Promoting uptake of flexible sigmoidoscopy ‘Bowel Scope’ screening at St Mark’s Hospital in London.

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A thesis submitted for the degree of Doctor of Philosophy

UNIVERSITY COLLEGE LONDON
Declaration

I, Robert Stephen Kerrison, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated.
Acknowledgements

I would like to thank my supervisors Dr Christian von Wagner, Dr Lesley McGregor and the late Professor Jane Wardle for this opportunity. I have enjoyed this experience and would like to thank them for their patience and excellent mentorship. I look forward to continuing a professional relationship with them for years to come.

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Abstract

In March 2013, NHS England extended its national bowel cancer screening programme to include once-only flexible sigmoidoscopy (‘bowel scope’) screening for men and women aged 55. Since roll-out of the programme began, uptake has been low and inequitable, with people living in the most deprived areas being the least likely to take part in screening. This thesis examines uptake at St Mark’s Hospital, a centre which serves a socioeconomically diverse population with below average uptake, and goes on to describe the development and evaluation of an intervention targeted at those who do not participate. Study 1 identifies and describes possible targets for intervention. The results of the study informed the design of a self-referral reminder letter and theory-based information leaflet to be sent to individuals who did not attend bowel scope screening (BSS) within one year of their original invitation. Study 2 describes a test of the intervention’s feasibility, with results demonstrating its potential to increase BSS uptake. Study 3 examines the effectiveness of the reminder letter and theory-based leaflet by comparing uptake against appropriate controls, namely: no reminder or the designed reminder letter sent with the standard information booklet used by the National Health Service. The results of the randomised controlled trial (RCT) demonstrate that uptake was significantly higher among the two groups receiving the reminder, with the group receiving the theory-based leaflet showing the highest rate of uptake. In Study 4, the materials were re-sent to those who had not attended BSS within 24 months of their initial invitation. The results of this extension to the RCT corroborate the outcome of the first reminder. This series of studies demonstrates the usefulness of additional reminders in the BSS programme, which is discussed alongside other implications for policy in the discussion of this thesis.
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**List of Abbreviations**

aOR – Adjusted Odds Ratio

ADR – Adenoma Detection Rate

BCSP – Bowel Cancer Screening Programme

BCSS – Bowel Cancer Screening System

BCSC – Bowel Cancer Screening Centre

BCW – Behaviour Change Wheel

BCT – Behaviour Change Technique

BME – Black and Minority Ethnicity

BSS – Bowel Scope Screening

BSSP – Bowel Scope Screening Programme

CCD – Charged Coupled Device

CCG – Clinical Commissioning Group

CI – Confidence Intervals

CONSORT – Consolidated Standards of Reporting Trials

CRC – Colorectal Cancer

FAP - Familial Adenomatous Polyposis

FIT – Faecal Immunochemical Test

FOBt – Faecal Occult Blood test

FS – Flexible Sigmoidoscopy
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>gFOBt</td>
<td>Guaiac Faecal Occult Blood test</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>HBM</td>
<td>Health Belief Model</td>
</tr>
<tr>
<td>HPNCC</td>
<td>Hereditary Non-Polyposis Colon Cancer</td>
</tr>
<tr>
<td>ID</td>
<td>Identification</td>
</tr>
<tr>
<td>IMD</td>
<td>Index of Multiple Deprivation</td>
</tr>
<tr>
<td>ISRCTN</td>
<td>International Standard Randomised Controlled Trials Number</td>
</tr>
<tr>
<td>JRO</td>
<td>Joint Research Office</td>
</tr>
<tr>
<td>MRC</td>
<td>Medical Research Council</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
</tr>
<tr>
<td>ONS</td>
<td>Office for National Statistics</td>
</tr>
<tr>
<td>OR</td>
<td>Odds Ratio</td>
</tr>
<tr>
<td>PAPM</td>
<td>Precaution Adoption Process Model</td>
</tr>
<tr>
<td>PHE</td>
<td>Public Health England</td>
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<tr>
<td>PN</td>
<td>Patient Navigation</td>
</tr>
<tr>
<td>R and D</td>
<td>Research and Development</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
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<tr>
<td>SCT</td>
<td>Social Cognitive Theory</td>
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<tr>
<td>SES</td>
<td>Socioeconomic Status</td>
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<tr>
<td>TPB</td>
<td>Theory of Planned Behaviour</td>
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TTM – Transtheoretical Model

UK – United Kingdom

USA – United States of America

WHO – World Health Organisation
Thesis aims and overview

Aims

The overall aim of this thesis was to design and evaluate an intervention to improve uptake in the National Health Service (NHS) Bowel Scope Screening Programme (BSSP) at St Mark’s Hospital in London.

The specific aims were to:

1. Analyse uptake and response to the screening invite at St Mark’s Hospital for the first fourteen months of the NHS BSSP’s initial implementation.
2. Systematically develop an intervention to improve participation at St Mark’s Hospital using the Behaviour Change Wheel (BCW) as a theoretical framework for the intervention’s design.
3. Evaluate the feasibility and effectiveness of implementing the devised intervention in studies informed by the Medical Research Council’s (MRC’s) Guidelines for Developing and Evaluating Complex Interventions.

Overview

The first four chapters of this thesis present the background literature.

Chapter 1 presents bowel cancer as a significant public health problem characterised by high mortality and an advanced stage at diagnosis. It makes the case for screening as a public health strategy to improve outcomes from the disease and provides an overview of the modalities which have the best evidence to support their use to date.

Chapter 2 describes the organisation and delivery of bowel cancer screening in the United Kingdom. It highlights the importance of uptake to the clinical effectiveness of organised screening programmes and documents the known sources of inequality described in the previous literature.

Chapter 3 provides an overview of the theoretical perspectives that have most frequently been applied in research examining bowel cancer screening uptake and discusses the evidence in relation to each theory. It summarises that a number of models have been examined, but that no one model is currently recognised as being best.

Chapter 4 reviews the evidence for the intervention strategies that have previously been used to improve bowel cancer screening participation and provides the concluding background literature to this thesis.
Chapters 5 – 9 comprise the empirical chapters.

Chapter 5 examines uptake and response to the screening invite at St Mark’s Hospital during the first fourteen months of the NHS BSSP’s initial implementation (March 2013 to May 2014).

Chapter 6 reports the development of a self-referral reminder and theory-based leaflet designed to improve uptake at St Mark’s Hospital using behaviour change techniques (BCTs) selected using the BCW.

Chapter 7 assesses the feasibility of sending non-participants the self-referral reminder and theory-based leaflet 12 months after their initial invitation.

Chapter 8 tests the effectiveness of sending non-participants the self-referral reminder, with and without the theory-based leaflet, 12 months after their initial invitation in a formal RCT.

Chapter 9 extends the evaluation of the self-referral reminder and theory-based leaflet by examining their effectiveness when sent a second time (24 months after the initial invitation) in an extension of the RCT.

Chapter 10 concludes the thesis by drawing together the findings from the studies. It discusses the limitations of the work as well as its implications for the BSSP and future research.
Chapter 1. Colorectal cancer and screening

1.1 Colorectal cancer incidence and mortality

1.1.1 Global burden

Colorectal cancer (CRC, also referred to as bowel cancer) is a leading cause of morbidity and mortality throughout the world (Ferlay et al., 2015). In 2012, CRC accounted for nearly 10% of all newly diagnosed cancer cases (1.36 million of 14 million), and more than 8% of all newly registered cancer deaths (690,000 of 8.2 million), making it the third most frequently diagnosed cancer and the fourth leading cause of cancer-related deaths that year (Cancer Research UK., 2015a; Cancer Research UK., 2015b).

CRC incidence rates are highest in developed countries, where the majority of cases (55%) are diagnosed. Globally, there is nearly a tenfold difference in CRC incidence rates between regions with the highest and lowest rates of CRC, with CRC incidence rates ranging from over 40 cases per 100,000 people in the United States of America (USA), Australia, New Zealand and Western Europe, to less than five per 100,000 in parts of Africa, Asia and South America (Cancer Research UK, 2015a; Figure 1-1).

Figure 1-1. Worldwide CRC incidence: age standardised CRC rates by world region (Cancer Research UK., 2015a)
1.1.2 UK burden

In the United Kingdom (UK) specifically, CRC is the fourth most frequently diagnosed cancer (Cancer Research UK., 2016a) and the second leading cause of cancer-related deaths (Cancer Research UK., 2016b; Figure 1-2), accounting for more than 9.8% of all newly diagnosed cancer cases and over 8.7% of all newly registered cancer deaths (Cancer Research UK., 2015c; Cancer Research UK., 2015d).

**Figure 1-2.** The top 20 most common causes of cancer death in the UK by gender, 2014 (Cancer Research UK., 2016a)

Incidence rates in the UK are higher among men than women. In 2012, the incidence rate of CRC was 58 new cases per 100,000 men and 38 new cases per 100,000 women. This was the highest incidence rates had been since 1971, when the Office for National Statistics (ONS) started collecting data on the incidence of CRC (see Figure 1-3; ONS., 2013).

As with incidence rates, CRC mortality rates in the UK are higher among men than women. However, unlike CRC incidence rates, which have steadily increased over the past forty years, CRC mortality rates have steadily declined (Figure 1-3; ONS., 2013). In 2012, the mortality rate of CRC in the UK was 21 deaths per 100,000 men, and 13 deaths per 100,000 women; nearly half of what they had been in 1971 (Figure 1-3; ONS., 2013).
Figure 1-3. CRC incidence and mortality rates for men and women living in the UK between 1971 and 2010 (ONS., 2013)

1.2 Aetiology

1.2.1 Risk factors for the development of CRC

1.2.1.1 Environmental and lifestyle factors

The aetiology of CRC is influenced by a number of environmental and lifestyle factors, including: fruit and vegetable intake (van Duijnhoven et al., 2009), drinking alcohol (Cho et al., 2004), smoking cigarettes (Botteri et al., 2008; Liang et al., 2009), eating red and processed meat (Chan et al., 2011), being overweight or obese (Moghaddam et al., 2007; Ning et al., 2010) and not exercising regularly (Slattery et al., 2004; Wei et al., 2004; Wolin et al., 2009; Boyle et al., 2011). In addition to being affected by multiple environmental and lifestyle factors, the aetiology of CRC is greatly influenced by a person's age and previous medical history. As shown in Figure 1-4 (Cancer Research UK., 2016e), the likelihood of being diagnosed with CRC rapidly increases with age, so much so that men aged 60-64 are nearly fourteen times more likely to be diagnosed with CRC than men aged 20 years younger (i.e. aged 40-44). The effect of age is less pronounced in women, although older women (e.g. over the age of 80-84) are also much more likely to develop CRC than younger women (e.g. under the age of 69).
In terms of medical history, a previous history of bowel polyps (Winawer., 2007), severe ulcerative colitis and Crohn’s disease are all associated with an increased risk of developing CRC (Canavan et al., 2006; Jess et al., 2012). There are also two known genetic syndromes linked to the malignancy, namely: ‘hereditary non-polyposis colon cancer’ (HPNCC) and ‘familial adenomatous polyposis’ (FAP). These syndromes with known genetic defects (i.e. HPNCC and FAP) only account for one to five percent of all CRCs (Winawer., 2007), so that, at present, genetic screening can only make a limited contribution to risk reduction in the general population.

1.2.2 The adenoma-carcinoma pathway

The majority of CRCs (over 90%) develop from adenomas (also referred to as ‘adenomatous polyps’): benign growths that develop from gland cells which line the bowel wall (Winawer and Zauber., 2002; Stryker et al., 1987; Risio., 2010). An estimated 33% to 50% of all adults will develop one or more adenomas during their lifetime (Bond., 2000; Schatzkin et al., 1994) and, while all have the potential to become malignant, fewer than 10% ever develop into invasive cancer (Levine and Ahnen., 2006; Risio., 2010).

The likelihood that an adenoma will ever develop into invasive cancer is highly dependent on a number of factors, including the size and histological type of the adenoma, the degree of epithelial dysplasia (i.e. the extent to which cells appear to be abnormal), and the involvement of specific tumour suppressor genes (Vogelstein and Kinzler., 2004).

1 The likelihood that an adenoma will ever develop into invasive cancer is highly dependent on a number of factors, including the size and histological type of the adenoma, the degree of epithelial dysplasia (i.e. the extent to which cells appear to be abnormal), and the involvement of specific tumour suppressor genes (Vogelstein and Kinzler., 2004).
1.3 Survival by stage at diagnosis

Chances for survival are strongly contingent on the stage at diagnosis (Cancer Research UK., 2014a). Patients with localised disease (Stage I) have the best chances for survival, with 95% surviving for at least five years (Cancer Research UK., 2014a; Table 1-1). In patients with CRC that has infiltrated the colon wall (Stage II), the chances of surviving five or more years are reduced to 80%, and for patients where the cancer has spread to one or more lymph nodes (Stage III), the chances of survival are reduced further still (66%). Patients with distant metastases (Stage IV) have the poorest chances of survival, with as few as 10% surviving for five or more years (Cancer Research UK., 2014a). Unfortunately, due to the extensive pre-clinical phase of CRC (Komuta et al., 1999), most patients are diagnosed when the cancer has spread to the surrounding tissues or lymph nodes (stages III and IV), and the prognosis for survival is generally poor (Verdecchia et al., 2009; Table 1-1).

Table 1-1. Five-Year relative survival of colorectal cancer patients in England (2002-2006) by stage at diagnosis

<table>
<thead>
<tr>
<th>Stage at diagnosis</th>
<th>Staging criteria</th>
<th>% of diagnoses</th>
<th>5-year relative survival (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage I (Early)</td>
<td>Cancer is limited to inner lining of the colon or rectal (submucosa), but has not spread fully into the muscle.</td>
<td>9</td>
<td>95</td>
</tr>
<tr>
<td>Stage II</td>
<td>Cancer has infiltrated the submucosa to the surrounding muscle, but no lymph nodes are implicated.</td>
<td>25</td>
<td>80</td>
</tr>
<tr>
<td>Stage III</td>
<td>At least one Lymph node has been affected in the area close to the bowel.</td>
<td>25</td>
<td>66</td>
</tr>
<tr>
<td>Stage IV (Late)</td>
<td>The cancer has metastasised to other organs.</td>
<td>10</td>
<td>25-40</td>
</tr>
<tr>
<td>Unknown</td>
<td>N/A</td>
<td>31</td>
<td>35.4</td>
</tr>
</tbody>
</table>

Sources: Edge et al., 2010; Cancer Research UK., 2014a
Chapter 1. Colorectal cancer and screening

1.4 Treatment

As well as being associated with a poorer prognosis for survival, late stage CRC is generally associated with more expensive and more invasive treatment regimens. For most early stage CRCs, surgery is the main treatment (Cancer Research UK., 2016c), whereas for late stage CRCs, a combination of surgery and chemotherapy or radiotherapy is recommended (Cancer Research UK, 2016d). The lifetime cost per head to treat a CRC can consequently range from £3,337 for a stage I CRC, to £12,519 for a stage IV CRC (Cancer Research UK., 2014b). Impetus to improve the early diagnosis of CRC is therefore high not only because doing so will have improved outcomes for the patient, but reduced treatment costs for the NHS as well.

1.5 Strategies to improve CRC outcomes

1.5.1 Awareness of the symptoms of CRC

As mentioned above, the majority of CRCs are asymptomatic in the initial stages of development2 (Risio., 2010). As such, raising awareness of the symptoms of CRC is unlikely to help detect cases early. Researchers have instead focused mostly on alternative strategies to improve outcomes from CRC, such as those which prevent disease (e.g. through lifestyle changes and screening for adenomas which can be removed before they develop into cancer), and those which test for disease before symptoms develop (i.e. through screening for cancer in the early stages of development).

1.5.2 Lifestyle changes

It is estimated that over half (54.4%) of all CRC cases diagnosed in the UK are associated with lifestyle and environmental factors (Parkin., 2011). However, while these factors are associated with an increased risk of developing CRC, there is little evidence demonstrating whether lifestyle approaches to reducing CRC risk are effective (Whitlock et al., 2008). In addition, many of the risk factors associated with CRC development (such as smoking and being overweight or obese) are also associated with an increased risk of developing multiple other chronic illnesses (such as heart disease and type 2 diabetes, etc.). As such, awareness of these behaviours as risk factors for disease form part of a broader approach to improving public health, and not a targeted one specific to CRC (Mason and McGinnis., 1990).

---

2 Symptoms include a persistent change in bowel habit, bleeding from the back passage, a lump in the abdomen, blood in the stool, anaemia, unexplained tiredness or weight loss and abdominal pain (Cancer Research UK., 2015e).
1.5.3 Screening for CRC

Unlike lifestyle changes, screening offers a targeted approach to improving health outcomes by identifying apparently healthy individuals who might be at an increased risk of a disease or condition and then offering them information, further tests and appropriate treatment to reduce their risk or any complications arising from the condition (Public Health England., 2013b). However, not all conditions are suitable for screening, and so criteria for appraising the viability, effectiveness and appropriateness of screening are recommended by the World Health Organisation (WHO; see Appendix 1-1 for an overview of the criteria used by the UK National Screening Committee). Based on various iterations of the WHO criteria, screening for CRC has been recommended by a number of government and health organisations, including the United States Preventive Services Task Force (Levin et al., 2008), the Asia Pacific Colorectal Cancer Working Group (Sung et al., 2008; Sung et al., 2015), and the Council of the European Union (The Council of the European Union., 2003). As a result, there are now CRC screening programmes in over 60 countries spanning five continents (Schreuders et al., 2015).

1.6 CRC screening tests

Several investigations are capable of testing for CRC and the pre-cancerous growths from which they develop (Whitlock et al., 2008). They can be broadly categorised into two groups: early detection screening tests and preventive screening tests. The following provides a brief overview of the methods which are most frequently used and have the strongest evidence-base to support their use to date.

1.6.1 Early detection screening tests

Early detection screening tests improve outcomes from CRC by detecting cases early (i.e. Stages I and II), when chances for survival are highest. The most widely used early detection tests are faecal occult blood tests (FOBts; Benson et al., 2012; Schreuders et al., 2015). FOBts test for CRC by detecting occult blood in the stool, which is often detectable in the early (as well as late), asymptomatic stages of disease (Greegor., 1967).

There are two primary ways of testing for faecal occult blood, both of which use reagents that react with one of the two functional moieties of haemoglobin (the oxygen-binding metalloprotein of red blood cells; Perutz., 1976). These two methods are the guaiac faecal occult blood test (gFOBt), which reacts with haem (the non-protein, oxygen-binding, portion of haemoglobin), and the faecal immunochemical test (FIT), which reacts with globin (the structural protein portion of haemoglobin; Sanford and McPherson, 2009).
1.6.1.1 Guaiac faecal occult blood test screening

1.6.1.1.1 Procedure

 Individuals complete the gFOBt by applying a small amount of stool sample onto a test card impregnated with guaiac (a resin that acts as phenolic redox indicator) using a cardboard applicator (see Figure 1-5 for an example of the gFOBt kit used in the English Bowel Cancer Screening Programme). Two samples are usually taken from each bowel motion, so as to reduce the chances of obtaining a false negative result (i.e. a negative result for a sample that is positive for faecal occult blood). As tumours and adenomas can bleed intermittently, and the test may not be sensitive enough to detect particularly low concentrations of faecal haemoglobin (Van Rossum et al., 2008), the stool sampling process is repeated so that sample is taken from up to six separate motions (the number of samples taken varies from programme to programme; Schreuders et al., 2015). The test kit is usually completed at the individual’s home and then returned by post to a screening centre for analysis (Halloran., 2009), where a solution of hydrogen peroxide is applied to the reverse of each of the sample panels by a medical laboratory assistant or equivalent member of staff. A change in colour from white to blue in most of the panels usually indicates an abnormal result (as with the number of samples taken, the algorithm for a positive result varies between screening programmes) and a referral for follow-up investigation by a gastroenterologist is made (Benson et al., 2008; Halloran., 2009).

Figure 1-5. Guaiac faecal occult blood test kit used by the NHS Bowel Cancer Screening Programme (Royal Devon and Exeter NHS Foundation Trust., 2017)
1.6.1.1.2 Evidence

A meta-analysis of four large RCTs examining the effectiveness of biennial gFOBt screening to reduce CRC mortality found a cancer-specific mortality reduction of 13% at the population level and of 18% for individuals who completed the first round of screening (Scholefield et al., 2011). In addition, findings from the first one million completed gFOBt kits in England showed that, among individuals with staging data, 71.3% of screen-detected cancers were diagnosed at stage I or II (Logan et al., 2012), suggesting that biennial screening with the gFOBt does indeed reduce cancer-specific mortality through early detection.

With regards to the prevention of CRC, there is mixed evidence to support gFOBt screening. For example, one large RCT conducted in Minnesota (USA) found that screening with the gFOBt reduced CRC incidence over an 18-year follow-up (Mandel et al., 2000), while more recent data from a large pilot in England indicated no change in incidence over a 20-year follow-up period (Scholefield et al., 2011). As a result, there is good evidence to support the use of biennial gFOBt screening in terms of preventing CRC deaths, but weak evidence to support its use in terms of preventing CRC incidences.

1.6.1.2 Faecal immunochemical test screening

1.6.1.2.1 Procedure

Individuals completing the FIT are typically required to collect a single sample of their stool (in some programmes two samples are collected; Schreuders et al., 2015) in a bottle containing buffer solution (i.e. a solution that resists pH change) using a plastic applicator (Levi et al., 2007). As with the gFOBt, the FIT is completed in the individual’s home and then returned to a screening centre where it is analysed by a medical laboratory assistant (see Figure 1-6 for an example of the FIT kit piloted in the English Bowel Cancer Screening Programme). Unlike the gFOBt, the FIT provides a quantitative test result which allows the cut-off for a positive result to be manipulated depending on whether the screening programme being set up wants to use a higher level of sensitivity, and thereby increase the number of pre-cancerous lesions detected (these are associated with lower concentrations of faecal haemoglobin), or decrease the sensitivity of the test to reduce the number of colonoscopy referrals being made (i.e. due to limited endoscopy capacity; Moss et al., 2016).
1.6.1.2.2 Evidence

There are currently no published RCTs demonstrating that screening with the FIT is more or less superior to screening with the gFOBt or no screening in terms of reducing CRC-related mortality in average risk adults (Tinmouth et al., 2015a). Two studies, including an ecological study conducted in Italy (Zorzi et al., 2015) and a large prospective cohort study conducted in Taiwan (Chiu et al., 2015) have, however, found that CRC-related mortality was reduced (10% and 22% respectively) in regions where screening with FIT was implemented compared with regions where screening had not been implemented. Despite a lack of definitive evidence demonstrating that FIT is as effective, or more effective, than gFOBt screening, or no screening, many countries have implemented FIT-based CRC screening programmes (Schreuders et al., 2015). Data collected by these programmes, as well as large RCTs with extensive follow-up periods, are likely to contribute evidence to support the use of FIT screening, on the basis that the test is analytically superior to the gFOBt, which itself has been shown to be effective (Scholefield et al., 2011).

1.6.2 Preventive screening tests

Preventive screening tests help to prevent CRC by identifying and removing colorectal adenomas before they develop into cancer. Much like early detection tests, preventive screening tests also offer the potential to identify CRC early, but this is not the primary mechanism by which they help prevent deaths from CRC.

Figure 1-6. Faecal immunochemical test kit piloted by the NHS Bowel Cancer Screening Programme (Moss et al., 2016)
1.6.2.1 Flexible sigmoidoscopy screening

1.6.2.1.1 Procedure

Flexible sigmoidoscopy (FS) is the endoscopic examination of the rectum and sigmoid colon (the most distal third of the large bowel) with a thin flexible tube equipped with a charged coupled device (CCD) or fibre-optic camera (see Figure 1-7; Atkin et al., 2001). The test is performed at a clinic or hospital by a trained nurse or physician and takes between five and ten minutes to complete, depending on the need for polypectomy (the removal of polyps) and biopsy (the sampling of tissue; Eddy., 1990). Individuals undergoing the test are typically given an enema to prepare the distal bowel (the rectum and sigmoid colon) for examination. The enema can be self-administered by the person in their own home or by a nurse at the hospital on the day of the test. If the bowel is not adequately prepared for examination, it may be necessary for the patient to receive a second enema to ensure a satisfactory test can be performed. The person does not need to be sedated during the procedure, although FS can be uncomfortable, particularly when the bowel needs to be inflated (this is done to aid the endoscope through the bowel and is achieved by pumping small amounts of air or carbon dioxide into the bowel). Most people (87%), however, report no pain or only mild pain (Robb et al., 2012), and almost all (98%) find the test to be highly acceptable (Taylor et al., 2000).

Figure 1-7. Illustration demonstrating patient positioning and room set-up for flexible sigmoidoscopy examination (Johns Hopkins Cancer Center., 2017)
While in absolute terms only a relatively small portion of the large bowel can be examined using FS (approximately one third), the sites which can be observed represent those most frequently affected by cancer (Figure 1-8; Cancer Research UK., 2015c). Around two thirds (58% to 75%) of all CRCs and 80% of all colorectal adenomas (72% to 86%) develop in the rectum and sigmoid colon (Cancer Research UK., 2015c; Corley et al., 2013; Whitlock et al., 2008), meaning that the majority of cases can be detected without examining the whole bowel. In addition, the detection of one or more distal adenomas during FS can be used as an indicator for lesions occurring in the proximal colon, with approximately one third (31%) of all people with a distal adenoma detected at FS also having one or more proximal adenomas detected at colonoscopy (Imperiale et al., 2000; Lieberman et al., 2000). Follow-up colonoscopy can thereby be used in conjunction with FS to enable the subsequent detection of most adenomas and CRCs (Whitlock et al., 2008). As with other screening modalities, the extent to which follow-up colonoscopy increases the number of adenomas and CRCs detected is highly susceptible to dropout, with only those who attend colonoscopy benefitting from the advantages of having the test (Plumb et al., 2016).

**Figure 1-8.** Distribution of CRC cases within the large bowel, Great Britain, 2007-2009 (Cancer Research UK., 2015c)
1.6.2.1.2 Evidence

The evidence to support the effectiveness of FS screening (versus no screening) is highly compelling. Findings from a recent meta-analysis of five large RCTs revealed that, when examined on an intention-to-treat basis (i.e. all invitees), once-only FS screening was associated with a cancer-specific mortality reduction of 28%, and a cancer-specific incidence reduction of 18% (Elmunzer et al., 2012). When examined on a per-protocol basis, (i.e. on the basis that a person was screened), the results from the meta-analysis are even more convincing, with once-only FS screening being associated with a cancer-specific mortality reduction of 50% and a cancer-specific incidence reduction of 32% (Elmunzer et al., 2012).

In the longest-running RCT, the benefits of once-only FS screening were shown to be sustained over a 17 year follow-up period (Atkin et al., 2017). In that specific study, once-only FS screening was associated with a cancer-specific incidence reduction of 26%, and a cancer-specific mortality reduction of 31% in the intention-to-treat analysis (CRC incidence and mortality were reduced by 35% and 40% respectively in the per-protocol analysis). Results were similar at eleven years (Atkin et al., 2010), where once-only FS screening was associated with a cancer-specific incidence reduction of 23%, and a cancer-specific mortality reduction of 30% in the intention-to-treat analysis (33% and 43% respectively in the per-protocol-analysis).

As well as there being compelling evidence to suggest that once-only FS screening is more effective than no screening, there is evidence to support the effectiveness of once-only FS screening to detect colorectal adenomas and cancers over stool-based tests. In a recent meta-analysis of data collected from 13 RCTs, FS was found to be over seven times more effective at detecting advanced adenomas than gFOBt, and more than three times more effective than FIT (Littlejohn et al., 2012). One study comparing attendance and adenoma detection rates (ADRs) between gFOBt, FIT and FS confirmed that, per 100 invitees, FS had a higher diagnostic yield than both FIT and gFOBt (diagnostic yield per 100 invitees was 2.6 for FS, 0.55 for gFOBt and 1.5 for FIT – diagnostic yield was defined as proportion of invitees with advanced neoplasia; Hol et al., 2010), despite having considerably lower uptake (uptake was 32.4% for FS, 49.5% for gFOBt and 61.5% for FIT).

1.6.2.2 Colonoscopy

1.6.2.2.1 Procedure

Colonoscopy is the endoscopic examination of the large bowel with a flexible tube equipped with a CCD or fibre-optic camera (Figure 1-9; Atkin et al., 2001). It is different from FS in that it enables the examination of the whole bowel and not just the rectum and sigmoid colon. The test is usually performed at a hospital by a trained physician and takes around thirty to forty-five minutes to complete, depending on the need for biopsy and polypectomy (Overholt., 1975).
Prior to colonoscopy, patients are required to prepare for the test at home using a ‘full-laxative’ preparation. This involves drinking a purgative medicinal solution and adhering to a strict set of dietary instructions. A common form of dietary advice is to eat only non-solid food and drink plenty of fluids for two days before the test, and to then forego solid food for the final day before the test. If the bowel preparation is not sufficient, the patient may be invited to come back for another appointment.

