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Invitation strategies for colorectal cancer screening programmes: The impact of an advance notification letter

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ABSTRACT

Aim. To estimate the impact of an advance notification letter on participation in sigmoidoscopy (FS) and fecal immunochemical test (FIT) screening.

Methods. Eligible subjects, invited in 3 Italian population based programmes using FS and in 5 using FIT, were randomised (1:1:1), within GP, to: A) standard invitation letter; B) advance notification followed after 1 month by the standard invitation; and C) B + indication to contact the general practitioner (GP) to get advice about the decision to be screened. We calculated the 9-month attendance and the incremental cost of each strategy. We conducted a phone survey to assess GP's utilization and predictors of participation.

Results. The advance notification was associated with a 20% increase in the attendance among 15,655 people invited for FS (B vs A — RR: 1.17, 95% CI: 1.10–1.25; C vs A — RR: 1.19, 95% CI: 1.12–1.27); the incremental cost ranged between 10 and 9 Euros. Participation in FIT screening (N = 23,543) was increased only with simple pre-notification (B vs A — RR: 1.06, 95% CI: 1.02–1.10); the incremental cost was 22.5 Euros. GP consultation rate was not increased in group C.

Conclusions. An advance notification represents a cost-effective strategy to increase participation in FS screening; its impact on the response to FIT screening was limited.

Introduction

Available evidence from three trials (Cole et al., 2007; Libby et al., 2011; Van Roon et al., 2011) indicates that an advance notification letter may represent an effective strategy to increase the response rate among subjects invited for colorectal cancer (CRC) screening with FOBT, as compared to the direct mailing of the screening invitation. The positive impact of this approach has been explained based on the framework of stage models of behavioural change, such as the trans-theoretical model (TTM) (Prochaska and DiClemente, 1986; Prochaska et al., 1994; Rakowski et al., 1996, 1997). According to this model, the adoption of preventive behaviours represents the final step of a multi-phase decision process. In this process the subject passes through a growing degree of readiness for change before actually engaging in the proposed behaviour. An advance notification letter, conveying information on CRC risk, available preventive tests and screening programme procedures, may increase the likelihood of a positive response to the actual invitation, as the subject will have progressed in his degree of readiness for change.

Information on the impact of advance notification among people targeted for alternative effective screening strategies are still lacking. Interventions aimed at increasing individual's awareness and at favouring

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progression from contemplation of action to the decision to adopt the required behaviour might be particularly helpful, however, when offering more invasive and less diffused tests, such as sigmoidoscopy (FS). Moreover, only one study (Libby et al., 2011) has been conducted in the context of a large population programme, offering guaiac FOBT (gFOBT) screening, while the two studies assessing the impact of pre-notification among people invited for immunochemical FOBT (FIT) screening (Cole et al., 2007; Van Roon et al., 2011) were conducted in the context of small pilot studies. Since media coverage can be effective in increasing public awareness of CRC risk, the impact of additional information conveyed by the advance notification letter might be overestimated in pilot settings where large scale mass-media campaigns aimed at promoting screening participation are usually not implemented.

The aim of this study was to assess the impact on the participation rate in population based CRC screening programmes, using either FIT or FS, of an advance notification letter, mailed to eligible subjects one month before the screening invitation.

Two different pre-notification approaches were tested: a simple information letter and the same letter including the offer of a personal encounter with the invitee's general practitioner (GP). GP's advice may have a strong influence on the decision to be screened, in particular among less educated subjects (Senore et al., 2010). Therefore, the offer of tailored personal counselling by the GP, in addition to the pre-notification letter, could extend the reach of the intervention also to subjects who may have little confidence in relying on written material alone to make health-related decisions.

We estimated also the cost per additional attendee and we assessed frequency of GP's utilization and the association of subjects' characteristics with the response to the different strategies.

Methods

We designed a randomised controlled trial (ISRCTN 84448636) involving 8 population based CRC screening programmes in Italy: 5 of them (Este, Milan, Rimini, Rome and Trento) are inviting all men and women aged 50 to 69 for biennial FIT screening; all men and women are invited to perform a FS once in the lifetime at age 58 in Novara and Turin, or at age 60 in Verona.

GPs are asked to exclude from invitation subjects with previous diagnosis of adenomas or CRC, inflammatory bowel disease, severe illness, positive family history (>1 first degree relative with CRC) and people unable to give informed consent. All residents covered by the Italian NHS are listed in the rosters of a GP and, depending on local policies, GPs may receive a small incentive to collaborate in the programme, proportional to the observed participation rate among their patients. Screening and assessments, if necessary, are provided free of charge for the patients.

