general annual endoscopy screening could potentially decrease GC-related mortality by 44.5%.[11]

While direct evidence regarding GC screening remains limited, studies on other gastrointestinal cancers have highlighted prevalent reasons for non-participation, including lack of motivation, active aversion,

and systemic barriers within healthcare systems.[12] Consequently, numerous studies have explored strategies to enhance gastrointestinal cancer screening, with some focusing on financial incentives as potential motivators.[13 14] However, findings regarding the efficacy of financial incentives in influencing cancer screening have been mixed,[6] prompting exploration of alternative interventions such as motivational interventions,[15] health education initiatives,[16] and messaging services.[17] Despite these efforts, significant evidence gaps persist in the context of GC screening, particularly concerning the applicability of these interventions within the unique cultural and healthcare landscape of China. Moreover, existing studies have predominantly been conducted within Western settings,[14 18] leaving uncertainties regarding their effectiveness in Chinese populations. Furthermore, the long-term compliance of individuals undergoing GC screening, particularly those with precancerous lesions or conditions requiring regular screening, has received inadequate attention. In this study, we aim to address these gaps by evaluating the effectiveness of financial incentives and motivational interventions in improving GC screening rates in China, considering both short-term and long-term outcomes.

METHODS AND ANALYSIS

This study adopts a non-double-blind individual-level randomized controlled trial (RCT) design. The targeted participants are individuals identified as "high risk" by the Gastric Cancer Risk Scoring System (GC-RSS),[19] a self-assessment tool developed by the China Anti-Cancer Association. The GC-RSS evaluates risk based on age, gender, family history, smoking, drinking habits, and other relevant variables. Participants receive a risk assessment score, with a total score of 13 points, and a score of≥5 indicating a recommendation for further GC screening. In regions with limited medical resources, the screening threshold may be adjusted to≥8 points.[19]

Inclusion and exclusion criteria

Inclusion criteria are:

1. Provision of informed consent by patients;
2. Identification as "high risk" (≥5 scores) by GC-RSS.

Exclusion criteria are:

1. History of previous GC screening, including endoscopy and serum biomarker examination (*pepsinogen*, *G-17*, and *MG7-Ag*);
2. Diagnosis of cancer or presence of precancerous lesions or conditions;
3. Having family members who have already participated in this study;
4. Diagnosis of severe depression or psychiatric disorder;
5. Presence of other medical conditions that preclude receipt of endoscopy services.

Location

The study will take place in two provinces of China known for their high GC burden: Qinghai and Fujian.

Qinghai Province encompasses a significant portion of the Qing-Tibetan Area, characterized by its cross-cultural and less-developed nature within China. Studies have indicated a high prevalence of *Helicobacter pylori* infection among individuals of zangzu (Tibetan ethnicity) with GC, reaching up to 80.0%.[20] The incidence of GC in Qinghai Province was 0.032%, ranked at the top of all kinds of cancers.[21] Fujian Province is a coastal region of China known for its relatively high prevalence of GC.[19] Three cities will be selected from each province, and participants will be recruited from randomly selected communities within these cities.

Recruitment and procedure

The study procedure involves collaboration with community health centers in selected communities within Qinghai and Fujian provinces, where questionnaires based on the GC-RSS will be distributed face-to-face to residents. Community health center staff will assist by distributing the questionnaires to individuals seeking medical assistance and guiding them through the completion process. To enhance participation, we will publicize the project within the communities and encourage residents to take the survey at these centers. Residents who are unwilling to complete the questionnaire or participate in the study will be excluded from the sample. For those who complete the GC-RSS questionnaire, researchers will categorize them into "high-risk" or "low-risk" groups based on their risk assessment scores, as previously outlined. This approach ensures a focused and effective identification of participants for further interventions. Residents identified as "high-risk" will receive further guidance for potential inclusion in the study.

Participants will be randomly assigned to either the financial incentive intervention, motivational intervention, mixed intervention or control group using a computer-generated random permuted-block design, stratified by community. We will print individually numbered cards reflecting the group assignments. These cards will be sealed in opaque envelopes and distributed to the study sites. As participants are recruited, study personnel will open the envelopes to determine group allocation.

