ORIGINAL ARTICLE

Gut and Liver, Vol. 14, No. 3, May *2020, pp. 323-330*

Increase in the Colorectal Cancer Screening Rate by a Round-Mailed Fecal Immunochemical Testing Kit and Associated Factors in Underserved Regions of Korea: A Community-Based Intervention Study

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See editorial on page 277.

Background/Aims: Postal distribution of a fecal immunochemical test (FIT) kit has been recommended as an effective method of increasing participation in colorectal cancer (CRC) screening. The present study was performed to assess the impact of the round-mailed FIT kit on screening participation in underserved regions of Korea and to identify factors related to nonparticipation. **Methods:** Residents were recruited from three rural regions of Korea that lack screening units for the National Cancer Screening Program. A package containing a FIT kit for stool self-sampling and a return envelope addressed to the local health center was postally distributed to each subject. Thirty days after the kits were mailed, nonresponders were reminded via telephone as the second intervention. The participation rates and odds ratios with 95% confidence intervals (CIs) for each intervention response were calculated to evaluate the effect of the interventions and factors related to screening participation in response to the interventions. **Results:** CRC screening participation rates increased from 24.5% (95% CI, 21.6% to 27.4%) to 42.6% (95% CI, 39.3% to 46.0%) as a result of postal screening and increased further to 51.4% (95% CI, 48.0% to 54.9%) after the telephone reminder. After controlling for the sex, age, and household type of each subject, factors associated with poor response to postal screening were identified as low educational attainment and poor previous participation in the National Cancer Screening Program. **Conclusions:** Round-mailed FIT kits with phone call reminders were an effective intervention, nearly doubling the screening rate in underserved regions of Korea. **(Gut Liver 2020;14:323-330)**

Key Words: Early detection of cancer; Colorectal neoplasms; Early medical intervention

INTRODUCTION

The global burden of colorectal cancer (CRC) is rising, and it continues to be a leading cause of cancer worldwide, associated with significant morbidity and mortality.[1] In Korea, CRC has been consistently ranked the third highest cause of mortality among cancers since 2016.[2] The fecal immunochemical test (FIT) is an effective screening tool that can reduce CRC incidence and mortality, and its use is supported by considerable recent research.[3-5] The U.S. Multi-Society Task Force on CRC recently published guidelines recommending FIT as the first-tier screening method for CRC, along with colonoscopy, both of which are appropriate for programmatic systems.[6]

One of the major challenges for any screening program is the participation rate, which determines the effectiveness of screening in reducing disease mortality, and therefore the program's cost-effectiveness.[7,8] U.S. and European guidelines recommend a minimum uptake or completion rate for CRC screening of 60% and 65%, respectively, although European guidelines also consider 45% participation to be acceptable.[3,9] Recent screening rates for CRC among the Korean population involved in the National Cancer Screening Program (NCSP) are reported to be just 30%, making it the lowest screening rate of the five major cancer sites in Korea (stomach cancer, CRC, liver cancer, breast cancer, and cervical cancer).[10] The authors denoted that inconvenience of stool sampling using conventional container and visiting the screening unit at least twice for stool blood test (FIT), the principle test used by the NCSP, has been reported to be a

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Received on April 15, 2019. Revised on June 12, 2019. Accepted on June 24, 2019. Published online September 19, 2019.
pISSN 1976-2283 eISSN 2005-1212 https://doi.org/10.5009/gnl19124

major barrier to participation.

It is widely accepted that distribution of a FIT kit by post is an effective intervention to increase CRC screening compliance.[5,11,12] It seems to be able to play an important role in Korea where programmatic screening for CRC is established with FIT; because such an intervention can reduce disparities in accessibility caused by geographical or system-related barriers. Such barriers can be difficult to overcome, even with an organized screening program.[13] Research regarding the ability of this intervention to increase CRC screening rates in Korea has been limited, and additional research in this area is urgently needed.

