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Anticipated regret to increase uptake of colorectal cancer screening (ARTICS): A randomised controlled trial

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ABSTRACT

Screening is important for early detection of colorectal cancer. Our aim was to determine whether a simple anticipated regret (AR) intervention could increase uptake of colorectal cancer screening. A randomised controlled trial of a simple, questionnaire-based AR intervention, delivered alongside existing pre-notification letters, was conducted. A total of 60,000 adults aged 50–74 years from the Scottish National Screening programme were randomised into the following groups: (1) no questionnaire (control), (2) Health Locus of Control questionnaire (HLOC) or (3) HLOC plus AR questionnaire. The primary outcome was return of the guaiac faecal occult blood test (FOBT). The secondary outcomes included intention to return test kit and perceived disgust (ICK). A total of 59,366 people were analysed as allocated (intention-to-treat (ITT)); no overall differences were seen between the treatment groups on FOBT uptake (control: 57.3%, HLOC: 56.9%, AR: 57.4%). In total, 13,645 (34.2%) individuals returned the questionnaires. Analysis of the secondary questionnaire measures showed that AR indirectly affected FOBT uptake via intention, whilst ICK directly affected FOBT uptake over and above intention. The effect of AR on FOBT uptake was also moderated by intention strength: for less-than-strong intenders only, uptake was 4.2% higher in the AR (84.6%) versus the HLOC group (80.4%) (95% CI for difference (2.0, 6.5)). The findings show that psychological concepts including AR and perceived disgust (ICK) are important factors in determining FOBT uptake. However, the AR intervention had no simple effect in the ITT analysis. It can be concluded that, in those with low intentions, exposure to AR may be required to increase FOBT uptake. The current controlled trials are presented at the website www.controlled-trials.com (number: ISRCTN74986452).

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1. Introduction

Colorectal cancer is the second leading cause of death from cancer in many Western countries including the UK (SIGN, 2011). Screening is important for early detection, which in turn is associated with reduced mortality (Jørgensen et al., 2002). Therefore, many countries have introduced national programmes of colorectal cancer screening. In Scotland, all adults aged 50–74 years are invited, every 2 years, to complete a guaiac faecal occult blood test

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(FOBT) by collecting their own faecal samples and returning the test kit by post for testing. A recent matched cohort study found that this national programme has reduced the overall colorectal cancer mortality by 10%, and by 27% amongst those who returned a completed test kit (Libby et al., 2012).

Despite the clear benefits of screening, uptake is often suboptimal, with overall participation rarely exceeding 60% (von Euler-Chelpin et al., 2010). In Scotland, from November 2011 to October 2013, the participation rates ranged from 42% for men living in the most deprived areas to 68% for the least deprived women (ISD, 2014), indicating a common marked social gradient in participation. This social gradient is of particular concern, as poorer survival following a diagnosis of colorectal cancer is also associated with lower socio-economic status (von Euler-Chelpin et al., 2010). Thus, the potential benefit of FOBT screening, in terms of early detection

and better survival, will depend on the level of uptake, therefore increasing this is a priority particularly amongst lower socio-economic groups.

A large ($n = 60,000$), randomised controlled trial (RCT) was conducted to investigate the efficacy of a simple pre-notification letter (with and without an explanatory booklet) within the Scottish national colorectal cancer screening programme. The results showed significantly higher uptake with both the pre-notification letter (59.0%) and the letter plus booklet (58.5%), than with the usual invitation without prior notification (53.9%) (Libby et al., 2011). Importantly, the increases were observed for men and women of all age groups and all deprivation categories, including the groups with the highest and lowest levels of uptake, that is, the least deprived women (letter 69.9%, usual invitation 66.6%) and the most deprived men (42.6% and 36.1%). This indicates that simple postal interventions can be effective in increasing FOBT uptake across all socio-economic groups. As a result of these findings, the pre-notification letter has become standard practice in the Scottish screening programme. However, many fail to reap the benefits of screening, for example, around 45% of people who are posted FOBT kits still do not complete and return them.