The test is performed using sedation. After the examination, patients are monitored for at least one hour (while the sedative wears off) before being discharged by a nurse if there are no complications. However, the sedative can take up to 24 hours to wear off, and so patients are advised to make transport arrangements which do not involve driving during this time.

**Figure 1-9.** Illustration demonstrating patient positioning and room set-up for colonoscopy examination (Cancer Research UK 2016f)

### 1.6.2.2 Evidence

There are currently no RCTs demonstrating the effectiveness of colonoscopy screening to improve CRC outcomes compared with no screening or screening with other tests. Several RCTs are currently underway, but will not be completed for another five to ten years (Department of Veteran Affairs, 2012; Quintero et al., 2012; Kaminski et al., 2012). As a result, the current evidence to support the use of screening colonoscopy is limited to case-control studies conducted in regions where colonoscopy screening has already been implemented (Baxter et al., 2009; Doubeni et al., 2016).
Results from a case-control study conducted in Canada found that case patients (i.e. patients who had died of CRC) were less likely to have undergone colonoscopy than control patients (i.e. patients who had not died of CRC, but were similar in terms of their age, sex, socioeconomic status and Charlson Comorbidity Index Scores; Baxter et al., 2009). In addition, colonoscopy was strongly associated with fewer deaths from left-sided CRC, but not right-sided CRC, suggesting that colonoscopy prevents deaths from left-sided CRC, but not right-sided CRC. Findings were similar for a recent case-control study conducted in the USA, with case patients (i.e. patients who died of CRC) being less likely to have previously undergone colonoscopy than control patients (Doubeni et al., 2016). However, the results were different with regards to the effects of colonoscopy on left and right-sided CRC, with colonoscopy being associated with a reduction in CRC deaths for both left and right-sided CRCs and not just CRCs occurring on the left-side of the bowel. As a result, there is consistent evidence to suggest that colonoscopy prevents deaths from left-sided cancers, but inconsistent evidence to suggest that colonoscopy prevents deaths from right-sided cancers.

On-going RCTs may provide more robust evidence to support the use of colonoscopy screening when they are completed (Department of Veteran Affairs., 2012; Quintero et al., 2012; Kaminski et al., 2012). Preliminary results from one RCT (the Nordic-European Initiative on Colorectal Cancer - NordICC) already suggest that colonoscopy will be effective at reducing the incidence, and thereby the mortality, of both left and right-sided CRC, with high-risk adenomas being detected and removed from the left side of the colon in 5.8% of screened adults, and from the right side of the colon in a further 4.5% (Bretthauer et al., 2016).

1.7 Summary

CRC is a leading cause of morbidity and mortality throughout the world. Screening can help prevent cases through the timely detection and removal of adenomas in asymptomatic adults. The following chapter describes the organisation and uptake of CRC screening in the UK – the country where the studies comprising this thesis were carried out.
Chapter 2. Colorectal cancer screening in the United Kingdom: organisation and uptake

2.1 The NHS Bowel Cancer Screening Programme

2.1.1 Introduction

The English NHS Bowel Cancer Screening Programme (BCSP) is a population-based screening programme for CRC that invites men and women, aged 60-74, to complete a gFOBt once every two years (Halloran., 2009). It was initiated in October 2006, following the results of a large UK RCT, which demonstrated that biennial screening with the gFOBt reduced CRC-specific mortality on an intention-to-treat basis (Hardcastle et al., 1996). The programme was fully implemented across the country in 2010. At that time, screening was only available to men and women aged 60-69 (the original age range for the programme), however, and it was not until 2014 that full coverage of the programme, with the age extension (i.e. 70-74 year olds), was ultimately achieved. Similar programmes are offered in Scotland, Wales and Northern Ireland; with some slight regional variations in delivery between these countries. For example, in Scotland, screening is offered to men and women from the age of 50, rather than 60 (Halloran., 2009).

2.1.2 Organisation and delivery

To organise and record all screening episode actions, the English NHS BCSP uses web-based software managed by NHS Digital. The software is populated with information from the NHS database of General Practice-registered patients, which is updated on a daily basis and contains the basic patient-identifiable data needed to fulfil the requirements for invitation (i.e., Name, Address, Date of Birth and NHS Number; Halloran., 2009). Call and recall (i.e. invitation and re-invitation) of the eligible population, issue and analysis of test kits and a Freephone helpline for the public are provided by five regional hubs based in Guildford, London, Rugby, Nottingham and Gateshead (Figure 2-1; Logan et al., 2012). Each Hub serves approximately 15 JAG (Joint Accreditation Group) accredited screening centres, each of which receives patients referred by the Hub following a positive test result (Halloran., 2009).
2.2 The NHS BSSP

2.2.1 Introduction

A once-only FS screening programme for men and women aged 55 – 59 (i.e. the NHS BSSP) is also offered in England and was introduced in March 2013.

2.2.2 Organisation and delivery

As with the NHS BCSP, the NHS BSSP uses software managed by NHS Digital to organise and record all screening episode actions. Invitation to screening and a Freephone helpline for the public are similarly managed by the five regional bowel cancer screening Hubs (see Chapter 2.1.2). Appointments, however, are managed by the screening centres, which generate the clinic lists each week. The Hub then invites eligible men and women to attend3 (Figure 2-2).

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3 The Screening Centre uses age to identify adults for invitation. However, not everyone aged 55 years is eligible to have the test. For example, individuals are not eligible for screening if they have had all of their large bowel removed, use a stoma bag to collect their stool, are being treated for inflammatory bowel disease (e.g. ulcerative colitis of Chron’s disease), have had heart surgery in the last three months, or cannot walk more than 100 yards without resting because of a lung or heart problem. These exclusions are highlighted in the information booklet sent with the invitee’s pre-invitation letter (see: 2.3.2 The NHS BSSP Invitation Pathway).
Figure 2-2. The NHS BSSP Pathway
2.2.3 The NHS BSSP invitation pathway

Appointments are offered to men and women aged 55 (the optimal age for the greatest quality adjusted life year gain; Whyte et al., 2012). Invitees receive a pre-invitation letter notifying them that they will be invited for a BSS appointment two months after their 55th birthday (i.e. eight weeks prior to their actual appointment; Figure 2-2). The pre-invitation letter explains that BSS helps prevent CRC by removing small growths that have the potential to become malignant, and that the test is offered to all adults aged 55 (see Appendix 2-1). An invitation letter is then sent two weeks after the pre-invitation letter. The invitation letter offers the recipient a timed appointment for the test at their local screening centre. It also reiterates that FS helps prevent CRC by removing small pre-cancerous growths in the bowel and emphasises that participation is an individual choice (see Appendix 2-2). A booklet, called: ‘the NHS Bowel Scope Screening informed choices booklet’, is sent with the invitation letter and is designed to provide the individual with the information required to make an informed choice about whether to take part in the programme (see Appendix 2-3). Individuals can confirm their appointment by returning their appointment slip to their local Hub using the Freepost envelope provided. Alternatively, they can confirm, cancel or change their appointment by calling. Anyone who does not respond to their appointment offer within two weeks is sent a reminder letter (see Appendix 2-4). If there is no response within an additional two weeks, the individual’s appointment is cancelled and a non-response letter is mailed (see Appendix 2-5). The non-response letter explains that the individual’s appointment has been cancelled and states that they can self-refer for an appointment up until the age of 60, should they later decide that they want to take part in screening. A copy of the letter is also sent to the individual’s general practitioner (GP; Appendix 2-6).

2.2.3.1 Bowel preparation

For individuals who confirm that they will be attending their appointment, a confirmation letter is sent two weeks in advance to verify the date, time and location of the appointment (see Appendix 2-7). The confirmation letter also explains that to have the test, the individual will receive a bowel preparation kit (an enema and instruction booklet), which they will need to self-administer on the day of their appointment (approximately one hour before starting their journey to the screening centre). The enema is sent with a letter and instructions for use approximately one week before the appointment (see Appendices 3-8 and 3-9 respectively). If the recipient is not confident about self-administering the test, or they have any disability preventing them from doing so, they can contact the screening centre to request to have it done by one of the screening practitioners. Other assistance, such as the need for an interpreter to be present at the appointment, can also be requested in the same way.
2.2.3.2 Pre-appointment consultation

On the day of the appointment, there is a pre-appointment consultation between the screening practitioner and the attending adult. The screening practitioner explains what will happen during the appointment and reiterates the risks and benefits of the procedure to ensure that an informed decision to be screened (or not) is made. The pre-appointment consultation also provides an opportunity for the screening practitioner to address any questions or concerns that the individual may have. Should the attending adult wish to proceed with the examination, they are required to sign a consent form (Appendix 2-10), indicating that the risks of the test have been explained to them.

2.2.3.3 The procedure

The procedure itself takes approximately five to ten minutes, depending on the need for polypectomy and biopsy. The attending adult is given a hospital gown or shorts (referred to as ‘dignity shorts’) to wear in place of their clothes during the procedure (should they prefer to). Once they have changed into their gown or shorts in a private changing area, they are ready to proceed with the investigation, which is performed in an endoscopy suite. The individual lies on their side on a bed which is slightly elevated so that the endoscope can be inserted into the person’s back passage (anus). Once the endoscope has been inserted, the screening practitioner examines the rectum and sigmoid colon for any polyps, which can be removed during the procedure using a snare. To help manoeuvre the endoscope through the lower bowel, a small amount of carbon dioxide gas is usually pumped into the bowel to inflate it slightly. This is achieved via one of the endoscopes internal channels, of which there are several. Another channel can be used to clean parts of the bowel where the preparation has not been effective. This is usually done by squirting a small amount of saline solution to the site(s) where faecal matter has not been cleared. Once the practitioner has examined the rectum and sigmoid colon (i.e. up to, but not beyond, the traverse colon), they begin the process of withdrawing the endoscope. As the practitioner withdraws the endoscope, they continue to examine the bowel for any polyps to remove. The procedure is narrated to the attendee, who is able to watch the examination (if they choose) on a monitor used by the screening practitioner.

2.2.3.4 After the test

After the test the screened adult is taken to a recovery area, where they are monitored for approximately 15 minutes before being discharged from the hospital with some additional information regarding what to do if they experience any adverse effects from the procedure (e.g. severe pain, bleeding from their back passage, etc.). The person is informed of the results of their test several weeks later (or on the day if nothing is found).
If the person has a normal result (i.e. no abnormalities detected), their episode is closed and they are not contacted again until the time of their 60th birthday (except to inform them in writing that they have a normal result), when they are invited to take part in the NHS BCSP. If they have an abnormal result (e.g. three or more adenomas <1cm, one adenoma >1cm, etc.), they are referred for a colonoscopy to examine the whole bowel. Individuals with intermediate and high-risk pathology are referred for surveillance, where they are offered a colonoscopy every one or three years, depending on their pathology results (see Figure 2-2).

2.3 Uptake of CRC screening in England

2.3.1 Uptake of gFOBt

The benefits of screening are limited to those who take up the screening test offer (Parkin et al., 2008; Geurts et al., 2015). Thus, in terms of improving population outcomes, uptake is highly important. In an early analysis of the first 2.6 million gFOBt invitations administered in England (October 2006 – January 2009), the uptake of biennial gFOBt screening was 54% (von Wagner et al., 2011). While this was high compared with other countries (e.g. Australia and the Netherlands, where initial uptake was 46% and 49% respectively; Australian Government, Department of Health and Ageing, Monitoring and Evaluation Steering Committee., 2005; Deutekom et al., 2009), it was far from optimal and contained considerable ethnic and socioeconomic variation.

More recent research examining uptake in England suggests that participation has steadily increased since it was first introduced, with uptake rising from 50.9% during the first fiscal year (2006 / 2007), to 58.2% in the most recently examined (2014 / 2015; Moss et al., 2016). Despite this gradual improvement in uptake, participation in England remains considerably lower than other countries (such as Spain, Sweden and Finland, where uptake is 64%, 65% and 67% respectively; Klabunde et al., 2015), and remains below the Council of the EU’s target of 65% (von Karsa et al., 2013).

As well as being low compared with other European countries, the uptake of gFOBt screening in England is low compared with that of the more established Cervical and Breast Cancer Screening Programmes, both of which routinely achieve uptake of over 70% (Health and Social Care Information Centre., 2016a; Health and Social Care Information Centre., 2016b). Recent evidence suggests that when the gFOBt is replaced with the FIT (Summer, 2018), uptake will be higher than the European target of 65% (uptake of FIT in a recent English pilot study was 66.4%; Moss et al., 2016). Further improvements in uptake will still be required if the English BCSP is to achieve the target of 75% uptake in all clinical commissioning groups (CCGs) by 2020 (the Independent Cancer Taskforce., 2015). This will be an even bigger challenge for the NHS BSSP, for which the uptake of screening is much lower.
2.3.2 Uptake of FS

The uptake of once-only FS screening has been examined in the early stages of the NHS BSSP (McGegor et al., 2015a), as well as a number of pre-programme trials and pilot settings (Atkin et al., 2002; Brotherstone et al., 2007; Robb et al., 2010a; Bevan et al., 2014). The largest trial of FS screening conducted in the UK (i.e. the UK FS trial; Atkin et al., 2010) was designed in such a way that extrapolation of uptake was very difficult. It used a design which was intended to reduce non-adherence and thereby increase the statistical power of the trial. Potential participants were sent a pre-screening interest questionnaire, which asked: ‘if you were invited for the bowel screening test, would you attend?’, with response options: ‘yes definitely’, ‘yes probably’, ‘no probably’ and ‘no definitely’ (Atkin et al., 2001). Only those who returned the questionnaire and indicated that they ‘probably would’ or ‘definitely would’ attend were subsequently included in the trial (Atkin et al., 2002). In the NHS BSSP, no such pre-screening interest questionnaire is used to select invitees, and all eligible adults are invited for BSS irrespective of their screening interest. However, as the aim of the study was to determine the effectiveness of once-only FS screening to reduce the incidence and mortality of CRC, and not the acceptability of the screening test to the public, the design used was appropriate.

Knowing that any such design (i.e. one involving a pre-screening interest questionnaire) would not likely be used in any future screening programme, the researchers conducted two additional studies: one to test the feasibility of offering FS screening at a single centre in London (Brotherstone et al., 2007) and another to test the acceptability of the test using a conventional screening invitation (i.e. one that did not involve using a pre-screening interest questionnaire to preferentially select invitees; Robb et al., 2010a). Both studies were conducted at St Mark’s Hospital – the centre where the studies described in this thesis were carried out (see Chapters 5-9). In the first study, Brotherstone colleagues (2007) measured uptake to be 55%, which was higher than the second study, in which Robb and colleagues (2010a) found uptake to be 45%. In both studies, uptake was high compared with similar trials conducted (at the same time) in the Netherlands and Italy, where uptake was 32.5% and 26.5%, respectively (Segnan et al., 2007; Hol et al., 2010b).

More recent research conducted after the NHS BSSP was confirmed has produced less positive results. In a pathfinder study conducted in 2011, uptake of screening was only 29% (Bevan et al., 2014), although in this study there was no reminder to non-responders (i.e. people who did not confirm whether they would be attending their appointment within a given timeframe), something which was believed (but not proved) to be important for increasing uptake in the previous feasibility and pilot studies (Brotherstone et al., 2007; Robb et al., 2010a).
In the first and only study to examine uptake since the NHS BSSP’s official launch in 2013, my colleagues and I found uptake to be 43% (McGregor et al., 2015a). This was 22 percentage points below the Council of the EU’s target for acceptable participation (65%; von Karsa et al., 2013), and 32 percentage points below the Intendent Cancer Taskforce target for 2020 (i.e. 75% in all CCGs; The Independent Cancer Taskforce,. 2015). With no publicity or marketing strategies currently in place, achieving uptake of 75% in all CCGs by 2020 will require a concerted effort, particularly in the most socioeconomically deprived areas, where uptake is considerably lower (i.e. 20 percentage points lower) than the least deprived areas (see 2.5.1 Socioeconomic status).

2.4 Demographic variation in uptake

The identification of population subgroups who have particularly low uptake is an important quality assurance process in the delivery of screening. It helps to evaluate whether the introduction of a new programme is likely to exacerbate existing inequalities in health, and thereby enables strategies to promote uptake to be implemented in ways which help to achieve equality in healthcare delivery (Marmot et al., 2010).

2.4.1 Socioeconomic status

Organised screening programmes are designed to minimise inequalities in uptake through the use of direct invitations to the target population. In England, all screening and treatment is provided free of charge, thereby minimising financial barriers to participation. However, although there is no cost to patients, several studies have found that there are important socioeconomic inequalities in uptake that need to be addressed to ensure equality in screening. For example, in their study (mentioned above), von Wagner and colleagues (2011) reported that uptake of the first 2.6 million gFOBt invitations in England ranged from 35% in the most deprived quintile of areas, to 61% in the least deprived quintile of areas. This socioeconomic gradient in participation was observed not only across the whole population, but within each individual regional screening hub as well (von Wagner et al., 2011).

The uptake of FS screening has been found to be similarly graded in England’s National BSSP (McGregor et al., 2015a), with only 33% of the invited population participating in the most deprived quintile of areas in England, compared with 53% in the least deprived quintile of areas. The same observation was reported in the pathfinder study (Bevan et al., 2014); however, in that study, uptake ranged from 19.4% in the most deprived quartile of areas, to 36.5% in the least deprived quartile (Bevan et al., 2014).

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4 In their study, von Wagner and colleagues (2011) assessed area-level deprivation using the Index of Multiple Deprivation, which is the government’s official measure of relative deprivation for small areas / neighbourhoods in England (Department for Communities and Local Government, 2011).
Individual-level data on socioeconomic status (SES) collected through prospective questionnaires sent to individuals who were due to be invited for screening have confirmed the findings of studies using area-level data for deprivation (Sutton et al., 2000; Power et al., 2008). These studies show that higher SES is associated with an increased likelihood of attending FS screening. For example, in one study, Power and colleagues (2008) used education, housing tenure and car ownership to generate a socioeconomic scale ranging from 0 (most deprived) to 3 (least deprived), and found that this was highly predictive of attendance at screening (Power et al., 2008). The same study found that ‘employment status’, which did not form part of the scale, was independently associated with uptake (Power et al., 2008).

2.4.2 Ethnicity

Similar, but slightly less graded variations in uptake have been observed for area-level ethnic diversity. In von Wagner and colleagues 2011 analysis (described above), the most ethnically diverse areas in England had lower uptake than the least ethnically diverse areas, with uptake rates ranging from 38% in the most ethnically diverse quintile of areas, to 58% in the least ethnically diverse quintile (von Wagner et al., 2011).

Neither of the London-based FS pilot studies, nor the English pathfinder study, examined variations in uptake by area-level ethnic diversity (Brotherstone et al., 2007; Robb et al., 2010a; Bevan et al., 2014). Only the early uptake analysis has consequently ever examined the association between area-level diversity and uptake in England (McGregor et al., 2015a). Unlike studies for gFOBt screening, my colleagues and I (McGregor et al., 2015a) found a non-significant difference in uptake between the most and least ethnically diverse areas (uptake was 37.8% and 44.9% in the most and least ethnically diverse areas respectively).

The association between ethnicity and uptake using individual-level data has been reported in two questionnaire studies conducted as part of the UK FS trial (Sutton et al., 2000; Robb et al., 2008a). In one study, Sutton and colleagues (2000) examined the association between ethnicity (dichotomised as ‘White’ and ‘non-White’) and uptake by asking participants about their ethnicity in a prospective questionnaire (attendance at screening was assessed on the day of the appointment). They found no association between ethnicity and uptake (Sutton et al., 2000). In a second study also conducted within the UK FS trial, Robb and colleagues (2008a) examined the association between ethnicity and uptake using a different code for ethnicity. When individuals were categorised as being of either a ‘White’, ‘Black’, or ‘Asian’ ethnicity, there was no difference in uptake between Black and White men and women, but there was a significantly lower uptake for Asian adults (Robb et al., 2008a).
2.4.3 Age and Gender

Uptake of the gFOBt in England’s national BCSP has been shown to vary by age and gender, as well as by area-level deprivation and area-level ethnic diversity, with men being less likely to take up the test than women (50.96% vs. 56.35% respectively), and adults aged 60-64 being less likely to take up the test than adults aged 65-69 (52.78% vs. 54.54% respectively; von Wagner et al., 2011). However, while men have been shown to be less likely to participate in gFOBt screening than women, their uptake increases with age, whereas for women uptake remains relatively stable (von Wagner et al., 2011). This increase in uptake with age by male adults somewhat diminishes gender differences in uptake, so that older men and women have somewhat similar participation (von Wagner et al., 2011).

While men are less likely to participate in gFOBt screening (von Wagner et al., 2011; Moss et al., 2012; Lo et al., 2014), there is uncertainty with regards to whether or not they are also less likely to participate in FS screening. For example, in the two feasibility studies conducted in London, women were either as likely (Robb et al., 2010a) or more likely (Brotherstone et al., 2007) to take part in screening, whereas in the UK FS trial (Sutton et al., 2000) and early uptake analysis (McGregor et al., 2015a), women were less likely to take part.

Age, which ranged from 55 to 64 years, was not a predictor of uptake in the UK FS trial (Sutton et al., 2000). As FS screening invitations are only sent to adults aged 55 in the NHS BSSP, uptake of FS screening by age was not examined in the early uptake analysis (McGregor et al., 2015a) or preceding pathfinder study (Bevan et al., 2014). Despite being offered to a range of adults, neither the London-based feasibility study nor the pre-programme pilot study included age as a variable in their uptake analyses (Brotherstone et al., 2007; Robb et al., 2010a).

2.5 Geographic variation

As well as there being much variation in the uptake of screening by demographic characteristics, such as age and gender, there is also considerable variation in uptake by geographic location. Such variations in uptake are independent of neighbourhood characteristics in which, as I have described previously, uptake varies based on the socioeconomic deprivation and ethnic diversity of people living in each area. For example, in an evaluation of the first one million tests issued by the English BCSP, Logan and colleagues (2012) found that uptake was highest in areas covered by the North-Eastern hub and lowest in areas covered by the London Hub. The overall uptake of screening in the North-Eastern Hub was subsequently 20 percentage points higher than the London Hub (uptake was 60% and 40% in the North-Eastern and London Hubs respectively; Logan et al., 2012).
Similar variations in uptake have been observed for FS screening. In the London-based pilot study conducted by Robb and colleagues (2010a), uptake varied between CCGs and was nearly 15 percentage points lower in the London borough of Brent than the London borough of Harrow (uptake was 44.4% and 58.8% respectively). More recently, in the early analysis of uptake data in the NHS BSSP, my colleagues and I found that there was considerable geographic variation in uptake between screening centres (McGregor et al., 2015a). Here too, differences in uptake were independent of area-level deprivation and area-level ethnic diversity. Uptake ranged from 36.8% in the centre with the lowest uptake (South of Tyne), to 52.0% in the centre with the highest (Surrey).

2.6 Summary

In England, the NHS offers once-only FS screening to all men and women aged 55-59 and biennial gFOBt screening to all men and women aged 60-74. Although offered automatically and for free, the uptake of these screening tests is low and contains a strong social gradient. In the following chapter, I consider the theoretical perspectives that have most frequently been applied in research examining bowel cancer screening participation and discuss the evidence to support their use.
Chapter 3. Psychological perspectives of uptake in colorectal cancer screening: theory and evidence

3.1 Social Cognition Models

The theoretical models that have most commonly been applied to understanding CRC screening behaviour are the Health Belief Model (HBM; Becker, 1974), the Theory of Planned Behaviour (TPB; Ajzen, 1991) and Social Cognitive Theory (SCT; Bandura, 2004; Kiviniemi et al., 2011). All three are social cognition models: models which propose that cognitions (such as attitudes and beliefs) are the most proximal determinants of behaviour and can be used to explain the relationship between distal factors (such as SES and gender) and inequalities in health (Michie et al., 2014).

3.1.1 The Health Belief Model

The HBM was developed specifically to understand the uptake of health screening and has been used to identify factors associated with health behaviours for many years since its introduction to the literature (Becker, 1974). The HBM proposes that behaviour is regulated by four central constructs, which, in turn, are modified by sociodemographic factors, personality and social influence (Figure 3-1). The model hypothesises that behaviour is regulated by a person’s perceived chances of getting the health condition (perceived risk), how serious getting the health condition would be (perceived severity), how effective the advised action to reduce the risk of getting the condition is (perceived benefits), and what the tangible and psychological costs of the advised health action are (‘perceived barriers’). Cues to action are also included in the model and are thought to be directly and independently associated with behaviour. Cues are essentially factors that promote action and can either be internal (such as the presence of symptoms), or external (such as exposure to a mass media campaign). They (cues to action) are thought to be more likely to change behaviour if an individual is already motivated to maintain good health (Conner and Norman, 1996). The following section discusses the evidence for these constructs as they relate to CRC screening behaviours.
3.1.1.1 The HBM and CRC screening

Studies examining the association between HBM constructs and CRC screening behaviour have mostly found that high perceived benefits and low perceived barriers are independently associated with participation (Hoogewerf et al., 1990; Kelly and Shank., 1992; Myers et al., 1994; Lewis and Jensen., 1996; Wardle et al., 2000; James et al., 2002; Harewood et al., 2002; Manne et al., 2002; Rawl et al., 2005). High levels of perceived susceptibility have also been shown to be associated with CRC screening participation. The association between high perceived severity and uptake, however, is less certain (Blalock et al., 1990; Burack and Liang, 1987; Janz et al., 2003; Price., 1993; Weller et al., 1995).

In a review of the literature exploring the relation of individual health behaviour constructs with CRC screening behaviour, Kiviniemi and colleagues (2011) reported the proportion of articles in which each of the HBM constructs was associated with compliance. They found that high perceived benefits and low perceived barriers were associated with uptake in 73% and 68% of studies respectively (Kiviniemi et al., 2011). In addition, they found that perceived susceptibility was associated with uptake in the majority of studies (64%), but that, by contrast, perceived severity was only rarely associated with uptake (16%). These findings are consistent with a number of meta-analyses examining the associations between perceived risk and perceived severity in relation to other health behaviours (e.g. Floyd et al., 2000; Harrison et al., 1992; McCaul et al., 1996; Mline et al., 2000), all of which concluded that perceived risk was associated with behaviour, while perceived severity was not.
3.1.2 The Theory of Planned Behaviour

The TPB proposes that intentions, which represent a person’s willingness to act (and how much effort they are willing to exert in order to perform the health behaviour), are the proximal cause of behaviour (Figure 3-2; Ajzen., 1991). In formulating intentions, the TPB theorises that people take into account their attitudes towards the behaviour (attitudes), the perceived social pressure to perform it (subjective norms), and the amount of control they believe they have over the behaviour (perceived behavioural control). According to the theory, attitudes are thought to be the function of beliefs about the likely consequences of the action (similar to perceived benefits and barriers in the HBM), while subjective norms are thought to be derived from the perceived normative expectations of relevant referent groups and the motivation to comply with significant others wishes. Perceptions about behavioural control, meanwhile, are thought to be influenced by beliefs concerning whether one has the necessary resources and opportunities to perform the behaviour. These can be internal (e.g. personal skills), or external (e.g. the opportunities available), and are proposed to have a direct influence on behaviour; Figure 3-2).

Figure 3-2. The Theory of Planned Behaviour (Adapted from Ajzen., 1991)
3.1.2.1 TPB and CRC screening

The TPB has been applied to a range of health behaviours and there are meta-analytic reviews to support the theory’s capacity to predict behaviour (and intentions of behaviour) across a variety of contexts (Godin and Kok., 1996; Armitage and Conner., 2001). In one meta-analytic review, Godin and Kok (1996) reviewed studies applying the TPB to screening behaviours specifically. They found that attitudes were strongly correlated with intentions to take part in screening (r = 0.51), and that correlations between subjective norms and intentions (r = 0.33), and perceived behavioural control and intentions (r = 0.46), were lower, suggesting that attitudes are more strongly correlated with screening intentions than subjective norms and perceived behavioural control. The strength of the correlations between intentions and behaviour (r = 0.35), and perceived behavioural control and behaviour, were average (r = 0.29).

In a prospective study of FS screening intentions and behaviour, Power and colleagues (2008) found that, in the univariable analyses, social cognition variables were strongly associated with intentions and were also significant predictors of screening attendance. In the multivariable analysis, however, associations with behaviour became non-significant when intention was added to the model (Power et al., 2008). These findings, along with those cited in other studies (Godin and Kok., 1996; Armitage and Conner., 2001), suggest that screening behaviour is mediated by intention, which in turn is mediated by social cognition variables, subjective norms and perceived behavioural control. In their study, Power and colleagues (2008) also found that social cognition variables and factors related to life difficulties (e.g. socioeconomic deprivation, poor health status, etc.) were able to discriminate between non-intenders, intenders, and people who attended screening from those who had positive intentions, but did not attend. Furthermore, mean differences between groups were large, suggesting that life difficulty factors may play an important role in translating intentions into behaviour (Power et al., 2008).