Therefore, the purpose of this study was to evaluate the impact of the round-mailed FIT kit distribution on the CRC screening rate in underserved regions, and to identify potential factors affecting this impact. In addition, data was extrapolated to predict improvements in final screening rates if this intervention was applied to all underserved regions in Korea.

MATERIALS AND METHODS

1. Study population and data collection

Residents were recruited from three rural regions (Jangsu, Goseong, and Uiryeong) lacking NCSP screening units, between July 2015 and February 2016. Participation in the NCSP for CRC in 2014 and 2015 was initially assessed by questionnaire and was confirmed retrospectively using the National Health Insurance Service screening record. A detailed explanation of the NCSP system is provided elsewhere.[10] Subjects who were not eligible for CRC screening at baseline, that is, aged less than 50 years in 2015, and those who could not be assessed for their participation in the NCSP in 2014/2015, were excluded.

The subjects' baseline data were collected through face-to-face interviews conducted by trained research staff. Each subject completed a structured questionnaire regarding their socio-demographic characteristics and their perception of CRC screening. Previous NCSP participation was categorized as follows: poor, nonparticipation in 2014 and 2015 although they were invited; moderate, participation in either 2014 or 2015; and good, participation in every invited screening among 2014 and 2015. Written informed consent was obtained from all subjects at the time of recruitment. Ethical approval was obtained from the Institutional Review Board at the National Cancer Center in Korea (IRB number: NCCNC2015-0095).

2. Intervention and measurement of outcomes

In the current study, round-mailed FIT screening was performed by delivering a FIT kit to the residents of three rural regions lacking a screening unit. In 2015, we conducted a preliminary investigation and pilot study to assess the feasibility of the intervention in this regional environment; and the main intervention was conducted in early 2016. The postage of the FIT kit and enclosed instruction manual constituted the primary intervention in this study. All subjects were sent a package containing: (1) a one-sample FIT kit (Eiken Chemical Co., Ltd., Tokyo, Japan); (2) an instruction manual for stool collection using the FIT kit; and (3) a postage-paid, self-addressed envelope for returning the stool sample. Subjects were instructed to take stool samples themselves, and return them using the enclosed response envelope addressed to their regional health center. Thirty days after postage of the FIT kit, nonresponders were reminded via telephone and this constituted the second intervention. The final response was followed up until the end of April 2016.

For analysis, CRC screening rates of the study subjects were compared to the screening rates for the same individuals via the NCSP in the previous year, 2015. The primary outcome measure was overall participation in CRC screening via postal FIT, which could be divided into two groups: responders who submitted stool specimens through round-mailed FIT within a month of kit postage, requiring only the first intervention; and responders who submitted their specimen following the second intervention, more than one month after kit postage, and who required phone call reminders. The overall participation rate was defined as the proportion of study subjects who returned a stool sample to the National Cancer Center within two months of FIT kit postage (responders).

3. Estimation of the expected outcomes of the hypothetical (expanded) intervention

Study data was extrapolated to estimate final screening rates for the hypothetical use of this intervention in eight regions of Korea which lack an NCSP screening unit. To achieve this, information was obtained regarding the size of the target population, the estimated number of FIT kits needed to increase screening participation by one person, and the current participation rates in each area. Detailed assumptions and methods for these calculations are described in Supplementary Material 1.

The estimated cost of this intervention was assessed, and the average cost-effectiveness ratio (cost per returned FIT kit) and incremental cost-effectiveness ratio (incremental cost per additional one screening relative to increase in screening rate) were calculated. Detailed methods for these analyses are described in Supplementary Material 2.

