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REPORT



## Testing Enhanced Active Choice to Optimize Acceptance and Participation in a Population-Based Colorectal Cancer Screening Program in Malta

Sandro T. Stoffel<sup>a,b,c</sup> , Mariella Bombagi<sup>d</sup>, Robert S. Kerrison<sup>b</sup> , Christian von Wagner<sup>b</sup> , and Benedikt Herrmann<sup>a</sup>

<sup>a</sup>Joint Research Centre, European Commission, Ispra, Italy; <sup>b</sup>Research Department of Behavioural Science and Health, University College London, London, UK; <sup>c</sup>Institute of Pharmaceutical Medicine, University of Basel, Basel, Switzerland; <sup>d</sup>Ministry for Health Malta, Valetta, Malta

### ABSTRACT

Opt-out strategies have been shown to improve participation in cancer screening; however, there are ethical concerns regarding the presumed consent. In this study, we tested an alternative opt-in strategy, called: “enhanced active choice,” in which the response options summarize the consequences of the decision. The study was conducted as part of the Maltese colorectal cancer screening program, which offers men and women, aged 60–64, a “one-off” fecal immunochemical test (FIT). A total of 8349 individuals were randomly assigned to receive either an invitation letter that featured a standard opt-in strategy (*control condition*), or an alternative letter with a modified opt-in strategy (*enhanced active choice condition*). Our primary outcome was participation three months after the invitation was delivered. Additionally, we also compared the proportion who said they wanted to take part in screening. We used multivariable logistic regression for the analysis. Overall, 48.4% (N = 4042) accepted the invitation and 42.4% (N = 3542) did the screening test. While there were no statistically significant differences between the two conditions in terms of acceptance and participation, *enhanced active choice* did increase acceptance among men by 4.6 percentage points, which translated to a significant increase in participation of 3.4 percentage points. We conclude that enhanced active choice can improve male screening participation. Given the higher risk of CRC in men, as well as their lower participation screening, we believe this to be an important finding.

### KEYWORDS

active choice; cancer screening; decision making; enhanced; field experiment; nudge; opt-in; participation; uptake active choice

### Introduction

Colorectal cancer (CRC) is the second leading cause of cancer death in Malta. Mortality from the disease has declined in recent years, due to the implementation of effective methods for prevention, early detection, and treatment.<sup>1,2</sup> Free routine screening, for example, was introduced in 2012, with all residents aged between 60 and 64 years being offered a “one-off” fecal immunochemical test (FIT).<sup>3</sup> The Maltese Colorectal Cancer Screening Programme (CRSP) consists of two stages: a preliminary stage, in which all individuals eligible to participate in the program were sent a pre-invitation letter through the mail, and a second stage, where individuals who responded to the first stage to “opt in” were sent a free FIT kit and pre-addressed return envelope.<sup>4</sup>

At present, screening uptake is below the international Benchmark for acceptable participation set out by the European guidelines for quality assurance in bowel cancer screening (i.e. 65%), with only 35.7% of the invited population accepting the screening test offer.<sup>5</sup> For screening programmes to be effective and cost-effective, it is imperative they achieve and maintain high participation. There is thus a strong public health mandate in Malta for low cost, evidence-based approaches to make screening more accessible.

Previous studies have shown that opt-out invitations, which automatically invite those who do not reply, result in higher participation than “opt-in” invitations, as individuals participate by default, without having to explicitly consent.<sup>6–9</sup> However, there have been concerns about the ethics of this practice.<sup>10,11</sup>

**CONTACT** Benedikt Herrmann  benedikt.herrmann@ec.europa.eu  Joint Research Centre, European Commission, Via E. Fermi, 2749, 21027 Ispra, Italy.

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The opt-out approach is based on the status-quo bias and loss aversion, which result in individuals choosing the default option.<sup>8,12</sup>

While opt-out defaults have the advantage of including individuals who would not otherwise participate, there are some limitations for using them in CRC screening. Firstly, although as a result of inaction, participation may be enhanced in the short-term, screening programs with regular screening intervals require a longer commitment to screening to ensure public health benefits are achieved. Secondly, the provision of a single rigid "opt-out option" can disadvantage some individuals, if there is no single optimal behavior for everybody. In such situations, opt-out are less beneficial.<sup>13</sup> Thirdly, substantial waste and inefficiency may result from "no-shows" among those sent test kits as a consequence of a default policy.<sup>13</sup> Finally, unsolicited participation in the testing phase can be considered unethical, and may be legally challenged, since informed consent to participate was not obtained.<sup>10,11</sup>