3.1.3 Social Cognitive Theory

SCT describes behaviour as an interaction of personal factors with the environment (Figure 3-3; Bandura., 1980). According to the theory, four factors affect the likelihood that someone will perform a behaviour. Specifically, SCT proposes that behaviour is mediated by self-efficacy, goals, environmental impediments and facilitators (i.e. sociocultural factors) and outcome expectancies (Bandura., 2004). Self-efficacy refers to people’s beliefs that they can exert control over their motivation and behaviour over their social environment. Self-efficacy is thought to help people regulate their behaviour by determining how high people set their goals and how much effort they exert in attempting to achieve them. Outcome expectancies, meanwhile, refer to people’s beliefs about the possible consequences of their actions and are thought to be directly affected by self-efficacy. Outcome expectancies are thought to help people regulate their behaviour by influencing goal-setting and, similarly, how much effort they are willing to exert in order to achieve their goals.
SCT distinguishes between predictors of intention and action by proposing that, while outcome expectancies are important determinants of goals, self-efficacy is more important in predicting action and regulates the translation of intentions into action. As such, SCT recognises that goal-setting is necessary, but not always sufficient, to regulating behaviour.

**Figure 3-3. Social Cognitive Theory (Adapted from Bandura., 1980)**

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### 3.1.3.1 SCT and CRC screening

Since its initial introduction to the research literature, SCT has been used to explain a wide variety of health behaviours (Godin et al., 2008; Kiviniemi et al., 2011; Young et al., 2014). The majority of research studies using SCT have focussed on the two more dominant constructs: self-efficacy and outcome expectancies (Godin et al., 2008; Kiviniemi et al., 2011; Young et al., 2014). Findings from studies using SCT in the context of CRC screening specifically have shown that people who believe participating in screening will have positive consequences (outcome expectancies) and have more confidence in their ability to attend screening (self-efficacy) are more likely to take part (Myers et al., 1998; Kremers et al., 2000; Watts et al., 2003; Sun et al., 2004). Self-efficacy specifically has been associated with positive intentions (goals) to attend CRC screening (Friedman et al., 2004), lending further evidence to support this model.

### 3.2 Stage models

Stage models use similar concepts to social cognition models, but organise them in a different way (Sutton., 2000). According to this approach, people move through a sequence of discrete, qualitatively distinct stages prior to changing their behaviour (or adopting a new behaviour; Weinstein et al., 1998b). Different factors are thought to be important for different stage transitions. Hence, people in different stages are assumed to require different interventions to help them move to the next stage in the sequence (such interventions are commonly referred to as ‘stage-matched’ interventions).
There are a number of stage-based models, the most relevant for CRC screening being the transtheoretical model (TTM; Prochaska et al., 1992) and the precaution adoption process model (PAPM; Weinstein and Sandman., 1992). The following discusses the evidence for these models as they relate to CRC screening behaviours.

### 3.2.1 The Transtheoretical Model

Although it is often referred to simply as the ‘stages of change’ model of behaviour, the TTM contains theoretical constructs from many different models of behaviour (hence the name: the *transtheoretical* model of behaviour). Constructs within the model include the stages of change (which form the basic organising principle of the model; see Figure 3-4), the processes of change (which facilitate movement from one stage to the next), self-efficacy (taken from Bandura’s Social Cognitive Theory; Bandura., 1980), temptation (which is the opposite of self-efficacy; DiClemente et al., 1991) and the perceived pros and cons of changing (which represent the perceived barriers and benefits of behaviour change, as described by the HBM; Prochaska and DiClemente., 1982; Prochaska et al., 1992).

The main organising principle is that behaviour change occurs in five sequential stages: pre-contemplation (not planning to change behaviour within the next six months), contemplation (thinking about changing behaviour within the next six months, but not planning to change behaviour within the next month), preparation (taking steps towards changing behaviour within the next month), action (attempting to change behaviour) and maintenance (having changed behaviour for at least six months). The first three stages (pre-contemplation, contemplation and preparation) are all defined in terms of a person’s intentions and past behaviour (Prochaska and DiClemente., 1982). By contrast, the last two stages (action and maintenance) are defined purely in terms of behaviour (intentions are not taken into consideration). Progression through the stages is assumed to be sequential, although it may not necessarily be linear (indeed, most people tend to relapse and do not achieve their aims on the first attempt; Michie et al., 2014). For example, in the case of smoking cessation (the behaviour for which the model was initially developed; Prochaska and DiClemente., 1982), someone might quit for more than six months (maintenance), but then start smoking again, thereby regressing to a previous stage (e.g. pre-contemplation, contemplation, etc.). As a result, the stages of change are presented as a spiral in which people start at the top (pre-contemplation) and then move through the stages in order (contemplation, preparation, action, maintenance). This gives the model the flexibility to account for people who relapse to a previous stage and the way in which some people cycle and recycle through the stages several times before achieving long-term behaviour change.
Chapter 3. Psychological perspectives of uptake in colorectal cancer screening: theory and evidence

3.2.1.1 The TTM and CRC screening

The TTM has been applied to a wide range of health behaviours (Bridle et al., 2005), including condom use (Prochaska et al., 1994a), sunscreen use (Prochaska et al., 1994b), healthy eating (Kasila et al., 2003), cancer screening (Spencer et al., 2005) and exercise (Marcus and Simkin, 1994). The model has been particularly popular among clinicians and practitioners and there is a large body of evidence which is interpreted by its proponents as supporting the model (Sutton et al., 2002). With regards to cancer screening specifically, the TTM has been applied many times with varying degrees of success (Spencer et al., 2005). For example, in a review of the literature, Spencer and colleagues (2005) found that there was good evidence to suggest that the TTM applies well to mammography screening, but mixed evidence to support its application to cervical and CRC screening (Spencer et al., 2005). Several studies conducted since the review have provided evidence to support some of the assumptions of the TTM, but not all (Cole et al., 2007; Tung et al., 2008; Zajac et al., 2016). For example, in a study conducted in Australia, Cole and colleagues (2007) found that the uptake of CRC screening was increased when people received an advanced notification letter, which increased uptake by transitioning people from a stage of pre-contemplation, to a stage of contemplation (and subsequently preparation and action; Cole et al., 2007).
3.2.2 The precaution adoption process model

Increasing attention on the criticisms of the TTM\(^5\) has diverted attention away from its application to research (Armitage., 2009). Instead, more recent studies have focussed on the PAPM, which was developed in response to the limitations of the TTM (Weinstein., 1988). Unlike its predecessor, the PAPM aims to explain the deliberative processes involved in turning decisions into action (e.g. whether to have a newly available vaccine). It does not aim to explain the gradual development of behaviour patterns (e.g. diet, exercise, etc.), or the adoption of risk behaviours (e.g. smoking, drug use, etc.), and it does not define stages based on time (one of the major criticisms of the TTM; Armitage., 2009). Instead, the PAPM consistently defines stages based on psychological criteria (Figure 3-5; Weinstein., 1988).

The PAPM proposes that behaviour change occurs in seven distinct stages (see Figure 3-5). In the first stage (Stage 1), people are unaware of the health issue and have formed no opinion about it. When they first learn something about the hazard, they start to form opinions of the precautionary behaviour (Stage 2). At this point, they are thought to be unengaged and think that the health danger or hazard does not apply to them. At the point when people make a personal conception (e.g. through personal experience, including reading about the topic in more detail and drawing parallels to their own situation), they are thought to become engaged and move to the decision-making stage (Stage 3). The decision-making process can result in one of three possible outcomes. First, the individual may choose to suspend judgement, remaining in Stage 3 temporarily or permanently. Second, they may decide not to act (Stage 4). Third, they may decide to adopt the target behaviour, and thus move to Stage 5 (i.e. ‘Decided to act’). Those who decide to adopt should then begin to initiate the behaviour (Stage 6). A seventh stage, if relevant, indicates that the behaviour has been maintained over time (people in this stage are successfully repeating the protective action).

As with the TTM, the PAPM suggests that there are specific factors associated with movement from one stage to the next. However, unlike the TTM, the PAPM does not specify what these factors are (Weinstein., 1988). As such, the model is not directly testable, and only serves as an assessment framework for determining what stage of adopting a precautious behaviour people are situated (Weinstein and Sandman., 1992). What is assumed, however, is that factors influencing transitions through the stages are likely to differ across populations and behaviours.

\(^5\) Problems with the TTM include a lack of standardisation of measures, particularly for the stages of change, logical flaws in current staging algorithms, inadequate specification of the causal relationships among the different constructs, misinterpretation of cross-sectional data on the stages of change and confusion concerning the nature of stage models and how they should be tested (Armitage., 2009).
On this basis, Weinstein and Sandman (1992) suggest that the population and behaviour specific factors should be identified and thus used to inform the design and or tailoring of interventions. Example factors include media messages about the protective behaviour, which may stimulate progression from stage 1 (unaware) to stage 2 (unengaged), and beliefs about personal susceptibility to the health threat, which may stimulate progression from either stage 3 (undecided) to stage 4 (decided not to act), or from stage 3 to stage 5 (decided to act).

**Figure 3-5.** The Precaution Adoption Process Model (Adapted from: Weinstein and Sandman., 1992)

3.2.2.1 PAPM and CRC screening

Since its introduction to the research literature, the PAPM has been applied to a wide range of protective health behaviours, including: home radon testing (Weinstein and Sandman., 1992), mammography screening (Clemow et al., 2000), fruit and vegetable intake (De Vet et al., 2008), cervical screening (Marlow et al., 2017), CRC screening (Costanza et al., 2005; Ferrer et al., 2011) and calcium intake and exercise in patients with epilepsy (Elliott et al., 2007). With regards to CRC screening specifically, several studies have applied the PAPM to describe which stage of adopting the behaviour people are currently in (Costanza et al., 2005; Ferrer et al., 2011).
In one study, Ferrer and colleagues (2011) used a modified version of the PAPM to categorise people into one of eight behaviour change stages (ranging from ‘unaware’, to ‘initial’, ‘maintenance’ and ‘relapse’). In their study, they collected staging data on 2470 respondents (men and women aged 50-75 years) via the National Cancer Institute’s 2003 Health Informatics Trends Survey (a US-based national telephone survey; Nelson et al., 2004). Participants were asked: “Have you ever heard of a stool blood test/ sigmoidoscopy / colonoscopy?”. Anyone who answered “no” was classed as being “unaware” of screening (stage 1), while anyone who answered “yes” was asked further questions about their readiness to screen and previous screening history (see Figure 3-6). Responses to these questions were used to stage individuals accordingly. Additional questions were then asked to assess participants perceived risk of cancer, worry about cancer, fatalism, and beliefs about ambiguity of cancer prevention recommendations (e.g. worry about CRC was assessed by asking: “How often do you worry about getting colon cancer?” with four response options ranging from ‘rarely or never’ to ‘all the time’). The study found that there were significant differences in health perceptions by stage, with individuals in the ‘not engaged’ stage reporting significantly lower levels of worry than those in any other stage, and those in the ‘decided to act’, ‘initial’ and ‘maintenance’ stages reporting significantly less prevention ambiguity than individuals in any of the other stages. Similar findings were made by Costanza and colleagues (2005), who found that provider recommendation, a family history of CRC and higher decisional balance scores were all associated with higher PAPM stages.

**Figure 3-6.** CRC screening readiness staging algorithm (Ferrer et al., 2011).
3.3 Summary

A range of theoretical models have been applied in research examining CRC screening participation. No single model is recognised as being best and the topic of whether participation in CRC screening is a continuous or staged process is an ongoing debate. In the following chapter, I provide an overview of the different strategies that have been used to modify CRC screening behaviour and the evidence to support their use to date.
Chapter 4. Strategies to improve participation in colorectal cancer screening

4.1 Overview

Strategies to improve participation in organised screening programmes, such as those offered in the UK, can be broadly categorised according to six intervention types (i.e. reminders in addition to usual invitation, primary care endorsement, additional interventions in non-participants, enhanced invitation materials, direct contact and varying the screening test) and six intervention time points during which they can be delivered (i.e. before the invitation, at the time of the invitation, between invitation and screening, during screening [e.g. once a home-based kit has been delivered], before the next invitation and at the time of the next invitation; Figure 4-1). Using these concepts as the basis for a conceptual framework, Duffy and colleagues (2016) performed a rapid review to assess the effectiveness of each intervention type to increase uptake across a wide range of cancer screening studies. Reminders, primary care endorsement, offering more acceptable screening tests and interventions which target non-participants were all consistently found to improve uptake. The magnitude of their effects, however, varied greatly within the intervention categories (e.g. studies exploring the use of primary care endorsement to increase screening uptake ranged from a two percent increase in uptake, to a 20% increase in uptake). The authors suggested that this was most likely due to the oversimplification of studies into broad categories (e.g. interventions which target non-participants), which may have overlooked some of the important distinctions between studies in terms of their design and the ways in which interventions were implemented (in the NHS, screening is organised differently for each of the major screening programmes). In this chapter, I discuss the evidence for each intervention category as it relates to CRC screening specifically.

Figure 4-1. Intervention types and time points (Duffy et al., 2016)
4.2 Reminders in addition to usual invitation

Broadly speaking, reminders are short messages which prompt individuals to use a health service (Stone et al., 2002). These messages can be delivered in a number of ways and at a number of different time-points, depending on the set-up and delivery of the service (Baron et al., 2008; Duffy et al., 2016). For example, reminders can be delivered physically by post, verbally over the phone, or digitally by text-message and email. Each method has its own unique set of advantages and limitations. For example, while text-message reminders (also referred to as short messaging service reminders, or SMS reminders) provide a relatively inexpensive method for delivering reminders (i.e. relative to postal and telephone-based reminders; von Karsa et al., 2013), they allow only a limited number of characters to be sent at any one time and are limited to those individuals who have a mobile telephone number registered with their healthcare provider (recent English studies have found that coverage ranges from 40-50%; Kerrison et al., 2015; Hirst et al., 2017). By contrast, telephone reminders are relatively expensive, as they involve direct contact with a healthcare professional (Halloran et al., 2012). At the same time, telephone reminders allow more information to be communicated and provide an opportunity for the patient to ask questions about the test (Saywell et al., 2003).

In a systematic review of patient-directed reminders to increase community demand for breast, cervical and CRC screening, Baron and colleagues (2008) found that, according to Community Guide methods (Briss et al., 2000; Zaza et al., 2000), there was strong evidence to suggest that patient reminders increase demand for gFOBt screening, Papanicolaou test screening and mammography screening, but no evidence to assess whether patient reminders were effective for FS screening (i.e. no qualifying studies addressed these procedures at that time; Baron et al., 2008). Within their review, Baron and colleagues (2008) identified seven studies examining the use of reminders for individuals who were overdue for gFOBt screening specifically. They found that, on average, reminders increased median uptake by 11.5 percentage points, and that, irrespective of the method used (e.g. telephone, postal, etc.), the results were consistently positive (Baron et al., 2008).

A recent review of strategies to promote CRC screening identified one study in which participation rates were examined before and after the delivery of a non-responder reminder for FS screening (Senore et al., 2015b). The study randomly allocated people to one of three groups: Group 1 (n = 5220) received a standard invitation letter, Group 2 (n = 5212) received an advanced notification letter before the standard invitation letter, and Group 3 (n = 5223) received a modified version of the advanced notification letter that included the offer to discuss screening with the individual’s own GP. A reminder letter was sent in all three groups if there was no response to the invitation within three months (Senore et al., 2015a). The results showed that uptake was significantly higher in all three groups six months after the reminder was sent. Uptake increased from 22%, to 26%, in Group 1; from 26%, to 31%, in Group 2; and from 26%, to 31%, in Group 3.
Across all three groups combined, the total proportion attending an appointment increased from 25%, to 29% (Senore et al., 2015a). Unfortunately, as there was no control group in which individuals did not receive a reminder, the extent to which the changes in uptake could attributed to the reminder was not determinable.

**4.3 Interventions in non-participants**

**4.3.1 Repeated invitations**

Another established means of improving CRC screening uptake is to offer repeated invitations (Steele et al., 2010; Lo et al., 2014; Pisera et al., 2016). Repeated invitations are additional rounds of invitation that follow an initial screening invite, usually on an annual, biennial or triennial basis. Unlike reminders, which tend to prompt people about an existing opportunity to take part in screening, repeated invitations offer people a new opportunity to take part in screening, either by offering them a new appointment, or by sending them another kit to complete. In the English BCSP, the proportion of people completing at least one round of gFOBt screening (i.e. prevalence screening) increases with each round of repeated invitation, i.e. from 54% in the first instance, to 60% in the second, and 63% in the third (Steele et al., 2010). The same is true for incidence screening (i.e. the proportion of people completing a second, third or fourth round of screening), with first incidence (gFOBt) screening increasing from 87% following a single round of repeated invitation, to 94% after a second (Lo et al., 2014).

The use of such a strategy to promote the uptake of once-only FS screening has not previously been examined (Senore et al., 2015a; Duffy et al., 2016). One previous study conducted as part of the Nordic-European initiative on Colorectal Cancer (NordICC) trial did, however, examine the use of a second invitation to facilitate the uptake of once-only colonoscopy screening in previous non-participants (Pisera et al., 2016). In that study, one thousand individuals aged 55 to 64 years who did not respond to an invitation and reminder were randomly assigned in a 1:1 ratio to receive either: 1) a second invitation and reminder six and three weeks (respectively) before a new colonoscopy appointment date, or 2) an invitation six weeks before an educational meeting. Uptake was significantly higher in the repeated invitation group compared with the educational session group (uptake was 16.5% and 4.3% in the repeated invitation and educational group respectively). As the study did not include a control group, however, it was not possible to say whether either intervention was more effective than usual care (i.e. no repeated invitation or educational meeting). Furthermore there was no information about the interval between invitations (Pisera et al., 2016).
4.3.2 Modified repeated invitations

Several studies have shown that, when used in conjunction with other interventions, such as primary care endorsement, the effectiveness of repeated invitations can be enhanced (Duffy et al., 2016). For example, one study showed that gFOBt uptake was more than twice as high among previous non-participants who received a second invitation with a gFOBt kit than it was for previous non-participants who received a second invitation by itself (uptake was 20.1% and 9.6% respectively; Tinmouth et al., 2015b). Similar results have been observed for other screening programmes (e.g. breast screening), where modified repeated invitations have also been shown to be effective (Vernon et al., 2010).

4.4 Primary Care endorsement

In England, the NHS Cancer Screening Programmes are carried out with very little primary care involvement (Halloran., 2009). GPs are notified which individuals take part in screening, as well as the outcomes of the screening test, but are not actively involved in the delivery or coordination of the screening programmes, which are managed centrally by Public Health England (PHE). For some screening (e.g. cervical screening), GPs receive monetary benefits (i.e. Quality and Outcomes Framework points) for achieving national targets at their practice, and so are incentivised to promote uptake (NHS Employers., 2016). However, the NHS BSSP is not one of these.

When embedded within the invitation letter, a primary care endorsement (i.e. an endorsement from primary care, such as the invitee’s own GP or GP practice) can be an effective and low-cost intervention that is easy to implement (Wardle et al., 2016; Raine et al., 2016a). Indeed, primary care endorsement has been shown to improve the uptake of gFOBt screening by as much as 14 percentage points (Segnan et al., 1997; Cole et al., 2002; Richardson et al., 1994; Camilloni et al., 2013). The extent to which primary care endorsement can improve uptake is highly dependent on the way in which it is delivered. For example, one study demonstrated that, while the endorsement of the individual’s primary care practice can be effective, it is less effective than when the endorsement comes from the individual’s primary care practitioner (Cole et al., 2002). Another study showed that the effectiveness of the endorsement is modified by the inclusion of the GPs signature (Hewitson et al., 2011). The same study also demonstrated that the inclusion of an enhanced leaflet designed to address barriers to screening had an additional effect (Hewitson et al., 2011).

Primary care endorsement has also been shown to consistently improve uptake across multiple rounds of invitation (Zajac et al., 2010) and when added to a second non-responder reminder letter (Benton et al., 2017). Its potential to improve FS screening participation, however, has not been examined (Senore et al., 2015B).
4.5 Varying invitation materials or strategy

As discussed in Chapter 3, participation in screening is mediated by personal factors, such as worry, perceived risk, and the perceived barriers and benefits of screening (O’Sullivan and Orbell, 2004; Champion et al., 2007). By modifying invitation materials to target these constructs, behavioural scientists have attempted to influence behaviour, and thereby promote uptake and improve population health.

4.5.1 Targeted and tailored invitation materials

Targeting, as defined by Kreuter and Skinner (2000), is the development of a single intervention approach for a defined population subgroup which takes into consideration characteristics shared by the subgroup’s members (Kreuter and Skinner, 2000). The practice of targeting is one that has been widely applied in the health education and health communication literature (Kreuter and Wray, 2003; Rimal and Adkins, 2003) and is an age-old practice of social marketing, where consumers are divided into market segments, towards which communications are then targeted (Campo et al., 2012).

To fully capture the idea of targeting, it is important to understand a second concept, called tailoring. Tailoring is a process in which communications are personalised using individual-level data gathered through questionnaires. The technique was originally developed to match communications to the stages of change described in the TTM (see 3.2.1 The Trantheoretical Model), but has since been used to tailor messages to many more individual characteristics, such as attitudes and beliefs (Stroebe, 2011). A meta-analytic review of tailored print health behaviour change interventions demonstrated that tailored messages were more effective than a no-intervention control and a non-tailored comparison group, and were most effective when tailored to a number of factors, including theoretical concepts, a person’s behaviour and individual demographics (Noar et al., 2007; Revere and Dunbar, 2001).

One RCT examining the impact of tailored and targeted interventions on CRC screening participation found that, while screening was found to be significantly higher in all three intervention groups (i.e. targeted intervention, tailored intervention, and tailored intervention plus telephone reminder) compared with standard invitation (i.e. non-tailored, non-targeted, and with no telephone call), it did not vary significantly between intervention groups (Myers et al., 2007). In a second study examining the cost-effectiveness of these interventions, the authors reported that the tailored interventions were more expensive per additional person screened (both with and without the telephone reminder) compared with the targeted intervention (Lairson et al., 2008), and thereby offered no financial or operational benefit over an intervention targeting fewer characteristics.
Chapter 4. Strategies to improve participation in colorectal cancer screening

In another RCT examining the effectiveness of a culturally tailored navigator programme to improve the uptake of CRC screening, culturally tailored navigation was more effective than usual care (Percac-Lima et al., 2009). However, no group receiving non-tailored navigation was included, making it difficult to assess the added benefit of tailoring the intervention. Further research is therefore needed to justify the use of tailoring, which, as noted above, is generally more expensive. The current evidence suggests that tailoring could be useful for improving uptake of specific groups, such as ethnic minority groups, where materials written in English are not always suitable.

4.5.2 Stage-matched interventions

Stage-matched interventions are designed to address the psychological factors associated with specific stage movements (e.g. progression from one stage, such as pre-contemplation, to another, more advanced stage, such as contemplation – see 3.2 Stage models) and, as such, are thought to be more effective at facilitating stage transitions than non-stage-matched interventions. The strongest evidence to support their use comes from match–mismatch studies, in which people who are at different stages of a behavioural process are offered either stage-matched or mismatched information (i.e. information which is matched to a different stage to that of the individual; Weinstein et al., 1998a). Forward stage movement is then compared between individuals of the same stage in the different groups. To date, however, only a handful of match-mismatch studies have been conducted.

Four previous studies were unable to confirm that matched interventions were more effective than mismatched interventions (Blissmer and McAuley., 2002; Allen et al., 1997; Kadden et al., 1998; Quinlan and McCaul., 2000). Two other studies using different stage-based models of behaviour, however, did find evidence for matching effects (Weinstein et al., 1998a; Dijkstra et al., 1998). In one study, Weinstein and colleagues (1998) offered people stage-matched or stage-mismatched materials to stimulate radon testing in their homes (Weinstein et al., 1998a). They found that the information on the reasons and background of testing was more effective for people in the ‘undecided’ stage (i.e. stage 3 of the PAPM; Figure 3-5), while information on selecting and using a test kit was more effective for people in the ‘decided-to-act’ stage (i.e. stage 5 of the PAPM; Figure 3-5).

In another study, Dijkstra and colleagues (1998) offered information on the outcomes of quitting, information on quitting strategies, or a combination of both types of information to smokers in three qualitatively distinct stages of smoking cessation (Dijkstra et al., 1998). For smokers in the pre-contemplation stage (i.e. not motivated to quit – taken from the TTM), no matching effects were found. For smokers in the contemplation stage (i.e. thinking about quitting), however, a combination of both types of information was most effective, and smokers in the preparation stage (i.e. planning to quit on the short-term) benefited most from information on quitting strategies only.
In a more recent study, Dijkstra and colleagues (2006) examined the effectiveness of stage-matched interventions using a complete stage model, which included smokers, ex-smokers, and three theoretically defined information conditions to stimulate the process of behaviour change (Dijkstra et al., 2006). They found that, at two months follow-up, the matched interventions were significantly more effective at stimulating forward-stage transition than the mismatched interventions. No long-term data on the effectiveness of these interventions currently exists.

Very little research examining the effectiveness of stage-matched interventions to facilitate forward stage transitions in CRC screening uptake has been reported (Senore et al., 2015A, Duffy et al., 2016). One recent study conducted in Australia demonstrated that a modified advance notification letter designed to facilitate forward-stage movement in people who were in the pre-contemplation stage improved overall uptake (Zajac et al., 2016). The same study also found that, while the advanced notification letter was effective, an enhanced invitation letter designed to facilitate forward stage movement in people who were thought to be in a stage of contemplation (i.e. had received the advance notification letter) did not improve uptake.

### 4.5.3 Advance notification letters

Advance notification letters, also referred to as ‘teaser letters’, are letters that are sent to screening eligible adults prior to an invitation for screening. They are intended to ‘prime’ people for their invitation by moving them from a stage of pre-contemplation to a stage of contemplation or readiness (Cole et al., 2007; Zajac et al., 2016). Evidence for their effectiveness originates from a Cochrane review, which documented that previous studies in which this technique was used to increase the return rate of postal questionnaires had reported highly positive results (Edwards et al., 2007). Four RCTs examining the effectiveness of advance notification letters to improve CRC screening uptake have been conducted since the publication of this review (Senore et al., 2015B). All four found that the receipt of an advance notification letter was associated with an increased uptake of CRC screening (Cole et al., 2007; Libby et al., 2011; van Roon et al., 2011; Senore et al., 2015A). Three found that advance notification was associated with an increased participation in gFOBt- and FIT-based screening (van Roon et al., 2011; Libby et al., 2011; Cole et al., 2007) and one found an association for FS-based screening (Senore et al., 2015A).

In one study, Libby and colleagues (2011) found that advance notification letters were an effective method for increasing uptake in CRC screening for men and women, younger and older adults, and people living in the most and least deprived areas (Libby et al., 2011). A follow-up economic analysis found that the inclusion of the letter within the Australian programme was associated with an incremental ratio of $6796 (approximately £5200) per quality adjusted life-year (QALY) gained (Cronin et al., 2013), which was well within the £20,000 threshold set by the National Institute for Health and Care Excellence (NICE; McCabe et al., 2008). Many organised CRC screening programmes now include an advanced notification letter based on the results of these studies (Schreuders et al., 2015).
4.5.4 Educational interventions

Several studies examining the barriers to CRC screening have suggested that better education and low-literacy information materials might improve uptake (Olynyk et al., 1996; Sutton et al., 2000; Brotherstone et al., 2006; von Wagner et al., 2009; Kobayashi et al., 2014; Kobayashi et al., 2016; Ghanouni et al., 2017). However, previous research testing these strategies has reported mixed results (Vernon., 1997). In one study conducted in the UK, gFOBt compliance was increased when a health education intervention was included with the invitation letter (Hardcastle et al., 1983), and similar observations were made in the US for the inclusion of an educational leaflet and follow-up telephone call (Tilley et al., 1999). In the UK FS trial, Wardle and colleagues (2003) found that the inclusion of a leaflet designed to modify negative attitudes towards FS screening was also associated with a modest increase in uptake. Other studies have produced less positive results (Kelly and Shank., 1992; Nichols et al., 1986), including one study which found that including a health education leaflet unexpectedly reduced compliance (Pye et al., 1988). In a recent study reporting the outcomes of four large RCTs conducted within the NHS BCSP, neither a narrative-based leaflet nor a GIST-based leaflet improved uptake when sent in conjunction with the standard invitation materials (Wardle et al., 2016; McGregor et al., 2016b; Smith et al., 2017), despite pilot studies demonstrating their face validity (McGregor et al., 2015b; Smith et al., 2015).

4.6 Direct contact interventions

4.6.1 Patient navigation

In the USA, Harold Freeman pioneered a concept, called Patient Navigation (PN), in which the healthcare provider actively seeks out and removes barriers to cancer-related care, including cancer screening (Freeman., 2012). PN involves a trained individual giving tailored support to patients to help them overcome the barriers preventing them from optimising their healthcare along the cancer pathway. It can take on many different communication formats, including face-to-face and over the phone.