4. Statistical analysis

Descriptive analyses for various socio-demographic characteristics of the study population were carried out in each response category, both at baseline and after the intervention. Characteristics of the study subjects are reported as percentages. The chi-square test was conducted to evaluate differences in characteristics between responders and nonresponders. The effects of intervention were evaluated by comparing the overall participation rate after the intervention to that of the reference status (baseline or no intervention). After adjusting for factors with the potential to affect screening participation, logistic re-

gression analysis was performed to estimate the odds ratios (ORs) for intervention response, either by FIT kit delivery (primary intervention) only, or by FIT kit delivery and phone call reminders (primary and secondary intervention). Reported p-values were two-sided, and $p<0.05$ was considered statistically significant. All statistical analyses were conducted using SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Of the 1,051 individuals initially recruited, subjects aged less than 50 years in 2015 (n=120), and those for whom participation in the NCSP in 2015 could not be identified (n=103) were excluded. Accordingly, a total of 828 subjects (331 males and 497 females) were included in this study. General characteristics of the study population are presented in Table 1. The overall mean age was 68.1 years (range, 50 to 92 years); more than 60% of subjects had an educational level below middle school graduation; and more than 20% lived alone.

In contrast to the CRC screening rate (via NCSP) for the study population in 2015 of 24.5% (95% confidence interval [CI], 21.6% to 27.4%), the screening rate in 2016 was higher, at 42.6% (95% CI, 39.3% to 46.0%) after the initial intervention (FIT kit postage); and further increased to 51.4% (95% CI, 48.0% to 54.9%) after the second intervention (phone call reminder 1 month after FIT kit postage) (Fig. 1). The differences between these three screening rates were statistically significant. The distribution of sample return time, that is, the time taken for a FIT kit to be delivered to the subject, stool to be sampled, and the sample returned, is graphically represented as cumulative return rate over time in Fig. 2.

Table 2 presents the distributions of study subjects and their characteristics, by participation in CRC screening before (baseline) and after the intervention. Among the baseline nonparticipants of 2015 NCSP (n=625), roughly half (n=303; 48.5%) participated in CRC screening after the intervention conducted in the next year; these subjects tended to be younger, highly-educated, living with family, and more participating in previous 2014/2015 NCSP than subjects who remained nonparticipants for two consecutive years (2015 and 2016). Of the 203 baseline participants of 2015 NCSP, 123 (60.6%) also participated in screening in 2016 (after intervention); these subjects had similar characteristics to those described for nonparticipants who participated in 2016.

Table 3 shows the ORs and 95% CIs for the multivariate logistic regression analyses. After adjusting for sex, age, and household type, both low educational level and poor previous NCSP screening participation were identified as significant factors limiting the efficacy of the intervention. Individuals with less than nine years of education were less likely to respond to the postal FIT intervention, even with phone call reminders (OR, 0.61; 95% CI, 0.39 to 0.97), compared to those with more than 9 years of education. Similarly, subjects with poor or moderate participation in NCSP screening during previous years were less

Table 1. Baseline Characteristics of the Study Population

Characteristic	No. (%)
Overall study population	828 (100.0)
Region	
Jangsu	503 (60.8)
Goseong	196 (23.7)
Uiryeong	129 (15.6)
Sex	
Male	331 (40.0)
Female	497 (60.0)
Age, yr	
50–59	171 (20.7)
60–69	246 (29.7)
70–79	350 (42.3)
≥80	61 (7.4)
Educational attainment, yr*	
<9	468 (67.4)
9–11	105 (15.1)
≥12	121 (17.4)
Household type*	
Single-person	146 (20.5)
Family (≥2 people)	567 (79.5)
Screening participation rate (%)†	
2014	34.0
2015	24.5

*Nonresponders were excluded; †2014 and 2015: participation in National Cancer Screening Program.

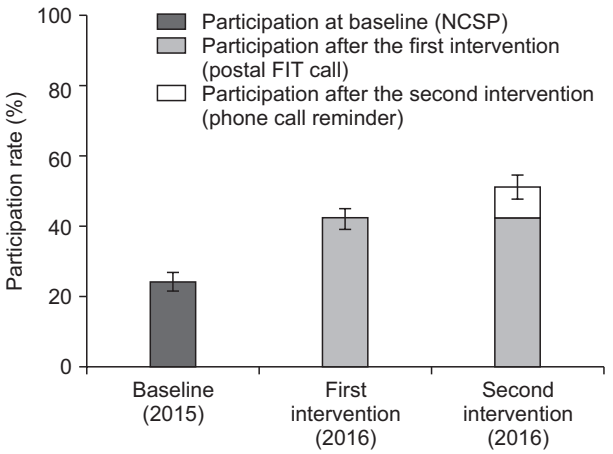

Fig. 1. Colorectal cancer screening participation rates (Jangsu, Goseong, and Uiryeong) at baseline and following the first and second interventions.
NCSP, National Cancer Screening Program; FIT, fecal immunochemical test.

