

Original article



Tailored telephone counselling to increase participation of underusers in a population-based colorectal cancer-screening programme with faecal occult blood test: A randomized controlled trial

Conseil téléphonique personnalisé pour augmenter la participation à un programme de dépistage organisé du cancer colorectal par recherche de sang occulte dans les selles : un essai contrôlé randomisé

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Abstract

Background. – Despite the involvement of general practitioners, the mailing of several recall letters and of the faecal occult blood test (FOBT) kit, the uptake remains insufficient in the French colorectal cancer-screening programme. Some studies have demonstrated a greater efficacy of tailored telephone counselling over usual care, untailored invitation mailing and FOBT kit mailing. We evaluated the feasibility and the effectiveness of telephone counselling on participation in the population-based FOBT colorectal cancer-screening programme implemented in Alsace (France).

Methods. – Underusers were randomized into a control group with untailored invitation and FOBT kit mailing ($n = 19,756$) and two intervention groups for either a computer-assisted telephone interview ($n = 9367$), system for tailored promotion of colorectal cancer screening, or a telephone-based motivational interview ($n = 9374$).

Results. – Only 5691 (19.9%) people were actually counseled, so that there was no difference in participation between the intervention groups taken together (13.9%, 95% confidence interval [CI] [13.5–14.4]) and the control group (13.9%, 95% CI [13.4–14.4]) ($P = 1.0$) in intent-to-treat analysis. However, in per-protocol analysis, participation was significantly higher in the two intervention groups than in the control group (12.9%, 95% CI [12.6–13.2]) ($P < 0.01$), with no difference between computer-assisted telephone interview (24.6%, 95% CI [22.7–26.4]) and motivational interview (23.6%, 95% CI [21.8–25.4]) ($P = 0.44$).

Conclusion. – There was no difference of effectiveness between tailored telephone counselling and untailored invitation and FOBT kit mailing on participation of underusers in an organized population-based colorectal cancer screening programme. A greater efficacy of telephone counselling, around twice that of invitation and FOBT kit mailing, was observed only in people who could actually be counseled, without difference between computer-assisted telephone interview and motivational interview. However, technical failures hampered telephone counselling, so that there was no difference in intent-to-treat analysis. The rate of technical success of telephone interviews should be evaluated, and enhanced if insufficient, before implementation of telephone counselling in population-based cancer screening programmes.

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Keywords: Colorectal neoplasms/prevention & control; Early detection of cancer/methods; Occult blood; Telephone; Patient education as topic; Counselling; Motivational interviewing

Abbreviations: CATI, computer-assisted telephone interview; CI, confidence interval; CRC, colorectal cancer; EDI, European Deprivation Index; gFOBT, guaiac-based faecal occult blood test; GP, general practitioner; INSEE, French National Institute for Statistics and Economic Studies; ITT, intent-to-treat; MI, motivational interview; OR, odds ratio; PAMP, Precaution Adoption Process Model; RCT, randomized controlled trial; SD, standard deviation.

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Résumé

Position du problème. – La participation dans le programme français de dépistage organisé du cancer colorectal reste insuffisante malgré l'implication des médecins généralistes, et l'envoi postal de plusieurs relances et du test de recherche de sang occulte dans les selles. Plusieurs études ont montré que le conseil téléphonique personnalisé était plus efficace que les soins habituels, l'invitation par courrier standardisé et l'envoi postal du test de dépistage. Le but de cette étude était d'évaluer la faisabilité et l'efficacité du conseil téléphonique sur la participation au programme de dépistage du cancer colorectal organisé en Alsace (France).

Méthodes. – Un échantillon de personnes non dépistées a été randomisé en un groupe contrôle invité par courrier de relance standardisé accompagné du test de recherche de sang occulte dans les selles ($n = 19\,756$) et en deux groupes intervention téléphonique, l'un bénéficiant d'un conseil simple par entretien téléphonique assisté par ordinateur ($n = 9367$), l'autre d'un entretien motivationnel ($n = 9374$).

Résultats. – Seules 5691 (19,9 %) personnes ont effectivement bénéficié d'un conseil téléphonique, si bien qu'en analyse en intention de traiter aucune différence de participation n'a été observée entre les groupes intervention téléphonique réunis (13,9 %, intervalle de confiance [IC] 95 % [13,5–14,4]) et le groupe témoin (13,9 %, IC 95 % [13,4–14,4]) ($p = 1,0$). Cependant, en analyse per-protocole, la participation était significativement plus importante dans les deux groupes intervention que dans le groupe contrôle (12,9 %, IC 95 % [12,6–13,2]) ($p < 0,01$), sans différence significative entre conseil simple (24,6 %, IC 95 % [22,7–26,4]) et entretien motivationnel (23,6 %, IC 95 % [21,8–25,4]) ($p = 0,44$).

Conclusion. – Il n'y avait pas de différence entre conseil téléphonique personnalisé et courrier standardisé accompagné du test de dépistage sur la participation au dépistage du cancer colorectal. Une plus grande efficacité du conseil téléphonique, le double de celle de l'envoi postal, n'était observée que chez les personnes effectivement conseillées par téléphone, sans différence entre conseil simple et entretien motivationnel. Les personnes étant difficiles à joindre, la participation n'augmentait pas significativement en intention de traiter. Le taux de succès technique des entretiens téléphoniques devrait être évalué, et amélioré si insuffisant, avant d'instaurer le conseil téléphonique dans un programme de dépistage organisé des cancers.

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Mots clés : Cancer colorectal/prévention ; Détection précoce du cancer/méthodes ; Dépistage ; Sang occulte ; Téléphone ; Éducation du patient ; Entretien motivationnel

1. Introduction

Colorectal cancer (CRC) is the second leading cause of cancer death in Europe and the United States [1,2]. Four randomized controlled trials (RCTs) have demonstrated the efficacy of screening with guaiac-based faecal occult blood test (gFOBT) on CRC mortality [3]. France thus launched an organized gFOBT-based CRC screening programme for average risk people aged 50–74 years in a few pilot areas in 2003 that was extended to the whole country in 2009.