PN has been used to increase participation for various screening, including breast, cervical and CRC screening (Percac-Lima et al., 2009; Battaglia et al., 2011; Percac-Lima et al., 2013; Phillips et al., 2011; Donaldson et al., 2012; Green et al., 2013; Honeycutt et al., 2013). It has been found to be particularly effective among hard-to-reach groups (Muliira and D’Souza., 2015). In a review of the PN literature, Muliira and D’Souza (2015) identified 15 studies examining the effectiveness of PN to improve the uptake of CRC screening in primary care settings, six of which were RCTs. Only three of the RCTs reported that PN was associated with a statistically significant increase in participation; the remaining three all reported statistically non-significant improvements in uptake (Muliira and D’Souza., 2015).
In the UK, PN has been used to lesser extent. No studies examining the effectiveness of PN to promote the uptake of CRC screening were identified in three recent reviews of the research literature (Senore et al., 2015b; Muliira and D’Souza, 2015; Duffy et al., 2016). Several telephone interventions identified in the rapid review by Duffy et al (2016) did involve detailed scripts and briefing of the staff so that they were able to answer patient questions. One such study in CRC screening showed positive results (Shankleman et al., 2014). However, results from a more recent RCT suggest that a telephone reminder with support to address barriers to screening is no more effective than a telephone reminder without support (Chambers et al., 2016). Research exploring the effectiveness of PN in the context of the English BSSP is currently underway and will add significantly to the research literature in this area (McGregor et al., 2016a).

4.7 Alternative screening tests

Alternative screening tests can increase uptake if they are more acceptable to the screening eligible population than the current modality. A recent rapid review of the literature identified ten studies evaluating the effectiveness of offering alternative screening tests to improve uptake (Duffy et al., 2016), including three for CRC screening and seven for cervical screening (no studies were identified for breast screening). In two studies, FIT was associated with a higher participation rate than both colonoscopy and gFOBt screening, with differences in the order of 15 and 20 percentage points (Gupta et al., 2013; Santare et al., 2015). In another study, capsule colonoscopy (a procedure in which the patient swallows a small, wireless camera that takes pictures of the colon and rectum as it passes through the digestive system) was associated with a small increase in uptake over conventional colonoscopy screening (Groth et al., 2012). In the seven cervical screening studies (predominantly conducted with women who had a history of non-participation), Human Papilloma Virus self-sampling was associated with higher uptake than smear testing, with differences in the order of about 10 percentage points.

In a meta-analysis of 13 RCTs comparing the acceptability of FS, gFOBt and FIT screening, uptake was significantly lower for FS compared with gFOBt and FIT (Littlejohn et al., 2012). Only one study included within the analysis reported similar uptake for FS screening with FOBt- and FIT-based screening (Segnan et al., 2007). The remaining 12 all found uptake for FS to be lower.

In another meta-analysis, Vart and colleagues (2012) included studies comparing uptake between gFOBt screening with FIT (Vart et al., 2012). They found that, in all but one study included in the analysis, uptake was significantly higher among individuals offered FIT. In the other study, uptake was significantly higher among people offered the gFOBt (Levi et al., 2011). The results from this review were recently corroborated by the English BCSP FIT pilot (Moss et al., 2016). Moss and colleagues (2016) found that, of those who did not complete the gFOBt in the first round, 23.9% took part in the second round when they were offered the FIT, which compared favourably with those re-offered the gFOBt (only 12.5% of which took part).
4.8 Other intervention strategies

4.8.1 Incentives

Incentives are a group of interventions in which people are rewarded for their behaviour (Bech., 2005). They differ from disincentives, which motivate people to change their behaviour using penalties (e.g. through fines, higher taxation and increased insurance renewal), and can be broadly split into two categories: those which offer a monetary incentive (these are frequently referred to as ‘economic incentives’ or ‘financial incentives’) and those which offer a non-monetary incentive (such as a voucher or coupon). They have been shown to be effective for a range of health behaviours, including smoking, drug abuse and screening for Tuberculosis (Lussier et al., 2006; Prendergast et al., 2006; Giles et al., 2014), but are considered coercive, and so have rarely been tested in organised programmes, such as the English BCSP, which promotes informed decision making.

In a systematic review of the literature, Giles and colleagues (2014) identified three studies examining the effectiveness of incentives to promote screening uptake: one examining the effectiveness of incentives to promote the uptake of breast and cervical screening (Debari et al., 2007) and two examining the effectiveness of incentives to promote the uptake of Tuberculosis screening (Malotte et al., 1998; Malotte et al., 1999). In the study examining the effectiveness of incentives to promote the uptake of breast and cervical screening, Debari and colleagues (2007) found that the offer of a five-dollar gift voucher was not effective. In the first of their two studies examining the effectiveness of incentives to increase Tuberculosis screening compliance among active drug users, Malotte and colleagues (1998) found that both a five-dollar incentive and a ten-dollar incentive were more effective than no incentive, and that a ten-dollar incentive was more effective than a five-dollar incentive (Malotte et al., 1998). In the second study, Malotte and colleagues (1999) found that drug users who received ten-dollars in cash were more likely to attend screening than those who received ten-dollars in grocery store vouchers, bus tokens or fast food coupons, and that individuals receiving coupons were more likely to attend screening than individuals who did not receive any incentive. They also found that there was no difference in uptake between the type of non-monetary incentive used (e.g. between people offered store coupons, bus tokens or fast food vouchers) and uptake of screening.

Several other studies examining the effectiveness of incentives to promote the uptake of cancer screening have been published since the systematic review by Giles and colleagues (2014) took place (Kiran et al., 2014; Gupta et al., 2016; Forster et al., 2017; Mehta et al., 2017). One examined the effectiveness of patient-directed incentives to promote the uptake of CRC screening in Fortworth, Texas (Gupta et al., 2016). Another examined the effectiveness of a primary care ‘pay-for-performance’ scheme to promote the uptake of breast, cervical and CRC screening in Ontario, Canada (Kiran et al., 2014). These studies mostly yielded only small increases in uptake.
4.9 Summary

A number of strategies to improve participation in CRC screening have been examined. Some of the most researched strategies include: ‘reminders in addition to usual invitation’, ‘primary care endorsement’, ‘interventions which target non-participants’ and ‘offering alternative screening tests’. Evidence demonstrating the effectiveness of intervention strategies to promote the uptake of FS screening specifically, however, is currently lacking for all intervention types. No RCTs demonstrating the effectiveness of non-participant reminders, primary care endorsement or repeated invitations were identified within this review, or others conduct before it. These findings, combined with the low uptake of the English BSSP, formed the basis for this thesis, the aims of which were to design and evaluate an intervention strategy to promote BSS participation at St Mark’s Hospital (see Thesis aims and overview). The following chapter presents the first empirical chapter of this thesis.
Chapter 5. Examining uptake at St Mark’s Hospital (Study 1)

5.1 My contributions to the work presented in this chapter

I conceived the idea for the study and wrote the study protocol. The data used were extracted from the Bowel Cancer Screening System (BCSS) by Dave Vernon (Interim Data Analyst, Eastern Bowel Cancer Screening Hub). The data were pseudonymised by Shaila Kumar (Health Improvement Specialist at St Mark’s Hospital), who transferred the data to me for analysis. I coded the data and derived the values for area-level deprivation, ethnic diversity and distance to the screening centre using pseudonymised postcode sectors that were later matched to individuals within the dataset by Shaila. I analysed the data after receiving statistical advice on the appropriateness of my proposed analysis plans from Dr Gianluca Baio (Reader in Statistics and Health Economics, UCL). I interpreted the results with input from my supervisors Dr Lesley McGregor, Dr Christian von Wagner and Professor Jane Wardle. Lesley led on the publication of the manuscript (McGregor et al., 2015a), which examined uptake across all six pilot centres (mentioned in the background literature – see Chapter 2). I contributed to the analysis and interpretation of the results of the published manuscript, as did the other co-authors.

6 A version of this Chapter has been published in the Journal of Medical Screening (Appendix 5-1)

5.2 Introduction

Evidence presented in Chapter 2 highlighted that there were important inequalities in BSS participation between men and women and people living within the most and least deprived areas of England (McGregor et al., 2015a). The aim of this study was to examine variation in uptake at St Mark’s Hospital specifically, with the wider aim of informing the development of the interventions to be developed and evaluated in the latter chapters of this thesis (see Chapters 6, 7, 8 and 9).

5.2.1 Aims

The specific aims of this study were to: 1) examine the association between demographic and service-related variables with invitees’ response to the screening invite and attendance at screening and, 2) examine variation in attendance among those who confirm their appointment.

5.3 Methods

5.3.1 Study design

I performed a retrospective analysis of uptake data collected for St Mark’s Hospital during the first fourteen months of the NHS BSSP’s initial implementation.

5.3.2 Study population and setting

5.3.2.1 Study setting

St Mark’s Hospital is a specialist hospital located within the Northwest London Borough of Brent. It played an important role in the UK FS trial (Atkin et al., 2010), leading on the delivery of several pre-programme feasibility and pilot studies that were influential in the decision to implement the NHS BSSP (Brotherstone et al., 2007; Robb et al., 2010a). In addition, it was one of six centres to begin piloting BSS invitations as part of the national BSSP after its official introduction in March 2013 (McGregor et al., 2015a). It commissioned this PhD as part of its 2013 health improvement strategy.

5.3.2.2 Study population

St Mark’s Hospital serves the socioeconomically and ethnically diverse London boroughs of Brent and Harrow (ONS., 2015). The following provides a brief overview of the areas. A comprehensive overview of the population is provided in the appendix (see Appendix 5-2).
5.3.2.2.1 Ethnic diversity

The London Boroughs of Brent and Harrow are among the most ethnically diverse boroughs in all of England (ONS., 2015). Of the two, Brent is the more diverse, with almost two thirds (63.6%) of its residents being of a non-white ethnic background, compared with just over half (57.7%) in Harrow. Ethnically, the two boroughs are very different. Harrow has a greater proportion of Asian residents (42.7% in Harrow vs. 34% in Brent), and in this borough, Asian is the single most common ethnic group (in Brent it is the second most common ethnic group after White). Black and Chinese / any other ethnicity comprise the remaining non-White populations in Brent and Harrow. Collectively, these ethnicities account for 28.8% and 15.0% of people in Brent and Harrow respectively. The somewhat higher proportion of these minority groups in Brent is reflective of the overall higher diversity of this region (see Appendix 5-2).

Compared with the broader population of London, both Boroughs have a higher proportion of Asian residents (ONS., 2015). Brent also has a higher proportion of Black, Chinese and other ethnic group residents also. Compared with England, both boroughs have fewer White residents and more Asian, Black and Chinese / any other ethnic group residents, which is consistent with the overall higher diversity of London (see Appendix 5-2).

5.3.2.2.2 Household language

English is not the main language in 22.5% and 15.9% of households in Brent and Harrow respectively (ONS., 2015). As such, English is not spoken as the main language in a larger proportion of households in Brent and Harrow than the broader populations of London and England, where 12.9% and 4.4% of households (respectively) do not speak English as the main language (see Appendix 5-2).

5.3.2.2.3 Economic activity

In terms of economic activity, Brent and Harrow are very similar (ONS., 2015). In Brent, 70.1% of people are economically active, compared with 70.7% of people in Harrow. Economic activity in these areas is also comparable to that of the broader populations of London and England, where 71.7% and 69.9% of people (respectively) are economically active (see Appendix 5-2).

5.3.2.2.4 Car or van availability

With regards to household car or van availability, Brent and Harrow are very different (ONS., 2015). In Harrow, household car or van availability is similar to that of the broader population of England, where over 75% of residents live in a household which has access to one or more cars or vans. In Brent, household car or van availability is closer to that of London, where over 40% of residents live in households which have no access to a car or van (see Appendix 5-2).
5.3.2.2.5 Education

The level of education of people living in Brent and Harrow is comparable; 70.4% of people in Brent and 72.3% of people in Harrow have at least one level 2 qualification or above (e.g. GCSE, A-level, etc. ONS., 2015). Proportions are also similar for those who have no qualifications (19.2% in Brent compared with 16.8% in Harrow; see Appendix 5-2).

5.3.2.2.6 Housing tenure

Home ownership is lower in Brent than Harrow. Only 42.9% of residents in Brent either own their home outright or with a mortgage or loan, whereas in Harrow, home ownership is 65.2% (ONS., 2015). Compared with the broader populations of London and England, where nearly two thirds (48.2% and 63.2% respectively) of people either own their home outright or with a mortgage or loan, home ownership is low in Brent but high in Harrow (see Appendix 5-2).

5.3.3 Analytic sample

The analytic sample for this study was all men and women invited for BSS at St Mark’s Hospital between March 2013 and May 2014.

5.3.4 Data extraction

The data used for this study were extracted from the BCSS by a data analyst at the Eastern Bowel Cancer Screening Hub (see Table 5-1 for an overview of the data specification submitted to the Eastern Bowel Cancer Screening Hub by the clinical programme manager at St Mark’s Bowel Cancer Screening Centre, BCSC). The data were transferred to St Mark’s BCSC via a secure NHS.net connection, and any identifiable information removed by a member of the direct care team, prior to being transferred to myself at UCL for analysis (see Appendix 5-3 for an overview of the flow of data through the study).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Reason for request</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS Number</td>
<td>Required for extraction</td>
</tr>
<tr>
<td>Gender</td>
<td>Required for analysis</td>
</tr>
<tr>
<td>CCG</td>
<td>Required for analysis</td>
</tr>
<tr>
<td>Postcode</td>
<td>Required for analysis</td>
</tr>
<tr>
<td>Confirmed an appointment</td>
<td>Required for analysis</td>
</tr>
<tr>
<td>Attended an appointment</td>
<td>Required for analysis</td>
</tr>
<tr>
<td>Date and time of appointment offered</td>
<td>Required for analysis</td>
</tr>
<tr>
<td>Date and time of appointment attended</td>
<td>Required for analysis</td>
</tr>
</tbody>
</table>
Chapter 5. Examining uptake at St Mark’s Hospital (Study 1)

5.3.5 Measures

To examine possible associations between demographic and service-related variables with odds for ‘confirming an appointment’ and ‘attendance at screening’, a range of data available on the BCSS were extracted and added to the study database (see Table 5-1). Several of these, including gender and area-level deprivation, were shown to predict participation in the early uptake study (McGregor et al., 2015a) and were included to examine their associations with uptake at St Mark’s Hospital specifically. Others, such as appointment type and area-level ethnic diversity, were not found to be significant predictors of uptake in the early uptake study (McGregor et al., 2015a), and were included to assess whether they were associated with uptake at St Mark’s Hospital in particular. Two additional variables, distance to the screening centre and CCG, which were not included in the early uptake study, were also included in the analysis to assess their associations with uptake. Difficulty in getting to the screening centre has previously been reported as a barrier to uptake (Cole et al., 2012), and so distance to the screening centre was added as a proxy for this potential practical barrier to uptake. CCG has been identified as a predictor of uptake in other studies (Robb et al., 2010a), and so was included as a variable in this study for this reason.

5.3.5.1 Gender and CCG

The gender and CCG of each person was added to the study database as part of the initial extraction.

5.3.5.2 Area-level deprivation

I converted the postcode of each person’s home address into a score on the 2010 Index of Multiple Deprivation (IMD) using Geoconvert: an online tool that enables users to convert geographies into Census-derived statistics (UK Data Service Census Support., 2017). I then categorised the scores into quintiles of the national distribution to compare uptake between individuals living in the most and least deprived areas. To ensure people were not identifiable during the conversion, postcodes were pseudonymised by a member of the direct care team at St Mark’s BCSC, who merged the converted data with the study database using a unique participant identification (ID) number contained within both datasets (this was deleted once the data had been merged, so that postcodes could not be retrospectively identified).

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7 The index of multiple deprivation is the government’s official measure of relative deprivation for small areas in England (Department for Communities and Local Government., 2011). It uses administrative data and census-derived indicators of income, education, employment, living environment, health and disability, barriers to housing and services, and crime at small-area level to generate a scale ranging from 0 (least deprived) to 80 (most deprived).
5.3.5.3 Area-level ethnic diversity

The process of obtaining and converting each person’s home postcode address into an area-level ethnic diversity score (i.e. ‘percent non-White’) was similar to that described for area-level deprivation (see 5.3.5.2 Area-level deprivation). I received a pseudonymised list of home postcode addresses and unique study IDs from St Mark’s BCSC, converted them into area-level ethnic diversity scores using Census data on the proportion of non-White residents within each postcode (ONS., 2011), categorised them into quintiles of their national distribution, and returned them to a member of the direct care team at St Mark’s BCSC, who merged the data with the study database. Again, a unique study ID was used to facilitate the process of merging the data and was deleted after the data had been merged so that postcodes could not be identified retrospectively.

5.3.5.4 Appointment type

The date and time of the appointment offered in the initial invitation was extracted for each person from the BCSS as part of the initial extraction. Appointments offered on weekday afternoons (i.e. between 1pm and 3:30pm) were coded as ‘routine appointments’, and appointments offered on weekday evenings (i.e. between 4:45pm and 7pm) and Saturdays as ‘out-of-hours appointments’. The process of converting the day and time of the appointment into the type of appointment offered was facilitated by myself using the anonymised study database.

5.3.5.5 Distance to the screening centre

The process of obtaining and converting each person’s home postcode address into distance to the screening centre (in miles) was similar to that described for area-level deprivation and area-level ethnic diversity. I received a pseudonymised list of home postcode addresses and unique study IDs from St Mark’s BCSC, converted them into distances from the screening centre using the ‘Google Maps Distance Function’ in Microsoft Excel and returned them to the direct care team at St Mark’s BCSC, who merged the data with the study database. Again, a unique study ID was used to facilitate the process of merging the data and was deleted after the data had been merged, so that postcodes could not be identified retrospectively.

5.3.5.6 Changed appointment

To assess the proportion of individuals who rescheduled their appointment, the time and date of the appointment offered and the time and date of the appointment attended were extracted from the BCSS as part of the initial extraction. These data were then compared to determine whether people attended the appointment they were initially offered, or whether the appointment attended was a different day / time. As with appointment type, I converted the data myself within the anonymised study database.
5.3.5.7 Confirmed an appointment and attendance at screening

Response to the screening invite (i.e. confirmed an appointment yes / no) and attendance at screening (i.e. attended an appointment yes / no) were extracted from the BCSS as part of the initial extraction.

5.3.6 Analysis

Descriptive statistics were used to describe the sample population. Univariable and multivariable binary logistic regression were used to investigate possible associations between baseline characteristics and confirming and attending an appointment (Engel., 1988). A subgroup analysis was performed on individuals who confirmed an appointment to examine whether variables were associated with odds of attending a confirmed appointment specifically. The amount of variance explained by each model was reported using the Nagelkerke R square statistic (Nagelkerke., 1991). The data were assessed using SPSS (version 24).

5.3.7 Ethical approval, research governance and trial sponsorship

Ethical approval and trial sponsorship were not required for this study.

5.4 Results

5.4.1 Sample characteristics

Over the first 14 months of the NHS BSS programme’s initial implementation, 4933 men (n = 2449, 49.6%) and women (n = 2848, 50.4%) were invited for screening at St Mark’s BCSC (Table 5-2). The majority were registered with an address within the London Borough of Brent (n = 3134, 63.5%) and were offered an out-of-hours appointment (n = 3023, 61.3%). More than 70% were registered with an address within the most ethnically diverse quintile of areas (n = 3644, 73.9%) and only a small portion were registered with an address within the least ethnically diverse quintile of areas (n = 337, 6.8%). The majority were also registered with an address in either the most deprived (n = 903, 18.3%) or second most deprived (n = 1848, 37.4%) quintile of areas in England. The proportion of invitees from the most diverse quintile of areas varied by CCG and was higher in Brent (n = 2557, 81.6%) than Harrow (n = 1087, 60.4%), as was the proportion of invitees from the most socioeconomically deprived areas (n = 857, 27.3% and n = 46, 2.6% for Brent and Harrow respectively; Table 5-2).

The mean distance between each person’s home address and the screening centre was 2.9 miles (Standard Deviation, SD = 1.4). On average, invitees from Brent lived slightly further from the screening centre than invitees from Harrow (mean distance to the screening centre was 2.2 miles and 3.3 miles, respectively). These findings were consistent with data reported by the ONS (ONS., 2015).
### Table 5-2. Description of the study population

<table>
<thead>
<tr>
<th></th>
<th>Brent (n = 3134)</th>
<th>Harrow (n = 1799)</th>
<th>Total (n = 4993)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>1552 (49.5)</td>
<td>932 (51.8)</td>
<td>2484 (50.4)</td>
</tr>
<tr>
<td>Men</td>
<td>1582 (50.5)</td>
<td>867 (48.2)</td>
<td>2449 (49.6)</td>
</tr>
<tr>
<td><strong>Quintile of deprivation (IMD score), n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Most deprived</td>
<td>857 (27.3)</td>
<td>46 (2.6)</td>
<td>903 (18.3)</td>
</tr>
<tr>
<td>(33.50 – 80.00)</td>
<td>(27.3)</td>
<td>(2.6)</td>
<td>(18.3)</td>
</tr>
<tr>
<td>Quintile 2</td>
<td>1560 (50.5)</td>
<td>283 (15.7)</td>
<td>1848 (37.4)</td>
</tr>
<tr>
<td>(21.62 – 33.49)</td>
<td>(49.8)</td>
<td>(15.7)</td>
<td>(37.4)</td>
</tr>
<tr>
<td>Quintile 3</td>
<td>647 (20.6)</td>
<td>591 (32.9)</td>
<td>1238 (25.1)</td>
</tr>
<tr>
<td>(14.61 – 21.61)</td>
<td>(20.6)</td>
<td>(32.9)</td>
<td>(25.1)</td>
</tr>
<tr>
<td>Quintile 4</td>
<td>55 (1.8)</td>
<td>552 (30.7)</td>
<td>607 (12.3)</td>
</tr>
<tr>
<td>(9.88 – 14.60)</td>
<td>(1.8)</td>
<td>(30.7)</td>
<td>(12.3)</td>
</tr>
<tr>
<td>Least deprived</td>
<td>11 (0.4)</td>
<td>326 (18.1)</td>
<td>337 (6.8)</td>
</tr>
<tr>
<td>(0.01 – 9.87)</td>
<td>(0.4)</td>
<td>(18.1)</td>
<td>(6.8)</td>
</tr>
<tr>
<td>Missing</td>
<td>4 (0.1)</td>
<td>1 (0.1)</td>
<td>5 (0.1)</td>
</tr>
<tr>
<td><strong>Quintile of ethnic diversity (% of non-white residents within a postcode sector), n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Most diverse</td>
<td>2557 (81.6)</td>
<td>1087 (60.4)</td>
<td>3644 (73.9)</td>
</tr>
<tr>
<td>(0.00-28.17)</td>
<td>(81.6)</td>
<td>(60.4)</td>
<td>(73.9)</td>
</tr>
<tr>
<td>Quintile 2</td>
<td>318 (10.1)</td>
<td>325 (18.1)</td>
<td>643 (13.0)</td>
</tr>
<tr>
<td>(28.18 – 36.94)</td>
<td>(10.1)</td>
<td>(18.1)</td>
<td>(13.0)</td>
</tr>
<tr>
<td>Quintile 3</td>
<td>80 (2.6)</td>
<td>112 (6.2)</td>
<td>192 (3.9)</td>
</tr>
<tr>
<td>(14.61 – 21.61)</td>
<td>(2.6)</td>
<td>(6.2)</td>
<td>(3.9)</td>
</tr>
<tr>
<td>Quintile 4</td>
<td>64 (2.0)</td>
<td>127 (7.1)</td>
<td>191 (3.9)</td>
</tr>
<tr>
<td>(46.89 – 62.92)</td>
<td>(2.0)</td>
<td>(7.1)</td>
<td>(3.9)</td>
</tr>
<tr>
<td>Least diverse</td>
<td>111 (3.5)</td>
<td>147 (8.2)</td>
<td>258 (5.2)</td>
</tr>
<tr>
<td>(62.93 – 100.00)</td>
<td>(3.5)</td>
<td>(8.2)</td>
<td>(5.2)</td>
</tr>
<tr>
<td>Missing</td>
<td>4 (0.1)</td>
<td>1 (0.1)</td>
<td>5 (0.1)</td>
</tr>
<tr>
<td><strong>Appointment type, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Out-of-hours</td>
<td>1909 (60.9)</td>
<td>1114 (61.9)</td>
<td>3023 (61.3)</td>
</tr>
<tr>
<td>(60.9)</td>
<td>(61.9)</td>
<td>(61.3)</td>
<td></td>
</tr>
<tr>
<td>Routine</td>
<td>1225 (39.1)</td>
<td>685 (38.1)</td>
<td>1910 (38.7)</td>
</tr>
<tr>
<td>(39.1)</td>
<td>(38.1)</td>
<td>(38.7)</td>
<td></td>
</tr>
<tr>
<td><strong>Distance to the screening centre, Miles (SD)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distance, Mean (SD)</td>
<td>3.27</td>
<td>2.18</td>
<td>2.87</td>
</tr>
<tr>
<td>(0 – 13 miles)</td>
<td>(1.45)</td>
<td>(0.91)</td>
<td>(1.38)</td>
</tr>
</tbody>
</table>

Abbreviations: IMD, Index of Multiple Deprivation; SD, Standard Deviation
5.4.2 Confirmed an appointment

Of the 4933 men and women invited for screening at St Mark’s BCSC, 2480 (50.3%) confirmed their appointment. Differences in the proportion confirming an appointment by gender, CCG, area-level deprivation, area-level ethnic diversity, appointment type and distance to the screening centre are reported in Table 5-3.

In the univariable analyses, the proportion of individuals confirming an appointment did not vary by gender or the type of appointment offered (both $P$s > 0.05), but did vary by CCG, area-level deprivation, area-level ethnic diversity and distance to the screening centre (all $P$s < 0.05). Confirmation of an appointment was highest in the least deprived areas and lowest in the most deprived (57.9% vs. 43.7%; Odds Ratio [OR] = 1.8, 95% Confidence Interval [CI] = 1.4 – 2.3, $P$ < 0.001), with an almost linear trend across deprivation quintiles (Table 5-3). Confirmation of an appointment was also higher in the least ethnically diverse areas compared with the most ethnically diverse areas (58.5% vs. 48.6%; OR = 1.5, 95% CI = 1.2 – 1.9, $P$ < 0.01). As with area-level deprivation, there was an almost linear trend across diversity quintiles (Table 5-3). The proportion of invitees confirming an appointment decreased as distance to the screening centre increased (OR = 0.9, 95% CI = 0.9 – 1.0, $P$ < 0.001) and was higher in Harrow than Brent (uptake was 55.3% and 47.4% in Harrow and Brent respectively; OR = 1.4, 95% CI = 1.2 – 1.5, $P$ < 0.001).

