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ARTICLE

Pre-formulated implementation intentions to promote colorectal cancer screening: a cluster-randomized trial

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Abstract

Objective – To evaluate an intervention based on implementation intention principles designed to increase uptake of colorectal cancer screening, and examine differential efficacy by socioeconomic deprivation.

Methods – In England, adults aged between 60 and 69 are invited to do biennial FOB testing, with test kits and an information leaflet mailed to each individual by the 'Hubs' that deliver the national screening program. In the intervention group, three preformulated implementation intentions based on known barriers to carrying out the test, were added to the information leaflet. Over a twelve-week period, each week was randomly allocated to either the intervention (n = 12,414 invitations) or control condition (n = 10,768), with uptake recorded at the Hub. Socioeconomic deprivation of each individual's area of residence was categorized into tertiles.

Results – There was no overall difference in uptake between control (40.4%) and intervention (39.7%) conditions (OR = 0.97, 95% CI: 0.91-1.04). There was an interaction with deprivation (OR = 1.11, 95% CI: 1.04 - 1.18), but the positive effect observed in the lowest SES tertile was small (35.2% vs. 33.0%; OR= 1.103, 95% CI: 1.01-1.21) and offset by a negative effect in the least deprived tertile (45.6% vs. 48.2%; OR= 0.90, 95% CI: 0.82-0.99). The intervention had no significant effect in the middle tertile (38.9% vs. 40.8%; OR= 0.92, 95% CI: 0.81-1.04).

Conclusions – Pre-formulated implementation intentions did not increase overall colorectal cancer screening uptake and failed to make a sufficiently large impact on uptake among lower SES groups to merit their future use in this context.

Keywords: Colorectal cancer; screening; implementation intentions; interventions; socioeconomic deprivation

Introduction

Colorectal cancer (CRC) is the second commonest cause of cancer death in developed countries (International Agency for Research on Cancer, 2012). Many of these deaths could be prevented by regular screening. FOB (fecal occult blood) testing reduces CRC mortality by 27% (Hewitson, Glasziou, Watson, Towler, & Irwig, 2008; Scholefield, Moss, Sufi, Mangham, & Hardcastle, 2002) and endoscopic screening can reduce CRC mortality by over 40% (Atkin et al., 2010; Schoen et al., 2012; Zauber et al., 2012). However, uptake rates for all forms of CRC screening tend to be low (Denis et al., 2009; Deutekom et al., 2010; Meissner, Breen, Klabunde, & Vernon, 2006; Meissner et al., 2004; Senore et al., 2012; Shapiro et al., 2012). An additional concern is the markedly lower uptake in lower socioeconomic status (SES) groups. Even in the United Kingdom (UK), where the National Health Service sends a personal invitation for free CRC screening to all adults age 60-69, uptake rates in the most deprived quintile of residential areas are barely half those of the least deprived quintile of areas (35% vs. 61%; von Wagner et al., 2011). Strategies to increase CRC screening uptake, and particularly strategies that are effective in lower SES groups, have the potential to reduce overall mortality and reduce health inequalities. This study reports the results of an intervention aimed at increasing home-based FOB screening among a population sample of men and women in the UK.

Public attitudes towards CRC screening in the UK are broadly positive, with more than 80% of survey respondents indicating it was 'a good idea' in one study (Taskila et al., 2009), and more than 95% of respondents intending to screen with FOB in another (Vart, 2010). Although these results are limited to survey respondents whose attitudes may be relatively more positive, they suggest that low uptake is due, at least partly, to failure to translate positive screening intentions into action. Interventions to increase screening participation might therefore look to strategies that reduce the 'intention-action gap'. One such intervention is the use of 'implementation intentions'; in which respondents are encouraged to answer simple questions about where, when and how to carry out the intended behavior (e.g. 'If I am in situation X, then I will do Y') (Gollwitzer, 1999; Gollwitzer & Sheeran, 2006). Studies across many health and non-health domains have shown beneficial effects when intending respondents use implementation intentions (Sheeran, 2002; Webb & Sheeran, 2006). The hypothesized mechanism is that planning how to achieve a goal helps manage the 'self-regulatory problems that can undermine the translation of intentions into behavior' (Sheeran, Aubrey, & Kellett, 2007).