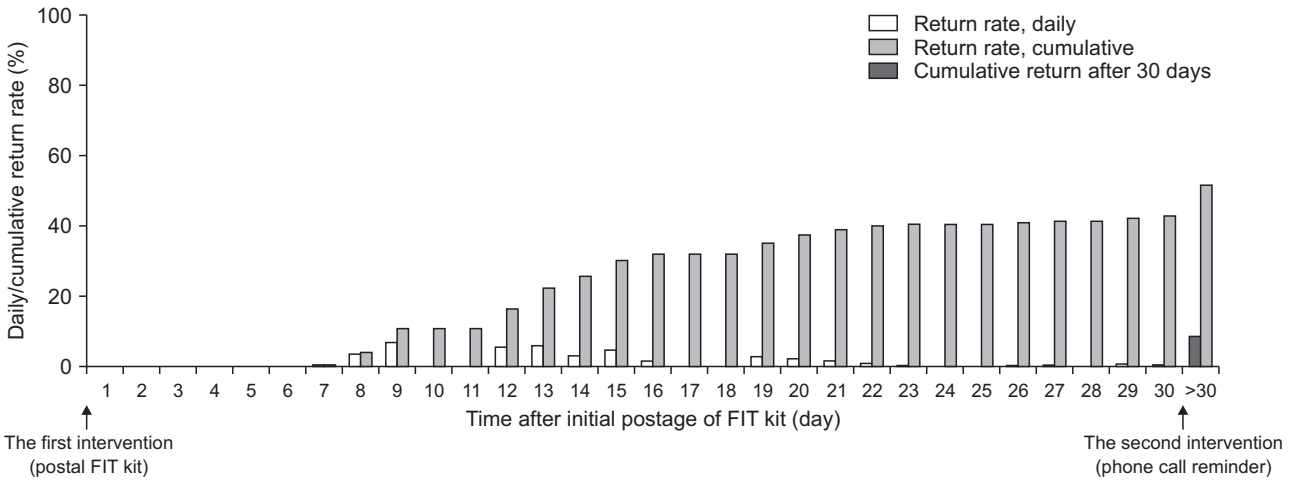

Fig. 2. Distribution of sample return times and cumulative return rates over time following the first intervention.
FIT, fecal immunochemical test.

Table 2. Distribution of Subjects by Characteristics and Screening Participation at Baseline and after the Round-Mailed FIT Kit Interventions

Characteristics	Baseline screening (NCSP, 2015): nonparticipants (n=625)			Baseline screening (NCSP, 2015): participants (n=203)		
	Nonparticipants after intervention	Participants after intervention	p-value	Nonparticipants after intervention	Participants after intervention	p-value
Total subjects	322 (38.9)	303 (36.6)		80 (9.7)	123 (14.9)	
Region			0.070			0.236
Jangsu	189 (58.7)	188 (62.1)		44 (55.0)	82 (66.7)	
Goseong	64 (19.9)	71 (23.4)		28 (35.0)	33 (26.8)	
Uiryeong	69 (21.4)	44 (14.5)		8 (10.0)	8 (6.5)	
Sex			0.054			0.817
Male	116 (36.0)	132 (43.6)		34 (42.5)	49 (39.8)	
Female	206 (64.0)	171 (56.4)		46 (57.5)	74 (60.2)	
Age, yr			0.202			0.251
50–69	160 (49.7)	167 (55.1)		31 (38.8)	59 (48.0)	
≥70	162 (50.3)	136 (44.9)		49 (61.3)	64 (52.0)	
Educational attainment, yr*			0.027			0.040
<9	179 (71.9)	168 (62.7)		51 (79.7)	70 (62.0)	
9–11	37 (14.9)	41 (15.3)		5 (7.8)	22 (19.5)	
≥12	33 (13.3)	59 (22.0)		8 (12.5)	21 (18.6)	
Household type*			0.036			0.040
Single-person	63 (24.8)	47 (17.0)		19 (28.4)	17 (14.7)	
Family (≥2 people)	191 (75.2)	229 (83.0)		48 (71.6)	99 (85.3)	
Compliance to NCSP†			<0.001			0.015
Poor	239 (74.2)	184 (60.7)		-	-	
Moderate	83 (25.8)	119 (39.3)		58 (72.5)	67 (54.5)	
Good	-	-		22 (27.5)	56 (45.5)	