Results were similar in the multivariable analysis (Table 5-3), with strong evidence of significant differences between the most and least deprived areas (adjusted OR [aOR] = 1.4, 95% CI = 1.0 – 1.92, $P$ < 0.05), as well as the most and least ethnically diverse (aOR = 1.3, 95% CI = 1.0 – 1.7; $P$ < 0.05). After adjusting for covariates, there was no longer evidence for a difference in confirming an appointment by CCG (aOR = 1.1, 95% CI = 0.9 – 1.3, $P$ > 0.05) or distance to the screening centre (aOR = 1.0, 95% CI = 0.9 – 1.0, $P$ > 0.05).
### Table 5-3. Sample variation in response to the screening invite at St Mark’s BCSC

<table>
<thead>
<tr>
<th></th>
<th>Responded n (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR(^1) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall response (n = 4933)</td>
<td>2480 (50.3)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women(^a) (n = 2484)</td>
<td>1240 (49.9)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Men (n = 2449)</td>
<td>1240 (50.6)</td>
<td>1.03 (0.92 - 1.15)</td>
<td>1.04 (0.93 - 1.16)</td>
</tr>
<tr>
<td><strong>CCG</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brent(^a) (n = 3134)</td>
<td>1486 (47.4)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Harrow (n = 1799)</td>
<td>994 (55.3)</td>
<td>1.37*** (1.22 - 1.54)</td>
<td>1.08 (0.92 - 1.27)</td>
</tr>
<tr>
<td><strong>Quintile of deprivation (IMD score)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Most deprived(^a) (n = 903)</td>
<td>395 (43.7)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>(33.50 – 80.00)</td>
<td>879 (47.7)</td>
<td>1.17* (1.00 - 1.38)</td>
<td>1.10 (0.93 - 1.30)</td>
</tr>
<tr>
<td>Quintile 2 (n = 1843)</td>
<td>(47.7)</td>
<td>(1.00 - 1.38)</td>
<td>(0.93 - 1.30)</td>
</tr>
<tr>
<td>(21.62 – 33.49)</td>
<td>661 (53.4)</td>
<td>1.47*** (1.24 - 1.75)</td>
<td>1.29** (1.06 - 1.58)</td>
</tr>
<tr>
<td>Quintile 3 (n = 1238)</td>
<td>(53.4)</td>
<td>(1.24 - 1.75)</td>
<td>(1.06 - 1.58)</td>
</tr>
<tr>
<td>(14.61 – 21.61)</td>
<td>347 (57.2)</td>
<td>1.72*** (1.40 - 2.11)</td>
<td>1.42* (1.10 - 1.83)</td>
</tr>
<tr>
<td>Quintile 4 (n = 607)</td>
<td>(57.2)</td>
<td>(1.40 - 2.11)</td>
<td>(1.10 - 1.83)</td>
</tr>
<tr>
<td>(9.88 – 14.60)</td>
<td>195 (52.3)</td>
<td>1.77*** (1.40 - 2.11)</td>
<td>1.42* (1.10 - 1.83)</td>
</tr>
<tr>
<td>Least deprived (n = 337)</td>
<td>(52.3)</td>
<td>(1.40 - 2.11)</td>
<td>(1.10 - 1.83)</td>
</tr>
<tr>
<td>(0.01 – 9.87)</td>
<td>151 (59.2)</td>
<td>1.53** (1.14 - 2.06)</td>
<td>1.33* (0.97 - 1.79)</td>
</tr>
<tr>
<td>(62.93 – 100.00)</td>
<td>(59.2)</td>
<td>(1.14 - 2.06)</td>
<td>(0.97 - 1.79)</td>
</tr>
<tr>
<td><strong>Quintile of ethnic diversity (% of non-white residents within a postcode sector)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Most diverse(^a) (n = 3644)</td>
<td>1770 (48.6)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>(0.00-28.17)</td>
<td>336 (52.3)</td>
<td>1.16 (0.98 - 1.37)</td>
<td>1.12 (0.93 - 1.35)</td>
</tr>
<tr>
<td>Quintile 2 (n = 643)</td>
<td>(52.3)</td>
<td>(0.98 - 1.37)</td>
<td>(0.93 - 1.35)</td>
</tr>
<tr>
<td>(28.18 – 36.94)</td>
<td>107 (55.7)</td>
<td>1.33* (1.00 - 1.79)</td>
<td>1.22 (0.91 - 1.64)</td>
</tr>
<tr>
<td>Quintile 3 (n = 192)</td>
<td>(55.7)</td>
<td>(1.00 - 1.79)</td>
<td>(0.91 - 1.64)</td>
</tr>
<tr>
<td>(14.61 – 21.61)</td>
<td>113 (59.2)</td>
<td>1.53** (1.14 - 2.06)</td>
<td>1.32 (0.97 - 1.79)</td>
</tr>
<tr>
<td>Quintile 4 (n = 191)</td>
<td>(59.2)</td>
<td>(1.14 - 2.06)</td>
<td>(0.97 - 1.79)</td>
</tr>
<tr>
<td>(46.89 – 62.92)</td>
<td>151 (58.5)</td>
<td>1.49** (1.14 - 2.06)</td>
<td>1.33* (1.02 - 1.72)</td>
</tr>
<tr>
<td>Least diverse (n = 258)</td>
<td>(58.5)</td>
<td>(1.14 - 2.06)</td>
<td>(1.02 - 1.72)</td>
</tr>
<tr>
<td>(62.93 – 100.00)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Appointment type</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Out-of-hours(^a) (n = 3,023)</td>
<td>1518 (50.2)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Routine (n = 1,910)</td>
<td>962 (50.4)</td>
<td>1.01 (0.90 - 1.13)</td>
<td>1.02 (0.91 - 1.14)</td>
</tr>
<tr>
<td><strong>Distance to screening centre (Miles)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distance (0 – 13 miles)</td>
<td>-</td>
<td>0.93*** (0.89 - 0.97)</td>
<td>0.96 (0.92 - 1.01)</td>
</tr>
</tbody>
</table>

Abbreviations: OR, Odds Ratio; CI, Confidence Interval; CCG, Clinical Commissioning Group; IMD, Index of Multiple Deprivation
\(^1\)Adjusted ORs and 95% CIs are adjusted for all other covariates in the table.
\(^a\)Reference group
*P < 0.05, **P < 0.01, ***P < 0.001
Nagelkerke R Square = 0.015
5.4.3 Uptake (all invitees)

Of the 4933 men and women invited for screening, 1997 (40.5\%) attended an appointment. Differences in uptake by gender, CCG, area-level deprivation, area-level ethnic diversity, appointment type and distance to the screening centre are reported in Table 5-4.

In the univariable analyses, uptake did not vary by gender or the type of appointment offered (both $P$s > 0.05; Table 5-4), but did vary by CCG, area-level deprivation, area-level ethnic diversity, and distance to the screening centre (all $P$s < 0.05). Uptake was highest in the least deprived areas and lowest in the most deprived areas (47.8\% vs. 32.7\%; OR = 1.7, 95\% CI = 1.4 – 2.0, $P$ < 0.001), with an almost linear trend across intermediate quintiles of area-level deprivation (Table 5-4). Uptake was also higher in the least ethnically diverse quintile of areas compared with the most ethnically diverse quintile (47\% vs. 38.7\%; OR = 1.4, 95\% CI = 1.2 – 1.7, $P$ < 0.01). However, unlike area-level deprivation, there was no evidence of a linear trend across quintiles of area-level diversity (Table 5-4). As was the case for odds of confirming of an appointment, odds of attending an appointment decreased as distance to the screening centre increased (OR = 0.9, 95\% CI = 0.9 – 1.0, $P$ < 0.01), and were higher in Harrow than Brent (OR = 1.3, 95\% CI = 1.2 – 1.5, $P$ < 0.001; Table 5-4).

Results were similar in the multivariable analysis (Table 5-4), with strong evidence of significant differences between the most and least deprived quintiles of areas (aOR = 1.5, 95\% CI = 1.2 – 1.9, $P$ < 0.01), as well as the most and least ethnically diverse quintiles of areas (aOR = 1.3, 95\% CI = 1.1 – 1.6, $P$ < 0.01). After adjusting for covariates, there was no longer evidence for a significant difference in participation by CCG (aOR = 1.0, 95\% CI = 0.9 – 1.2, $P$ > 0.05) or distance to the screening centre (aOR = 1.0, 95\% CI = 0.9 – 1.0, $P$ > 0.05).
### Table 5-4. Sample variation in screening uptake at St Mark’s BCSC

<table>
<thead>
<tr>
<th>Uptake n (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR¹ (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall uptake (n = 4933)</td>
<td>1997 (40.5)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women* (n = 2848)</td>
<td>990 (39.9)</td>
<td>-</td>
</tr>
<tr>
<td>Men (n = 2449)</td>
<td>1007 (41.1)</td>
<td>1.05 (0.94 - 1.18)</td>
</tr>
<tr>
<td><strong>CCG</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brent* (n = 3134)</td>
<td>1190 (38.0)</td>
<td>-</td>
</tr>
<tr>
<td>Harrow (n = 1799)</td>
<td>807 (44.8)</td>
<td>1.33*** (1.18 - 1.50)</td>
</tr>
<tr>
<td><strong>Quintile of deprivation (IMD score)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Most deprived* (n = 988)</td>
<td>345 (34.9)</td>
<td>-</td>
</tr>
<tr>
<td>Quintile 2 (n = 999)</td>
<td>360 (36.0)</td>
<td>1.05 (0.87 - 1.26)</td>
</tr>
<tr>
<td>Quintile 3 (n = 974)</td>
<td>397 (40.8)</td>
<td>1.28* (1.07 - 1.54)</td>
</tr>
<tr>
<td>Quintile 4 (n = 982)</td>
<td>422 (43.0)</td>
<td>1.40** (1.17 - 1.69)</td>
</tr>
<tr>
<td>Least deprived (n = 984)</td>
<td>470 (47.8)</td>
<td>1.70** (1.42 - 2.04)</td>
</tr>
<tr>
<td><strong>Quintile of ethnic diversity (% of non-white residents within a postcode sector)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Most diverse* (n = 1008)</td>
<td>383 (38.0)</td>
<td>-</td>
</tr>
<tr>
<td>Quintile 2 (n = 1017)</td>
<td>391 (38.4)</td>
<td>1.02 (0.85 - 1.22)</td>
</tr>
<tr>
<td>Quintile 3 (n = 933)</td>
<td>359 (38.5)</td>
<td>1.02 (0.85 - 1.23)</td>
</tr>
<tr>
<td>Quintile 4 (n = 986)</td>
<td>407 (41.3)</td>
<td>1.15 (0.96 - 1.37)</td>
</tr>
<tr>
<td>Least diverse (n = 984)</td>
<td>454 (47.8)</td>
<td>1.40** (1.17 - 1.67)</td>
</tr>
<tr>
<td><strong>Appointment type</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Out-of-hours* (n = 3023)</td>
<td>1225 (40.5)</td>
<td>-</td>
</tr>
<tr>
<td>Routine (n = 1910)</td>
<td>772 (40.4)</td>
<td>1.00 (0.89 - 1.12)</td>
</tr>
<tr>
<td><strong>Distance to the screening centre (Miles)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distance (0 – 13 miles)</td>
<td>-</td>
<td>0.94** (0.90 - 0.98)</td>
</tr>
</tbody>
</table>

Abbreviations: OR, Odds ratio; CI, Confidence Interval; CCG, Clinical Commissioning Group; IMD, Index of Multiple Deprivation

¹Adjusted ORs and 95% CIs are adjusted for all other covariates in the table.

*Reference group

*P < 0.05, **P < 0.01, ***P < 0.001; Nagelkerke R Square = 0.015
5.4.4 Attendance (invitees who confirmed an appointment only)

Of the 2480 men and women who confirmed an appointment, 1997 (80.5%) attended. Differences in uptake among those who confirmed an appointment by gender, CCG, area-level deprivation, area-level ethnic diversity, appointment type and distance to the screening centre are reported in Table 5.5.

In the univariable analyses, uptake among individuals who confirmed an appointment \((n = 2480)\) did not vary by gender, CCG, area-level deprivation, appointment type or distance to the screening centre \((all \; P_s > 0.05; \text{Table 5}-5)\), but did vary by area-level ethnic diversity, with people in the least ethnically diverse areas being significantly more likely to attend an appointment than individuals living in the most ethnically diverse quintile areas \((80.1\% \text{ vs. } 87.4\% \text{ respectively}; \text{aOR} = 1.7, 95\% \text{ CI} = 1.1 - 2.8, \; P < 0.05)\).

Results were similar in the multivariable analysis, with gender, CCG, appointment type and distance to the screening centre all remaining non-significant predictors of uptake among people who confirmed an appointment \((all \; P_s > 0.05; \text{Table 5}-5)\). Area-level ethnic diversity, however, was no longer a significant predictor in the multivariable analysis \((\text{aOR} = 1.6, 95\% \text{ CI} = 1.0 - 2.7, \; P > 0.05)\). Conversely, area-level deprivation, which was not a significant predictor in the univariable analysis, was a significant predictor in the multivariable analysis, with people living in the least deprived quintile of areas being significantly more likely to attend a confirmed appointment than individuals in the most deprived quintile of areas \((86.7\% \text{ vs. } 80.8\%; \text{aOR} = 1.8, 95\% \text{ CI} = 1.0 - 3.1, \; P < 0.05)\).
## Table 5-5. Sample variation in attendance among responders at St Mark’s BCSC

<table>
<thead>
<tr>
<th>Uptake</th>
<th>Unadjusted OR</th>
<th>Adjusted OR$^1$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(95% CI)</td>
<td>(95% CI)</td>
</tr>
<tr>
<td>Overall attendance (n = 2480)</td>
<td>1997 (80.5)</td>
<td>-</td>
</tr>
</tbody>
</table>

### Gender

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted</th>
<th>Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR (95% CI)</td>
<td>OR (95% CI)</td>
</tr>
<tr>
<td>Women* (n = 1240)</td>
<td>990 (79.8)</td>
<td>-</td>
</tr>
<tr>
<td>Men (n = 1240)</td>
<td>1007 (81.2)</td>
<td>1.09 (0.90 - 1.33)</td>
</tr>
</tbody>
</table>

### CCG

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted</th>
<th>Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR (95% CI)</td>
<td>OR (95% CI)</td>
</tr>
<tr>
<td>Brent* (n = 1486)</td>
<td>1190 (80.1)</td>
<td>-</td>
</tr>
<tr>
<td>Harrow (n = 994)</td>
<td>807 (81.2)</td>
<td>1.07 (0.88 - 1.32)</td>
</tr>
</tbody>
</table>

### Quintile of deprivation (IMD score 0-80)

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted</th>
<th>Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR (95% CI)</td>
<td>OR (95% CI)</td>
</tr>
<tr>
<td>Most deprived* (n = 395)</td>
<td>319 (80.8)</td>
<td>-</td>
</tr>
<tr>
<td>(33.50 – 80.00)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quintile 2 (n = 879)</td>
<td>879 (78.7)</td>
<td>0.88 (0.66 - 1.19)</td>
</tr>
<tr>
<td>(21.62 – 33.49)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quintile 3 (n = 661)</td>
<td>529 (80.0)</td>
<td>0.96 (0.70 - 1.31)</td>
</tr>
<tr>
<td>(14.61 – 21.61)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quintile 4 (n = 347)</td>
<td>285 (82.1)</td>
<td>1.10 (0.76 - 1.59)</td>
</tr>
<tr>
<td>(9.88 – 14.60)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Least deprived (n = 195)</td>
<td>169 (86.7)</td>
<td>1.55 (0.96 - 2.51)</td>
</tr>
<tr>
<td>(0.01 – 9.87)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Quintile of ethnic diversity (% of non-white residents within a postcode sector)

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted</th>
<th>Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR (95% CI)</td>
<td>OR (95% CI)</td>
</tr>
<tr>
<td>Most diverse* (n = 1770)</td>
<td>1418 (80.1)</td>
<td>-</td>
</tr>
<tr>
<td>(11.81 - 100)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quintile 2 (n = 336)</td>
<td>269 (80.1)</td>
<td>1.00 (0.74 - 1.34)</td>
</tr>
<tr>
<td>(3.66 – 11.80)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quintile 3 (n = 107)</td>
<td>84 (78.5)</td>
<td>0.91 (0.56 - 1.46)</td>
</tr>
<tr>
<td>(1.78 – 3.65)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quintile 4 (n = 113)</td>
<td>91 (80.5)</td>
<td>1.03 (0.64 - 1.66)</td>
</tr>
<tr>
<td>(1.05 – 1.77)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Least diverse (n = 151)</td>
<td>132 (87.4)</td>
<td>1.73 (1.05 - 2.83)*</td>
</tr>
<tr>
<td>(0 – 1.04)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Type of appointment offered

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted</th>
<th>Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR (95% CI)</td>
<td>OR (95% CI)</td>
</tr>
<tr>
<td>Out-of-hours* (n = 1518)</td>
<td>1225 (80.7)</td>
<td>-</td>
</tr>
<tr>
<td>Routine (n = 962)</td>
<td>772 (80.2)</td>
<td>0.97 (0.79 - 1.19)</td>
</tr>
</tbody>
</table>

### Distance to the screening centre (Miles)

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted</th>
<th>Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR (95% CI)</td>
<td>OR (95% CI)</td>
</tr>
<tr>
<td>Distance (0 – 13 miles)</td>
<td>- (1.00)</td>
<td>1.00 (1.00 - 1.01)</td>
</tr>
</tbody>
</table>

Abbreviations: OR, Odds Ratio; CI, Confidence Interval; CCG, Clinical Commissioning Group; IMD, Index of Multiple Deprivation

$^1$Adjusted ORs and 95% CIs are adjusted for all other covariates in the table.

*Reference group

$^*P < 0.05, **P < 0.01, ***P < 0.001; Nagelkerke R Square = 0.010$
5.4.5 Proportion of appointment times offered, attended and rescheduled

Of the 4933 men and women invited for screening, 1910 (38.7%) were offered a routine (weekday afternoon) appointment and 3023 (61.3%) were offered an out-of-hours (weekday evening or weekend) appointment (Table 5-6). Of those who attended an appointment (n = 1997), only 39.9% (n = 797) attended the appointment they were originally offered, and the level of attendance was similar for both types of appointment offered (39.1% vs. 41.1%; Table 5-6). A further 34.5% (n = 689) attended an appointment within their original appointment slot (i.e. same day, different time). The remaining 25.6% (n = 511) attended an appointment within a different appointment slot (i.e. different day and / or different time of day). The proportion attending an appointment within the same appointment slot was higher for people who were offered an out-of-hours appointment than those offered a routine appointment (uptake was 38.4% and 28.4% respectively; Table 5-6).
### Table 5-6. Proportion of appointment times offered, attended and re-scheduled at St Mark’s BCSC.

<table>
<thead>
<tr>
<th>Appointment slot offered</th>
<th>Offered n (%)</th>
<th>Overall attendance n (%)</th>
<th>Same appointment</th>
<th>Changed appointment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Attendance at appointment offered n (%)</td>
<td>Attended appointment within appointment slot n (%)</td>
</tr>
<tr>
<td>Out-of-hours</td>
<td>3023 (61.3)</td>
<td>1225 (40.5)</td>
<td>479 (39.1)</td>
<td>470 (38.4)</td>
</tr>
<tr>
<td>Routine</td>
<td>1910 (38.7)</td>
<td>772 (40.4)</td>
<td>318 (41.1)</td>
<td>219 (28.4)</td>
</tr>
<tr>
<td>Total</td>
<td>4933</td>
<td>1997 (40.5)</td>
<td>797 (39.9)</td>
<td>689 (34.5)</td>
</tr>
</tbody>
</table>
5.5 Discussion

This study examined uptake at St Mark’s Hospital during the first fourteen months of the NHS BSSP’s initial implementation. The results demonstrate that half (50.3%) of all people invited for screening confirmed their appointment, and that most (80.5%) went on to attend. These findings were consistent with previous research conducted within the UK FS trial (Atkin et al., 2010), which also found that most people who confirmed an appointment attended, and that only a minority do not attend or cancel (Brotherstone et al., 2007; Robb et al., 2010a).

While most people who confirmed an appointment went on to attend, there were almost 500 missed appointments at the centre during the study period, and many more that had to be rescheduled. Such inefficiencies in healthcare delivery are associated with considerable monetary costs to the healthcare provider and adverse clinical implications for the non-attending adult (Moore et al., 2001; Guttman et al., 2011). Each year, the direct cost of missed appointments to the NHS are thought to equate to approximately £34 million for practice nurse appointments, £185 million for GP appointments, and over £700 million for hospital appointments (Developing Patient Partnerships., 2004). As non-attendance has not previously been examined within the NHS BSS programme, the exact cost of missed appointments to the NHS are currently unknown. Estimates from the most recent appraisal of the options for CRC screening, however, suggest that the cost of a single missed appointment is at least £5.00 (Whyte et al., 2012). At this rate (i.e. £5.00 per missed appointment), the cost of the 483 missed appointments observed in this study would equate to approximately £2,500; although the actual cost may be much greater than this. Consideration should, therefore, be given to strategies which are designed to prevent missed appointments, as well as those which promote uptake by other means (e.g. improving response to the initial invitation, etc.). Such interventions would not only improve the overall uptake of BSS (by up to ten percentage points), but reduce the total cost of missed appointments as well.

Perhaps the greatest opportunity to improve uptake (highlighted by these data) lies in targeting individuals who do not respond to the initial invitation (i.e. ‘non-responders’). The present study finds that these individuals comprise almost half of the total eligible population at St Mark’s Hospital, making them the single largest group of individuals invited for screening at the centre. Given their higher socioeconomic deprivation and ethnic diversity, interventions targeting these individuals would be most effective if they focused on issues which are particularly pertinent to lower socioeconomic and ethnic minority groups (Robb et al., 2008b; Robb et al., 2010b). Targeting barriers which are specific to these groups may have the added benefit of reducing socioeconomic and ethnic disparities in uptake at the centre, as have been observed in this study and several others before it (Brotherstone et al., 2007; Robb et al., 2008a; Robb et al., 2010a).

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8 Estimated by multiplying the cost of a single missed appointment by the number of missed appointments observed during the study period.
5.5.1 Strengths

This study had several strengths. First, it used objective measures of confirming and attending an appointment, both of which have previously been shown to be more reliable than self-reported measures (Baier et al., 2000; Rauscher et al., 2008; Lo et al., 2016). Second, it used a large sample that contained a high proportion of individuals from the most ethnically diverse and socioeconomically deprived parts of England, meaning that it was possible to examine response to the screening invite and uptake in a hard-to-reach population, which is of particular importance with regards to developing strategies to reduce inequalities in health (PHE., 2013a; McGregor et al., 2015a). Lastly this study was not reliant on the return of study questionnaires, and so it was not vulnerable to the inherent risks of these methods of data collection (e.g. missing data, low response rates, etc.; Baruch et al., 2008; Sterne et al., 2009).

5.5.2 Limitations

As well as several strengths, this study had a number of important limitations. First, this study was limited to routine data stored on the BCSS. As such, it was not possible to include other potential predictors of responding to the screening invite and attendance at screening (e.g. previous bowel symptoms, ethnicity, etc. Wardle et al., 2000; Power et al., 2008; Robb et al., 2008a). Second, the analytic sample was more deprived than the rest of England (average 2010 IMD score in analytic sample and England was 24.7 and 21.7 respectively), and a higher proportion were from the most ethnically diverse areas (73.9% in the analytic sample compared with 20% in the general population). As a result, the findings may not be generalisable to other parts of the country, particularly those where the eligible population is less diverse and more affluent than the national average (e.g. Surrey; ONS., 2011). Lastly, the census data used to assess area-level deprivation and area-level diversity was collected in 2001 (Department for Communities and Local Government., 2011). As a result, the measure used may have been outdated and become less reliable.

5.6 Conclusion

This study found that half of all people invited for screening confirmed their appointment, and that a little over 40% attended. The results indicate that there is considerable room for improvement, particularly to improve uptake among non-responders, who constitute the largest group of non-participants at St Mark’s Hospital.
Chapter 6. Development of a self-referral reminder and leaflet for bowel scope screening non-participants

6.1 My contributions to the work presented in this chapter

I conceived the idea for the interventions, planned their development and applied for UCL ethics with advice from my supervisors. The self-referral reminder letter and theory-based leaflet were co-developed by Resonant: a social marketing company that specialises in health behaviour (Resonant, 2015). Initial designs were tested in a co-production workshop led by John Isitt (Director of insight, Resonant). I helped conduct the workshop and took notes on the responses of participants, which were used to inform future iterations of the study materials. I also carried out one-to-one interviews and focus groups with members of the public in the London Boroughs of Brent and Harrow to get their views on the revised materials. Resonant were responsible for incorporating the advised changes into the intervention materials and produced the final versions based on my recommendations. I planned the interviews with input from my supervisors, who also gave advice on how to develop the intervention materials from beginning to end.
6.2 Introduction

In the previous chapter, I found that nearly half of all people invited for BSS at St Mark’s Hospital did not confirm their appointment, and thereby constituted the largest group of non-participants. The aim of this chapter was to develop an intervention strategy to improve BSS uptake among this group at St Mark’s Hospital.

6.2.1 Aims

The specific aims were to: 1) develop an intervention strategy to promote uptake using the BCW, 2) obtain feedback on initial intervention materials from residents in Brent and Harrow and, 3) revise the content of the intervention materials for assessment in follow-up studies informed by the MRC’s guidelines for developing and evaluating complex interventions (see Chapters 7, 8 and 9).

6.2.2 Introduction to the Behaviour Change Wheel

In Chapter 3, I provided a brief overview of the theoretical models that have most frequently been applied in research examining bowel cancer screening participation. None stood out as being superior, and many suffered from rigid structures that prohibited the inclusion of other known correlates of behaviour. In considering which framework for developing interventions to use in this thesis then, it made sense to use a framework that had an integrative model of behaviour at its core, one that incorporated constructs (if possible) from a range of models, ideally including the HBM, TPB and SCT (i.e. the models that had the best evidence to support their use in the context of CRC screening behaviours – see Chapter 3). The BCW is one such framework which does this.. It was developed by reviewing all of the theoretical frameworks for behaviour change identified in a systematic search, and then linking together the relevant components in a way that allowed for a comprehensive and systematic approach to intervention design (Michie et al., 2011).

At its core, the BCW contains the COM-B model (Figure 6-1): an integrative model of behaviour that theorises that behaviour is part of an interacting system made up of three components (which can be divided into 14 theoretical domains; Michie et al., 2014), which include a person’s capability, opportunity and motivation to change (Figure 6-1; Michie et al., 2014). Surrounding this is a layer of nine intervention functions to choose from, depending on the COM-B analysis one arrives at (i.e. whether it is capability, opportunity, motivation, or a combination of all three which need to change in order to achieve the desired behaviour). These nine intervention functions are described only in very general terms (e.g. ‘education’, ‘persuasion’, ‘enablement’, etc.), with a more specific description of the 93 BCTs having been published separately (Michie et al., 2013). The outer layer identifies seven types of policy that one can use to deliver the intervention functions (e.g. regulation, legislation, service provision, etc.).
Chapter 6. Development of a self-referral reminder and leaflet for bowel scope screening non-participants

Figure 6-1. The Behaviour Change Wheel (Michie et al., 2014).

The key benefit of using the BCW is that it encourages intervention designers to consider the full range of intervention options and choose those that are most likely to be successful through a systematic evaluation of theory and evidence. It provides a system for making the best use of the understanding and resources available to arrive at an intervention strategy (Michie et al., 2014). Other frameworks for developing interventions are also available (e.g. MINDSPACE, Intervention Mapping, etc. Bartholomew et al., 1998; Dolan et al., 2010), but the BCW is the only framework which covers the full range of intervention options available for behavioural interventions (Michie et al., 2014).

6.3 Intervention development

6.3.1 Step 1: Using the BCW to identify the intervention strategy

The BCW intervention design process is comprised of eight steps (summarised in Figure 6-2), which cover: (1) understanding the behaviour, (2) identifying intervention options and (3) identifying implementation options. Collectively, they address the key questions: (1) what is the behavioural problem you are trying to solve? (2) what behaviour(s) are you trying to change and in what way? (3) what will it take to bring about the desired behaviour change? (4) what types of intervention are likely to bring about the desired change? and (5) what should be the specific intervention content and how should this be implemented? (Michie et al., 2014).
As per the BCW intervention design process guidelines (Figure 6-2), I began by defining the problem in behavioural terms (i.e. ‘uptake among eligible men and women invited for BSS at St Mark’s Hospital is low’ – see Chapter 5; Appendix 6-1), before selecting and specifying the target behaviour (i.e. ‘self-referral’; Appendix 6-2 and 6-3 respectively) and identifying what needs to change for the target behaviour to occur (i.e. self-referral may be brought about by targeting the COM-B constructs: ‘psychological capability’, ‘physical opportunity’, ‘social opportunity’ and ‘reflective motivation’; Appendix 6-4). Once I arrived at the behavioural diagnosis (i.e. that, to facilitate self-referral, psychological capability, physical opportunity, social opportunity and reflective motivation needed to change), I was able to identify the intervention functions (i.e. ‘modelling’, ‘environmental restructuring’, ‘persuasion’, ‘education’ and ‘enablement’; Appendix 6-5) and policy categories (i.e. ‘marketing and communication’; Appendix 6-6) that would be most likely to bring about that change (these were identified using the APEASE criteria, the initials stand for ‘Affordability’, ‘Practicability’, ‘Effectiveness and cost-effectiveness’, ‘Acceptability’, ‘Safety’ and ‘Equity’). A meeting with the London BCSP Hub and St Mark’s Hospital was arranged to discuss the practicability of intervention options found to be effective in a review of the literature (Chapter 4). Several were dismissed for ethical reasons. For example, the offer of a financial incentive to self-refer was dismissed on the basis that it was unfair and went was contra to the principles of informed decision making. Others were rejected due to logistical restraints within the programme. For example, it was not possible to vary invitation materials, such as the cancellation letter, to include interventions that might reduce barriers to self-referral for St Mark’s Hospital specifically (i.e. due to the centralised nature of the mailing system). Finally, after identifying the relevant and practicable intervention functions and policy categories, I was able to identify possible BCTs (i.e. ‘demonstration of the behaviour’, ‘adding objects to the environment’, ‘prompts / cues’, ‘credible source’, ‘information about health consequences’, ‘pros and cons’ and ‘instruction on how to perform the behaviour’; Appendix 6-7) and modes of delivery (i.e. ‘leaflets’; Appendix 6-8) that could be used to achieve the desired behaviour. An overview of the intervention design is provided in Table 6-1. The completed worksheets used to arrive at the intervention design are provided in the appendix (see appendices 6-1 to 6-8).
<table>
<thead>
<tr>
<th>Intervention functions</th>
<th>COM-B components served by the intervention functions</th>
<th>Selected BCTs</th>
<th>Policy categories through which BCTs can be delivered</th>
<th>Mode of delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modelling</td>
<td>Social opportunity</td>
<td>Demonstration of the behaviour</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Environmental restructuring | Physical opportunity  
Social opportunity                               | Adding objects to the environment  
Prompts / cues                    |                                                      |                  |
| Persuasion            | Reflective motivation                                | Credible source  
Information about health consequences               | Communication / marketing             | Leaflets        |
| Education.            | Psychological capability  
Reflective motivation                                | Instruction on how to perform behaviour  
Pros and Cons                        |                                                      |                  |
| Enablement            | Psychological capability  
Physical opportunity  
Social opportunity                               |                                                          |                                                      |                  |
6.3.2 Step 2: Establishing the leaflet content

Having identified the intervention strategy (i.e. using the BCTs ‘demonstration of behaviour’, ‘adding objects to the environment’, ‘prompts / cues’, ‘credible source’, ‘information about health consequences’, ‘instructions on how to perform the behaviour’ and ‘pros and cons’ to modify ‘social opportunity’, ‘reflective motivation’, ‘psychological capability’, and ‘physical opportunity’; see Table 6-1) and the mode of delivery (i.e. leaflets; see Table 6-1), the next step was to develop the content for the intervention materials. This was done by: 1) literature review of the barriers and benefits of BSS (i.e. ‘pros and cons’), 2) interviewing previously screened adults to obtain testimonials ‘demonstrating the behaviour’ and, 3) contacting local GP Cancer Leads to provide a primary care endorsement (i.e. ‘credible source’). The following provides a brief overview of these activities and the way in which they were performed.