Organized screening programmes depend on high participation rates to be effective and efficient. Despite the involvement of general practitioners (GPs), the mailing of several recall letters and of the gFOBT kit, the uptake remains insufficient in France, estimated at 29.8% in 2013–2014 [4]. There is strong evidence that one-on-one education, either in person or by telephone, is effective in increasing screening for breast and cervical cancers, and sufficient evidence that it is effective in increasing CRC screening with FOBT [5]. Several studies demonstrated that a tailored intervention is significantly more efficacious than an untailored intervention and that a recommendation made by a health professional is the most powerful extrinsic factor to induce adhesion to screening [5,6]. Tailoring was defined by Kreuter and Skinner as follows “Any combination of strategies and information intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and derived from an individual assessment” [7]. Most studies on CRC screening have found a modestly greater efficacy of tailored telephone counselling over usual care [8–10],

untailored invitation mailing [11,12] and FOBT kit mailing [13–18]. However, all these studies had small sample sizes and/or were performed in defined settings, all but one in the USA. Whether their findings are generalizable is questionable. Moreover, telephone-based interventions to promote CRC screening vary from simple interventions as automated reminder calls [19,20] to complex interventions such as telephone-based navigation [21]. Computer-assisted telephone interview (CATI) and motivational interview (MI) are tailored interventions of intermediate intensity [22,23]. A single study compared their efficacy on participation in CRC screening [9].

We hypothesized that tailored telephone counselling calls would increase gFOBT screening adherence of underusers in an organized CRC screening programme. We conducted a RCT to evaluate the feasibility and the effectiveness of telephone counselling to increase the uptake in the population-based gFOBT CRC screening programme implemented in Alsace as part of the French national programme, and to compare the effectiveness of two telephone-based interventions using either a CATI system or a MI.

2. Methods

We compared gFOBT use subsequent to one of three interventions targeting non-responders who had received two mailed invitations for a CRC screening: (1) usual care, i.e. direct mailing of the gFOBT kit along with another untailored recall letter (second recall); (2) direct mailing of the gFOBT kit based on the result of a telephone counselling call using a CATI

system; and (3) direct mailing of the gFOBT kit based on the result of a telephone counselling call using a MI.

2.1. Study setting and participants

French guidelines recommend an organized CRC screening with gFOBT for average risk individuals aged 50–74 years and an opportunistic screening with colonoscopy for high risk individuals. This RCT was conducted in Alsace, a region in Eastern France with 1.8 million inhabitants composed of two administrative areas, Haut-Rhin and Bas-Rhin. An organized CRC screening programme was implemented in both areas, in September 2003 and December 2007 respectively. The design has been previously described [24]. Briefly, all residents aged 50–74 years were invited by mail every other year to participate. A first letter invited them to visit their GP for CRC screening. Three recall letters were mailed to all those who had not complied. The second recall letter was mailed along with the gFOBT kit itself (Hemoccult II, Beckman Coulter, Brea, CA, USA). People with serious illness, recent CRC screening or high CRC risk (symptoms, personal or family history of colorectal neoplasia, inflammatory bowel disease) were excluded from gFOBT screening. Completed gFOBTs were sent to a central laboratory where they were processed without rehydration.

Potentially eligible participants in this RCT were all residents aged 50–74 who met the following criteria: (1) no previous exclusion from gFOBT screening; (2) non-compliance after two mailed invitations (a first letter and a first recall letter); (3) a second recall letter scheduled for February–November 2011 as part of the second (Bas-Rhin) and fourth (Haut-Rhin) rounds of the screening programme. A random sample from the database of potentially eligible people was randomly divided into two groups: a control group and an intervention group. As we knew that around a third of the telephone numbers could not be retrieved from telephone directories, we oversized the initial intervention sample so that we could get around 20,000 persons in the control group and 10,000 persons whose phone number could be retrieved in each of the two intervention groups. People assigned to the control group continued to receive usual care, i.e. direct mailing of a gFOBT kit along with a second recall letter. The telephone number of people assigned to the intervention group was searched from telephone directories using commercial software. People whose phone number could be retrieved were randomly divided into two equal-sized groups for a first telephone counselling call, using the CATI system in one group and MI in the other, the result of which conditioned the direct mailing of a gFOBT kit. If the telephone interview was completed, the telephone interview was considered successful and the person was sent a gFOBT kit if interested. If the telephone contact failed for technical reasons (a telephone number was not retrieved; the person was not reached by telephone; the person declined to participate in the telephone interview), the usual care scheme was applied, i.e. the person was sent a gFOBT kit four months after randomization. This study was considered a non-interventional study by the Est IV ethics committee.

2.2. Intervention

Telephone counselling calls were performed from February 2011 to April 2012 by four counselors (three nurses and one psychologist) who had been trained for both interventions using the CATI system or MI. The development and computerization of the counselling algorithm, the script, and the counselling protocol were inspired from studies applying a stage model of behavior change to CRC screening [8,22,25]. The Precaution Adoption Process Model (PAPM) is a stage-based theory with roots in social learning theory and the health belief model. It asserts that the adoption of a health behavior proceeds through distinct stages that are: (1) unaware (never heard of the risk/screening test); (2) unengaged (aware of and acknowledges others' risks); (3) undecided/deciding (acknowledges personal risk and is deciding); (4) decided no; (5) decided yes/planning; (6) acting (adopts the behavior); and (7) maintenance (repeats the behavior) [25].

Using a CATI system, we developed a counselling protocol that tailored counselling to a subject's response to questions that the computer prompted the counselor to ask. When the answer was entered into the computer, the computer automatically displayed the counselling script appropriate for the subject's responses.