Participants in the intervention groups of this RCT will undergo predesigned interventions facilitated by researchers, with contact information collected for further communication. Researchers will follow-up with participants at 3 and 6 months postintervention to assess if they underwent endoscopy, and participants consenting to endoscopy will have their results and potential pathological findings collected. For participants advised by clinical doctors to undergo regular screenings—typically scheduled for 1 or 2 years—the researchers will follow-up by phone to confirm whether these participants have adhered to the recommended screening schedule. During these follow-up calls, researchers will also send questionnaires to those who are still willing to participate, collecting additional information as needed. Throughout

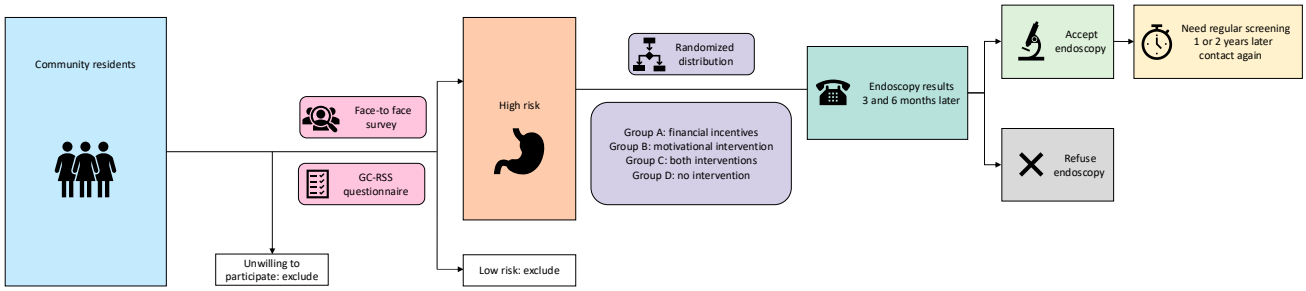

Figure 1 Overview of the procedure. GC-RSS, Gastric Cancer Risk Scoring System.

the process, basic socioeconomic information will also be collected. See figure 1 for an overview of the procedure.

Interventions

Three types of interventions have been designed: Financial incentive, motivational intervention, and a mixed intervention combining both financial incentives and motivational intervention. In the financial incentive group, participants will receive reimbursement for transportation, accommodation, and food costs, along with RMB200 (about US$30) to compensate for potential income loss due to endoscopy, provided they undergo the procedure. For the motivational intervention group, researchers will provide detailed information about the social norms surrounding endoscopy screening, including the prevalence of screening participation, the potential risks of GC, and the health benefits of screening. Participants in the mixed intervention group will receive both financial incentives and motivational intervention. As previously mentioned, researchers will follow-up with participants who require regular screenings, although no additional interventions will be administered during these follow-up periods.

Sample size

Based on previous research on colonoscopy, we estimate that the baseline rate of individuals undergoing endoscopy without any intervention (control group) is 8% (P_1).[17] We set a minimum acceptable rate of endoscopy uptake with any intervention at 18% (P_2). With an α error (type 1 error) of 0.05 and a detection power (β) of 0.9, calculations using PASS 2021 (V.21.0.9, NCSS, LLC, USA) suggest a sample size of 466 is required. However, to ensure robustness and account for potential variations, we conducted sensitivity analyses, ranging from a lower limit rate of 12–24%, as illustrated in figure 2.

Previous studies on populations aged 40 and above found that approximately 12.3% of patients undergoing opportunistic upper endoscopy presented with preneoplastic lesions,[22] a condition requiring regular screening. Since our study does not have age restrictions, we estimate that around 10% of participants will require regular follow-up screening, which would necessitate a sample size of 4,660 participants. To account for potential dropout over the 1 or 2-year follow-up period, we have decided to set the sample size for this study at 5,000 participants.

We set 1:3:3:3 for each group, namely 500 participants in the control group and 1,500 participants for each intervention group.

Outcomes of interest

Primary outcome

Our primary outcome is the rate of individuals undergoing endoscopy screening within three and 6 months,

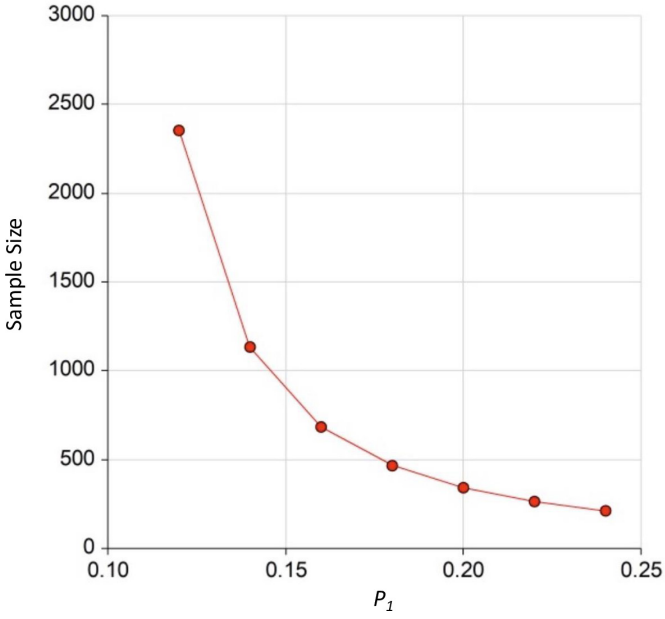

Figure 2 Sensitive analysis of sample size. Note: P_1: rate of endoscopy uptake in the control group.

compared between the intervention groups (financial incentive, motivational intervention, mixed intervention) and the control group.