6.3.2.1 Identifying the perceived barriers and benefits of BSS

Studies were selected for review on the basis that they examined the barriers and benefits to BSS (as opposed to other modalities or CRC screening generally) and were published after 1997 (findings from prior to this were obtained from Vernon’s 1997 review of the literature on barriers to CRC screening, which included a breakdown of the barriers to screening by test). Appendix 6-9 provides an overview of the reviewed papers.

6.3.2.2 Obtaining testimonials from BSS participants

Testimonials were obtained from previous BSS participants (see Appendices 6-10 and 6-11). These individuals had been recruited via St Mark’s BCSC (see Appendix 6-12). Permission to use their quotes for the purposes of the leaflet were obtained accordingly (see Appendix 6-13 for a copy of the interview schedule and Appendix 6-14 for a copy of the consent form). The quotes used are given below.

“I must admit I was nervous, but the specialist nurse explained everything very clearly. It wasn’t painful at all. I was told I had no polyps and given the all clear, which was a huge relief. My friend died from bowel cancer five years ago, so I was determined this wouldn’t happen to me!”

“The staff at St Mark’s Hospital were great. The doctor found a polyp, which he removed. I didn’t feel a thing. The doctor explained that polyps often don’t have any symptoms, so people don’t always know if they have them. I’m glad they found the polyp before it had a chance to become something more serious”
6.3.2.3 Obtaining a primary care endorsement

The GP Cancer Lead for the Northwest London Borough of Hillingdon agreed to endorse the BSSP (see Appendix 6-15). The quote used within the leaflet is given below.

“I would urge anyone aged 55 to 59 to take this quick, potentially lifesaving, one-off test that significantly reduces your risk of getting bowel cancer.”

6.3.3 Step 3: Incorporating a prompt / cue

A prompt / cue was added to the intervention strategy by developing a ‘self-referral’ reminder letter alongside which the leaflet could be delivered to non-responders. The specification for the reminder letter was such that it encompassed the remaining three BCTs recommended by the BCW (see 6.3.1 Using the BCW to identify the intervention strategy), namely: ‘instructions on how to perform the behaviour’ (see 6.3.3.1 Instruction on how to perform the behaviour), ‘adding objects to the environment’ (see 6.3.3.2 Adding objects to the environment), and ‘information about health consequences’ (see 6.3.3.3 Information about health consequences).

On the basis that the timing of interventions can have a positive effect if they coincide with annual milestones (e.g. birthdays; Hoff and Bretthauer, 2008), the self-referral reminder was designed to be sent one year after the initial invitation. A ‘follow-up’ reminder letter was also developed to supplement the self-referral reminder letter (previous research has shown that additional reminders can have benefits over and above reminders used in isolation; see Chapter 4).

The specification for the follow-up reminder letter was the same as the self-referral reminder letter (see above). It was to be designed to be sent four weeks after the self-referral reminder. This was a pragmatic decision, one intended to give people enough time to respond to the self-referral reminder without feeling harassed.

6.3.3.1 Instructions on how to perform the behaviour

Instructions on how to self-refer for BSS were provided by the clinical programme manager at St Mark’s BCSC (see Appendix 6-16 for an excerpt from the final reminder letter).

6.3.3.2 Adding ‘objects’ to the environment

Several ‘objects’ or facilitators were added to the reminder letters to help initiate self-referral. First, an ‘appointment-request slip’ was added to the reminder letter (see Appendix 6-17). The slip included options for the preferred time and day of the appointment and the gender of the practitioner performing the test [both of which [i.e. the day and time of the appointment and gender of the practitioner performing the test] have previously been cited as barriers to uptake;
see Appendix 6-9 for an overview of the perceived barriers and benefits of BSS). Second, I added a Freepost return envelope addressed to St Mark’s BCSC to the intervention package. Lastly, a map with instructions on how to get to the centre was also included (this was contained with the information leaflet as opposed to the reminder letter; see Appendix 6-18 for an excerpt from the final leaflet). This was added to help people plan their journey to the hospital (to overcome a commonly endorsed barrier to attendance; see Appendix 6-9 for an overview of the perceived barriers and benefits of BSS).

6.3.3.3 Information about health consequences

Information about the health consequences of attending BSS (i.e. reduced risk of CRC incidence and reduced risk of CRC death) was obtained from the most recent evidence available at the time (i.e. Elmunzer et al., 2012; see Appendix 6-19 for an excerpt from the drafted reminder letter). See Table 6-2 for an overview of the intervention strategy, descriptions of the BCTs used and examples of their use in the draft intervention materials developed.
<table>
<thead>
<tr>
<th>BCT</th>
<th>Definition</th>
<th>Examples of use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pros and Cons</td>
<td>Advise the person to identify reasons for wanting (pros) or not wanting (cons) to change behaviour</td>
<td>A list of the benefits of BSS was added to the leaflet (see Appendices 6-20).</td>
</tr>
<tr>
<td>Demonstration of the behaviour</td>
<td>Provide an observable sample of the performance of the behaviour, directly in person or indirectly (e.g. via film, pictures) for the person to aspire to or imitate.</td>
<td>Testimonials of people who had performed the behaviour were added to the leaflet (see Appendices 6-10 and 6-11).</td>
</tr>
<tr>
<td>Credible source</td>
<td>Present verbal or visual communication from a credible source in favour or against the behaviour</td>
<td>A primary care endorsement from the GP Cancer Lead endorsing the NHS BSSP was added to the leaflet (see Appendix 6-15).</td>
</tr>
<tr>
<td>Prompts / cues</td>
<td>Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance.</td>
<td>A prompt was added to the intervention strategy by developing a ‘self-referral’ reminder letter and a ‘follow-up’ reminder letter (see Templates 1 and 3 at the end of this chapter).</td>
</tr>
<tr>
<td>Instruction on how to perform a behaviour</td>
<td>Advise or agree on how to perform behaviour.</td>
<td>Instructions on how to self-refer for BSS were added the reminder letter (see Appendix 6-16 for an excerpt from the self-referral reminder letter).</td>
</tr>
<tr>
<td>Adding objects to the environment</td>
<td>Add objects to the environment in order to facilitate performance of the behaviour</td>
<td>Several ‘objects’ or facilitators were added to the s reminder letters, including an ‘appointment-request slip’ and Freepost return envelope (see Appendix 6-17).</td>
</tr>
<tr>
<td>Information about health consequences</td>
<td>Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour</td>
<td>Information about the health consequences of BSS (e.g. reduced risk of CRC incidence and death) was added to the reminder letters (see Appendix 6-19).</td>
</tr>
</tbody>
</table>
Chapter 6. Development of a self-referral reminder and leaflet for bowel scope screening non-participants

6.3.4 Step 4: Development of initial versions

6.3.4.1 First drafts in collaboration with a social marketing team

Initial versions of the intervention materials were developed by the behavioural insights team of a social marketing company (Resonant). I sent them a briefing document outlining the intervention strategy described above (see Appendix 6-21), alongside draft content to be used for the reminder letters. They prepared draft versions of the materials based on the specified criteria for which they:

1) Based the colour scheme and typography around St Mark’s Hospital’s branding.

2) Chose images representative of a diverse population, so as to reflect and engage respective members of the audience.

3) Used a conversational tone to introduce a social presence to the information.

4) Used formatting to divide the content of the leaflet into focused sections (e.g. a ‘benefits of the bowel scope screening test’ section, a ‘polyps and cancer’ section), using subheadings to help people navigate the text.

A meeting was held to review the materials. Adjustments were made to make the language: 1) less promotional and, 2) more accurate (e.g. saying that: ‘most people say they felt no pain or only mild pain’ as opposed to ‘no discomfort or only mild discomfort’).

6.3.5 Step 5 – Review of draft materials

6.3.5.1 Public engagement

Initial designs of the reminder letter and leaflet were tested in a co-design workshop (facilitated by myself and Resonant) in which screening eligible adults from the London Boroughs of Brent and Harrow (n = 4; three male, one female; ages 55–58) gave feedback to inform future iterations of the materials (see Appendix 6-22 for a copy of the co-design workshop guide and Appendix 6-23 for the workshop report). To collect feedback on the revised materials, I conducted a series of face-to-face interviews and focus groups with members of the public (n = 20). The purpose of these was to obtain an informal review of the intervention materials to ensure their acceptability and that there were no obvious problems with the materials.
Participants \((n = 20)\) were representative of screening-eligible candidates (12 female, eight male, aged 50–59 years) and were from a range of ethnic backgrounds reflective of Brent and Harrow. Interviewees were encouraged to give their first impressions and interpretations and understanding of the information provided (see Appendix 6-24 for the interview schedule and Appendices 6-25 and 6-26 for the relevant approvals from UCL’s joint research office, JRO). They were also prompted to provide feedback on the: i) acceptability of the imagery and format, ii) readability and clarity of the wording, iii) communicative effectiveness, iv) amount of information provided and v) acceptability of different terminology (see Appendix 6-27 for a copy of the consent form).

### 6.3.5.2 Revisions and development

Intervention materials were edited and revised according to the feedback received from the members of the public interviewed. Examples of the feedback received include: 1) the preventive benefits of the test should be emphasised throughout the letter and leaflet, 2) images should better reflect the ethnicity of individuals living in Brent and Harrow, 3) the letter should be on NHS letter-headed paper, 4) materials should be written as simply as possible, 5) the layout, colour scheme and use of quotes was liked and, 6) that the leaflet should include details on public transport links to the screening centre. The final materials were revised by the social marketing company and approved by the UCL research team and clinical programme manager prior to evaluation in studies informed by the MRC guidelines for developing and evaluating complex interventions\(^9\) (see Figure 6-3; Craig et al., 2008).

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\(^9\) The MRC framework for developing and evaluating complex interventions goes beyond the development of interventions (covered by the BCW) to provide guidance on their subsequent implementation and evaluation (Craig et al., 2008). The guidelines are often used in medicine for informing the development and evaluation of novel treatments.
6.3.6 Summary of the final intervention materials

**Self-referral reminder letter:** The final version of the cover letter for the self-referral reminder was a personally addressed letter from St Mark’s Hospital which: 1) invited individuals to make a screening appointment by returning an ‘appointment-request-slip’ or by calling the Freephone telephone number for the centre; 2) reminded them that they had previously been invited for an appointment and were eligible to self-refer up until their 60th birthday; 3) gave participants the opportunity to select a preference for the day and time of the appointment and the gender of the practitioner performing the test and; 4) highlighted 3 key messages: i) that the risk of developing bowel cancer is highest in the recipient’s age group (55+ years), ii) screening is for people who do not have any signs or symptoms of bowel cancer and iii) screening can help prevent bowel cancer by removing polyps (Template 1).

**Theory-based leaflet:** The leaflet re-iterated key points mentioned in the self-referral reminder letter and was tailored to the London areas served by St Mark’s Hospital (e.g. included a map with information about local transport links to the hospital, included photographs of individuals reflective of the London Boroughs of Brent and Harrow, etc.). The leaflet also included an educational / knowledge-building component to reinforce messages regarding the benefits of screening (effectiveness and rationale), a descriptive social norms message outlining uptake of BSS at St Marks’ Hospital (i.e. ‘270 people screened every month’), and several practical components designed to improve self-efficacy (e.g. instructions on how to book an appointment and directions to the hospital).
Follow-up reminder: The follow-up reminder repeated key information included in the self-referral reminder letter (see Template 3).
Template 1. Self-referral reminder letter (Page 1 of 2)

The North West London Hospitals NHS
St. Mark's Bowel Cancer Screening Centre
St Mark's Hospital
Watford Road
Harrow
Middlesex
HA1 3UJ
Freephone Helpline 0800 707 6060

Dear <Title> <First Name> <Initial> <Last Name>,
NHS No: <NHS Number>

Important information about your health:

We are writing to invite you for bowel scope screening, a new test available only in England that helps prevent bowel cancer. We last invited you for this test about a year ago.

People aged 55+ are most at risk of bowel cancer, this test helps prevent it:
We have written to you because people who are aged 55 and over are the most at risk of developing bowel cancer. Having a Bowel Scope Screening test between the age of 55 & 59 helps prevent you from getting bowel cancer in the future. This is an important test highly recommended for everyone who is 55-59 years of age.

Saving lives
The NHS offers bowel scope screening because it saves lives from bowel cancer.

Bowel scope screening is for people who don't have any signs of bowel cancer. The test is designed to help prevent bowel cancer by finding and removing small growths in the lower bowel before they turn into something more serious. These growths, called polyps, can turn into cancer over a period of years if they are left untreated. Removing these growths halves your risk of getting bowel cancer in the future.

We're lucky in Brent, Harrow and Ealing that we have the opportunity to participate in bowel scope screening. Every month about 270 people take up the test.

What you need to do now
To book your test, simply fill in and post back the form overhead in the Freepost envelope provided (you don't need a stamp).

We will then arrange a date and time for your bowel scope screening appointment. It takes place locally at St Mark's Hospital, which is a centre of excellence for bowel and gut medicine at Northwick Park.

Please read the enclosed leaflet, which gives more information about the test, and also has stories from people who have already been to St Mark’s for bowel scope screening.

If you have any questions, please call the St Mark's Bowel Cancer Screening Centre on 020 8869 3543, or Freephone 0800 707 60 60 to book an appointment.

Yours sincerely,

Sarah Marshall
Clinical Programme Manager, Bowel Scope Screening

1/2
Template 1. Self-referral reminder letter (Page 2 of 2)

The North West London Hospitals NHS

IMPORTANT – PLEASE CHECK YOUR DETAILS AND RETURN IN THE FREEPOST ENVELOPE

Name: <Title> <First Name> <Last Name>
NHS Number: <NHS Number>
Post Code: <Postcode>

Please fill in your details (either your home telephone number or your mobile number is required; this is so we can contact you to confirm your appointment):

Home number: ______________________
Mobile number: ______________________

Please tick this box if you would like to have a bowel scope screening appointment:

☐ I’d like to arrange a bowel scope screening appointment at St Mark’s Hospital in Harrow.

Please tick your preference:

☐ I would prefer to have a Male practitioner to perform my test.
☐ I would prefer to have a Female practitioner to perform my test.

Please tick as appropriate: My preferred appointment time(s) would be:

<table>
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<tr>
<th>Afternoon</th>
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<td>13:00-15:30</td>
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<td>Thursday</td>
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</table>

When we receive your form, we’ll contact you with a suggested date and time for your appointment.

(Tear here)
Chapter 6. Development of a self-referral reminder and leaflet for bowel scope screening non-participants

Template 2. Theory-based leaflet (A5, outer pages)

What you need to do now

Don’t miss out
Only people aged 55 to 59 can have a bowel scope screening test free on the NHS. You will normally only get one invitation.
If you haven’t had a bowel scope screening test, you live in Brent, Harrow or parts of Ealing*, and are aged between 50 to 59, call 0800 707 6060 to book an appointment.

* Included Ealing areas: Northolt, Greenford and Harrow.

About 270 people take up the bowel scope screening test at St Mark’s Hospital every month.

St Mark’s, at Northwick Park Hospital
St Mark’s is easy to reach by tube, bus and car. Northwick Park tube station (Metropolitan line) is only five minutes walk away. See www.nhs.uk for more information on reaching the hospital.

Contact us
If you have any questions on bowel scope screening, please give our team a call on: 0800 707 6060
St Mark’s Hospital
Northwick Park
Harrow, Middlesex HA1 3UJ
stmarkshospital.org.uk

Are you aged 55 to 59?
Then you need to know two things about bowel cancer:

1. It’s the second biggest cancer killer in the UK. (After the age of 55, your risk of developing bowel cancer begins to rapidly increase).

2. One easy NHS test is the best way to help prevent bowel cancer.

Your chance to help prevent bowel cancer with one easy step

One thing you shouldn’t ignore
I would urge anyone aged 55 to 59 to take this quick, potentially life-saving, one-off test that significantly reduces your risk of getting bowel cancer.

Dr Stephen Mort, GP Cancer Lead for Willington Church Road Surgery

If you would like to find out more about bowel scope screening: 0800 707 6060
cancerscreening.nhs.uk/bowel

Easier than I thought. I’m so glad I did it
Template 2. Theory-based leaflet (A5, inner pages)

**Chapter 6. Development of a self-referral reminder and leaflet for bowel scope screening non-participants**

**At 55+ you need to know about bowel cancer**
- Bowel cancer is the second biggest cancer killer in the UK (it’s the third most common cancer)
- From the age of 55, your risk of getting bowel cancer begins to increase rapidly

Bowel cancer is any cancer that begins in the large bowel—a part of your digestive system.

**Good News**
The good news is that there is a test which helps prevent bowel cancer, it’s called the bowel scope screening test.

**Preventing bowel cancer**
The single test dramatically cuts your chances of getting bowel cancer in the future.

Unlike other cancer screening programmes, you only need to take part in bowel scope screening once.

In the unlikely event that you already have bowel cancer, bowel scope screening can pick this up early when the cancer is more treatable.

---

**One easy test could save your life**

For people living in Brent, Harrow and parts of Ealing*, bowel scope screening takes place at St Mark’s Hospital, next to Northwick Park Hospital. It’s only a five minute walk from Northwick Park tube station.

St Mark’s is the only hospital in the world to specialise solely in bowel and gut problems.

---

**Polyps and bowel cancer**

Bowel cancer develops from polyps, which are small growths in your bowel.

Most polyps are harmless, but some can turn into cancer if left untreated.

By removing any polyps in your bowel during the test, bowel scope screening is a very effective way of reducing the chance that you will get bowel cancer in the future.

---

**Benefits of the bowel scope screening test**

- Free, done by experts at the world-famous St Mark’s Hospital
- Quick, the test takes around 20 minutes
- Helps prevent bowel cancer
- If detected early, the cancer is much easier to treat

---

I must admit I was nervous, but the specialist nurse explained everything very clearly. It wasn’t painful at all. I was told I had no polyps and given the all clear, which was a huge relief.

My friend died from bowel cancer five years ago, so I was determined this wouldn’t happen to me.

*Judith Mason, 86, from Kentish Green in Brent*

---

The staff at St Mark’s Hospital were great. The doctor found a polyp, which he removed. I didn’t feel a thing. The doctor explained that polyps often don’t have any symptoms, so people don’t always know if they have them.

I’m glad they found the polyp before it had a chance to become something more serious.

*Ranjit Patel, 86, from Wembley*
Template 3. Follow-up reminder letter (Page 1 of 2)

Dear <Title> <First Name> <Initial> <Last Name>,

NHS No.: <NHS Number>

Reminder: Please book your appointment - Important information about your health

We recently wrote to invite you for bowel scope screening, a new test available only in England which helps prevent bowel cancer.

Saving Lives
People aged 55+ are most at risk of getting bowel cancer, this test helps to prevent it. This test is for people who don’t have any signs of bowel cancer.
You are being invited because people who are aged 55 and over are the most at risk of developing bowel cancer. Having a Bowel Scope Screening test between the age of 55 & 59 helps prevent you from getting bowel cancer in the future. This is an important test highly recommended for everyone who is 55-59 years of age.

What you need to do
Please read the enclosed leaflet, which gives more information about the test, and also has stories from people who have already been to St Mark’s for bowel scope screening.

To book your test, simply fill in and post back the form overleaf in the Freepost envelope provided (you don’t need a stamp). We will then arrange a date and time for your bowel scope screening appointment. It takes place locally at St Mark’s Hospital. Alternatively, you can Freephone 0800 707 60 60 to book an appointment.

If you have any questions, please call the St Mark’s Bowel Cancer Screening Centre on 020 8869 3543.

Yours sincerely,

Sarah Marshall
Clinical Programme Manager, Bowel Scope Screening
Template 3. Follow-up letter (Page 2 of 2)

The North West London Hospitals NHS Trust

IMPORTANT – PLEASE CHECK YOUR DETAILS AND RETURN IN THE FREEPOST ENVELOPE

Name: <Title> <First Name> <Last Name>
NHS Number: <NHS Number>
Post Code: <Postcode>

Please fill in your details (either your home telephone number or your mobile number is required; this is so we can contact you to confirm your appointment):

- Home number: ____________________
- Mobile number: ____________________

Please tick this box if you would like to have a bowel scope screening appointment:

☑ I’d like to arrange a bowel scope screening appointment at St Mark’s Hospital in Harrow.

Please tick your preference:

- ☐ I would prefer to have a Male practitioner to perform my test.
- ☐ I would prefer to have a Female practitioner to perform my test.

Please tick as appropriate: My preferred appointment time(s) would be:

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<th>Afternoon</th>
<th>Evening</th>
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<tbody>
<tr>
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<td>Monday</td>
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<tr>
<td>Friday</td>
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</tbody>
</table>

When we receive your form, we’ll contact you with a suggested date and time for your appointment.

(Tear here)
6.4 Summary

This chapter described the development of a ‘12-month’ self-referral reminder letter and theory-based leaflet. The strategy was informed by the BCW, which was used to identify: 1) psychological capability, physical opportunity, social opportunity and reflective motivation as putative targets for change and; 2) the specific BCTs (i.e. Demonstration of the behaviour, adding objects to the environment, prompts / cues, credible source, information about health consequences, instruction on how perform behaviour and pros and cos) likely to be effective in promoting uptake. The development was further enhanced by a literature review and the presence of additional stakeholders, i.e. a social marketing company, the screening centre and members of the public, which allowed me to develop and refine iterations of the initial prototype. In the next chapter, I present a feasibility study exploring the practicality of delivering these reminders. The chapter comprises the next step in the MRC guidelines for developing and evaluating complex interventions.
Chapter 7. Evaluating the feasibility of the self-referral reminder and theory-based leaflet (Study 2)

7.1 My contributions to the work presented in this chapter

I conceived the idea for the study and wrote the trial protocol with input from my supervisors (Christian, Jane and Lesley), Ms Sarah Marshall (Clinical Programme Manager, St Mark’s BCSC) and Ms Lorraine Gorman (Deputy Programme Manager, St Mark’s BCSC). I wrote the ethics application and calculated the sample size for the study after receiving statistical advice from Mr Nick Counsell (Medical Statistician, UCL) confirming the appropriateness of my proposed calculation plans. Mr Tark Elouihrani (Data Analyst, London Bowel Cancer Screening Hub) was responsible for identifying eligible adults from the BCSS. Shaila Kumar was responsible for maintaining the study database, delivering the reminders and anonymising and transferring the data at the end of the study. I coded the data and derived the values for area-level deprivation, which were later matched to individuals within the dataset (by Shaila Kumar) using unique participant study IDs. I analysed the data, after receiving statistical advice on the appropriateness of my proposed analysis plans from Nick Counsell. I also interpreted the results with input from my supervisors and led on the publication of the manuscript (Kerrison et al., 2016). All of the co-authors contributed to the interpretation of the results.

7.2 Introduction

In the previous chapter, I developed a self-referral reminder, follow-up reminder and theory-based leaflet to improve uptake at St Mark’s Hospital in London. In this chapter, I examine the feasibility of sending these interventions to individuals who do not take part in screening within 12 months of receiving their initial invitation.

7.2.1 Aims

The primary aims of this study were to: 1) test the feasibility of sending previous non-responders a self-referral reminder letter and theory-based leaflet 12 months after their initial invitation and; 2) assess whether the strategy met a basic level of efficacy that merited further investigation in a formal RCT (one of the possible next steps in the MRC guidelines for developing and evaluating complex interventions). The secondary aims were to: 1) explore gender preferences for a same-sex practitioner among self-referrers; 2) explore variation in uptake by baseline characteristics and; 3) assess whether the follow-up reminder sent four weeks after the self-referral reminder added to this strategy. A review of the methods and process employed was included to help refine the strategy of any subsequent RCT.

7.3 Methods

7.3.1 Study design

This study was a single-centre feasibility study with one trial arm.

7.3.2 Study population and setting

Eligible adults were men and women registered with a general practice within the London Boroughs of Brent and Harrow, who had not attended a BSS appointment within 12 months of their initial invitation. Individuals who originally confirmed their appointment, but did not attend, were excluded from the study to minimise confounding.

7.3.3 Identification

Eligible adults were identified on the BCSS by a member of the direct care team at the London Bowel Cancer Screening Hub (hereafter referred to as ‘the Hub’). The data were extracted one week prior to the beginning of the study (September 2014) following a formal data request from the clinical programme manager at St Mark’s BCSC, who asked the Hub to identify individuals invited for BSS at St Mark’s Hospital between September and November 2013 (i.e. 12 months before the study start date). The request specified that individuals should be excluded if they: (1) were no longer registered with a general practice within Brent and Harrow, (2) confirmed their initial appointment, but then did not attend, (3) currently had an appointment booked at the
screening centre, (4) were registered on the BCSS as ‘deceased’, or (5) had attended a BSS appointment since they were first invited one year ago. An overview of the data specification is presented in Table 7-1.

Table 7-1. Data specification from St Mark’s BCSC to the Hub

<table>
<thead>
<tr>
<th>Variable</th>
<th>Reason for request</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS Number</td>
<td>Required for mail out</td>
</tr>
<tr>
<td>Title</td>
<td>Required for mail out</td>
</tr>
<tr>
<td>First Name</td>
<td>Required for mail out</td>
</tr>
<tr>
<td>Middle Name(s)</td>
<td>Required for mail out</td>
</tr>
<tr>
<td>Last Name</td>
<td>Required for mail out</td>
</tr>
<tr>
<td>Address</td>
<td>Required for mail out</td>
</tr>
<tr>
<td>Postcode</td>
<td>Required for mail out</td>
</tr>
<tr>
<td>Initial invite date</td>
<td>Required for mail out</td>
</tr>
<tr>
<td>Gender</td>
<td>Important baseline characteristic</td>
</tr>
<tr>
<td>CCG</td>
<td>Important baseline characteristic</td>
</tr>
<tr>
<td>Initial episode status</td>
<td>Important exclusion criteria</td>
</tr>
<tr>
<td>Current episode status</td>
<td>Important exclusion criteria</td>
</tr>
<tr>
<td>Date of initial appointment</td>
<td>Important exclusion criteria</td>
</tr>
</tbody>
</table>

7.3.4 Enrolment

Eligible adults were enrolled into the study over a 10 week period spanning from September to November 2014. On the basis that there was capacity to facilitate an additional five appointments each week, and the impact of the interventions on self-referral was unknown, the clinical programme manager at St Mark’s BCSC limited the number of eligible adults who could be enrolled into the study each week. As a result, not all eligible adults (i.e. previous non-responders) were included in the study, and individuals were randomly selected for inclusion from a variable weekly total of previous non-responders based on their initial invitation date. This was done using blocked pseudo-random selection methods, with non-participants blocked according to the week they received their initial invitation, and a subset (n = 16) randomly selected for inclusion in the study (Efird., 2010).

7.3.5 Procedures

Individuals included in the study were mailed a self-referral reminder letter, theory-based leaflet, appointment-request-slip and Freepost return envelope (addressed to St Mark’s BCSC) 12 months after their initial invitation (Figure 7-1). Recipients were able to book an appointment either by returning the appointment-request-slip to the centre (thereby initiating a call from a member of
the administrative team), or by calling the centre directly on the Freephone telephone number provided. Responders were also able to indicate a preference for the gender of the practitioner performing the test, as well as the day and time of the appointment, either by selecting options on the appointment-request-slip, or when prompted during their call (administrative staff were given instructions to provide these options by the clinical programme manager).

Anyone not responding to the self-referral reminder within four weeks was sent the follow-up reminder, which also included an appointment-request-slip, the theory-based leaflet and a Freepost return envelope. Individuals were then given a further eight weeks to respond. At this time, their attendance status was assessed by the health improvement specialist at the centre (using routine data stored on the BCSS) and added to the study database. Any self-referrals made after this time were not included in the study results, but were still fulfilled by St Mark’s BCSC.

Individuals who self-referred for the test received a pre-appointment text-message reminder and telephone call, as per routine practice at St Mark’s BCSC. During the telephone call, the specialist screening practitioner: 1) confirms receipt of the bowel preparation (i.e. an enema with instructions for use), 2) elicits whether the individual would prefer to receive assistance with administering the enema at the hospital (i.e. rather than self-administering the enema in their own home) and, 3) reminds the individual that they should bring their consent form to the appointment.
Figure 7.1. BSS invitation flowchart with self-referral reminder added

Key:
- Programme procedures
- Reminder procedures

Programme procedure

- BSS pre-invitation letter sent
  - 2 weeks
  - Appointment letter sent
    - 2 weeks to respond
      - Appointment confirmed
      - No appointment confirmed
        - Reminder letter sent
          - 2 weeks to respond
            - Appointment confirmed
            - No appointment confirmed
              - Enema preparation sent
                - 2 weeks
                  - Appointment not attended
                  - Appointment attended

Reminder procedure

- Self-referral reminder letter and leaflet sent
  - 4 weeks to respond
    - Appointment made
    - Appointment not made
      - Self-referral reminder letter and leaflet sent
        - 8 weeks to respond
          - Appointment made
          - Appointment not made
          - 11 months
Chapter 7. Evaluating the feasibility of the self-referral reminder and theory-based leaflet (Study 2)

7.3.6 Intervention details

Detailed descriptions of the self-referral reminder, follow-up reminder and theory-based leaflet used in this study are provided in the previous chapter (i.e. Chapter 6).

