

# Impact of a Doctor's Invitation on Participation in Colorectal Cancer Screening: A Cluster Randomized Trial



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## ABSTRACT

**BACKGROUND:** There is a need to improve participation in colorectal cancer screening. Our objective was to assess the impact of a signature from the patient's general practitioner on a letter inviting patients to participate in a colorectal cancer screening.

**METHOD:** We conducted a cluster randomized controlled trial with 57 general practitioners established in Paris for more than 5 years, randomized to intervention or usual-care arms. There were 3422 patients included, ages 50-74 years, from general practitioner patient files, and eligible for an invitation letter or a reminder letter to participate in the national population-based screening program. In the intervention arm, patients received a standard letter signed by their general practitioner inviting them to visit the general practitioner's office for a fecal occult blood test if they were eligible. Control patients received the standard invitation letter or the standard reminder. All letters were sent by the district screening organization. The main outcome was the proportion of patients who took the fecal occult blood test within 6 months after the invitation.

**RESULTS:** Among patients eligible for the study, 508 (14.8%) took a fecal occult blood test after being invited; 285 (15%; 95% confidence interval [CI], 13.5-16.7) in the intervention group and 223 (14.6%; 95% CI, 12.9-16.5) in the control group, with no statistical difference between the 2 groups (odds ratio 1.04; 95% CI, 0.83-1.31;  $P = .731$ ).

**CONCLUSIONS:** The addition of a general practitioner's signature to a standard letter inviting patients to take a fecal occult blood test had no impact on the frequency of patients taking the fecal occult blood test in the Paris program of colorectal cancer screening.

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**KEYWORDS:** Colonic neoplasm; General practitioner; Mass screening; Occult blood; Patient participation

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Population-based programs to screen for colorectal cancer with the fecal occult blood test can reduce the risk of colorectal cancer mortality by about 20%.<sup>1,2</sup> Fecal occult blood test screening may detect cancer in the asymptomatic population at average risk at an earlier stage than in those with digestive symptoms.<sup>1</sup> Patients with risk factors for colorectal cancer (chronic inflammatory bowel disease, personal history of colorectal cancer or adenoma, first-degree family history of colorectal cancer before age 65 years or 2 first-degree family members with history of colorectal cancer regardless of age, and genetic predisposition for colorectal cancer) are excluded from fecal occult blood test screening and need to be screened by colonoscopy.<sup>3</sup>

France has had a national population-based program to screen for colorectal cancer since 2008. Screening is organized at the district level. Targeted patients ages 50 to 74 years are identified from health insurance files.<sup>3</sup> Every 2 years, patients receive a standardized invitation letter from the district screening office encouraging them to consult their general practitioner, who will deliver a screening test if they are eligible. The guaiac-based fecal occult blood test involves collecting 2 stool samples to be deposited on a card. The procedure is repeated for 3 consecutive stools. The 3 cards are sent by free mail to a central laboratory. If the test result is positive, a colonoscopy is recommended. Patients who do not respond to the invitation receive a reminder letter 3 months later. If they still do not respond, they receive the test at home, 6 months after the first invitation.

General practitioners play a key role in the French colorectal cancer-screening program: they inform patients about the test and encourage them to take it. They deliver the fecal occult blood test to patients or exclude them from the screening program on the basis of their medical history, the presence of warning signs, or a recent colonoscopy. They are responsible for the follow-up, especially if the test result is positive.

The benefits of a colorectal cancer screening program was shown during a randomized controlled trial in which compliance with the fecal occult blood test was > 60%.<sup>1</sup> In France, participation rates are low, about 32% for 2012-2013. Moreover, in the Paris district, the overall participation was only about 15%.<sup>4</sup>

Interventions to increase participation are needed. A wide variety of interventions to increase participation have been tested. Patient interventions have focused on invitations (reminders) and education (decision aids, one-to-one interaction, and group education).<sup>5-7</sup> Provider interventions have focused on reminder systems<sup>8</sup> and

bonuses.<sup>5,6</sup> General practitioners prompting their patients led a significant improvement in health maintenance.<sup>9-11</sup> For example, frequency of taking the fecal occult blood test was improved when the test was proposed by general practitioners (85.2%-94% vs 26%-33.7% when sent by mail).<sup>12</sup> The absence of recommendations from general practitioners has been cited by the public as one of the main reasons for not undergoing screening.<sup>13</sup>

A potential strategy to improve participation could be to customize the standard invitation letter for colorectal cancer screening with the signature of the patient's general practitioner. We aimed to assess the impact of a general practitioner signature on a letter inviting patients to take a fecal occult blood test on their participation in the colorectal cancer screening.