Three implementation intention studies have been done in the medical screening field. Promisingly, Sheeran and Orbell (2000) found that attendance for cervical screening was substantially higher among a small sample of survey respondents who were asked to form an implementation intention than those who were not. However, two other studies found no significant overall effect on attendance for antenatal

screening or mammography, although post-hoc analyses showed that those who had formed implementation plans as requested were more likely to attend (<u>Michie</u>, <u>Dormandy</u>, <u>& Marteau</u>, 2004; <u>Rutter</u>, <u>Steadman</u>, <u>& Quine</u>, 2006). These findings raise the issue that compliance with a request to form implementation intentions may be limited. An alternative approach is to offer 'pre-formulated' implementation intentions. In a study of attendance at psychotherapy appointments, mailed, pre-formulated implementation intentions resulted in significantly higher attendance than usual care (<u>64% vs. 50%; Sheeran, et al., 2007</u>). The context of home-based screening tests, where there is no direct interaction with the service provider, could be another area where pre-formulated implementation intentions would be useful.

One important issue that has attracted little attention to date is whether implementation intention approaches are equally effective across the whole SES distribution. In the interest of promoting equity in health outcomes, health promotion strategies should not increase inequalities in health behaviors. The three screening studies described above were carried out in general population samples but did not specifically examine SES moderation of the treatment effect. Health education interventions often have more impact in higher SES groups (Victora, Vaughan, Barros, Silva, & Tomasi, 2000); however, implementation interventions might be an exception because there is evidence that socioeconomically deprived individuals more frequently fail to translate positive screening intentions to action (Power et al., 2008).

The first aim of the present study was therefore to test the hypothesis that implementation intentions would increase uptake of home-based FOB testing in a UK population. The second aim was to examine SES differences in the effect of the intervention. The study was carried out in the Greater London area, which is socioeconomically diverse and has poor overall FOB uptake (von Wagner, et al., 2011).

Methods

Setting and participants

The CRC screening program in England (UK) is delivered by five regional screening 'Hubs', without direct involvement of primary care providers. All men and women aged 60-69 years (to be extended to 74 years) are sent a biennial guaiac-based Fecal Occult Blood test (FOBt) to complete at home. The FOBt kit is sent with a detailed information leaflet explaining how samples should be taken and how to return the kit to the Hub by mail. The Hub processes the samples, sends results letters to the patients, and makes arrangements for any follow-up testing.

This study was carried out in the 'London Hub', and used data on all individuals who were sent an invitation for their first round of screening between August and November 2009. Randomization to intervention or control was by week within this period with a simple randomized cluster design using a random number generator to allocate a leaflet condition to each week (<u>StataCorp., 2009</u>).¹ The total sample size

¹ The intervention period ran for 12 weeks, with 8 weeks allocated to either the implementation intention condition or the control condition resulting in 4 clusters per condition. The remaining 4 weeks

was 23,182 across the eight clusters, with 12,414 individuals in the intervention clusters and 10,768 in the control clusters.

Procedure

FOB test kits are routinely sent out together with a leaflet on how to collect the stool samples (NHS Bowel Cancer Screening Programme, 2009). During the control weeks, the standard instruction leaflet was sent. In the implementation intention weeks, a modified leaflet was sent which contained all the material in the standard leaflet plus three pre-formulated implementation intention plans (see Figure 1).