The counselling protocol was divided into six main sections: (1) verifying the subject's eligibility for the RCT and for gFOBT screening; (2) determining whether the subject had a GP, the number of annual visits to the GP, whether CRC screening had ever been discussed with the GP, and whether the GP had ever recommended participation in the gFOBT CRC screening programme; (3) determining whether the subject had ever been screened for breast or prostate cancer; (4) determining the subject's initial intention for gFOBT CRC screening and PAPM stage; (5) providing tailored responses to the subject's stage of readiness, which might include education on CRC and gFOBT screening and help in addressing possible barriers; and (6) summarizing the subject's plans for gFOBT CRC screening, which included determining the subject's final PAPM stage and whether the subject wanted to receive a gFOBT kit at home.

For MI, the counselors conducted free interviews with open-ended questions and entered the subject's answers into the computer at the end of the telephone call. We developed the motivational call based on the same framework as the CATI call and the principles of MI [23]. Key intervention components included establishing rapport; asking permission to discuss CRC and screening; eliciting what the participant already knew; providing additional education and information when necessary; assessing motivation, confidence and readiness to get screened; exploring ambivalence; eliciting change talk; rolling with resistance; and (if appropriate) supporting self-efficacy and commitment to get screened [9]. Training included two full days of technique and role-playing, followed by telephone calls with the MI trainer and weekly supervision during four months.

Up to seven attempts were to be made at varying times of day to reach each subject by telephone.

2.3. Outcome measures

2.3.1. Primary outcome measure

The primary outcome measure was the participation rate determined one year after the intervention. It was calculated using the data registered by ADECA Alsace, the association in charge of the screening programme organization, by dividing the number of people having performed a gFOBT, irrespective of the result, by the number of people eligible for gFOBT screening, i.e. all participants initially randomized minus those excluded from gFOBT screening.

2.3.2. Variables of interest

Variables of interest were gender and age of the invited persons, their CRC screening history and the following geographical and socioeconomic determinants: administrative area, rural-urban place of residence, deprivation index, and statutory health insurance scheme. People were classified into three groups depending on their CRC screening history: first invitation for CRC screening (prevalence screening; had not been screened despite two invitations), never users (incidence screening; had never been screened despite previous invitations) and former users (incidence screening; had been screened at least once following previous invitations). As individual socioeconomic data were not available, the socioeconomic environment of the persons invited was assessed using an aggregated deprivation index, the French version of the European Deprivation Index (EDI), that provides a score for each of the smallest geographical census units, as defined by the French National Institute for Statistics and Economic Studies, INSEE [26,27]. Rural-urban place of residence was determined from the “Urban area 2010” computed from INSEE 2010 data [28]. Three categories were defined: large, medium and small urban areas, the latter corresponding to rural areas. In France, statutory health insurance is provided by several different schemes, the most common being the general scheme. People having completed a telephone interview were classified according to their PAPM stage as measured at the beginning of the call [25].

2.4. Statistical methods

For pragmatic reasons, the sample size was based on an estimation of the number of people that could be contacted by four counselors during 15 months. Quantitative variables were summarized using mean and standard deviation (SD) while categorical variables (ordered or not) were summarized using percentage of each category (with exact confidence interval using binomial distribution). Comparisons of percentages were carried out using Pearson's chi-squared test. To model participation rate we first applied chi-squared test or Student's t test to identify variables associated with the one-year participation rate at a 20% level of significance. We then applied multivariate analysis to these variables using logistic regression forward variable selection at a 5% level of significance. The Kaplan-Meier method was used for plotting cumulative participation rates along time and log-rank tests

were performed for comparing rates between intervention groups. Both per-protocol and intent-to-treat analyses were performed: subjects randomized to the intervention group who received usual care because the telephone contact failed for technical reasons were analyzed together with the control group in per-protocol analysis, and with the intervention group in intent-to-treat analysis (Fig. 1).

3. Results

3.1. Characteristics of intervention groups

Fig. 1 illustrates the flow of participants through the trial. We drew a random sample of 49,972 people from the database of 156,614 potentially eligible participants. Overall, 1622 subjects were ineligible so that 48,350 people remained eligible with a mean age of 61.2 years (SD 6.8). Of them, 24,469 (50.6%) were men, 8937 (18.5%) were invited for the first time, 5517 (11.4%) were former users and 33,896 (70.1%) never users. The telephone number of 9853 (34.5%) people could not be found, so that 18,741 people were randomly divided into two intervention groups, 9367 people in the CATI group and 9374 people in the MI group. Overall, 12,135 people could not be reached, 4490 despite one or more attempts and 7645 without attempt. The latter group was explained by the fact that we oversized the initial random sample because we could not predict the number of people that could be contacted during the trial period. Of 6606 people who were reached, 915 (13.9%) declined to speak with the counselor, so that 5691 (19.9%) persons actually completed a full telephone interview, 2775 in the CATI group and 2916 in the MI group. Amongst them, 629 people refused gFOBT screening at the very beginning of the interview in the CATI group and 661 in the MI group (22.7% in both groups). Thus a full telephone counselling call was completed with 3005 people, 1474 in the CATI group and 1531 in the MI group. Sociodemographic and geographic characteristics of the control and intervention groups are shown in Table 1. Study groups were comparable. By contrast, people in the intervention groups who completed a full telephone interview showed significant female predominance, older age, higher proportion of former users and lower deprivation index compared with people who had no telephone interview. Table 2 summarizes the characteristics of people eligible for gFOBT screening who received complete telephone counselling in the intervention groups. These groups were comparable. Of them, 97.6% had a GP and 12.5% visited their GP less than once a year. CRC screening had been discussed with the GP by 35.0% of them (59.3% of former users, 29.4% of never users and 28.8% of people invited for the first time). CRC screening had been recommended by the GP in 29.1% of them. Most (64.3%) had been screened for other cancers. At the time of initial PAPM staging, 2.9% of people were unaware, 21.8% unengaged, 46.3% undecided, 10.0% had decided to refuse screening and 18.5% had decided to accept screening.