Data are presented as number (%).
FIT, fecal immunochemical test; NCSP, National Cancer Screening Program.
*Nonresponders were excluded; †Poor=nonparticipation in both 2014 and 2015, moderate=participation in 2014 or 2015 but not both, good=participation in both 2014 and 2015.

Table 3. Adjusted Odds Ratios for Screening Participation after the Round-Mailed FIT Kit Intervention and Telephone Reminder

Characteristics	Participation after interventions			
	Round-mailed FIT intervention only		Overall (round-mailed FIT+phone call)	
	aOR* (95% CI)	p for trend	aOR* (95% CI)	p for trend
Sex		0.871		0.800
Male	1.00 (reference)		1.00 (reference)	
Female	0.94 (0.69–1.28)		0.92 (0.67–1.26)	
Age, yr		0.352		0.233
50–69	1.00 (reference)		1.00 (reference)	
≥70	0.90 (0.65–1.23)		0.88 (0.64–1.21)	
Educational attainment, yr		0.954		0.037
<9	1.08 (0.69–1.67)		0.61 (0.39–0.97)	
9–11	1.36 (0.80–2.32)		0.79 (0.45–1.37)	
≥12	1.00 (reference)		1.00 (reference)	
Household type		0.334		0.129
Single-person	0.82 (0.54–1.25)		0.72 (0.47–1.08)	
Family (≥2 people)	1.00 (reference)		1.00 (reference)	
Compliance to NCSP†		<0.001		<0.001
Poor	0.38 (0.23–0.63)		0.33 (0.19–0.56)	
Moderate	0.67 (0.40–1.12)		0.57 (0.33–0.99)	
Good	1.00 (reference)		1.00 (reference)	

FIT, fecal immunochemical test; aOR, adjusted odds ratio; CI, confidence interval; NCSP, National Cancer Screening Program.
*Adjusted for sex, age, educational level, household type, and previous compliance to NCSP; †Poor=nonparticipation in both 2014 and 2015, moderate=participation in 2014 or 2015 but not both, good=participation in both 2014 and 2015.

likely to respond to the intervention, compared to those with a good participation history (OR, 0.33; 95% CI, 0.19 to 0.56; OR, 0.57; 95% CI, 0.33 to 0.99, respectively).

It was estimated that approximately four FIT kits were used to increase screening compliance by one person using this intervention. In a hypothetical situation where FIT kits are distributed to all residents in eight areas lacking an NCSP screening unit, the final screening rate among these regions would be expected to reach an average of 53.8% (Supplementary Table 1). The average and incremental cost-effectiveness ratios are detailed in Supplementary Table 2. If FIT kits were distributed to all residents in underserved areas, the average cost would be an estimated 5,634 Korean won (KRW) ($5 USD) per FIT kit returned. The incremental cost-effectiveness was 9,022 KRW ($8.0 USD) per additional participant screened.

DISCUSSION

The intervention of delivering FIT kits to residents of three rural areas lacking an NCSP screening unit, followed by phone call reminders for nonresponders, resulted in an increase of about 2.1-fold in the CRC screening participation rate compared to the baseline rate (no intervention). Factors that reduced the effect of the intervention were low education level and a tendency toward nonparticipation in NCSP CRC screening in previous years.