Measures

The outcome dataset included anonymized individual-level data on whether the test kit had been returned (uptake), condition (implementation intentions vs. control), gender, age group (60-64 vs 65-69), and an area-level measure of socioeconomic deprivation derived from the 2007 Index of Multiple Deprivation (IMD) (Noble, McLennan, Wilkinson, & Barnes, 2007) which is based on census-derived indicators of income, education, employment, environment, health, and housing at small-area level. To see whether the intervention had differential impact in those with lower and higher socioeconomic deprivation we used a similar approach to Wardle et al. (2003) and used IMD scores to divide the sample into tertiles. This provided the simplest strategy for exploring the interaction between SES and the intervention without losing the ability to detect any non-linear trends.

Implementation intention intervention

The three pre-formulated implementation intentions (described in the leaflet as 'Top Test Tips') were inserted into the text of the standard leaflet. They addressed three common barriers that have been associated with failure to translate a positive CRC screening intention to behavior: lack of confidence to manage the practicalities of the stool sampling, forgetting to do the test, and feeling negative about the test procedure (see Box 1) (<u>Chapple, Ziebland, Hewitson, & McPherson, 2008; Hunter et al., 1991; Power, Miles, von Wagner, Robb, & Wardle, 2009; Wolf et al., 2001)</u>.

Data Analysis

To test for differences in FOB test kit return between conditions, and interactions with SES, random-intercept logistic regression modeling was used with FOB test kit return as the dependent variable, condition as the independent variable, tertiles of area-level deprivation as the planned moderator, and age group and gender as control variables. The random-intercept was based on the group-level variable 'invitation week' (i.e. the clusters in the trial) and was included to control for seasonal variation between weeks allocated to the experimental and control conditions using the multi-level modeling options built into Stata SE12 (<u>StataCorp., 2009</u>).

Results

were allocated to another experimental condition that was later excluded from the reported analyses because of a printing error.

Overall CRC screening uptake rate in the test period was 40.3%. Uptake by gender, age group, and deprivation tertile is shown in Table 1. As expected, women were more likely to return the kit than men (44.1% vs 36.6%; OR: 1.27, 95% CI: 1.18 - 1.38), and 65-69 year olds were more likely to return the kit than 60-64 year olds (42.1% vs 39.6%; OR = 1.11, 95% CI: 1.06 - 1.16). Those in the most deprived tertile (34.5%) were less likely to return the kit than those in the middle (39.8%) or least deprived tertile (47.2%) (OR = 0.77, 95% CI: 0.75 - 0.79). There was no significant cluster-level effect (intra-cluster correlation coefficient = .0004; χ^2 (1) = 1.78, p = .09) which indicated that individuals' screening uptake within each invitation week were independent of one another; in other words, effects of seasonal variation were negligible.

Overall uptake was not significantly different between intervention periods and control periods (39.7% vs. 40.4%; OR = 0.97, 95% CI: 0.91-1.04). Multivariate regression showed that there was a significant interaction between SES and condition (OR = 1.11, 95% CI: 1.04 - 1.18). As illustrated in Figure 2, the intervention had a small, positive effect for the most deprived tertile (OR = 1.10, 95% CI: 1.01-1.21), no significant effect in the middle tertile (OR = 0.92, 95% CI: 0.81-1.04), and a small, negative effect in the least deprived tertile (OR = 0.90, 95% CI: 0.82-0.99).

Discussion

This cluster-randomized trial is the first large-scale evaluation of implementation intentions in the context of an existing health care program. It tested the effect of adding pre-formulated implementation intentions to the standard information leaflet on FOBt uptake in the English CRC screening program. Contrary to our hypothesis, we saw no significant overall effect of pre-formulated implementation intentions on screening uptake. The small interaction between SES and the implementation intention intention was statistically significant due to the large sample size, but has limited clinical or public health significance. More importantly, the finding that the increase among the low SES group was offset by a negative effect among the high SES group further compromised the viability of this intervention as a strategy for large screening programs.

This negative finding is consistent with two previous studies of screening uptake that reported no success in the application of implementation intentions in general population samples (<u>Michie, et al., 2004</u>; <u>Rutter, et al., 2006</u>), although the previous cancer screening study by Sheeran and Orbell (2000) had positive results.