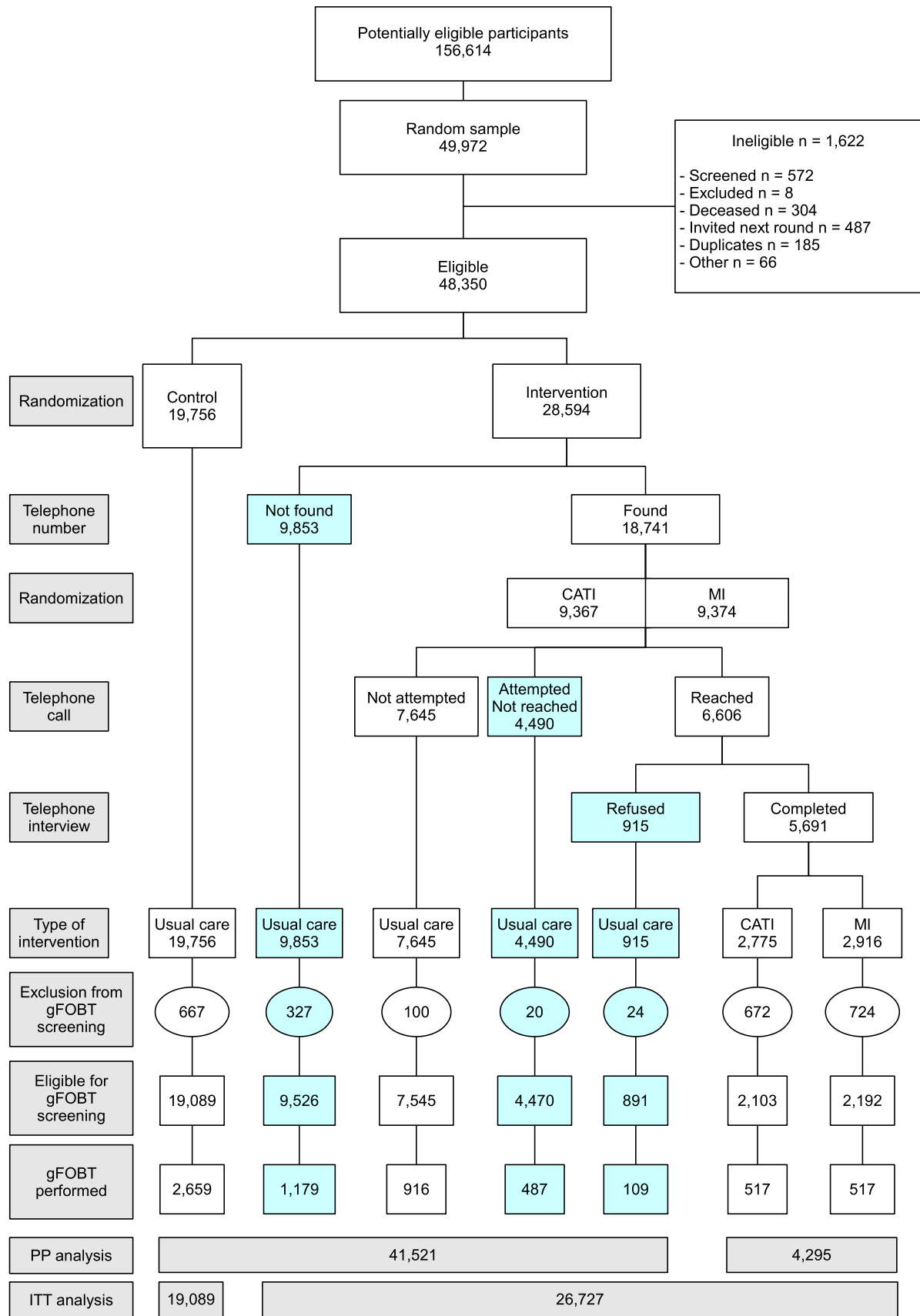


Fig. 1. Study flow diagram. Green boxes represent technical failures of telephone counselling. CATI: computer-assisted telephone interview; gFOBT: guaiac-based faecal occult blood test; ITT analysis: intent-to-treat analysis; MI: motivational interview; PP analysis: per-protocol analysis.

Table 1
Baseline characteristics of the control and intervention groups.

	Control group	Intervention groups		P-value
	Control group n (%)	No telephone interview n (%)	Completed telephone interview n (%)	
<i>Type of care received</i>	Usual	Usual	Phone counselling	
<i>Participants</i>	19,756	22,903	5691	–
<i>Male gender</i>	10,026 (50.7)	12,054 (52.6)	2389 (42.0)	< 0.01
<i>Age (years)</i>				< 0.01
50–54	6442 (32.6)	7278 (31.8)	1537 (27.0)	
55–59	4899 (24.8)	5873 (25.6)	1288 (22.6)	
60–64	3929 (19.9)	4649 (20.3)	1248 (21.9)	
65–69	2486 (12.6)	2803 (12.2)	879 (15.4)	
70–74	2000 (10.1)	2300 (10.0)	739 (13.0)	
<i>Screening history</i>				< 0.01
First invitation	3852 (19.5)	4122 (18.0)	963 (16.9)	
Never user	13,607 (68.9)	16,396 (71.6)	3917 (68.8)	
Former user	2297 (11.6)	2385 (10.4)	811 (14.3)	
<i>Bas-Rhin</i>	15,568 (78.8)	18,001 (78.6)	4451 (78.2)	0.62
<i>Urban areas</i>				< 0.01
Large	11,269 (57.0)	13,660 (59.6)	3332 (58.4)	
Medium	1363 (6.9)	1527 (6.7)	391 (6.9)	
Small	6928 (35.1)	7412 (32.4)	1936 (34.0)	
Missing	196 (1.0)	304 (1.3)	42 (0.7)	
<i>Deprivation Index</i>				< 0.01
Quintile 1 (least deprived)	4308 (21.8)	4728 (20.6)	1404 (24.7)	
Quintile 2	4230 (21.4)	4886 (21.3)	1241 (21.8)	
Quintile 3	2837 (14.4)	3446 (15.0)	767 (13.5)	
Quintile 4	3118 (15.8)	3487 (15.2)	924 (16.2)	
Quintile 5 (most deprived)	4955 (25.1)	5897 (25.7)	1302 (22.9)	
Missing	308 (1.6)	459 (2.0)	53 (0.9)	
<i>Health insurance scheme</i>				< 0.01
General scheme	15,182 (76.8)	17,826 (77.8)	4234 (74.4)	
Special scheme	520 (2.6)	538 (2.3)	171 (3.0)	
Self-employed scheme	1483 (7.5)	1770 (7.7)	419 (7.4)	
Civil service scheme	1794 (9.1)	1982 (8.7)	653 (11.5)	
Agricultural scheme	728 (3.7)	728 (3.2)	199 (3.5)	
Missing	49 (0.2)	59 (0.3)	15 (0.3)	