Several studies, therefore, have championed alternative behavioral interventions that allow individuals to make an explicit decision.<sup>14</sup> A possible alternative approach consists of individuals affirmatively choosing between attending screening or not. Different to the opt-out or opt-in, this "active choice" approach focuses on individuals making an explicit choice. Several studies on organ donation, retirement planning and immunization and enrollment in a prescription automatic refill program proposed and investigated such active decisions.<sup>13,15–17</sup>

Spital found in representative surveys that individuals would support active choice approaches that force them to state whether they want to donate their organs and advocate a policy that would require individuals to record their decision.<sup>16,18,19</sup> Carroll and colleagues found in an observational study that required individuals to explicitly choose between enrolling and not enrolling in a retirement plan significantly increased enrollment compared to opt-in.<sup>17</sup>

Keller and colleagues were the first to test the active choice approach in lab and field experiments in the context of flu shots and prescription refills.<sup>13</sup> They showed that the effectiveness of active choice can be enhanced by highlighting some of the key advantages and disadvantages of the two choice alternatives. Specifically, by framing the response options in such a way that they favor the desired option by highlighting its benefits and losses incumbent to the alternative, they found that active choice increased intentions and adherence compared to opt-in. They called their

approach "enhanced active choice," as it advantaged the option preferred by the communicator in the framing of the options.

Enhanced active choice targets procrastination, or decision avoidance, by appealing to regret aversion, or anticipated regret, from not choosing the desired option.<sup>13</sup> Using active choice approaches that require individuals to make an active decision about participating in a public health program could increase public commitment and public health.<sup>10,19,20</sup>

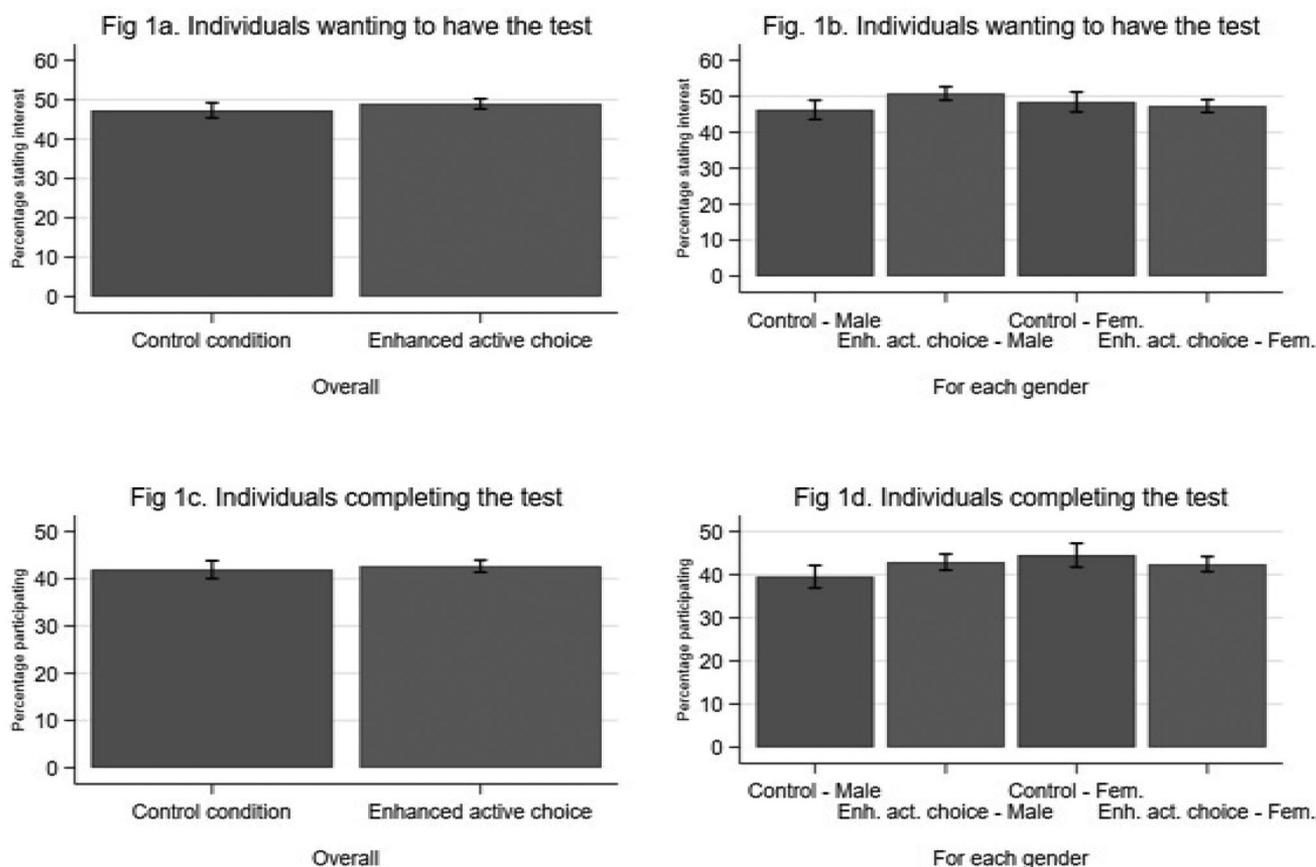
In this study, we tested the effectiveness of enhanced active choice, against a standard opt-in approach, to promote acceptability and uptake in the Maltese CRSP. To the best of our knowledge, this is one of the first study to investigate enhance active choice in cancer screening. A previous study by Metha and colleagues did not find that enhanced active choices increased colonoscopy uptake among an employee population.<sup>21</sup>