7.3.7 Consent procedures

For those individuals who made an appointment, a confirmation letter and consent form were sent to their home address. The confirmation letter and consent form sent were the same as those used for routine appointments (see Appendices 2-7 and 2-10 respectively). Participants were asked (within the confirmation letter) to read the consent form (which contained important information regarding the risks of the procedure) before attending their appointment, and to call the screening centre if they had any questions. Participants were also asked (again, within the confirmation letter) to bring the consent form to their appointment, where a specialist screening practitioner would discuss the risks of the procedure before the appointment took place (see Chapter 2).

7.3.8 Measures

7.3.8.1 Gender and CCG

Data on the gender and CCG of each person were extracted from the BCSS as part of the initial extraction performed by the Hub (see Table 7-1).

7.3.8.2 Area-level deprivation

I converted each person’s home postcode address into a score on the 2010 IMD using Geoconvert (see Chapter 5). I then categorised the scores into quintiles of the regional distribution to compare uptake between individuals living in the most and least deprived areas of Brent and Harrow. To ensure people were not identifiable during the conversion, postcodes were pseudonymised by a member of the direct care team at St Mark’s BCSC, who merged the converted data with the study database using a unique participant ID number contained within both datasets (this was deleted once the data had been merged, so that postcodes could not be retrospectively identified).

7.3.8.3 Method of self-referral

The method of self-referral (i.e. return of a slip or call to the centre) was added to the study database as the study progressed. Members of the administrative team at St Mark’s BCSC were informed of the study and were given instructions by the clinical programme manager to keep a record of any individuals who self-referred (and the method by which they did so) on the BCSS. As there was no entry field for the method of self-referral on the BCSS, the method of self-referral
was recorded in each individual’s ‘episode notes’ (on the BCSS), where details of patient-centre contact are routinely recorded using free-text (personal communication). These data were then extracted from the BCSS by the health improvement specialist responsible for maintaining the study database at St Mark’s BCSC. This was done on a weekly basis, four and 12 weeks after each person was sent their self-referral reminder (i.e. when the health improvement specialist checked the self-referral and attendance status of each person; see 7.3.8.6 Self-referral and attendance).

### 7.3.8.4 Preferred gender of the practitioner and time and day of the appointment

As with the method of self-referral (see 7.3.8.3 Method of self-referral), people’s preferences for the gender of the practitioner performing the test and the time and day of the appointment were added to the study database as the study progressed. Again, members of the administrative team at St Mark’s BCSC were asked by the clinical programme manager to record on the BCSS whether individuals who self-referred for an appointment expressed a preference for the gender of the practitioner and the time and day of the appointment. As with the method of self-referral, no entry field exists on the BCSS for the preferred gender of the practitioner, or the time and day of the appointment, and so this information was recorded within each individual’s episode notes (see 7.3.8.3 Method of self-referral). These data were then extracted from the BCSS by the health improvement specialist. This too was done on a weekly basis, four and 12 weeks after each person was sent a self-referral reminder (see 7.3.8.6 Self-referral and attendance).

At the end of the study, when all of the data had been collected and pseudonymised, I converted the ‘preferred sex of the practitioner’ into ‘preference for a same-sex practitioner’, with outcomes ‘yes’ and ‘no’ by comparing whether the preferred sex of the practitioner matched the gender of the person invited for screening. Differences between genders were then assessed using statistical methods (see 7.3.11 Analysis).

### 7.3.8.5 Offered gender of the practitioner and time and day of the appointment

The gender of the practitioner and the time and day of the appointment offered to each person who self-referred for screening were recorded on the BCSS and added to the study database in the same way as people’s preferences for these variables (see 7.4.8.4 Preferred gender of the practitioner and time and day of the appointment). The administrative staff at St Mark’s BCSC were instructed by the clinical programme manager to keep a record of these details in the BCSS episode notes, just as they had for people’s preferences. The health improvement specialist then added these details to the study database when checking the self-referral and attendance status of each person four and 12 weeks after they were sent a self-referral reminder (see 7.3.8.6 Self-referral and attendance).
At the end of the study, when all of the data had been collected and pseudonymised, I converted the ‘preferred gender of the practitioner’ and the ‘gender of the practitioner offered’ into ‘received gender preference’, with outcomes ‘yes’ and ‘no’, by comparing whether each person’s preferred practitioner gender matched the gender of the practitioner offered. I did the same with the ‘preferred day and time of the appointment’ and the ‘time and day of the appointment offered’ to derive ‘offered the preferred gender of the practitioner’ with response options ‘yes’ and ‘no’. The proportion of people who then received their preferences were then assessed using descriptive statistics (see 7.3.10 Analysis) as part of the review of the methods employed.

7.3.8.6 Self-referral and attendance

Self-referral and attendance were verified by the health improvement specialist at St Mark’s BCSC four weeks following the delivery of the self-referral reminder and eight weeks following the delivery of the follow-up reminder. The first assessment was carried out to establish which individuals had already self-referred / attended, and therefore were not eligible to receive a follow-up reminder. The second assessment was carried out to determine the ‘end of study’ attendance status for each individual.

7.3.9 Power calculation

The power of the study to detect a minimum level of efficacy was calculated using exact methods based on the binomial distribution (A’Hern., 2001). Exact methods indicated that the sample size (n = 160) provided sufficient levels of statistical power (β = 0.015) and confidence (α = 0.018) to test for a five percentage point increase in uptake, with an unacceptable response rate of 0.35%, and a desired response rate of 5.35% (Table 7-2).

<table>
<thead>
<tr>
<th>Table 7-2. Power calculation overview</th>
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<tr>
<td>P0 = expected uptake for a poor intervention</td>
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<tr>
<td>0.0035</td>
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</table>

R+1 = the minimum number of self-referred appointments required to merit further investigation in a RCT
7.3.9.1 Expected uptake

The unacceptable response rate was based on the response rate of non-responders during the previous year (0.35%), and the desired response rate on a five percentage point improvement thereof. The decision to test for a five percentage point improvement in self-referral was made by the clinical programme manager, who indicated that a five percentage point improvement in uptake among non-responders would equate to a three percentage point increase in uptake\textsuperscript{11}, which would be operationally significant.

7.3.10 Analysis

Descriptive statistics were used to describe the trial population, assess the proportion of individuals who received their appointment preferences, and determine whether the number of self-referred appointments exceeded the threshold for further investigation in a RCT (\(R+1 = 3\)). Univariable and multivariable binary logistic regression were used to investigate possible associations between baseline characteristics and uptake (Engel., 1988). Differences in people’s preferences for a same-sex practitioner were examined by gender using a standard test of difference between proportions (Pearson., 1900). The data were assessed on an intention-to-treat basis using SPSS (version 24).

7.3.11 Ethical approval, research governance and trial sponsorship

The study was approved by the UCL JRO (reference: 14/0532) on the 1\textsuperscript{st} of August 2014 (Appendices 7-2 and 7-3), the North East Tyne and Wear South Research Ethics Service (Ref: 14/SC/0088) on the 1\textsuperscript{st} of September 2014 (Appendices 7-4 and 7-5), and the Northwest London Hospitals Research and Development (R and D) group (Ref: RD14/088) on the 22\textsuperscript{nd} of September 2014 (Appendix 7-6).

7.4 Results

7.4.1 Sample characteristics

This study took place between September and November 2014, with follow-up until January 2015. A total of 160 adults were randomly selected for inclusion in the study, the majority of which were female (\(n = 89, 55.6\%\)) and registered with a general practice within Harrow (\(n = 83, 51.9\%\)). Table 7-3 describes the basic attributes of the study participants. Figure 7-2 provides an overview of the flow participants through the study as it progressed.

\textsuperscript{11} Estimated by multiplying the proportion of people who do not take part in screening (i.e. 0.6) by the response rate for a good intervention (i.e. 0.05).
## Table 7-3. Sample characteristics

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>%</th>
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<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>71</td>
<td>44.4</td>
</tr>
<tr>
<td>Female</td>
<td>89</td>
<td>55.6</td>
</tr>
<tr>
<td><strong>CCG</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brent</td>
<td>77</td>
<td>48.1</td>
</tr>
<tr>
<td>Harrow</td>
<td>83</td>
<td>51.9</td>
</tr>
<tr>
<td><strong>Tertile of deprivation (IMD Score)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 1 (Most deprived)</td>
<td>68</td>
<td>42.5</td>
</tr>
<tr>
<td>(27.51 – 80.00)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 2 (Median deprived)</td>
<td>42</td>
<td>26.3</td>
</tr>
<tr>
<td>(17.69 – 27.50)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 3 (Least deprived)</td>
<td>50</td>
<td>31.3</td>
</tr>
<tr>
<td>(0.00 – 17.68)</td>
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<td></td>
</tr>
</tbody>
</table>

Abbreviations: CCG, Clinical Commissioning Group; IMD, Index of Multiple deprivation
Figure 7-2. Flow of participants through the study

- **844** Non-participants identified by the Hub
- **16** Randomly selected each week to receive a 12-month self-referral reminder
- **644** Randomly excluded
- **160** Sent a 12-month self-referral reminder
- **5** ‘Returned to sender’
- **21** Self-referrals made
- **2** Did not attend
- **2** Cancelled
- **134** 4-week reminder letters sent
- **0** Not screened
- **9** Self-referrals made
- **1** Did not attend
- **0** Cancelled
- **30** Self-referrals made in total
- **17** Attended screening
- **17** Attended screening in total
- **8** Attended screening
- **1** Not screened
- **21** Self-referrals made
- **2** Did not attend
- **2** Cancelled
- **844** Self-referrals made in total
- **160** Sent a 12-month self-referral reminder
- **644** Randomly excluded
- **844** Non-participants identified by the Hub
7.4.2 Uptake

In total, 25 (15.6%) people attended a BSS appointment (Table 7-4). A further five (3.1%) self-referred, but either did not attend (n = 3) or cancelled (n = 2), leaving 130 (81.3%) adult men and women who did not self-refer or attend an appointment.

The results of the univariable and multivariable regression are presented in Table 7-4. There were no significant differences in uptake between men and women, CCGs, or tertiles of area-level deprivation (all Ps > 0.05; Table 7-4).

Table 7-4. Uptake by baseline characteristics (Univariable and multivariable regression)

<table>
<thead>
<tr>
<th>Comparisons</th>
<th>Uptake n (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR¹ (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (n = 160)</td>
<td>25 (15.6)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male⁷ (n = 71)</td>
<td>7 (9.9)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Female (n = 89)</td>
<td>18 (20.2)</td>
<td>2.32 (0.91 - 5.91)</td>
<td>2.39 (0.93 - 6.16)</td>
</tr>
<tr>
<td>CCG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harrow⁸ (n = 77)</td>
<td>13 (16.9)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Brent (n = 83)</td>
<td>12 (14.5)</td>
<td>0.83 (0.35 - 1.96)</td>
<td>0.86 (0.28 - 2.58)</td>
</tr>
<tr>
<td>Tertile of deprivation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 1*</td>
<td>10</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Most deprived (n = 68)</td>
<td>14 (14.7)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Tertile 2</td>
<td>7</td>
<td>0.91 (0.33 - 2.49)</td>
<td>0.96 (0.27 - 3.49)</td>
</tr>
<tr>
<td>Median deprived (n = 42)</td>
<td>16 (16.7)</td>
<td>0.86 (0.30 - 2.47)</td>
<td>0.81 (0.24 - 2.71)</td>
</tr>
<tr>
<td>Tertile 3</td>
<td>8</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Least deprived (n = 50)</td>
<td>16 (16.0)</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Abbreviations: OR, Odds ratio; CI, Confidence Interval; CCG, Clinical Commissioning Group; IMD, Index of Multiple deprivation
¹Adjusted ORs and 95% CIs are adjusted for all other covariates in the table.
⁷Reference group
7.4.3 Reminder process evaluation

*Self-referral method:* The majority of people self-referred for an appointment (n = 28, 93.3%) by returning an appointment request slip in the Freepost envelope provided. The remainder (n = 2, 6.7%) did so by calling the screening centre directly on the Freephone telephone number provided in the letter / leaflet.

*Follow-up reminder:* The majority of people who self-referred for an appointment (n = 21, 70%) did so within four weeks of being sent a self-referral reminder. The remainder (n = 9, 30%) self-referred after being sent the follow-up reminder. No responses were received beyond the 12 week cut-off period.

*Preferences for the day and time of the appointment:* Of the thirty men and women who self-referred for a BSS appointment, 24 (80%) expressed a preference for the day and / or time of the appointment. It was not possible to accommodate preferences for 12 people (50%). Only one cancelled because they could not schedule an appointment that suited them.

*Preferences for the gender of practitioner performing the test:* Of those who self-referred for a BSS appointment, 27 (90%) indicated a preference for a same-sex practitioner, none indicated a preference for a practitioner of the opposite sex, and three (10%) gave no preference. It was not possible to accommodate the preference of eight (30%) individuals. No-one asked to be rescheduled or cancelled because of this.

When examined by gender, women were significantly more likely to express a preference for a same-sex practitioner, with 100% of women who self-referred for an appointment expressing a preference for a same-sex practitioner, compared with only two-thirds of men (100% vs 67%; $\chi^2$=7.78, $P < 0.05$; Table 7-5).

<table>
<thead>
<tr>
<th>Table 7-5. Patient preferences for a same-sex practitioner by gender</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indicated preference, n (%)</strong></td>
</tr>
<tr>
<td><strong>Female (n = 21)</strong></td>
</tr>
<tr>
<td>Requested same-sex practitioner (100)</td>
</tr>
<tr>
<td>No preference (0)</td>
</tr>
</tbody>
</table>

*P < 0.05.*
7.5 Discussion

This study was initiated to test the feasibility and potential efficacy of incorporating a mailed self-referral reminder into the current BSS invitation process at St Mark’s Hospital. The results show that, when sent with the theory-based leaflet developed in Chapter 6, the self-referral reminder resulted in self-referral and uptake in 16% of individuals, and thereby exceeded the threshold for further investigation in a formal RCT (n = 25 vs. n = 3). In addition, the results show that the additional appointments were easy to facilitate, with most people receiving their preferred practitioner gender and time and day of appointment (only one person cancelled as a result of not being able to book a convenient appointment).

The finding that the interventions examined in this study met and exceeded the required level of efficacy is highly important. If the findings were replicated in a definitive RCT, then this simple intervention could have a considerable impact on BSS participation at St Mark’s Hospital. Indeed, a 16% increase in self-referral and attendance among previous non-responders would equate to an overall increase in uptake of approximately eight percentage points\(^\text{12}\), which would increase the overall uptake of BSS at St Mark’s Hospital from 40.5%, to almost 50% (five percentage points higher than the national average; McGregor et al., 2015a). It is important now not only to test the self-referral reminder against usual care in a RCT, but to examine the ADR among individuals who are screened in response to the reminder. If similar to the rate observed among those who attend the initial appointment (i.e. 9.8%; Bevan et al., 2014), the introduction of a self-referral reminder at St Mark’s Hospital might not only increase uptake, but have a considerable impact on the incidence and mortality of CRC in the local population as well (Geurts et al., 2015).

In contrast to previous research (Senore et al., 1996; Sutton et al., 2000; McGregor et al., 2015a), the present study found that more women attended an appointment in response to the self-referral reminder than men (20% of women attended an appointment, compared with only 10% of men). One possible explanation for this is that the gender of the practitioner performing the test is a more important barrier for women than men (Varadarajulu et al., 2002; Farraye et al., 2004; Menees et al., 2005; Schneider et al., 2009), one which was directly and explicitly addressed by allowing individuals to communicate a preference for the gender of the practitioner performing the test (women were more likely to express a preference for a same-sex practitioner than men). This effect may have been exacerbated by the ethnic diversity of the area in which this study was conducted. Previous research has shown that the gender of the practitioner performing the test is a more pertinent barrier to FS screening for Black and Minority Ethnic (BME) group women (Varadarajulu et al., 2002), and the women included in this study were invited from some of the most ethnically diverse parts of the country (see Chapter 5).

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\(^{12}\) Estimated by multiplying the proportion of adults not responding to the initial invitation [0.5] by the proportion of adults attending screening in response to the 12-month reminder [0.16].
Chapter 7. Evaluating the feasibility of the self-referral reminder and theory-based leaflet (Study 2)

7.5.1 Strengths

This study had several strengths. First, it used objective measures of self-referral and uptake, both of which have previously been shown to be more reliable than self-reported measures (Baier et al., 2000; Rauscher et al., 2008; Lo et al., 2016). Second, the data were analysed on an intention-to-treat basis, which is ecologically superior to the per-protocol method of analysis (Newell., 1992; Detry and Lewis., 2014; Abrahra et al., 2015). Lastly, the study was conducted within an organised screening programme, as opposed to a trial setting. As such, the data were not vulnerable to demand characteristics or social desirability bias, both of which have previously been shown to affect the ecological validity of quantitative research studies (Podsakoff et al., 2003).

7.5.2 Limitations

As well as several strengths, this study had a number of important limitations. First, it was performed at a single centre in London, and as such, it remains to be seen whether these reminders can be implemented at other centres outside of the study setting. Second, the study was limited to previous non-responders, and as such, the differential impact of the self-referral reminder on other subgroups of non-participants (e.g. previous non-attenders) could not be assessed. In addition, only a small proportion of the previously non-responding population were included in this study, and it remains to be seen whether self-referral reminders can be offered to the entire eligible population of non-responding adults. Lastly, the self-referral reminder used in this study contained multiple components, including the theory-based leaflet, and the effects of each component could not be assessed due to a lack of controls. The next step would be to perform a multi-arm RCT testing the impact of the self-referral reminder, with and without the theory-based leaflet, against usual care. Doing so would determine not only whether the self-referral reminder is effective, but whether the theory-based leaflet contributes to uptake. If the self-referral reminder and theory-based leaflet are confirmed to be more effective than usual care, the method examined in this study could provide a potential strategy to improve uptake and possibly even reduce inequalities in participation, with the materials being easily adapted for other low uptake areas.

7.6 Conclusion

This study found that sending previous non-responders a theory-based leaflet and self-referral reminder letter with options for the day and time of the appointment and the gender of the practitioner performing the test was feasible and exceeded the minimum level of efficacy required to merit further investigation in a RCT.
Chapter 8. Assessing the impact of the self-referral reminder and theory-based leaflet on uptake (Study 3)

8.1 My contributions to the work presented in this chapter

I conceived the idea for the study, wrote the trial protocol and submitted the ethics application with input from my supervisors. Sarah Marshall and Lorraine Gorman also contributed to the study’s design, providing pragmatic advice regarding the delivery of the reminder. I calculated the sample size for the study after receiving statistical advice confirming the appropriateness of my proposed calculation plans from Nick Counsell. Tark Elouihrani was responsible for identifying eligible adults on the BCSS. Ms Cherese Bennett (Health Improvement Specialist, St Mark’s BCSC) was responsible for maintaining the study database, randomising adults to study groups, mailing the reminders and anonymising and transferring the data at the end of the study. I coded the data and derived the values for area-level deprivation that were later matched to individuals within the dataset (by Cherese Bennett) using participant study IDs. I analysed the data after receiving statistical advice on the appropriateness of my proposed analysis plans from Nick Counsell. I also interpreted the results with input from my supervisors and led on the publication of the manuscript (Kerrison et al., 2017). All of the co-authors contributed to the interpretation of the results.

13 A version of this Chapter, entitled: ‘Improving uptake of flexible sigmoidoscopy screening: a randomized controlled trial of nonparticipant reminders in the English Screening Programme’ has been published in Endoscopy (see Appendix 8-1 for the published manuscript).

Chapter 8. Assessing the impact of the self-referral reminder and theory-based leaflet on uptake (Study 3)

8.2 Introduction

In the previous chapter, I assessed the feasibility of sending previous BSS non-responders a self-referral reminder 12 months after their initial invitation. I found that, when sent with the theory-based leaflet developed in Chapter 6, the self-referral reminder resulted in self-referral and uptake in 16% of previous non-responders, and thereby exceeded the minimum level of efficacy of a ‘good’ intervention (see 7.3.9 Power calculation).

While the results were highly promising, the study described in the previous chapter lacked a control group against which the effectiveness of the self-referral reminder could be compared. The effectiveness of the intervention and some of its key components, therefore, still require formal evaluation in multi-arm RCTs. One such component requiring further investigation is the theory-based leaflet developed as part of this thesis. Tailoring information materials for the whole programme would incur considerable financial and logistical costs, which would need to be justified.

Another component of the self-referral reminder that also requires further investigation is its differential impact on specific groups of non-participants. So far, the interventions have been tested exclusively on former non-responders (individuals who did not confirm the initial appointment offered), and their potential to improve uptake among other groups of non-participants (e.g. non-attenders) has not yet been explored.

Other aspects of the self-referral reminder and theory-based leaflet which have not yet been assessed include: 1) the cost of the interventions per additional attendee; 2) the ADR among individuals who self-refer for screening and; 3) individual preferences for a same-sex practitioner by factors other than gender.

The present study set out to extend the evaluation of the self-referral reminder and theory-based leaflet to increase uptake by: 1) comparing uptake between individuals receiving the self-referral reminder against usual care (i.e. no reminder); 2) testing the relative impact of including the theory-based leaflet against a third group receiving a self-referral reminder with the standard information booklet used by the NHS BSSP and; 3) subdividing non-participants into ‘previous non-responders’ and ‘previous non-attenders’.

8.2.1 Aims

The specific aims of this study were to: 1) establish the effectiveness of the self-referral reminder to improve uptake among previous non-participants; 2) assess the benefit of using the theory-based leaflet over the standard information booklet used by the NHS BSSP and; 3) explore the differential impact of the intervention materials to facilitate uptake among different groups of non-participants.
Chapter 8. Assessing the impact of the self-referral reminder and theory-based leaflet on uptake (Study 3)

The secondary aims were to: 1) examine the ADR among screened adults; 2) explore individual preferences for a same-sex practitioner by baseline characteristics and ethnicity, and; 3) estimate the cost of the intervention materials per additional person attending screening.

8.3 Methods

8.3.1 Study design

This study was a single-centre RCT with three parallel arms.

8.3.2 Study population and setting

Eligible adults were men and women registered with a general practice within the London Boroughs of Brent and Harrow, who had not attended a BSS appointment within 12 months of being sent their initial invitation. Individuals included both those who previously did not respond to the initial invitation (non-responders), as well as those who did respond, but did not attend (non-attenders).

8.3.3 Identification

Eligible adults were identified on the BCSS by a member of the direct care team at the Hub. The data were extracted one week prior to the beginning of the study (February, 2015) following a formal data request from the clinical programme manager at St Mark’s BCSC, who asked the Hub to identify individuals invited for BSS at the centre between February and August 2014 (i.e. 12 months before the study start date). The request specified that individuals be excluded if they: 1) were no longer registered with a general practice within the London Boroughs of Brent and Harrow, 2) currently had an appointment booked at the screening centre, 3) were registered on the BCSS as ‘deceased’, or 4) had attended a BSS appointment since they were first invited one year ago. An overview of the data requested is presented in Table 8-1.
Table 8-1. Data specification from St Mark’s BCSC to the Hub

<table>
<thead>
<tr>
<th>Variable</th>
<th>Reason for request</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS Number</td>
<td>Required for mail out</td>
</tr>
<tr>
<td>Title</td>
<td>Required for mail out</td>
</tr>
<tr>
<td>First Name</td>
<td>Required for mail out</td>
</tr>
<tr>
<td>Middle Name(s)</td>
<td>Required for mail out</td>
</tr>
<tr>
<td>Last Name</td>
<td>Required for mail out</td>
</tr>
<tr>
<td>Address</td>
<td>Required for mail out</td>
</tr>
<tr>
<td>Postcode</td>
<td>Required for mail out</td>
</tr>
<tr>
<td>Initial invite date</td>
<td>Required for mail out</td>
</tr>
<tr>
<td>Gender</td>
<td>Important baseline characteristic</td>
</tr>
<tr>
<td>CCG</td>
<td>Important baseline characteristic</td>
</tr>
<tr>
<td>Initial episode status</td>
<td>Important baseline characteristic</td>
</tr>
<tr>
<td>Current episode status</td>
<td>Important exclusion criteria</td>
</tr>
<tr>
<td>Date of initial appointment</td>
<td>Important exclusion criteria</td>
</tr>
</tbody>
</table>

8.3.4 Enrolment

Eligible adults were enrolled into the study over a 20 week period spanning February to August 2015. On the basis that there was capacity to facilitate an additional five appointments each week, and that approximately 5% of all individuals across the three study groups would book and attend an appointment (see: 8.3.11.1 Expected uptake), the clinical programme manager at St Mark’s BCSC limited the number of eligible adults who could be enrolled into the study each week. As a result, not all eligible adults (i.e. previous non-participants) were included in the study, and individuals were randomly selected for inclusion in the study from a variable weekly total of previous non-participants based on their initial invitation date. This was done using blocked pseudo-random selection methods, with non-participants blocked according to the week they received their initial invitation, and a subset (n = 69) randomly selected for inclusion in the study (Efird., 2010).

8.3.5 Randomisation and group allocation

Individuals randomly selected for inclusion in the study were randomly assigned in a 1:1:1 ratio (using simple pseudo-random allocation methods; Babbie., 2011) to receive either: no reminder (control), a 12-month self-referral reminder with the standard information booklet used by the NHS BSSP, or a 12-month self-referral reminder with the theory-based leaflet (TMR-TBL) developed in Chapter 6.
8.3.6 Blinding

As participants were randomised to receive no reminder, or a 12-month self-referral reminder with one of two leaflets (see 8.3.5 Randomisation and group allocation), it was not possible to blind them to the treatment they received. The health improvement specialist responsible for maintaining the study database was also aware of the treatment that individuals were allocated, as she had access to the data before it was pseudonymised. My supervisors and I, however, were blinded to the treatment participants received until the end of the study, when all of the data had been collected and any patient identifiable data removed.

8.3.7 Procedures

Individuals allocated to the control group received no reminder, as per usual care. They were able to self-refer for an appointment by calling the Freephone telephone number for St Mark’s BCSC. The standard process of self-referring for an appointment was outlined to them in the cancellation letter, which is sent to all individuals who do not attend a BSS appointment (see Appendix 2-6).

Individuals allocated to the reminder groups were sent a 12-month self-referral reminder with one of two leaflets (depending on their group allocation), an ‘appointment-request-slip’ and a Freepost return envelope (addressed to St Mark’s BCSC) 12 months after their initial invitation. Individuals in both reminder groups were able to book an appointment either by returning the appointment-request-slip to the centre (thereby initiating a call from a member of the administrative team), or by calling the centre directly on the Freephone telephone number provided. Individuals in both reminder groups were also able to indicate a preference for the gender of the practitioner performing the test, as well as the day and time of the appointment, either by selecting options on the appointment-request-slip, or when prompted during their call (administrative staff were given instruction to do this by the clinical programme manager).

Anyone not responding to the self-referral reminder within four weeks was sent the follow-up reminder, which also included an appointment-request-slip, the allocated information leaflet and a Freepost return envelope. Individuals were then given another eight weeks to respond. At this time, their attendance status was assessed by the health improvement specialist (using routine data stored on the BCSS) and added to the study database. Any self-referrals made after this time were not included in the study results, but were still fulfilled by St Mark’s BCSC.

Individuals who self-refferred for an appointment (in all study groups) also received a pre-appointment text-message reminder and telephone call, as per routine practice at St Mark’s BCSC. The procedures for the telephone call and text-message reminder are described in the previous chapter (see 7.3.7 Procedures).
8.3.8 Intervention details

Detailed descriptions of the self-referral reminder, follow-up reminder and theory-based leaflet and their development are provided in Chapter 6. A copy of the standard information booklet is provided in the appendix (see Appendix 2-3). The following section provides a brief overview of the changes made to the intervention materials following the results of the feasibility study.

12-month self-referral reminder: Two small changes were made to the 12-month self-referral reminder letter. One of these changes was made to the self-referral reminder letter for TMR-SIB group specifically. Namely, a line indicating that the leaflet ‘included stories from people who had previously had the test’ was omitted (see Appendix 8-2). The other change, which affected the self-referral reminder for both groups (i.e. TMR-SIB and TMR-TBL), was that some of the options for the day and time of the appointment were removed (see appendices 8-2 and 8-3 for the amended 12-month self-referral reminder letter used for the TMR-SIB group and the TMR-TBL group respectively). This change was made to the reminder on the basis that those appointments were not available at St Mark’s BCSC and were responsible for some of the difficulty in offering people their preferred appointment in the feasibility study (Chapter 7).