3.2. Characteristics of counselling calls

Overall, 33,374 attempts were made to call 11,096 people and 6606 (59.5%) of them could be reached. In total, 47.7% of the counselling calls were completed in one attempt, 22.4% in two, and 29.9% in > 2 attempts. The average duration of the counselling calls was 8 minutes, similar in CATI and MI groups. It varied from 7 to 9 minutes depending on the counselor. Overall and depending on the counselor, 2.9 to 3.9 people were reached per hour. At the end of the counselling call, 0.2% of people were unengaged, 10.8% undecided, 10.8% had decided to refuse screening and 78.2% had decided to accept screening.

3.3. Participation

At one year, in intent-to-treat analysis, there was no difference between intervention groups taken together (3725/26,727 = 13.9%) and control group (2659/19,089 = 13.9%) ($P = 1.0$). Participation was higher in the intervention groups than in the control group in never users (8.0% vs 7.3%, $P = 0.01$) and former users (47.4% vs 44.3%, $P = 0.03$) and not

different between groups in people invited for the first time (18.5% vs 17.8%, $P = 0.43$) (Table 3).

In per-protocol analysis, the participation rate was significantly higher in the intervention groups taken together (1034/4295, 24.1%, 95% confidence interval (CI) [22.8–25.4]) than in the control group (5350/41,521, 12.9%, 95% CI [12.6–13.2]) ($P < 0.01$). There was no difference between CATI (517/2103, 24.6%, 95% CI [22.7–26.4]) and MI groups (517/2192, 23.6%, 95% CI [21.8–25.4]) ($P = 0.44$).

There was no significant difference in cumulative participation rates between the intervention and control groups in intent-to-treat analysis (Fig. 2A). However, these rates were significantly higher in the intervention groups than in the control group in per-protocol analysis (Fig. 2B) ($P < 0.01$). The curves demonstrate that most people were screened within four months of the intervention.

3.4. Determinants of participation

The univariate analyses of the determinants of participation showed that gender, age, screening history, place of residence, level of deprivation and health insurance scheme were

Table 2

Baseline characteristics of the 3005 people eligible for guaiac-based faecal occult blood test screening who received complete telephone counselling.

	CATI <i>n</i> (%)	MI <i>n</i> (%)	<i>P</i> -value	Total <i>n</i> (%)
<i>Participants</i>	1474	1531	–	3005
<i>Male gender</i>	592 (40.2)	608 (39.7)	0.80	1200 (39.9)
<i>Age (years)</i>			0.05	
50–54	285 (19.3)	338 (22.1)		623 (20.7)
55–59	402 (27.3)	380 (24.8)		782 (26.0)
60–64	332 (22.5)	375 (24.5)		707 (23.5)
65–69	256 (17.4)	223 (14.6)		479 (15.9)
70–74	199 (13.5)	215 (14.0)		414 (13.8)
<i>CRC screening history</i>			0.15	
First invitation	258 (17.5)	301 (19.7)		559 (18.6)
Never user	918 (62.3)	954 (62.3)		1872 (62.3)
Former user	298 (20.2)	276 (18.0)		574 (19.1)
<i>General practitioner</i>				
Has a GP	1439 (97.6)	1495 (97.6)	0.97	2934 (97.6)
< 1 annual visit	165 (11.2)	210 (13.7)	0.04	375 (12.5)
CRC screening discussed	526 (35.7)	525 (34.3)	0.42	1051 (35.0)
CRC screening recommended	446 (30.3)	430 (28.1)	0.19	876 (29.2)
<i>Screened for breast/prostate cancer</i>	959 (65.1)	975 (63.7)	0.43	1934 (64.4)
<i>Initial PAPM stage</i>			0.40	
Stage 1 (unaware)	40 (2.7)	48 (3.1)		88 (2.9)
Stage 2 (unengaged)	300 (20.4)	354 (23.1)		654 (21.8)
Stage 3 (undecided)	697 (47.3)	694 (45.3)		1391 (46.3)
Stage 4 (decided no)	149 (10.1)	152 (9.9)		301 (10.0)
Stage 5 (decided yes)	278 (18.9)	277 (18.1)		555 (18.5)
Missing	10 (0.7)	6 (0.4)		16 (0.5)

CATI: computer-assisted telephone interview; CRC: colorectal cancer; GP: general practitioner; MI: motivational interview; PAM: Precaution Adoption Process Model.

significantly associated with screening (Table 3). Participation was significantly higher in former users than in people invited for the first time and in never users (56.2%, 29.6% and 15.4% in people actually counseled) ($P < 0.01$). It was higher in women (25.5%) than in men (21.9%) ($P < 0.01$) and in people younger than 65 years (26.7%) than in older people (19.1%) ($P < 0.01$). The multivariate analyses showed that gender, age, screening history, place of residence, level of deprivation and health insurance scheme were significantly associated with completed screening (Table 4). Screening history was the main determinant of participation, which was significantly higher in former users (odds ratio (OR) 11.2, 95% CI [10.4–12.0] in intent-to-treat analysis) and in people invited for the first time (OR 2.2, 95% CI [1.2–2.5]) than in never users. Whereas telephone counselling was not associated with completed screening in intent-to-treat analysis (OR 1.0, 95% CI [1.0–1.1]), it was significantly associated in per-protocol analysis (OR 2.1, 95% CI [1.9–2.3]).