In line with the previous literature, we hypothesized that enhanced active choice would increase the likelihood of accepting the screening invite and participate in the program.

## Methods

To investigate the effectiveness of enhanced active choice in a population-based CRC screening program, we conducted a randomized controlled trial (RCT) with two conditions. In total 8349 adults, aged between 60 and 64 (4287 [51.3%] screening naïve women and 4062 [48.7%] men), were invited in 2015 and individually randomized by a computer (2:1 allocation) to receive either the enhanced active choice condition (N=5749) or the control condition (N=2600). Unequal allocation was used to test within-group differences between individuals allocated to the enhanced active-choice condition.

As per usual care, the invitation mailing kit contained a pre-invitation letter with a short description of CRC and its screening methods. The mailing kit was in English and Maltese. The back of the letter contained a closed question about the person's interest in participating in the screening program and receiving a free FIT test by mail: "*Would you like to participate and get screened for colorectal cancer?*" The only difference between the two conditions was the framing of the response options to the question. In the English version, the control condition featured the response options "No" and "Yes," while the enhanced active choice condition had "*Yes, I want to participate and get screened for colorectal cancer to reduce the risk of*



**Figure 1.** Acceptance of the screening invite and participation in the screening programme in the two experimental conditions (N = 8349).

suffering from this cancer later and to benefit from the effectiveness of early treatments in case of having this cancer" and "No, I would not like to participate in the colorectal cancer screening programme, even if it makes later medical treatments in case I should have this cancer more difficult." The content was developed with the Ministry for Health Malta and was aimed at reminding individuals, at the moment of making the screening decision, about the potential difficulties of late cancer diagnosis. The English and Maltese versions of the invitation can be found at OSF: <https://osf.io/jrafq/>.

Both mailings included a pre-addressed return envelope. The primary outcome of interest was participation within each study group, which was defined as returning the FIT kit. A secondary outcome of interest was acceptance of the screening invite, which was defined as communicating with the screening program that they want to receive a test kit.

Descriptive statistics were used to report the number of people who accepted the invite and participated by returning the kit within three months. Multivariable logistic regression was used to test for differences between the control and experimental condition, after

adjusting for gender as a co-variate. Exploratory subgroup analyses were performed by gender, to test for independent effects for men and women. Sample size was calculated prior to data collection and based on real uptake and estimated effect sizes from the literature. The study was sufficiently powered to detect differences of at least 3% in participation between conditions, with a power of 80% and an alpha value of 0.05.<sup>22</sup> The study protocol was approved by the Health Ethics Committee.

## Results

Figure 1 and Table 1 show acceptance and participation across the two experimental conditions; 47.3% (N = 1229) in the control condition and 48.9% (N = 2813) in the enhanced active choice condition contacted the center to participate in screening, indicating that the new the enhanced active choice intervention did not significantly increase acceptance (adjusted Odds Ratio [aOR] 1.07; 95% confidence intervals [CI]: 0.98–1.18,  $p = 0.141$ ). Similarly, there was no statistically significant difference in

**Table 1.** Logistic regression on acceptance and participation (N = 8349).

	Acceptance to have the test					Recorded participation of the test				
	Total (%)	Model 1		Model 2		Total (%)	Model 3		Model 4	
		OR	95% CI	OR	95% CI		OR	95% CI	OR	95% CI
<b>Overall</b>	48.4					42.4				
<b>Condition</b>										
Control	47.3	Ref.				41.9	Ref.			
Enhanced active choice	48.9	1.07	0.98 – 1.18			42.7	1.03	0.94 – 1.13		
<b>Gender</b>										
Male	49.3	Ref.				41.8	Ref.			
Female	47.6	0.93	0.86 – 1.02			43.0	1.05	0.96 – 1.15		
<b>Interaction</b>										
Male - control	46.2			Ref.		39.5			Ref.	
Male - enh. act. choice	50.8			1.20	1.05 – 1.37**	42.9			1.15	1.01 – 1.31*
Female - control	48.4			1.09	0.94 – 1.27	44.5			1.23	1.05 – 1.43*
Female - enh. act. choice	47.3			1.04	0.92 – 1.19	42.4			1.13	0.99 – 1.27
<i>N</i>		8,349		8,349			8,349		8,349	