In each centre the study was conducted by the local Screening Organization Unit. The recruitment started in October 2010 and ended in October 2012. During the enrolment period all eligible subjects receiving the initial invitation in the screening round were randomised, within GP, in 3 groups (ratio 1:1:1): A) standard invitation letter signed by the GP (including an appointment date in the case of FS); B) advance notification letter, conveying information on CRC risk, screening test, characteristics of the programme, and discussing expected benefits and potential risk of the proposed strategy, followed after 1 month by the standard personal invitation; and C) same as B but the advance notification letter included the offer of a personal encounter with the GP, to get advice about the decision to be screened and to discuss pros and cons of participation.

A standard reminder letter was mailed to all non-responders three months following the initial invitation.

The randomization scheme was computer generated within the IT systems which govern the screening programmes and identify when individuals are to be invited to participate. The process of generating and mailing the different invitation materials was fully automated in all centres, therefore blinding the researchers to the allocation of the intervention to individuals.

As the study was implemented in the context of ongoing programmes, subjects randomised in the study showed slightly different characteristics across centres: in Trento and Rome only people at their first screening invitation were enrolled, while subjects invited for the first time as well as attendees and non-attendees in previous rounds, were recruited in the other centres. GPs were not aware of the intervention assigned to their patients, but they were informed that the study was testing an intervention involving the offer of a personal encounter with the subject's GP, to discuss screening participation. In Rimini GP's did not agree to collaborate (i.e. they did not accept to face a possible increase in the counselling requests during the study period and therefore group C could not be tested), in Milan only patients listed in the rosters of collaborative GPs were randomised in the study, while in the other centres all GPs whose patients were invited for screening during the study period, were included. In Rome, due to organisational and resources constraints, mail reminders were not sent and therefore that centre was not included in the analysis of overall response rate. Also, subjects aged 70 or over, who were randomised only in this latter centre, were excluded from the analysis.

People included in a random sample of attendees and non-attendees were contacted for a short phone interview between 9 and 12 months from the initial invitation, in order to collect information about determinants of participation, as well as about subjects' demographics and utilization of GP's advice. Items derived by validated questionnaires (Rakowski et al., 1992; Trauth et al., 2003) were included to explore the impact of the intervention on individual's degree of readiness for change. Given the interest in exploring the impact of advance notification on GP's utilization, the FIT centre recruiting only subjects listed in the rosters of GPs who volunteered in the study, as well as the one where GPs were not involved, were not eligible for the survey.

Ethics

Colorectal cancer screening is included in Italy among basic levels of care. All residents in the target age range are routinely invited to perform the recommended test. Screening and related assessments, if needed, do not entail any cost for participants. The study was approved by the Regional Health Authorities, responsible for conducting the local screening programme in each participating centre. No additional evaluation from Ethics Committees was required, as the study was just assessing different strategies to convey the necessary information to orient subject's decision to respond to the standard screening invitation.

Analysis

We planned to enrol 7500 people in each centre (2500 in each arm). The planned sample size corresponds to the annual target population in Verona and Novara and about 60% of the target in Turin; in the FIT centres it corresponds to a proportion ranging between 10% and 30% of the target. Assuming the standard level for statistical significance (two-sided $\alpha = 0.05$) this study size ensures an 80% power to detect as statistical significant a 4% absolute difference in the participation rate across the trial arms in each centre, assuming the average 45% participation rate observed in the Italian programmes (Zorzi et al., 2010) as the reference baseline. Based on the same assumptions, when combining the results of all FIT centres this same size allows to detect the same difference across invitation strategies when restricting the analysis to subgroups of subjects with different screening history in the FIT arms.

The sample size of the survey of attendees and non-attendees was planned to allow for an 80% power to detect as statistical significant ($\alpha = 0.05$) a 15% absolute increase in the GP's utilization among subjects allocated to group C compared to group A and a 12% increase among group C attendees compared to non-attendees, given an expected 25% GP's consultation rate (Senore et al., 2010). Based on these assumptions, we planned to interview 375 attendees and 375 non-attendees (125 in group A and 250 in group C) both among subjects targeted for FIT and among those invited for FS screening. To take into account the expected proportion of non-traceable subjects, we have drawn stratified (by gender and screening history whenever relevant) random samples of attendees and non-attendees in each group, including a larger number of subjects, both among people invited for FIT (65 attendees and 140 non-attendees) and for FS (45 attendees and 90 non-attendees). Only the 3 FIT centres (Este, Trento and Rome) where GPs recruitment could be implemented without restrictions were considered for the survey.

The response rate at 3 months from the initial invitation was calculated by study group and screening strategy (FIT and FS) including all the centres in the analysis. Overall participation rate at 9 months from the invitation letter (cumulating both the response to the initial invitation and mail reminder) was assessed over 4 FIT (as no reminder was mailed in Rome) and 3 FS centres. Relative risks (RR) and their 95% confidence intervals (CI) were used as a