The univariate analysis of the determinants of participation in 3005 people accepting a full telephone counselling call showed that gender, screening history, administrative area, discussing CRC screening with the GP, CRC screening recommendation by the GP, screening for other cancers, initial PAM stage and counselor were significantly associated with screening (Supplementary Table 1). Participation was 36.6% in people who had received a screening recommendation from their GP and 22.5% in those who had not received a recommendation ($P < 0.01$). It varied from 22.1% to 44.5%

depending on the counselor ($P < 0.01$). The multivariate analysis showed that screening history, initial PAM stage and counselor were significantly associated with screening. Screening history was the main determinant of participation, which was significantly higher in former users (OR 4.1, 95% CI [3.3–5.1]) and in people invited for the first time (OR 1.6, 95% CI [1.2–1.9]) than in never users (Supplementary Table 2). There was no difference between CATI and MI groups regardless the initial PAM stage.

Overall, 38.8% of people who had decided to accept screening at the end of the call were actually screened by three months, 5.8% of those undecided and none of those unengaged and who had decided to refuse screening.

4. Discussion

Our main finding is that there was no difference in participation of underusers between tailored telephone counselling and untailored invitation and gFOBT kit mailing in intent-to-treat analysis. A greater efficacy of tailored telephone counselling, around twice that of untailored invitation and gFOBT kit mailing, was observed only in people who could actually be counseled, without difference between MI and CATI. As only 19.9% of people randomized to intervention groups were actually counseled by telephone, there was no difference in intent-to-treat analysis. The low rate of people actually counseled was mainly explained by a low rate of 33.6% of technically successful telephone counselling: telephone

Table 3
Participation rates in people eligible for guaiac-based faecal occult blood test screening (intent-to-treat and per-protocol analyses).

Variable	Intent-to-treat analysis			Per-protocol analysis		
	Control group <i>n</i> = 19,089 %	Intervention groups <i>n</i> = 26,727 %	<i>P</i> -value	Control group <i>n</i> = 41,521 %	Intervention groups <i>n</i> = 4295 %	<i>P</i> -value
<i>Gender</i>						
Male	12.8	12.5	0.47	12.0	21.9	< 0.01
Female	15.1	15.4	0.48	14.2	25.5	< 0.01
<i>Age</i>						
50–54	17.5	17.2	0.70	16.6	28.8	< 0.01
55–59	13.2	13.2	0.99	12.1	26.7	< 0.01
60–64	12.8	13.8	0.17	12.2	25.1	< 0.01
65–69	13.1	13.1	0.91	12.4	19.2	< 0.01
70–74	12.5	12.0	0.55	11.7	19.0	< 0.01
<i>Screening history</i>						
Never user	7.3	8.0	0.01	6.9	15.4	< 0.01
First invitation	17.8	18.5	0.43	17.1	29.6	< 0.01
Former user	47.4	44.3	0.03	44.7	56.2	< 0.01
<i>Administrative area</i>						
Haut-Rhin	16.9	16.9	0.97	15.9	29.1	< 0.01
Bas-Rhin	13.1	13.1	0.96	12.3	22.6	< 0.01
<i>Urban areas</i>						
Small	14.7	14.6	0.94	14.0	24.5	< 0.01
Large	13.1	13.5	0.34	12.3	23.8	< 0.01
Medium	17.1	15.1	0.13	15.7	25.2	< 0.01
<i>Deprivation index</i>						
Quintile 1 (least deprived)	15.2	14.5	0.32	14.2	21.8	< 0.01
Quintile 2	14.4	14.7	0.67	13.6	25.5	< 0.01
Quintile 3	14.5	14.1	0.62	13.2	26.6	< 0.01
Quintile 4	14.7	13.7	0.21	13.6	23.8	< 0.01
Quintile 5 (most deprived)	11.6	13.0	0.03	11.3	24.4	< 0.01
<i>Health insurance scheme</i>						
General scheme	13.9	13.6	0.45	12.9	23.4	< 0.01
Special scheme	15.2	19.0	0.10	16.3	25.2	0.01
Self-employed scheme	12.4	11.6	0.49	10.9	23.3	< 0.01
Civil service scheme	15.7	17.7	0.10	15.8	28.1	< 0.01
Agricultural scheme	12.8	13.3	0.77	12.3	24.5	< 0.01

numbers were found in 65.5% of cases and telephone interviews could be completed in 51.3% of people that we attempted to call. Screening history was the main determinant of participation, which was eleven-fold higher in former users and two-fold higher in people invited for the first time compared with never users. Other determinants were gender, age, place of residence, level of deprivation and health insurance scheme. Most (65%) underusers had not discussed CRC screening with their GP.

Our study is, to the best of our knowledge, with more than 3000 people actually counseled by telephone, the largest ever published. Moreover, it is the first embedded in an ongoing organized screening programme conducted in a population-based setting. All previous studies were small [9–12,15,17,29–32], including a few hundred persons, and performed in volunteers [9,11,12,15–17,29–32] in predefined settings [8–18,29–32] so that the reproducibility and generalizability of their results are questionable.

