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Population-based screening for colorectal cancer using an immunochemical faecal occult blood test: A comparison of two invitation strategies

Sofie Van Roosbroeck *, Sarah Hoeck, Guido Van Hal

Research Group Medical Sociology and Health Policy, Department of Epidemiology and Social Medicine, University of Antwerp, Campus Drie Eiken, Universiteitsplein 1, BE-2610 Antwerp, Belgium

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ABSTRACT

Background: To date, there is no screening programme for colorectal cancer (CRC) in Flanders, Belgium. However, The European Code Against Cancer (2003) recommends a population-based approach for CRC screening. This study aimed to obtain information about potential participation rates for a population-based screening programme for CRC in Flanders, and to compare two invitation strategies. *Methods*: In 2009, a trial programme for CRC screening was set up in three Flemish areas for all average-risk people aged 50–74 years, using an immunochemical faecal occult blood test (iFOBT) with a cut-off value set at 75 ng/ml of haemoglobin. The faecal sampling set was sent at random by post (mail group) or provided by the general practitioner (GP group). *Results*: In total, 19,542 people were invited to participate. Of these, 8229 provided a faecal sample, resulting in an overall participation rate of 42.1%. Participation by mail and through the GP was 52.3% (95% CI, 51.3–53.2) and 27.7% (95% CI, 26.7–28.6), respectively. The difference of 24.6% was statistically significant (95% CI, 23.3–25.9, $p < 0.001$). Before the reminder letter was sent and the other invitation strategy was offered, the overall participation rate was 26.5% ($n = 5176$); 36.4% (95% CI, 35.5–37.4) for the mail group and 16.6% (95% CI, 15.8–17.3) for the GP group. The odds of participating in CRC screening was almost three times higher for people invited by mail as opposed to people invited through a GP (OR = 2.96, 95% CI, 2.78–3.14, $p < 0.001$). Women were more likely to participate in CRC screening than men (OR = 1.22, 95% CI, 1.15–1.30, $p < 0.001$). In addition, we found that inhabitants from residential (OR = 1.98, 95% CI, 1.85–2.11) and rural (OR = 2.90, 95% CI, 2.66–3.16) areas were more likely to participate than those in urban areas. Of the 8229 people who submitted a faecal sample, 435 (5.3%) had a positive iFOBT, and of those, CRC was diagnosed in 18 (5.7%) individuals. Compliance for follow-up colonoscopy was 72.9%, and did not differ between the mail (72.4%, 95% CI, 67.5–77.3) and GP groups (74.3, 95% CI, 66.2–82.5). *Conclusion*: Inviting people for CRC screening by means of a direct-mail invitation, and including a faecal sampling set (iFOBT), results in much higher participation rates than inviting people through the GP.

1. Introduction

Colorectal cancer (CRC) is the second most common form of cancer among women (13.4% of new cancer cases), after breast cancer (35.3%). Among men it is the third most common cancer (13.8%), after prostate (27.0%) and lung cancer (16.6%) [1]. In Flanders, 1717 deaths and 5207 cases of the disease were reported in 2008, which is highly comparable with the figures in Western and Northern European countries [1,2].

Due to its high incidence and mortality, the slow progression from adenoma to carcinoma, the high patient survival rate in case of early detection and removal of the cancer-containing polyp by colonoscopy or surgery, CRC seems to be an ideal candidate for screening.

To date, there is no screening programme for colorectal cancer in Flanders. However, screening programmes for CRC are being developed and implemented throughout the Western World [3–8]. The European Code Against Cancer recommends a population-based approach for CRC screening [9]. In February 2007, the Flemish Government called for a trial programme on CRC screening to explore whether a programme of early detection of CRC in people aged 50–74 years would be feasible in Flanders and how useful it would be. In screening programmes in general, the participation rate, together with a high performance test, is of primary importance since it determines to a large extent the efficiency of the programme [9].

* Corresponding author at: Centre for Cancer Prevention, Research Group Medical Sociology and Health Policy, Department of Epidemiology and Social Medicine, University of Antwerp, Campus Drie Eiken, Universiteitsplein 1, BE-2610 Antwerp, Belgium. Tel.: +32 3 265 28 78; fax: +32 3 265 28 75.
E-mail addresses: sofie.vanroosbroeck@ua.ac.be (S. Van Roosbroeck), sarah.hoeck@ua.ac.be (S. Hoeck), guido.vanhal@ua.ac.be (G. Van Hal).

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The aim of the study was to obtain information about potential participation rates for a population-based screening programme for CRC in Flanders and to compare two invitation strategies.

2. Methods

2.1. Study population

Between March and November 2009, all inhabitants aged 50–74 years (n = 19,542) from three selected areas in Flanders were invited by the centre for cancer prevention from the university of Antwerp to take part in the trial programme. Flanders is the northern, Dutch-speaking part of Belgium. The study focussed on people with an average risk for CRC, aged 50–74 years, living in one of these three areas: Borgerhout (n = 9732), selected as an urban area; Schilde (n = 6660), selected as a residential area, and Vosselaar (n = 3150), selected as a rural area.