### CLINICAL SIGNIFICANCE

- Fecal occult blood testing has been shown to reduce mortality from colorectal cancer when compliance was > 60%.
- The addition of a general practitioner signature to a standard letter inviting patients to participate in colorectal cancer screening had no impact on the frequency of patients taking fecal occult blood test.

## METHODS

### Study Design

The study was an open cluster randomized trial. Clusters (general practitioners) were randomly allocated in a 1:1 ratio to the intervention or control arm. The allocation units were the general practitioners because the intervention probably had an effect at both the patient and practitioner levels. Indeed, the aim of the intervention was to induce patients to ask for the test and to implicate the general practitioner in the screening. Furthermore, because the trial was an open trial, individual randomization could have led to a contamination between arms.

### Sample Selection

General practitioners established in Paris for more than 5 years were eligible. General practitioners with a specialist interest or who were willing to end their activity before the end of 2011 were excluded.

Inclusion criteria for patients were residence in Paris, to be assigned to the eligible general practitioners, age between 50 and 74 years, and eligible for an invitation letter or a reminder letter about the national population-based colorectal cancer-screening program. Exclusion criteria were having had a fecal occult blood test taken in the previous 2 years or having undergone colonoscopy in the previous 5 years.

### Intervention and Control Arms

In September 2010, patients received a standard invitation or reminder letter signed by their general practitioner inviting them for a consultation for a guaiac-based fecal

occult blood test if they were eligible. The letter contained 3 mentions of the general practitioner's name in capital letters (first line of the letter, name in the text, and signature). In the control arm, patients received the standard invitation letter or the standard reminder from the district colorectal cancer screening office.

## Outcomes

All outcomes were recorded at the patient level. The main outcome was the proportion of patients who took the guaiac-based fecal occult blood test within 6 months after the invitation letter or reminder letter was sent. Secondary outcomes were the proportion of patients who responded to the invitation by taking the test or declining the invitation within 6 months after the invitation was sent, the time between receipt of the letter and taking the test, the proportion of noninterpretable tests, and the proportion of patients undergoing colonoscopy after a positive test result.

## Ethic Statement

The study protocol was approved by the Institutional Review Board of Paris North Hospitals and was registered with [ClinicalTrials.gov](#) (Identifier NCT01279278).

## Sample Size

The study was designed to detect an increase of 20% in the proportion of patients who took the fecal occult blood test with a power of 80% and a risk of type I error of 5%. Assuming that each general practitioner would include a mean of 50 patients for this phase and an intraclass correlation coefficient of 0.25, the planned sample size was 822 patients in each arm.

## Randomization

General practitioners were allocated randomly and equally to be in the intervention or control arm. Because patient load was expected to have significant impact on the intervention, the allocation was stratified by the estimated median patient load for general practitioners ( $n = 216$ ). A randomization list was generated by use of SAS 9.2 (SAS Institute Inc., Cary, NC). The random allocation sequence was generated by a statistician who was not involved in the project and who also assigned general practitioners to interventions. General practitioners were asked by letter to participate in the study. For each randomized general practitioner, all patients who fulfilled the inclusion criteria according to the district colorectal cancer screening office database were included in the trial.

## Statistical Methods

Characteristics of general practitioners and patients at baseline are described with usual descriptive statistics. All outcomes were analyzed by the intention-to-treat principle. We used a logistic mixed model with random effects at the

general practitioner level to compare the proportion of patients who took the test in each arm. A second adjusted analysis was performed. Secondary outcomes estimated by proportions were planned to be analyzed by the logistic mixed model, but for the proportion of noninterpretable tests, the variance of the random effect was null, so a logistic model was used. For the proportion of patients undergoing colonoscopy after a positive fecal occult blood test result, the number of positive test results was too small for a logistic mixed model. The time between receipt of the letter and taking the test was compared by a Wilcoxon rank-sum test adjusted for cluster effect.<sup>14</sup> All analyses involved use of R.2.13<sup>15</sup> and SAS 9.2.