Secondary outcome

In addition to assessing the primary outcome of endoscopy screening uptake, secondary outcomes include evaluating the proportion of participants adhering to follow-up endoscopy appointments at 1 or 2 years postintervention, stratified by intervention group. Basic socioeconomic information will be collected from participants to explore factors influencing screening uptake. Collaboration with hospitals will enable the collection of population-level data, including preintervention and postintervention endoscopy screening rates per month and outcomes, such as detection rates of GC and precancerous lesions. Furthermore, a collection of oncological outcomes will be conducted to evaluate the effectiveness of the screening interventions in improving patient health outcomes. This will include tracking the incidence and stage of GC detected through screening, as well as survival rates and treatment outcomes among those diagnosed. These comprehensive data collection efforts will provide insights into both individual-level adherence and the broader impact of interventions on population-level screening rates and health outcomes.

Statistical analyses

Data analysis will be conducted using appropriate statistical methods to assess the effectiveness of the interventions in promoting endoscopy screening uptake and adherence. Descriptive statistics will be used to summarize baseline characteristics of participants, including demographic information and socioeconomic factors. The primary outcome, the rate of endoscopy screening uptake, will be compared between intervention groups (financial incentive, motivational intervention, mixed intervention) and the control group using χ^2 tests or logistic regression models, accounting for the matched pairs. Secondary outcomes, including adherence to follow-up endoscopy appointments and population-level screening rates, will also be analyzed using similar methods. Subgroup analyses may be conducted to explore differences in intervention effectiveness based on participant characteristics. Additionally, sensitivity analyses will be performed to assess the robustness of results to variations in key parameters.

At the population level, interrupted time series analysis will be employed to assess changes in endoscopy screening numbers and detection rates of GC and precancerous lesions over time, before and after the intervention, while controlling for relevant covariates such as age, sex, and other demographic factors.

DISCUSSION

To the best of our knowledge, this study represents the first experimental investigation at the individual level aimed at improving GC screening rates in low- and middle-income countries (LMIC). Through this research, we seek to elucidate the effectiveness of both financial incentives and motivational interventions in promoting GC screening uptake. Additionally, we will conduct an economic evaluation to assess the cost-effectiveness of these interventions and determine their feasibility for wider implementation. By pioneering this comprehensive approach, we aim to contribute valuable insights to the field of cancer screening and advance strategies for improving early detection and treatment outcomes in LMIC settings.

Given the substantial sample size of our study, should the observed effectiveness of the interventions prove significant, we will explore the possibility of transitioning to implementation research. This transition would enable us to further investigate the scalability and real-world application of the identified interventions in broader populations and healthcare settings. By extending our research beyond the experimental phase, we aim to facilitate the translation of findings into sustainable strategies for enhancing GC screening on a larger scale.

There are also several weaknesses in our study. First, our reliance on self-reporting for certain data, such as socioeconomic information, may introduce reporting bias. Second, the use of convenience sampling from specific provinces may limit the generalizability of our findings to broader populations. Third, the very act of being invited to participate in a clinical trial may serve as a motivator for some individuals to undergo endoscopy, independent of the assigned intervention, which suggests that individuals who are aware of their potential inclusion in a trial may be more likely to take proactive health measures simply due to the attention and perceived importance of the trial. As a result, the observed endoscopy uptake rates in both the intervention and control groups could be artificially inflated compared with what might be expected in a non-trial setting. Additionally, the potential for confounding variables, despite our efforts to mitigate them through statistical adjustments, could influence the observed outcomes. Furthermore, the short-term follow-up period may restrict our ability to assess long-term sustainability and impact. Finally, the complex nature of behavior change interventions may pose challenges in isolating the specific effects of individual components. Despite these limitations, our study represents a crucial step forward in addressing the pressing need for effective GC screening interventions, and we remain committed to refining our approaches and addressing these weaknesses to enhance the validity and applicability of our findings.

Contributors QW designed the study and finished the manuscript. CG calculated the sample size. YL, YT, and SL refined the manuscript. LY, as the corresponding author, refined the research question and manuscript. All authors approved the final manuscript submitted. LY was responsible for this study. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Competing interests None declared.

Patient and public involvement statement As this was an early-stage, patients and the public were not involved in this study.

Patient consent for publication Not applicable.

Ethics approval This study has been reviewed and approved by Institutional Review Board of Peking University Health Science Center (No. 2024097). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD

Quan Wang http://orcid.org/0000-0003-3501-9513

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