Telephone-based interventions to promote CRC screening vary from simple interventions as automated [19,20] or “live” untailed reminder calls [33–35] to complex interventions

such as telephone-based navigation [21]. The intensity of our intervention was intermediate. Overall, our results confirm the modest efficacy of tailored telephone counselling demonstrated in previous studies, but we found that this efficacy is restricted to people who can actually be counseled. Previous studies compared telephone counselling with usual care, that is either no intervention at all [8–10], or an untailed mailed invitation [11,12], and assessed CRC screening regardless of the screening method [8–12,14,29]. The results of studies that assessed, as we did, the impact of tailored telephone counselling on FOBT screening in comparison with mailing of the FOBT kit, lack consistency. Some found greater efficacy for telephone counselling [13–18], others not [30–32]. However, all reported an increase in screening uptake, varying from 2% to more than 20%, and none of them reported the results of per-protocol analyses evaluating the efficacy of telephone counselling in people who could actually be counseled. Two previous studies found, as we did, that the greater efficacy of telephone counselling was observed in per-protocol analysis only, not in intent-to-treat analysis [8,12]. Whereas the only earlier study comparing CATI and MI telephone counselling

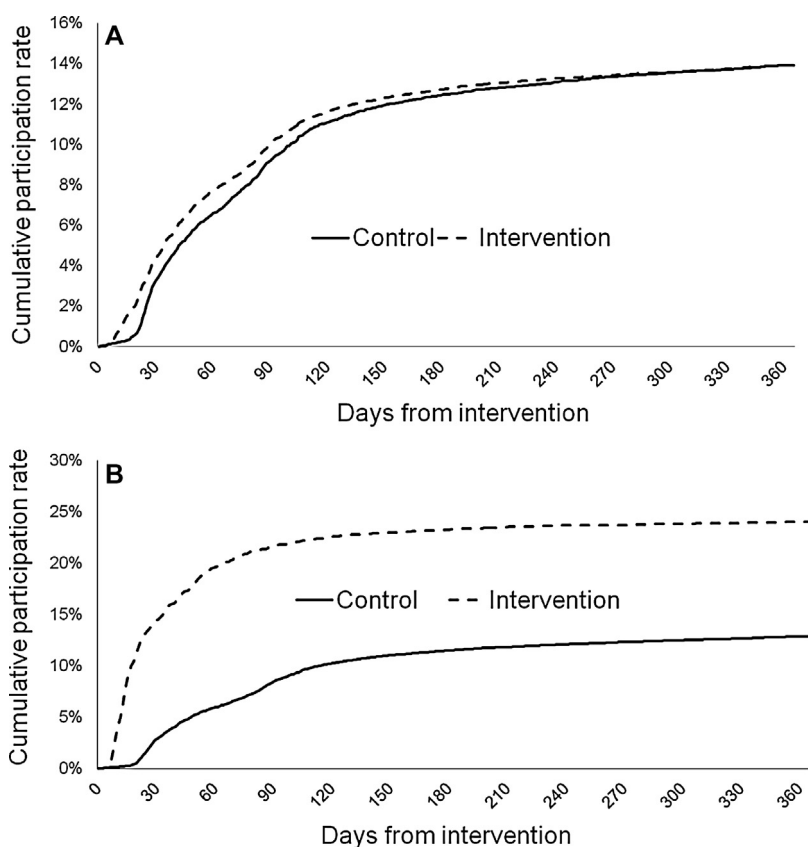


Fig. 2. Cumulative participation rates in the intervention and control groups. They are presented in intent-to-treat (Fig. 2A) and per-protocol analyses (Fig. 2B).

found that CATI was more effective for CRC screening adherence, we found no significant difference between the two methods [9].

The impact of telephone counselling on participation has been evaluated in only a few studies on female cancer screening in population-based settings outside the USA. Their results lack consistency. Some found that telephone counselling is effective [36–38], others not [39–41]. Noteworthy is the absence of difference observed in our region between telephone and mail reminders in reluctant women not screened for cervical cancer [41]. The rate of successful telephone counselling was 34.2% in that study, similar to our rate of 33.6%. Likewise, a study conducted in Germany found a 60–66% rate of retrieved telephone numbers, similar to our 65.5% [37]. The rates of people actually counseled in these population-based studies (34.2%–70.7%) [36–38,41] were closer to our rate of 33.6% than to those reported in US studies (60%–91%). In the latter, people who could not be reached by telephone were sometimes excluded from randomization [9,15,16,32].

As a whole, the efficacy of tailored telephone counselling to increase participation in cancer screening is now largely demonstrated along with its modest superiority over untailored mailed invitation. By contrast, its effectiveness is highly variable, depending on the setting that determines the rate of technical success of telephone interviews [5,8–18,22,29–32,36–41]. Even if only a minority of people could be reached and accepted to be counseled by telephone, we considered that

telephone counselling was feasible in our programme. However, our experience suggests that the rate of technical success of telephone interviews (telephone number found, individual reached by telephone and accepting to be counseled) should be evaluated before implementation of telephone counselling in population-based cancer screening programmes.

The population-based setting, the randomized design and the large number of people included are the main strengths of our study. Another strength is the pragmatic design of the trial, with minimal inclusion/exclusion criteria, which should ensure a better generalizability of its results. Moreover, the rigorous intent-to-treat analysis provides a conservative estimate of the effectiveness of the intervention. Our study is not without limitations however. These include the high proportion of people who could not be reached by telephone, the highest observed in similar studies. Only 65.5% of telephone numbers could be found whereas 93% of people aged 60–69 years in France have landlines [42]. Another weakness is the large number of people that we did not attempt to reach in the intervention groups that penalized the efficacy of telephone counselling in intent-to-treat analysis. Another weakness is that in the per-protocol analysis we included in the control group individuals randomized to the intervention group. This is not strictly correct as there will have been intervention on some of the subjects (i.e. those who refused the phone discussion), although this may not have affected their decision. We must acknowledge that the results of the per-protocol analysis are

Table 4
Multivariate analyses of the determinants of participation in people eligible for guaiac-based faecal occult blood test screening (intent-to-treat and per-protocol analyses).