One reason why implementation intentions may be less effective in FOB testing than in other domains is that there are motivational barriers to undertaking FOB testing, although the present study does not provide data to test this hypothesis. A recent study showed that as survey respondents learned the reality of undertaking FOB testing (e.g., fecal sampling, repeated sampling), their intentions to undertake the test declined significantly (von Wagner, Good, Smith, & Wardle, 2011). Implementation intentions are known to be more effective only for groups who are motivated to perform the behavior (Sheeran, Webb, & Gollwitzer, 2005). Thus, the implementation intention intervention tested here might not have benefited screening uptake because participants revised their intentions to undertake FOB testing downwards when they received the test. Interventions might be more effective if the motivational processes that lead to downward revision of intentions are addressed first (<u>Dillard, Fagerlin, Dal Cin, Zikmund-Fisher, & Ubel, 2010</u>; <u>Hewitson, Ward, Heneghan, Halloran, & Mant, 2011</u>).

Another factor that could have contributed to the lack of effect was the use of preformulated implementation intentions in an information leaflet. Unlike the present study, a previous successful intervention presented pre-formulated implementation intentions in a questionnaire (Sheeran, et al., 2007). Presentation in an information leaflet may not have engaged individuals sufficiently for the implementation intentions to facilitate planning which is believed to be a key process underlying their effectiveness in overcoming practical or emotional barriers to action (Gollwitzer & Sheeran, 2006).

Conclusion

This cluster-randomized, controlled trial examined the effectiveness of pre-formulated implementation intentions in increasing uptake in the English CRC screening program. Adding implementation intentions to standard information did not improve overall uptake of CRC screening in the general target population. This suggests that pre-formulated implementation intentions are not suitable as a general strategy to promote cancer screening.

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	Total	Control	Implementation intentions
	(n = 23,182)	(n = 12,414)	(n = 10,768)
Overall	40.3%	40.4%	39.7%
Gender			
Men	36.6%	37.5%	35.5%
Women	44.1%	43.3%	43.9%
Age			
60-64	39.6%	39.9%	39.3%
65-69	42.1%	42.0%	40.9%
Area-level deprivation			
Lower deprivation	47.2%	48.2%	45.6%
Medium deprivation	39.8%	40.8%	38.9%
Higher deprivation	34.5%	33.0%	35.2%

Table 1: FOBt screening uptake by gender, age, and deprivation

Figure 1

TOP TEST TIP 1. Get organized.

Plan how you will collect your samples (e.g., using kitchen roll or a container) and where you should place the items you need (near the toilet). Tell yourself: 'As soon as I have finished reading this leaflet, then I will place the test kit and the things I need to collect my samples in my chosen location near the toilet.'

TOP TEST TIP 2. Get going.

Tell yourself: 'As soon as I have the opportunity, then I will take my first sample!... As soon as I can after that I will take my second sample!... And when I have a third opportunity, then I will take my final sample!'

TOP TEST TIP 3. Don't get put off.

Taking a sample is simple to do. Remember, the test has proven medical benefits. Keep telling yourself: 'If I feel reluctant to do the test, then I will ignore that feeling and look at the situation as if I were a doctor!'

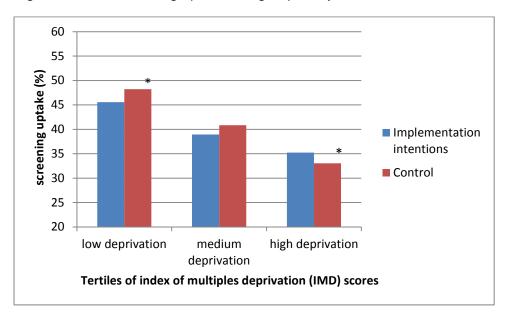


Figure 2: FOBt screening uptake: subgroup analyses