Health behaviours, such as screening participation, are considered to be shaped by the following two distinct systems: (1) a reflective, rational, goal-oriented system driven by values and intentions, requiring cognitive capacity and (2) an automatic, affective system, requiring little or no cognitive engagement, guided by immediate feelings and emotions (Strack and Deutsch, 2004). The emotion of 'anticipated regret' (AR) has been recently tested in health behaviour change interventions. Regret is a negative cognitive-based emotion experienced when an individual believes that the present situation could have been better had he or she acted differently. It is also possible to *anticipate* regret, and thus decide to take action to avoid actually experiencing this unpleasant emotion. AR may be particularly relevant to cancer screening, where a lack of screening may result in a poorer outcome if subsequently diagnosed (e.g., a more advanced and perhaps untreatable cancer). Abraham and Sheeran (2003) demonstrated that AR adds significantly to the prediction of intentions and exercise behaviour over and above the traditional attitudinal components of the theory of planned behaviour (TPB) (Ajzen, 1991). Further, the additional effect of AR has been observed across a range of health behaviours including those that may be considered protective (e.g., condom use and physical activity), risky (e.g., smoking and unhealthy diet) and/or preventive (e.g., dental check-ups and self-examination) (Conner et al., 2015; Sandberg and Conner, 2008; Sheeran et al., 2014). Essentially, AR strengthens behavioural intentions and drives people to action, because failing to act is associated with aversive emotions. AR has previously been tested in cervical cancer screening: Sandberg and Conner (2009) randomised women who were due to be invited for a screening into the following groups: (1) a control group, (2) a group sent a TPB questionnaire and (3) a group sent a TPB questionnaire plus two AR questions: 'If I did not attend for a cervical smear in the next few weeks I would feel regret' and 'If I did not attend for a cervical smear in the next few weeks, I would later wish I had'. The overall screening attendance was 21%, 26% and 26%, respectively (i.e., simply sending out a questionnaire appeared to increase attendance by 5%). The attendance rates of those who completed and returned the questionnaire (i.e., those who were definitely exposed to the intervention) were 44% (TPB) and 65% (TPB plus AR). Compared with the 21% uptake in the control group, this represents a remarkable effect for so simple an intervention. In the context of colorectal cancer screening, Ferrer et al. (2012) tested the effect of loss- versus gain-framed messages and, consistent with previous research, found that loss-framed messages (i.e., where people are

asked to consider the negative outcomes of not attending screening) were more effective in increasing intentions to screen. The authors speculated that AR and worry may be triggered in response to such loss-framed messages.

Another psychological barrier to participating in FOBT screening is the emotion of disgust (the 'ICK' factor: Morgan et al., 2008; O'Carroll et al., 2011). In a recent systematic review, Reynolds et al. (2012) concluded that anticipated disgust was a contributory factor in avoiding colorectal cancer screening. Reynolds et al. (2014) also demonstrated experimentally that trait disgust moderated the influence of state disgust on *anticipated* avoidance, specifically delaying seeking help for bowel symptoms. Another recent study of >6000 participants found that two major perceived barriers to colorectal cancer screening were commonly reported: 'I do not want to handle my stool' and 'I do not want to keep my stools on a card in my house' (Jones et al., 2010). Patients have also expressed discomfort or shame on posting their faecal samples in the mail (Chapple et al., 2008; Palmer et al., 2014). Other psychological factors possibly affecting participation in cancer screening are perceived benefit of screening and beliefs about control over one's health (Health Locus of Control (HLOC)) (Wallston et al., 1978), that is, the extent to which people believe their health and health outcomes are determined primarily by (a) themselves (internal), (b) chance/fate and (c) powerful others (e.g., doctors). It is hypothesised that individuals who believe their health is largely predetermined by fate (i.e., high chance) would be significantly less likely to participate in colorectal cancer screening.

For many years, it has been noted that health-related intentions, behaviour and/or related cognitions may change as a result of being measured, but the exact magnitude and mechanism of this effect is unclear. This has been called the *mere-measurement effect* (Sherman, 1980; Morwitz and Fitzsimons, 2004) or, more recently, the *question-behaviour effect* or QBE. In a recent review of this area, Rodrigues et al. (2015) stated: 'Investigation of the QBE on health-related behaviors is important for research as well as for evidence-based practice in health care (French and Sutton, 2010). The positive implications of the QBE on behavior for health care practice is that many forms of measurement, such as self-report questionnaires, are inexpensive and could be distributed widely. If their completion is found to lead to desirable changes in behavior, then distributing questionnaires could potentially be a viable and cost-effective public health intervention'. Accordingly, the primary aim of the present study was to test the feasibility of a simple AR questionnaire-based manipulation, sent along with the standard FOBT pre-notification letter, to increase uptake of FOBT screening in Scotland across all socio-economic groups. In order to test the effect of AR, or a non-specific QBE, on any change in behaviour, participants were randomised into one of the following three treatment arms: (1) no questionnaire (control), (2) control (HLOC) questionnaire and (3) HLOC + AR questionnaire (AR). The additional aims were to evaluate any effects of demographic factors on uptake (i.e., age, gender and socio-economic status), and to examine the effect of psychological factors (AR, ICK, HLOC and perceived benefit) on FOBT uptake via a mediating and/or moderating effect on intentions.

2. Methods

The present study was a single-centre trial based at the Scottish Bowel Screening Centre in Dundee. Full details of methods for this RCT are reported in the protocol paper (O'Carroll et al., 2013) and at the website www.controlled-trials.com (number: ISRCTN74986452).

2.1. Participants

Based on the method described by Libby et al. (2011), a large,

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