## RESULTS

### Flow of Participants in the Trial

From April to May 2010, 57 practitioners agreed to participate among the 210 general practitioners assessed for eligibility: 29 were allocated randomly to the intervention group and 28 to the control group (**Figure**). In the intervention group, general practitioners included a median of 59 patients (interquartile range [IQR] 43-73), for a total of 1895 patients. In the control group, general practitioners included a median of 48 patients (IQR 36-67), for a total of 1527 patients. A total of 14 patients (0.4%) received an invitation or a reminder by mistake: 7 (0.4%) in the intervention group and 7 (0.5%) in the control group (see **Figure**). They had responded to the previous invitation between the extraction of the address for the study and the delivery of the letter. No patient was lost to follow-up.

### Results

The characteristics of general practitioners and patients are in **Table 1**. Among the 4322 eligible patients, 508 (14.8%) took a fecal occult blood test after the invitation: 285 (15%; 95% CI, 13.5-16.7) in the intervention group and 223 (14.6%; 95% CI, 12.9-16.5) in the control group. There was no difference between the 2 groups in taking the test (odds ratio 1.04; 95% CI, 0.83-1.31;  $P = .731$ ). The adjusted analysis gave similar results (data not shown). The intraclass correlation coefficient for the primary outcome was 0.15 (0-0.40) for the intervention arm and 0.15 (0-0.38) for the control arm.

As well, the 2 groups did not differ in response to the invitation (fecal occult blood test or negative response;  $P = .753$ ), noninterpretable tests ( $P = .195$ ), or undergoing colonoscopy after a positive test result ( $P = .338$ ) (**Table 2**). The median times to take a test for the intervention and control groups were 89 days (IQR range 40-154) and 88 days (IQR range 41-153), respectively ( $P = .587$ ).

**DISCUSSION**

The customization of a letter with the signature from the patient’s general practitioner had no significant impact on patient participation in colorectal cancer screening at 6 months after patients received the letter. Our result needs cautious examination.

**Study Strengths and Limitations**

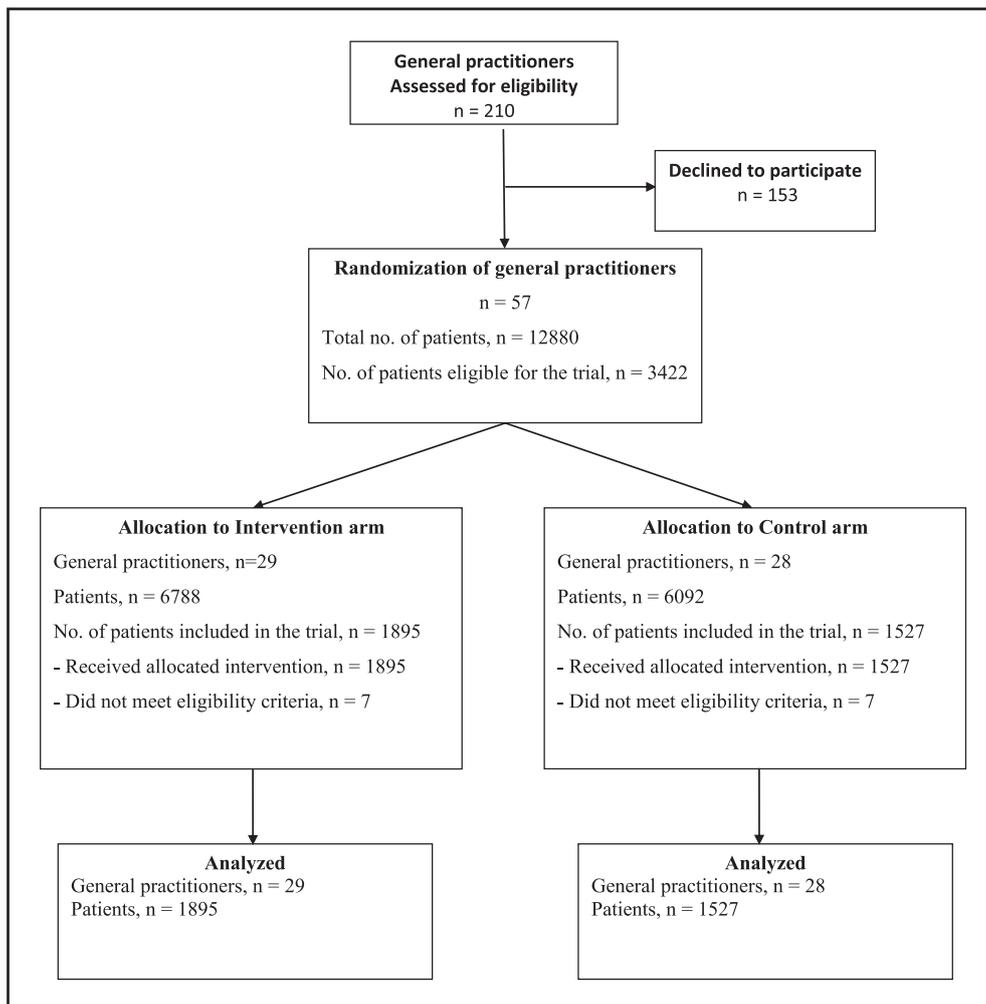
The study contained some limitations. The general practitioner’s signature may have had little visibility and might not have been noticed by the patient. First, in France, it is unusual for general practitioners to send letters to patients. Then, by its presentation, the standard invitation letter may also have looked like an advertising letter because, as the standard invitation letter, the intervention letter contained all the institutional logos (including those for the screening program funding bodies and health insurance agencies). Finally, patients who received standard invitation letters during previous screening rounds might have recognized the letter without reading it carefully and ignored the slight