There are diverse recipient (individual), provider, and organizational factors affecting CRC screening participation, but both rural location and geographical distance to a screening unit have been identified as particular barriers.[8,14] Other studies did not find these two factors to be significant barriers to screening, though this is possibly due to compensation or attenuation by other factors, such as frequent or regular doctor's visits.[15,16] Postal FIT, with or without introductory or reminder phone calls, is reported to be an effective and efficient approach to address barriers of geographical location.[8,17,18] In addition to supporting these findings, our study provided further evidence of the beneficial effects of postal FIT specifically targeted to rural residents with inadequate access to screening facilities.

The intervention conducted in our study mainly deals with organizational-level barriers (e.g., insufficient access to care providers or screening facilities, absence of systems for the identification of patients eligible for screening, financial barriers, and other structural barriers for screening)[19] rather than individual-level barriers. Therefore, individual-level barriers such as lack of knowledge regarding the test and its necessity, fear of diagnosis or treatment, financial concerns, lack of symptoms or current health problems, time, competing demands, and reluctance to handle stool or keep stool-identification cards in the house[19-21] may remain an issue and effect nonparticipa-

tion even after the intervention. Indeed, many subjects failed to participate after either the first or second intervention (57.4% and 48.6%, respectively). Regarding the primary reasons for nonattendance of CRC screening in Korea, Han *et al*.[22] reported a number of causes identified by their survey: "Without any symptoms (56.5%)," "Lack of time (14.4%)," "Fear of exam procedure (11.0%)," "Economic reasons (7.2%)," "Fear of detecting cancer (4.9%)," and "Ignorance about screening (3.4%)." In this study, we investigated the reasons for nonparticipation after the intervention by asking questions during the phone call reminders. Subjects' responses are summarized in Supplementary Table 2. Although there were limitations to the identification of specific reasons or barriers, these responses permitted the general evaluation of the attitudes and perceptions of nonparticipants. Although lack of insurance and other financial barriers are frequently cited in reports from foreign studies, these were rarely reported in the current study, and this is likely due to the NCSP and the National Health Insurance systems in Korea.

Among the potential factors affecting screening participation, low education level remained significantly associated with nonparticipation, despite the aim of this intervention to manage existing disparities in screening participation. Previous studies have also found low educational level to be a barrier to cancer screening participation, including CRC screening.[14] Experts have suggested that educated individuals are better at processing and responding to health information, recognizing their health risks, and adopting preventative behaviors, and this is reflected in their healthier lifestyle choices.[23] This explanation is consistent with our findings that lower education levels are a strong factor affecting nonparticipation with CRC screening, even after targeted interventions are applied. Similarly, participation in previous NCSP CRC screening was significant factor affecting participation in the postal FIT screening intervention in our study. It indicates that individuals unlikely to participate in the NCSP are also unlikely to participate in the following year, even with round-mailed FIT screening intervention. This suggests that more client- or patient-oriented intervention approaches are needed, which specifically deal with unfavorable barriers from the individual's point of view, such as augmenting active reminders to eligible clients, providing education regarding screening tests and test choices, or developing other methods to reduce barriers to screening participation.[19,24]

In Korea, organized CRC screening is conducted as a part of the NCSP via FIT, which implies that access to a screening unit is relatively common in the general population. However, individuals in underserved regions are considerably restricted in their access to screening units, due to geographical distance for example. The interventions applied in the present study are intended to be used to target such populations, provided that they prove cost-effective. Schlichting *et al*.[18] previously reported that the average cost per FIT returned from a postal intervention in the United States was $44.86 USD, for a FIT return rate of about 14%. After the inclusion of introductory and reminder phone calls, the return rate rose to 85% and the estimated cost per FIT returned decreased to $27.43 USD. These results were based on the purchase price of $5.0 USD per FIT kit, one-way postage costs of $1.2 USD, and hourly wages for calling personnel of $15.0. Schlichting's study therefore reported a higher cost for more intensive intervention, that is, phone calls, which was compensated by a strong effect on participation, resulting in a lower cost-effectiveness ratio. In the current study, we estimated the average cost per FIT kit returned to be approximately 2.8 times the purchase price of a FIT kit, compared to a cost of more than 5 times the purchase price in Schlichting's study. The above cost per FIT kit returned was almost equal to the sum of the purchase price of a FIT kit plus the estimated cost of a round-trip ticket for a screenee to a screening unit using public transport, indicating that the cost of this interventional would be reasonable.