Abbreviations: Enh. act. choice: enhance active choice; \*  $p < 0.05$ ; \*\*  $p < 0.01$ .

participation between the two conditions; participation was 42.7% (N = 2452) and 41.9% (N = 1090) in the enhanced active choice and control conditions, respectively (aOR 1.03; 95% CI: 0.94–1.13,  $p = 0.565$ ). Overall 48.4% accepted the screening invitation and 42.4% participated

The results of the interaction analysis demonstrate that enhanced active choice increased acceptance among men by 4.6 percentage points (50.8% vs 46.2%; OR 1.20; 95% CI: 1.05–1.37,  $p = 0.006$ ), which translated to a significant 3.4 percentage point increase in participation (42.9% vs 39.5%, aOR 1.15; 95% CI: 1.01–1.31,  $p = 0.040$ ). Among women, enhanced active choice did not affect acceptance or participation; 48.4% (N = 607) of women accepted the invitation in the control condition, while 47.3% (N = 1434) accepted it in the enhanced active choice condition ( $p = 0.502$ ). While not statistically significant, participation for women was higher in the control condition (44.5%) than in the enhanced active choice condition (42.4%,  $p = 0.214$ ). In the control condition, female participation was significantly higher than male participation (44.5% vs 39.5%; OR 1.23; 95% CI: 1.05–1.43,  $p = 0.010$ ).

## Discussion

Our field experiment found that enhanced active choice did not increase overall screening acceptance or participation compared to the standard opt-in process. Enhanced active choice did, however, significantly increase acceptance and participation among men. While the results for the male population are in line with previous research, which shows a positive impact of an enhanced active choice on individual commitment, the almost statistically significant negative effect impact of enhanced active choice on female

screening behavior merits some further investigation.<sup>13</sup> Some studies have argued that the higher participation rate may be caused by the increased perceived responsibility with the decision and anticipated regret.<sup>13,23,24</sup>

The finding that active choice improved CRC screening acceptance and participation among men, specifically, is highly important. Men have higher risk of CRC and CRC death compared with women.<sup>25</sup> In line with previous studies we find that men are less likely to participate in the control condition than women.<sup>25,26</sup> Adding active choice to the invitation letter, therefore, could improve participation and, thereby, the proportion of CRCs diagnosed in men at an early stage. This, in turn, would reduce differences in CRC deaths between the sexes.

Finally, while overall uptake was higher than in previously reported studies, it was still below the international Benchmark for acceptable participation, implying that other evidence-based interventions should be tested to make screening more accessible in Malta.<sup>5</sup>

Strengths of our study include the use of a randomized controlled trial design and the use of objective data for acceptance and participation. Our study shows the importance of proof-of-concept experiments to generate reliable evidence of the interventions in other settings.<sup>27</sup> While enhanced active choice has been used successfully in the context of immunization and enrollment in a prescription automatic refill program, we found limited evidence that it affects cancer screening behavior.<sup>13</sup>

A limitation of our study is that we only collected information about the participant's gender for the analysis. Little is known about how other socio-economic variables, such as education and health literacy, would influence the perception of enhanced active choice, as

Keller and colleagues only report univariate statistics, and do not provide information about the descriptive characteristics of their samples.<sup>13</sup> Future studies could test whether the effect of enhanced active choice affect is mitigated by socio-economic characteristics of the participants. A further limitation of this study is that the messages used as response options in the enhanced active choice condition were not co-developed with patients, but stakeholders in the screening program. It is, therefore, possible that the messages did not communicate the information accurately. We would, therefore, advocate using patient involvement and engagement to develop enhanced active choice interventions in future studies and implementation.

## Conclusions

Our study finds that the enhanced active choice is an equivalent alternative to standard opt-in settings in terms of overall screening behavior. Its positive effect on male participation could reduce differences in screening participation and diagnosis. The study shows that enhanced active choice is relatively easy to implement and cost-neutral as it only involves changes to the framing of the participation question. This intervention could benefit many countries with similar CRC screening programs and differences in participation.

## Open practices

The materials and data for the experiments are available at OSF: <https://osf.io/jrafg/>.

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## Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

## ORCID

Sandro T. Stoffel  <http://orcid.org/0000-0002-0124-0941>  
 Robert S. Kerrison  <http://orcid.org/0000-0002-8900-749X>  
 Christian von Wagner  <http://orcid.org/0000-0002-7971-0691>

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