difference with the general practitioner’s signature. Assessing whether the general practitioner’s signature was identified by patients would have been of interest, but our study design did not allow us to do so. Probably a more personal letter, without logos, and ideally on the general practitioner’s letterhead, might have been more effective, but would have necessitated institutional partners’ agreement and would have delayed the intervention.

Second, the study may exhibit selection bias at the general practitioner level. During the first campaign of the screening program, patient participation by general practitioners was higher than the average for Paris: 24.5% vs 14.2%. Therefore, general practitioners in our sample could have had less room for improvement.

Third, the follow-up lasted only 6 months. A longer follow-up might have shown an increase in taking the fecal occult blood test.

However, our study had a powerful design. To avoid contamination between patients with the same general practitioner, we randomized general practitioners. The calculation of sample size took into account the



**Figure** Flow of participants in the trial.

**Table 1** General Characteristics of General Practitioners and Patients Included in the Study

	Intervention	
	Arm	Control Arm
General practitioners	n = 29	n = 28
Sex female	16 (55.2)	15 (53.6)
Age, y	54 ± 8	55 ± 6
Years in practice	26 [20-30]	28 [22-31]
Group practice	19 (65.5)	16 (57.1)
Conventional sector		
1	22 (75.9)	18 (64.3)
2	7 (24.1)	10 (35.7)
Scheduled activity		
< 25%	3 (10.3)	1 (3.6)
25%-50%	4 (13.8)	3 (10.7)
50%-75%	1 (3.4)	3 (10.7)
> 75%	21 (72.4)	21 (75)
Mean no. of consultations per wk	89 ± 20	90 ± 20
Mean no. of consultation hours per wk	40 ± 9	42 ± 9
Trained for colorectal cancer screening	23 (79.3)	24 (85.7)
Mentor	27 (93.1)	18 (64.3)
Participation in a peer group	15 (51.7)	11 (39.3)
Interest for colorectal cancer screening		
Rather useful	10 (34.5)	11 (39.3)
Very useful	19 (65.5)	17 (60.7)
Screening after hemoccult testing		
Cancer	2 (6.9)	5 (17.9)
Polyps	15 (51.7)	10 (35.7)
Does not know	2 (6.9)	0 (0)
Nothing	11 (37.9)	18 (64.3)
Offer screening if patient does not ask		
Never	2 (6.9)	0 (0)
Rarely	11 (37.9)	9 (32.1)
Often	14 (48.3)	14 (50)
Always	2 (6.9)	5 (17.9)
Dedicate consultation to explain the test	10 (35.7)	6 (21.4)
Additional time to explain the screening, min	8 (5-10)	8 (5-10)
Smear test at the office	19 (65.5)	20 (71.4)
Patients	n = 1895	n = 1527
Age, y	61 ± 7	61 ± 7
Sex female	1102 (58.2)	837 (54.8)
Stage of reminder		
Invitation	1530 (80.7)	1156 (75.7)
First reminder	365 (19.3)	371 (24.3)

Data are number (%), median (interquartile range), or mean ± SD.

cluster-randomized design. At best, the impact of our intervention would be minimal.