Several limitations of our study should be considered. First, although our results were obtained by comparing the participation rates of a single group of subjects before and after the intervention, they could have been influenced by other factors relating to the 1-year time difference. Second, since the second intervention (phone call reminders) was conducted only among nonresponders from the first intervention (postal FIT kit), the effects of the two interventions could not be compared independently. Third, we analyzed a limited range of characteristics and socioeconomic indicators as potential factors affecting participation; and factors that were not evaluated, such as family history of CRC,[25] marital status,[26] knowledge or information about CRC,[14] may also have potential effects on the results. However, when we mainly focus on socioeconomic factors, organized CRC screening is performed free-of-charge, and the Korean population is covered by the National Health Insurance Service or medical aid; hence, disparities purely attributable to the subjects' economic status and insurance coverage should have a relatively small effect on screening participation. Finally, we cannot interpret the results from this study as general effects of the intervention, because the study was limited to regions of Korea that lack a regional screening unit and all subjects were volunteers. Prior to the practical implementation of interventions to increase CRC screening participation in Korea, it will be necessary to accumulate further evidence and to identify specific strategies of intervention through follow-up research.

To the best of our knowledge, the current study represents the first intervention study in Korea regarding round-mailed FIT strategy for regions with inadequate access to CRC screening units. This intervention was designed to improve participation in NCSP CRC screening, based on reports that FIT performs well compared with other screening tests.[3,6,27] Another domestic study carried out an alternative intervention to increase the CRC screening rate among middle-aged citizens in a particular area, consisting of postal or telephone notification and educa-

tion for CRC screening.[28] The authors concluded that telephone intervention, and combined telephone and postal intervention, were both effective in improving the participation rate for CRC screening.[28] Our study builds on this report, with novel findings regarding the effects of round-mailed FIT screening and its acceptable cost-effectiveness. In addition, our study is also meaningful as an intervention using a more convenient and satisfactory tool for sampling (the FIT kit or sampling bottle), which differs from the conventional container used for the NCSP.[29] However, it is important to note that even though FIT is accepted as a cost-effective screening tool that is suitable for programmatic screening,[6,12] a postal FIT screening program needs to be carefully designed and implemented based on thorough consideration of economic impact, competence of the eligible population, and local conditions in the target region.

In summary, this study demonstrates that round-mailed FIT combined with phone call reminders is an effective way to increase CRC screening rates in underserved regions, though it can be limited by the educational level and previous participation of subjects in NCSP screening. In addition to the community-level barriers addressed by this intervention, further interventions at an individual-level, such as systematic counseling, patient navigation, or education regarding screening could allow more comprehensive approach, provided they are based on sufficient evidence and have acceptable cost-effectiveness. Further research followed by a coordinated and sustained policy are required to implement an effective strategy to increase CRC screening in appropriate groups, which may lead to an overall reduction in the burden of CRC in Korea.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

ACKNOWLEDGEMENTS

This study was supported by a Grant-in-Aid for Cancer Research and Control from the National Cancer Center of Korea (grant number: 1910233-1).

AUTHOR CONTRIBUTIONS

Data analysis and interpretation: S.H. Data acquisition: H.Y.S., B.L., J.K.J. Administrative, technical, and material support: N.R.H., S.H.H. Drafting of the manuscript: S.H. Study concept and design, critical revision of the manuscript for important intellectual content, obtaining funding, and study supervision: J.K.J.

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