Variable	Intent-to-treat analysis		Per-protocol analysis	
	Odds ratio (95% CI)	P-value	Odds ratio (95% CI)	P-value
<i>Gender</i>		< 0.01		< 0.01
Male	1.0		1.0	
Female	1.2 (1.2–1.3)		1.2 (1.1–1.3)	
<i>Age</i>		< 0.01		< 0.01
50–54	1.0		1.0	
55–59	0.8 (0.7–1.0)	< 0.01	0.8 (0.7–0.9)	< 0.01
60–64	0.8 (0.7–0.9)	< 0.01	0.8 (0.7–0.9)	< 0.01
65–69	0.8 (0.7–0.9)	< 0.01	0.7 (0.6–0.8)	< 0.01
70–74	0.7 (0.6–0.8)	< 0.01	0.6 (0.5–0.7)	< 0.01
<i>Screening history</i>		< 0.01		< 0.01
Never user	1.0		1.0	
First invitation	2.2 (2.0–2.5)	< 0.01	2.2 (1.9–2.5)	< 0.01
Former user	11.2 (10.4–12.0)	< 0.01	11.3 (10.4–12.2)	< 0.01
<i>Administrative area</i>		< 0.01		< 0.01
Haut-Rhin	1.0		1.0	
Bas-Rhin	1.3 (1.2–1.4)		1.3 (1.2–1.4)	
<i>Urban areas</i>		< 0.01		< 0.01
Small	1.0		1.0	
Large	0.9 (0.8–1.0)	< 0.01	0.9 (0.8–0.9)	< 0.01
Medium	1.0 (0.9–1.2)	0.59	1.0 (0.9–1.2)	0.57
<i>Deprivation index</i>		0.02		0.05
Quintile 1 (least deprived)	1.0		1.0	
Quintile 2	1.0 (0.9–1.1)	0.77	1.0 (0.9–1.1)	0.96
Quintile 3	1.0 (0.9–1.1)	0.84	1.0 (0.9–1.1)	0.58
Quintile 4	1.0 (0.9–1.1)	0.85	1.0 (0.9–1.1)	0.99
Quintile 5 (most deprived)	0.9 (0.8–1.0)	0.01	0.9 (0.8–1.0)	0.03
<i>Health insurance scheme</i>		< 0.01		< 0.01
General scheme	1.0		1.0	
Special scheme	1.3 (1.1–1.6)	< 0.01	1.3 (1.1–1.5)	0.01
Self-employed scheme	0.9 (0.8–1.0)	0.01	0.8 (0.7–1.0)	0.02
Civil service scheme	1.3 (1.2–1.4)	< 0.01	1.3 (1.2–1.5)	< 0.01
Agricultural scheme	1.0 (0.8–1.1)	0.54	1.0 (0.8–1.2)	0.69
<i>Intervention</i>		0.26		< 0.01
Control	1.0		1.0	
Phone counselling	1.0 (1.0–1.1)		2.1 (1.9–2.3)	

biased since the two groups, i.e. people having received usual care and those having been actually counseled by telephone, differ significantly for the determinants of participation (Table 1). Another weakness is that the lack of difference between CATI and MI groups may be related to sub-optimal implementation of the MI intervention: the counselors and the average duration of the counselling calls were the same; the content was quite similar; not all counselors were proficient in the technique from the beginning of the study; some counselors were more skilled than other. Last, the long-term effectiveness and cost-effectiveness of telephone counselling were not assessed and have to be further evaluated. As things stand, the high cost of telephone counselling related to staff costs together with its marginal gain of effectiveness prohibit its widespread use in our population-based programme. Moreover, adopting it as it stands would amplify the programme's known socioeconomic inequities [43]. The rate of phone interview success was significantly lower in the most socioeconomically deprived people who participated less than the least deprived people. In

France, the percentage of people who have landlines falls from 97% to 67% as a function of household income [42]. Future research should be focused on further evaluation of telephone counselling in a subgroup of underusers offering the best chances for high yield, i.e. in never users living in most deprived areas since a significant increase in participation was demonstrated in this category of people in intent-to-treat analysis. For further evaluation, it would probably be better to rely on the CATI technique since MI requires more education and training. By contrast, a short telephone recall or even an automated telephone call might be enough in former users [19,20]. In addition, the number of people reached per hour, rather low in the present study, could be increased by limiting to two the number of attempts made to reach each subject. Last, as the effectiveness of our intervention was mainly penalized by failed telephone contact, another field of research would be directed at enhancing the rate of technical success of telephone interviews, mainly by improving the percentage of telephone numbers found, including cell phones and Internet phones.

However, the increasing use of unsolicited advertising calls is more and more perceived as a nuisance, so that a growing number of people will probably refuse telephone interviews, including health-related counselling calls.

5. Conclusion

The results of this pragmatic randomized intervention study do not confirm the effectiveness of tailored telephone counselling on participation of underusers in an organized population-based CRC screening programme. Even if the efficacy of tailored telephone counselling is about twice that of untailored invitation and gFOBT kit mailing in underusers who are actually counseled, its effectiveness depends on the rate of technical success of telephone interviews that is highly variable, depending on the setting, and rather modest in the real world. The rate of technical success of telephone interviews should be evaluated, and enhanced if insufficient, before implementation of telephone counselling in population-based cancer screening programmes.

Authors' contributions

BD, IG and PP were responsible for screening programme organization. GB and KG were responsible of the counselling calls. PP was responsible for data collection. EAS and PP did the statistical analyses. BD wrote the paper and all authors approved the final version. BD, GB and PP are guarantors.

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Disclosure of interest

The authors declare that they have no competing interest.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.respe.2016.06.336>.

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