### Comparison with Other Studies

Qualitative studies have shown the importance of participants receiving an invitation for colorectal cancer screening

**Table 2** Analysis of Primary and Secondary Outcomes

	Intervention, n/N (%)	Control, n/N (%)	P
FOBT	285/1895 (15.0)	223/1527 (14.6)	.731
FOBT or negative response	379/1895 (20.0)	298/1527 (19.5)	.753
FOBT results			
Negative	270/285 (94.7)	214/223 (96.0)	
Positive	6/285 (2.1)	6/223 (2.7)	
Not interpretable	9/285 (3.2)	3/223 (1.3)	.195
Colonoscopy	1/6 (16.7)	4/6 (66.7)	.338*

FOBT = fecal occult blood test.

\*Fisher's exact test.

from the family physician.<sup>16</sup> As well, a longitudinal study showed that maintenance of participation was better with general practitioner involvement in the screening process.<sup>17</sup> However, controlled randomized trials assessing endorsement by general practitioners on participation in colorectal cancer screening found mixed results. Two US trials found negative results.<sup>18,19</sup> One intervention tested a personalized letter from the patient's physician with an educational brochure, a fecal occult blood test kit, and a stamped return envelope. After 2 and 5 years of follow-up, the study found no increase in colorectal cancer screening as compared with usual care.<sup>18</sup> Another intervention included a physician recommendation letter with a personalized salutation, the name of the patient's personal physician, comments on the patient's age, family cancer history, and history of colorectal testing. At 1 year, colorectal cancer-screening completion did not differ with the intervention vs standard mail.<sup>19</sup> In contrast, other trials showed an improvement in participation. In South Australia, a letter signed by the patient's most recently contacted general practitioner or an invitation endorsed impersonally by the patient's medical practice improved participation at 12 weeks, as compared with a standard invitation from the central screening service (38% or 40% vs 32%).<sup>20</sup> Another trial in the south of England found that a general practitioner's endorsement letter or an information leaflet with the fecal occult blood test kit increased the frequency of taking the fecal occult blood test and that the electronic insertion of the general practitioner's signature on the letter was associated with increased participation.<sup>21</sup>

However, there is no explanation to clarify these mixed results. Our study is the first to exclusively assess the impact of a general practitioner's signature on a letter inviting a patient to take a fecal occult blood test. The positive results of other trials may have been an outcome of interactions between various interventions.

It is not clear that these findings can be translated from one country to another. Health care systems and screening methods differ.<sup>22</sup> The participation rate in the US is higher than in France: 66% vs 32% (15% in Paris).<sup>1,4,23</sup> The US lacks recommendations for a preferred screening strategy:

fecal occult blood test annually, sigmoidoscopy every 5 years, annual fecal occult blood test and sigmoidoscopy every 5 years, colonoscopy every 10 years, or barium enema every 5 years.<sup>18</sup> The tests used can be guaiac-based fecal occult blood test, immunochemical-based fecal test, or DNA-based fecal test. It seems that the participation rate is higher with the immunoassay from the guaiac test used in the study, probably because it needs just one stool, vs 3 stools for guaiac tests.<sup>23</sup> Fecal DNA testing is emerging, but further studies are needed to assess the impact on adherence.<sup>23</sup>

Some other reasons may explain the underutilization of the fecal occult blood test. A Dutch study showed that a common reason for patients declining screening was probably a lack of priority or awareness about colorectal cancer screening, which may interfere with being able to understand the invitation letter.<sup>24</sup> Other reasons for not taking the fecal occult blood test were the inconvenience, lack of interest, lack of advice and referral from a general practitioner, absence of symptoms of bowel disease, and embarrassment or difficulties with the test.<sup>19,24-26</sup> Reported obstacles for general practitioner involvement in colorectal cancer screening programs were insufficient training, doubts about the relevance of screening, insufficient time during the consultation to explain the test, and practical and administrative obstacles. Some general practitioners experienced difficulty persuading patients who had no signs of colorectal disease.<sup>27</sup> The consultation when general practitioners in France deliver the fecal occult blood test often is oriented toward the biomedical statement and technical explanations; patient-centered communication could improve the delivery of the fecal occult blood test.<sup>28</sup>

## CONCLUSIONS

In Paris, a signature from the patient's general practitioner on a standard letter inviting patients to take a fecal occult blood test had no impact on patient participation in colorectal cancer screening at 6 months.

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**Authorship:** PR and JD had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.