The effectiveness of telephone reminders and SMS messages on compliance with colorectal cancer screening: an open-label, randomized controlled trial

INVESTIGATORS

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BACKGROUND

Colorectal cancer (CRC) is one of the major global health challenges. CRC is currently the third most common cancer in men and the second common in women worldwide, accounting for approximately 10% of all cancers. It leads to 8% of all cancer mortality in the world and it is the fourth most common cause of cancer deaths [1]. There were 4,563 new cases and 3,893 new deaths in Hong Kong in 2012, while 47.4% of the new cases were diagnosed at stage III or above [2]. In the past decades the Asia Pacific countries like China, South Korea, Japan, and Singapore have witnessed a two to three-fold rise in incidence [3], gradually catching up the figures in Western countries. The direct medical cost for the care of colorectal neoplasia was estimated US$45,115 for stage IV CRC in the initial year of care, bringing a substantial, global public health burden to the healthcare systems [4].

Randomized controlled studies have shown that CRC screening using Faecal Occult Blood Testing (FOBT) is effective in reducing cancer mortality by 15-33% [5-7]. FOBT as a quick office-based procedure has the advantages of being non-invasive, inexpensive, acceptable, feasible, patient-friendly and devoid of needs for bowel preparation. A 25% relative risk reduction in CRC mortality was found for those attending at least one round of FOBT screening, according to a systematic review conducted in 2007 [8]. Guidelines from the US Preventive Services Task Force, the European Nations, the Asia Pacific

Consensus statements and other authorities recommended FOBT as one of the first-line screening modalities, especially in resource-limited regions [9-12]. Since yearly testing is recommended to maintain programmatic effectiveness [10, 13, 14], longitudinal adherence is a critical component of FOBT-based screening programs. Our previous study conducted in Hong Kong showed that the rate of compliance with CRC screening was declining since the first year of enrolment [15].

Nevertheless, it remains unknown whether interventions based on reminder systems could effectively enhance longitudinal compliance with FOBT, especially among those who have already enrolled in a CRC screening programme. Current evidence does not adequately compare whether interactive or one-way reminder messages are superior to usual care (i.e. no reminders).

STUDY AIMS

To compare the effectiveness of (1). interactive telephone reminders and (2). non-interactive SMS messages on enhancing compliance with CRC screening by FOBT, when compared with usual care (i.e. no intervention).

STUDY POPULATION

Inclusion Criteria

Subjects who joined the bowel cancer screening programme in the CUHK JC Bowel Cancer Education Centre who are expected to follow-up and return to the centre for annual Fecal Occult Blood Test.

Exclusion Criteria

(1) had medical conditions rendering them unable to understand telephone or SMS messages; or (2) had no mobile phone were excluded.

METHODOLOGY

1. All subjects will be recruited from the existing cohort of screening participants who joined the bowel cancer screening programme in the CUHK JC Bowel Cancer Education Centre in 2015 with FOBT negative in the first round of screening, and who are expected to follow-up and return to the centre in 2016 for their second round of FOBT screening.

2. Each study subjects will be offered one of the following: (1). a personal, interactive telephone reminder by a center colleague to remind return to the center for taking fecal tubes for screening; (2). a one-way, SMS message sent from the center to the screening participant's mobile phone; or (3). usual care, where no additional intervention will be offered. A simple random sampling process will be administered using computer-generated numbers so that each participant will have a probability of 1/3 for assignment into each group. All potential participants identified who are eligible for the study will be randomized by a computer randomizer, which will give a number indicating the group assigned. Each subject will have equal opportunity to be allocated to any one of the three arms (i.e. allocation ratio of 1:1:1)

3. The outcome of interest included the proportion of subjects who return to the centre and retrieve fecal tubes for screening 30 days within the scheduled time for the second year of the screening test.

4. Data will be analyzed using SPSS version 20.0 for Windows and were expressed as proportions. The baseline characteristics of the three groups are compared by chi-square tests of heterogeneity and Student’s t-tests for categorical and continuous variables, respectively. The associations between the study groups and the outcome variables are examined by backward stepwise, binary logistic regression analyses. The covariates included age, gender, educational level, monthly household income, job status, marital status, body mass index, waist circumference, family history of CRC in a first-degree relative, smoking, alcohol drinking, comorbidities and use of medications. The control group and the SMS group are used as the reference group in

separate analyses. Subgroup analysis according to marital status, household income and educational level was performed, since previous studies identified these variables as potential effect modifiers. A p value of ≤0.05 will be interpreted as statistically significant, and a p value between 0.5 and 0.1 is considered indicative of a trend towards significance.

END POINTS

1. Rate of completion of FOBT in the year of receiving the interventions/control
2. Rate of return to the centre for taking FOBT tubes in the year of receiving the interventions/control

SAMPLE SIZE

The total sample size is 600 with 200 subjects in each of the three groups. A power calculation indicates that a sample of 600 participants would provide 80% power (at the 5% level) of detecting an increase of 11% in the interactive phone call and automated SMS message groups versus no increase in the control group (there are no studies of similar nature comparing the effectiveness among interactive vs. automated telephone calls vs. control).

TIME LINE

Feb 15, 2016	Proposed study start date
September 30, 2016	Proposed study end date or date of last follow-up of all recruited subjects, whichever is later
Dec 31, 2016	Tentative final report date to Cluster REC

DECLARATION

The study will be conducted in compliance with ICH-GCP guidelines. This study will also comply with the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects.

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