Exclusion criteria were: having symptoms such as blood in the faeces, persistent bowel obstruction or diarrhoea; having had a colonoscopy in the past ten years; currently suffering from or having had CRC, Colitis Ulcerosa or Crohn's disease. In these cases, people were advised to contact their general practitioner (GP) instead of participating in the trial programme.

2.2. Invitation procedure

Two invitation strategies were used in the trial programme. Either a direct invitation letter with a faecal sampling set was sent by mail (mail group) or an invitation letter without a faecal sampling set was sent, with instructions to visit a general practitioner (GP) (GP group). The latter group was then later provided with the faecal sampling set by the GP. The faecal sampling set was free of charge, the cost of consulting the GP was charged to the participant (the personal contribution varies between 4 and 6 euros).

To put it differently, the main difference between the two invitations was that the invitation for the mail group also included a faecal sampling set, whereas the invitation for the GP group did not. People in the GP group had to consult the GP at the GP's practice to receive the faecal sampling set and possibly more information. All invitations included a letter, an information leaflet and a reply form.

From the municipal database, which keeps records for every inhabitant (including a unique personal identifier, address and year of birth), random samples were taken by street name to ensure relative blinding to the invitation strategy amongst people within one household and amongst neighbours, and allocated to the mail or GP group. Next, people were systematically invited by the centre for cancer prevention to participate in the screening. For logistic reasons invitations were sent out in four groups; one in March, one in May, one in September and one in November.

The information leaflet covered a wide range of topics, including the nature and purpose of the study, CRC incidence and mortality, the target population, the benefits of screening, the faecal sampling procedure, false positive and negative results, follow-up colonoscopy and organisational and logistic information. The invitation letter and the information leaflet were edited by a Dutch linguistic expert in order to make them easy readable and accessible to a broad population. Several experts such as GPs, gastroenterologists and academics collaborating on the screening trial monitored the content validity of the invitation letter and information leaflet.

Faecal sampling sets were distributed to all GPs in the three areas and in the neighbouring areas. GPs were also invited to attend an information session and provided with background information, a flow chart of the screening programme explaining the GP's role, the Flemish Guidelines for GPs regarding CRC screening, a concise slide show that the GPs could use to inform their patients about screening criteria, the use of the faecal sampling set and follow-up colonoscopy.

During the trial programme a free telephone helpline, and website were established to provide advice, support and further information for the people receiving the invitations as well as for the GPs [10]. Information leaflets in twelve different languages were accessible through the website [10].

All letters included the name of the leading screening programme manager, who is one of the authors (Guido Van Hal), and a statement that the programme was supported by the local District Council, the City Council of Antwerp, the GPs and gastroenterologists in the region.

A reminder letter with cross-over invitation design, as required by the Government, was sent after six weeks. Accordingly, people who initially received an invitation letter by mail and did not respond within six weeks were sent an invitation letter instructing them to consult a GP, who in turn could provide the faecal sampling set; and people who initially received an invitation to consult a GP and did not respond within six weeks were sent a direct invitation with a faecal sampling set by mail.

2.3. Procedure for participation

Participants were asked to obtain one faecal sample with the sampling set. Reply forms and faecal samples had to be returned to the laboratory by means of a pre-paid return envelope. Reply forms had previously been marked discreetly with a code in a lower corner indicating the invitation strategy that was used. Next, the faecal sample was analysed for human haemoglobin quantification using an immunochemical faecal occult blood test (iFOBT). Non-participants were asked to complete the reply form indicating a reason for non-participation, responding to closed questions based on the exclusion criteria, and return it using a pre-paid return envelope.

2.4. iFOBT and follow-up colonoscopy

IFOBT samples (OC-Auto Sampling bottle 3 (V-P226), Eiken Chemical Co., Ltd., Tokyo, Japan) were used for measurement of occult blood in the faeces and were processed using an automated reading technique (OC-sensor Diana, Eiken Chemical Co., Ltd., Tokyo, Japan) allowing quantitative measurement of the human haemoglobin content (in ng/ml) [11]. The cut-off value for a positive test was set at 75 ng/ml of haemoglobin. The use of an automated iFOBT was recommended by several experts because of its efficient use in mass-screening and its good sensitivity and specificity for detection of malignant neoplasias [12–17]. Further, the iFOBT was reported to have a lower level of overall burden compared to the guaiac FOBT (gFOBT), e.g., no dietary restriction and a single sample requirement, which translates into higher participation rates [18,19].

Both the participant and the participant's GP received the results within ten working days by post. Note that this procedure was applied for all participants, regardless of which invitation strategy was used. All participants were asked to provide the name of their GP on the reply form. Follow-up examination by means of colonoscopy was recommended when the iFOBT was positive, i.e., an iFOBT-value $\geq$ 75 ng/ml. In case of a positive iFOBT, the GP was informed two days earlier than the participant to ensure that GPs were informed in advance. Accordingly, the GP referred the participant for follow-up colonoscopy.

The faecal sampling set and the analysis in the laboratory were free of charge, the costs for a follow-up colonoscopy were charged to the participant.

All colonoscopies were performed in a hospital by experienced gastroenterologists. Participants were free to choose the hospital. If