Follow-up reminder: The same changes made to the self-referral reminder were also made to the follow-up reminder (see appendices 8-4 and 8-5 for amended versions of the follow-up reminder for the TMR-SIB group and TMR-TBL group respectively).

8.3.9 Consent procedures

Detailed descriptions of the consent procedures for self-referred appointments are provided in the previous chapter (see: 7.3.7 Consent procedures).

8.3.10 Measures

8.3.10.1 Gender, CCG and initial episode status

Data on the gender, CCG and initial episode status (i.e. non-responder / non-attender status) of each person were extracted from the BCSS as part of the initial extraction performed by the Hub (see Table 8-1).

8.3.10.2 Area-level deprivation

The postcode of each person’s home address was converted into a score on the 2010 IMD using the same methods described in the previous chapter (see 7.3.8.2 for detailed descriptions).
8.3.10.3 Ethnicity

The ethnicity of each person who attended screening was extracted from the BCSS and added to the study database by the health improvement specialist four and 12 weeks after the delivery of the self-referral reminder (i.e. when checking the self-referral and attendance status of each person; see 8.3.10.8 Self-referral and attendance).

8.3.10.4 Clinical outcome

As with ethnicity, the clinical outcome (i.e. test result) for each person was extracted from the BCSS and added to the study database by the health improvement specialist four and 12 weeks after the delivery of the self-referral reminder (see 8.3.10.3 Ethnicity).

8.3.10.5 Method of referral

The method of self-referral for each person was added to the study database using the same methods described in the previous chapter (see 7.3.8.3 for detailed descriptions).

8.3.10.6 Preferred gender of the practitioner

The preferred gender of the practitioner for each person who self-referred for an appointment was added to the study database using the same methods described in the previous chapter (see 8.3.8.4 for detailed descriptions).

8.3.10.7 Receipt of a pre-appointment reminder

Receipt of a pre-appointment reminder (i.e. by text or by telephone) was added to the study database as the study progressed. Members of the administrative team at St Mark’s BCSC were informed of the study and were given specific instructions by the clinical programme manager to keep a record of any individuals they contacted, either by text or over the phone, on the BCSS. As there was no entry field for ‘receipt of a pre-appointment reminder’ on the BCSS, receipt of a pre-appointment reminder was recorded in each person’s ‘episode notes’ (on the BCSS). These data were then extracted from the BCSS by the health improvement specialist responsible for maintaining the study database. This was done on a weekly basis, four and 12 weeks after each person was sent their self-referral reminder (again, when checking the self-referral and attendance status of each person; see 8.3.10.8 Self-referral and attendance).

8.3.10.8 Self-referral and attendance

As with the previous study (Study 2), self-referral and attendance were verified by the health improvement specialist at St Mark’s BCSC four weeks following the delivery of the self-referral reminder and eight weeks following the delivery of the follow-up reminder.
The first assessment was carried out to establish which individuals had already self-referred / attended screening, and therefore did not need to receive the follow-up reminder. The second assessment was carried out to determine the ‘end of study’ uptake for each group.

8.3.11 Sample size

The sample size (n = 1383) was calculated using a standard test of difference between two proportions. As the study included three trial arms, the calculation was repeated for each pairwise comparison comprising a primary research question in the planned analysis (see Table 8-2). The final calculation gave a sample size requirement of 461 adults per trial arm to test for a 5% difference in uptake between any two of the three study groups, with expected values of 0%, 5% and 10% for the control, TMR-SIB and TMR-TBL groups respectively (see 8.3.11.1 Expected uptake, below). The study was designed to detect differences at the two-sided 5% alpha level with a 20% margin for type II error. The sample size was calculated using PASS (version 15).

<table>
<thead>
<tr>
<th>Comparison</th>
<th>P1</th>
<th>P2</th>
<th>Alpha</th>
<th>Beta</th>
<th>n (per arm)</th>
<th>n (Total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control vs. TMR-SIB</td>
<td>0.004</td>
<td>0.049</td>
<td>0.05</td>
<td>0.2</td>
<td>194</td>
<td>582</td>
</tr>
<tr>
<td>Control vs. TMR-TBL</td>
<td>0.004</td>
<td>0.099</td>
<td>0.05</td>
<td>0.2</td>
<td>84</td>
<td>252</td>
</tr>
<tr>
<td>TMR-SIB vs. TMR-TBL</td>
<td>0.049</td>
<td>0.099</td>
<td>0.05</td>
<td>0.2</td>
<td>461</td>
<td>1383</td>
</tr>
</tbody>
</table>

P1 = expected uptake for comparison group 1
P2 = expected uptake for comparison group 2

8.3.11.1 Expected uptake

Control: the expected uptake of the control group was based on the self-referral rate of non-participants at St Mark’s Hospital during the same time period of the previous year (i.e. 0.4%; personal communication).

12-month reminder and standard information booklet: the expected uptake of the TMR-SIB group was based on a five percentage point difference in uptake between the TMR-SIB and TMR-TBL groups, with the TMR-TBL group achieving uptake five percentage points higher than the TMR-SIB group (a recent review of interventions to improve organised screening uptake demonstrated that theory-based modifications improved median uptake on average by five percentage points; Duffy et al., 2016).
12-month reminder and theory-based leaflet: the expected uptake of the TMR-TBL group was estimated by calculating the two-sided 95% CIs for uptake among non-responders in the previous chapter (using exact methods) and then selecting the value associated with the lower 95% CI on the basis that a 9.9% uptake rate among previous non-participants would be considered operationally significant by the clinical programme manager at St Mark’s BCSC.

8.3.12 Analysis

Descriptive statistics were used to describe the trial population and report the number of adenomas detected. Univariable and multivariable binary logistic regression were used to investigate possible associations between treatment groups, self-referral and uptake (Engel., 1988). To adjust for multiple comparisons, Bonferroni corrections were applied (0.05 / 3 = 0.017) and outcomes compared to an adjusted significance level of 0.015 (Bonferroni., 1936). Subgroup analyses were carried out on individuals who self-referred for an appointment. These analyses set out to: 1) explore possible associations between uptake and baseline characteristics, self-referral method, and receipt of a pre-appointment reminder and; 2) assess variation in people’s preference for a same-sex practitioner by baseline characteristics and ethnicity. Both sets of subgroup analyses were performed using univariable and multivariable logistic regression (Engel., 1988). The latter used a step-wise model to determine the change in variance after accounting for ethnicity. The change in variance was reported using the Nagelkerke R square statistic (Nagelkerke., 1991). The data were assessed on an intention-to-treat basis using SPSS (version 24).

8.3.13 Cost-analysis

I calculated the cost per additional attendee by dividing the cost of the self-referral reminder and follow-up reminder (with the standard information booklet and theory-based leaflet separately) by the number of people who attended screening. I also performed a sensitivity analysis by calculating the range of variation of the cost estimates within the confidence intervals of the participation rates (calculated using exact methods based on the binomial distribution).

8.3.14 Ethical approval, research governance and trial sponsorship

The study was approved by the UCL JRO (reference: 14/0863) on the 17th of December 2014 (Appendices 8-6 and 8-7), the North East Tyne & Wear South Research Ethics Service (Ref: 15/NE/0043) on the 30th of January 2015 (Appendix 8-8), and the Northwest London Hospitals’ R and D group (Ref: RD15/011) on the 9th of February 2015 (Appendix 8-9). In accordance with the Consolidated Standards of Reporting Trial’s (CONSORT’s) guidelines (Moher et al., 2001), the study was registered with the International Standard Randomised Controlled Trial’s Number (ISRCTN’s) Registry for transparency (trial ID: ISRCTN44293755).
8.4 Results

8.4.1 Sample characteristics

This study took place between February and August 2015, with follow-up until October 2015. A total of 1383 adults were randomised and analysed as allocated. The majority of individuals were registered with a general practice located within the London Borough of Brent \((n = 928, 67.1\%)\), did not respond to the initial invitation \((n = 1255, 90.7\%)\) and were female \((n = 727, 52.6\%)\). Table 8-3 describes the basic attributes of the study participants by trial arm. Figure 8-1 provides an overview of the flow of participants through the study.

<table>
<thead>
<tr>
<th>Table 8-3. Description of the trial population</th>
<th>Control ((n = 461))</th>
<th>TMR-SIB ((n = 461))</th>
<th>TMR-TBL ((n = 461))</th>
<th>Total ((n = 1383))</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>261 (56.6)</td>
<td>238 (51.6)</td>
<td>228 (49.5)</td>
<td>727 (52.6)</td>
</tr>
<tr>
<td>Male</td>
<td>200 (43.4)</td>
<td>223 (48.4)</td>
<td>233 (50.5)</td>
<td>656 (47.4)</td>
</tr>
<tr>
<td><strong>CCG, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brent</td>
<td>304 (65.9)</td>
<td>302 (65.5)</td>
<td>322 (69.8)</td>
<td>928 (67.1)</td>
</tr>
<tr>
<td>Harrow</td>
<td>157 (34.1)</td>
<td>159 (34.5)</td>
<td>139 (30.2)</td>
<td>455 (32.9)</td>
</tr>
<tr>
<td><strong>Tertile of deprivation (IMD Score), n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 1 (Most deprived) ((0.00 – 17.68))</td>
<td>152 (33.0)</td>
<td>144 (31.2)</td>
<td>133 (28.9)</td>
<td>429 (31.0)</td>
</tr>
<tr>
<td>Tertile 2 (Median deprived) ((17.69 – 27.50))</td>
<td>164 (35.5)</td>
<td>162 (35.1)</td>
<td>179 (38.8)</td>
<td>505 (36.5)</td>
</tr>
<tr>
<td>Tertile 3 (Least deprived) ((27.51 – 80))</td>
<td>140 (30.4)</td>
<td>151 (32.8)</td>
<td>144 (31.2)</td>
<td>435 (31.5)</td>
</tr>
<tr>
<td>Missing</td>
<td>5 (1.1)</td>
<td>4 (0.9)</td>
<td>5 (1.1)</td>
<td>14 (1.0)</td>
</tr>
<tr>
<td><strong>Initial episode status, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-responder</td>
<td>411 (89.2)</td>
<td>408 (88.5)</td>
<td>436 (94.6)</td>
<td>1255 (90.7)</td>
</tr>
<tr>
<td>Non-attender</td>
<td>50 (10.8)</td>
<td>53 (11.5)</td>
<td>25 (6.4)</td>
<td>128 (9.3)</td>
</tr>
</tbody>
</table>

Abbreviations: TMR, 12-Month Reminder; SIB, Standard Information Booklet; TBL, Theory-Based Leaflet; CCG, Clinical Commissioning Group; IMD, Index of Multiple deprivation
Chapter 8. Assessing the impact of the self-referral reminder and theory-based leaflet on uptake (Study 3)

Figure 8.1. Trial flowchart / CONSORT diagram.
8.4.2 Uptake

In total, 119 (8.6%) people attended a BSS appointment across all three study groups (Table 8-4). A further 41 (3.0%) self-referred, but either did not attend (n = 21) or cancelled (n = 20), leaving 1223 (88.4%) adult men and women who did not self-refer or attend.

In the univariable analysis, there was strong evidence of differences in self-referral and uptake between individuals in the reminder groups and the control (Table 8-4). A total of 48 individuals (10.4%) in the TMR-SIB group and 70 (15.2%) in the TMR-TBL group attended an appointment, compared to only one (0.2%) in the control group (OR = 53.5, 95% CI = 7.4 – 389.1, P < 0.001; OR = 82.4, 95% CI = 11.4 – 595.6, P < 0.001 for the TMR-SIB and TMR-TBL groups respectively). There was also a strong trend toward differences in uptake between the reminder groups, with individuals in the TMR-TBL group being more likely to attend an appointment than individuals in the TMR-SIB group (OR = 1.5, 95% CI = 1.1 – 2.3, P = 0.03).

Results were similar after adjusting for baseline characteristics in the multivariable analysis (Table 8-4), with strong evidence of significant differences between the reminder groups and control (TMR-SIB vs. control: OR = 53.7, 95% CI = 7.4 – 391.4, P < 0.001; TMR-TBL vs. control: OR = 89.0, 95% CI = 12.3 – 645.4, P < 0.001). After adjusting for baseline characteristics, there was also strong evidence for a difference in uptake between reminder groups, with individuals in the TMR-TBL group being more likely to self-refer and attend an appointment than individuals in the TMR-SIB group (OR = 1.7, 95% CI = 1.1 – 2.5, P = 0.01). There was also strong evidence of a difference in uptake by initial episode status after adjusting for study group and baseline characteristics (Table 8-5), with previous non-attenders being nearly twice as likely to self-refer and attend an appointment as previous non-responders (OR = 2.5, 95% CI = 1.4 – 4.4, P < 0.01). There was no evidence of an association between screening uptake and gender, regional IMD tertile or CCG (all Ps > 0.05).
### Table 8-4. Self-referral and uptake by trial arm (univariable and multivariable regression outcomes)

<table>
<thead>
<tr>
<th></th>
<th>Mean n (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR¹ (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Self-referred for an appointment comparisons</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control vs. TMR-SIB 1 vs. 64 (0.2 vs. 13.9)</td>
<td>74.16*** (10.24 - 536.97)</td>
<td>73.27*** (10.11 - 531.11)</td>
<td></td>
</tr>
<tr>
<td>Control vs. TMR-TBL 1 vs. 95 (0.2 vs. 20.6)</td>
<td>119.40*** (16.57 - 860.49)</td>
<td>130.36*** (18.05 - 941.54)</td>
<td></td>
</tr>
<tr>
<td>TMR-SIB vs. TMR-TBL 64 vs. 95 (13.9 vs. 20.6)</td>
<td>1.61 (1.14 - 2.28)</td>
<td>1.78** (1.25 - 2.54)</td>
<td></td>
</tr>
<tr>
<td><strong>Attended an appointment comparisons</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control vs. TMR-SIB 1 vs. 48 (0.2 vs. 10.4)</td>
<td>53.46*** (7.35 - 389.05)</td>
<td>53.73*** (7.38 - 391.39)</td>
<td></td>
</tr>
<tr>
<td>Control vs. TMR-TBL 1 vs. 70 (0.2 vs. 15.2)</td>
<td>82.35*** (11.39 - 595.58)</td>
<td>89.01*** (12.28 - 645.40)</td>
<td></td>
</tr>
<tr>
<td>TMR-SIB vs. TMR-TBL 48 vs. 70 (10.4 vs 15.2)</td>
<td>1.54* (1.04 - 2.28)</td>
<td>1.69** (1.13 - 2.52)</td>
<td></td>
</tr>
</tbody>
</table>

n for all groups, 1381; n per trial arm, 461

Abbreviations: OR, Odds Ratio; CI, Confidence Interval

¹Adjusted OR and 95% CI are adjusted for gender, CCG, area-level deprivation and initial episode status

* P ≤ 0.015; ** P ≤ 0.01; ***P ≤ 0.001
Table 8-5. Self-referral and uptake by baseline characteristics (univariable & multivariable regression outcomes)

<table>
<thead>
<tr>
<th></th>
<th>Self-referral n (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR$^1$ (95% CI)</th>
<th>Attended n (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR$^1$ (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>160 (11.6)</td>
<td>-</td>
<td>-</td>
<td>119 (8.6)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>(n = 1383)</td>
<td></td>
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<tr>
<td><strong>Gender</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Women$^a$</td>
<td>83 (11.4)</td>
<td>-</td>
<td>-</td>
<td>57 (7.8)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>(n = 727)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>77 (11.7)</td>
<td>1.03 (0.74-1.44)</td>
<td>0.94 (0.67-1.33)</td>
<td>62 (9.5)</td>
<td>1.23 (0.84-1.79)</td>
<td>1.18 (0.80-1.75)</td>
</tr>
<tr>
<td>(n = 656)</td>
<td></td>
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<tr>
<td><strong>CCG</strong></td>
<td></td>
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</tr>
<tr>
<td>Brent$^a$</td>
<td>101 (10.9)</td>
<td>-</td>
<td>-</td>
<td>75 (8.1)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>(n = 926)</td>
<td></td>
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<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Harrow</td>
<td>59 (12.9)</td>
<td>1.21 (0.86-1.71)</td>
<td>1.39 (0.89-2.18)</td>
<td>44 (9.6)</td>
<td>1.21 (0.82-1.79)</td>
<td>1.34 (0.80-2.22)</td>
</tr>
<tr>
<td>(n = 457)</td>
<td></td>
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<tr>
<td><strong>Tertile of deprivation</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Tertile 1$^a$</td>
<td>49 (11.4)</td>
<td>-</td>
<td>-</td>
<td>38 (8.9)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>(n = 429)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 2</td>
<td>59 (11.7)</td>
<td>1.03 (0.69-1.54)</td>
<td>1.20 (0.74-1.95)</td>
<td>41 (8.1)</td>
<td>0.91 (0.57-1.44)</td>
<td>1.05 (0.61-1.81)</td>
</tr>
<tr>
<td>(n = 505)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Tertile 3</td>
<td>51 (11.7)</td>
<td>1.03 (0.68-1.56)</td>
<td>1.29 (0.76-2.21)</td>
<td>40 (9.2)</td>
<td>1.04 (0.65-1.66)</td>
<td>1.28 (0.71-2.33)</td>
</tr>
<tr>
<td>(n = 435)</td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Initial episode status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-responder$^a$</td>
<td>138 (11.0)</td>
<td>-</td>
<td>-</td>
<td>101 (8.0)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>(n = 1256)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-attender</td>
<td>22 (17.3)</td>
<td>1.70 (1.04-2.78)</td>
<td><strong>2.24</strong> (1.30-3.85)</td>
<td>18 (14.2)</td>
<td>1.89 (1.10-3.24)</td>
<td><strong>2.45</strong> (1.36-4.40)</td>
</tr>
<tr>
<td>(n = 127)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: OR, Odds Ratio; CI, Confidence Interval; CCG, Clinical Commissioning Group
$^1$Adjusted OR and 95% CI are adjusted for group allocation (trial arm) and all other co-variates in the table
$^a$Reference category
$^*P < 0.015; **P < 0.01; ***P < 0.001$
8.4.3 Confirmed appointments

A total of 41 individuals booked an appointment but did not attend. Attendance was higher among previous non-attenders than non-responders (81.8% vs. 73.0%); however, the results of the regression revealed that there was no significant difference between these two groups (OR = 2.2, 95% CI = 1.0 – 4.7, P > 0.05). A significant difference in attendance was observed between men and women (80.5% vs. 68.3%), however, with men being more likely to attend an appointment than their female counterparts (OR = 2.2, 95% CI = 1.0 – 4.7, P = 0.05; Appendix 8-10). There were no significant differences in non-attendance for any other variables included in the analysis, including receipt of a pre-appointment reminder and the method of referral (all Ps > 0.05).

8.4.4 Clinical findings

Of the 119 men and women who self-referred and attended an appointment, 114 (95.8%) were screened (i.e. had the scope inserted), four (3.4%) did not meet the clinical eligibility criteria, and one (0.8%) refused consent (Appendix 8-11). Of those who attended an appointment and were screened (n = 114), 54 (47.4%) had no abnormalities detected, 29 (25.4%) had polyps and 31 (27.2%) had other pathology (Appendix 8-11). Nine (31.0%) of those who had polyps had adenomatous polyps, six (66.7%) of whom had pathology that met the clinical criteria for colonoscopy (see Chapter 2) and were subsequently referred for further examination. No-one was diagnosed with cancer.

8.4.4.1 Adenoma detection rate

The ADR among those who attended an appointment was 7.6% (n = 9). After exclusions (see 8.4.4 Clinical findings), this increased to 7.9%.

8.4.5 Preferences for the gender of practitioner performing the test by baseline characteristics

Of the 159 men and women in the reminder groups who self-referred for a BSS appointment, 116 (73.0%) expressed a preference for the gender of the practitioner performing the test. Of those indicating a preference (n = 116), the majority (n = 109, 94.0%) expressed a preference for a same-sex practitioner. When examined by baseline characteristics (Appendix 8-12), there were significant differences in the proportion of people expressing a preference for a same-sex practitioner between men and women, with men being significantly less likely to request a same-sex practitioner (57.1% of men compared with 79.3% of women; adjusted OR = 0.30, 95% CI = 0.14 to 0.64, P = 0.002). There was no evidence of an association for any other baseline characteristic (all Ps > 0.05). The variables included in the model accounted for 15.1% of the variance (Nagelkerke R Square = 0.151; Appendix 8-12).
8.4.6 Preferences for the gender of practitioner performing the test by ethnicity

Of the 118 people in the reminder groups who attended an appointment, 112 (94.8%) provided their ethnicity (Appendix 8-13). Asian men and women were the most likely to express a preference for a same-sex practitioner, with 71.2% (37/52) of Asian men and women expressing a preference for a same-sex practitioner, compared with 65.6% (21/32) of Black and minority ethnic (BME) group men and women and only 60.7% (17/28) of White men and women (Appendix 8-14). In the univariable analysis, men and women from a BME group background or an Asian ethnic background were no more likely to express a preference for a same-sex practitioner than those from a White ethnic background (both $P$s > 0.05), and the same was true in the multivariable analysis after adjusting for group allocation and baseline characteristics (both $P$s > 0.05). After adjusting for ethnicity, the total amount of variance explained by the model increased to 23.4% (Nagelkerke R Square = 0.234; Appendix 8-14).

8.4.7 Costs

The estimated cost of the interventions per additional person attending screening were £8.37 (range: £6.38 – £11.17) in the TMR-SIB group and £8.75 (range: £7.05 – £11.14) in the TMR-TBL group (see Appendices 8-15 and 8-16 for a breakdown of the intervention costs for each group respectively).

8.5 Discussion

The results of this study support the use of a ‘12-month’ self-referral reminder letter at St Mark’s Hospital and highlight an additional benefit to using the theory-based leaflet over the standard information booklet (uptake was 0.2%, 10.4% and 15.2% in the control, TMR-SIB & TMR-TBL groups respectively). In addition, the results indicate that the cost of the intervention per additional person attending screening was relatively low (similar to that of an advance notification letter; Senore et al., 2015a), suggesting that they may be cost-effective, as well as clinically effective.

At the current rate of attendance (40.5%; Chapter 5), the inclusion of a self-referral reminder to the invitation process would increase uptake at St Mark’s BCSC by between six and nine percentage points\(^\text{14}\), depending on which of the two leaflets were adopted (see Appendix 8-17 for projections). Irrespective of the method used, the inclusion of a self-referral reminder would increase overall uptake and the absolute number of adenomas detected by the centre.

\(^{14}\) Estimated by multiplying the proportion of adults not attending an initial appointment (0.59) by the proportion of adults attending in response to the 12-month reminder either with the SIB (0.10) or the TBL (0.15)
Given that attendance was consistent between tertiles of area-level deprivation, it seems unlikely that implementing a 12-month self-referral reminder with either leaflet would exacerbate existing inequalities in participation at St Mark’s Hospital (see Chapter 5). Through a process of elimination, these reminders might even reduce inequalities in participation at the centre. This will be explored further in the next study (Chapter 9).

While uptake did not vary by gender, CCG or area-level deprivation, it did vary by initial episode status, with previous non-attenders being more likely to self-refer and attend an appointment than previous non-responders (uptake was 14.2% and 8.0%, respectively). One possible explanation for this is that, previous non-attenders perceive fewer barriers and more benefits to screening than non-responders, and are qualitatively similar to screened adults, but have difficulty translating their intentions into actions due to circumstantial aspects such as poor health (Power et al., 2008). Previous research by Ferrer and colleagues (2011) has shown that participation in CRC screening is a behavioural process comprised of several qualitatively distinct stages through which individuals transition based on their readiness to be screened (see Chapter 3). Each stage is strongly associated with a specific set of attitudes and beliefs towards the test, and it may be that the interventions used in this study were more effective at facilitating forward-stage transitions in previous non-attenders by addressing issues which are specific to those who have already engaged with the programme by confirming an appointment. It is also possible that it may simply be easier to facilitate forward stage transitions in individuals who have previously responded to the initial invitation than in individuals who have not, and so a higher response in previous non-attenders may have been observed for this reason.

This study also found that, among those who self-referred and subsequently made an appointment, women were less likely to attend screening than men (68.3% vs. 80.5%). This was consistent with previous research examining factors associated with non-attendance, in which women who stated that they ‘probably would’ or ‘definitely would’ attend screening were less likely to attend than their male counterparts (Power et al., 2008). One possible explanation as to why women were less likely to attend a confirmed screening appointment is that they perceive more barriers to FS screening (e.g. they are more likely to indicate that they think the test would be uncomfortable, embarrassing, make them feel anxious, etc. Wardle et al., 2005), which may make it more difficult for them to translate their intentions into behaviour (Sutton et al., 2000). In particular, women have been found to view the preparation for endoscopic procedures to be a major barrier (more so than men), which might explain why women confirm an appointment, but then do not attend (Friedemann-Sánchez., 2007; Jones et al., 2010b).

It is possible that a telephone reminder would have been more effective (Stone et al., 2002; Power et al., 2009; Senore et al., 2015b; Duffy et al., 2016). However, telephone reminders are not considered cost-effective for CRC screening and subsequently are not recommended by the European Union Quality Assurance Guidelines for Colorectal Cancer Screening (von Karsa et al.,
Chapter 8. Assessing the impact of the self-referral reminder and theory-based leaflet on uptake (Study 3)

In addition, screening centres do not have access to people’s telephone numbers unless they confirm an appointment and provide it at this stage. It is also possible that additional reminders, delivered 24, 36 and 48 months after the initial invitation might improve uptake even further, just as repeated rounds of invitation do for gFOBt screening (Steele et al., 2010; Lo et al., 2014). However, further research assessing the effects of such reminders is required to test this hypothesis.

8.5.1 Strengths

This study had several strengths. First, this study used a randomised design, which is considered the gold standard approach for testing public health interventions (Sackett et al., 1996). Second, it used parallel groups (i.e. randomisation of individuals), which are considered less vulnerable to sample bias than clustered designs (i.e. randomisation of clusters of individuals, such GP practices; Donner and Klar, 2004). Lastly, both previous non-responders and non-attenders were included, which meant that it was possible to explore the differential impact of self-referral reminders by non-participant subgroup, and thereby directly address a limitation of the previous study (see 7.5.2 Limitations).

8.5.2 Limitations

In addition to several strengths, this study had a number of important limitations. First, it was performed at a single centre in London, and as such, it remains to be seen whether the interventions would be as effective at other centres. Second, in order to ensure endoscopy capacity, only a proportion of previous non-participants eligible to receive a self-referral reminder were selected for inclusion in the trial, and as such, it cannot be said whether or not St Mark’s BCSC would be able to deliver these reminders to the entire eligible population of previously non-participating adults. Lastly, this study did not examine demographic variation in uptake within study groups, and as such, it is not known whether specific subgroups of individuals (e.g. men) were more likely to respond in one group (e.g. the TMR-TBL group) than another (e.g. the TMR-SIB group). The next study will attempt to address this by providing a breakdown of uptake within each study group while also evaluating the impact of sending non-participants a second self-referral reminder 24 months after their initial invitation.

8.6 Conclusion

Sending previous non-participants a self-referral reminder 12 months after their initial invitation was effective at improving uptake. The inclusion of a theory-based leaflet added significantly to this strategy, increasing uptake even further.
Chapter 9. Assessing the impact of sending a second self-referral reminder on uptake (Study 4)

9.1 My contributions to the work presented in this chapter

I conceived the idea for the study, wrote the trial protocol and submitted the ethics application with input from my supervisors. Sarah Marshall and Lorraine Gorman also contributed to the study’s design, providing pragmatic advice regarding the delivery of the reminder. I calculated the power of the study to detect differences between study groups after receiving statistical advice confirming the appropriateness of my proposed calculation plans from Nick Counsell. Mr Andrew Prentice (Health Improvement Specialist, St Mark’s BCSC) was responsible for checking the eligibility of study participants and for updating and maintaining the study database, delivering the reminders, and anonymising and transferring the data at the end of the study. I analysed the data, after receiving statistical advice on the appropriateness of my proposed analysis plans from Nick Counsell. I also interpreted the results with input from my supervisors and led on the submission of the manuscript (Kerrison et al., under review), writing the first draft and then submitting for publication. All of the co-authors contributed to the interpretation of the results.

15 A version of this chapter, entitled: ‘Use of two self-referral reminders and a theory-based leaflet to increase the uptake of flexible sigmoidoscopy in the English Bowel Scope Screening Programme: results from a randomised controlled trial in London’ has been published in Annals of Behavioural Medicine (see Appendix 9-1 for the published manuscript).

9.2 Introduction

In the previous chapter, I examined the effectiveness of sending previous BSS non-participants a self-referral reminder 12 months after their initial invitation. I found that, when sent with the theory-based leaflet developed in Chapter 6, the self-referral reminder resulted in self-referral and uptake in 15% of individuals, which was significantly more than when sent with the standard information booklet sent with the initial invitation (uptake was 10%). I also found that the self-referral reminder and theory-based leaflet were both relatively inexpensive (i.e. compared with other interventions described in the previous literature), indicating that they might be cost-effective (for the NHS), as well as clinically effective (the ADR among screened adults coming forward in response to the reminder was approximately 8%, which is similar to the rate among initial attenders; Bevan et al., 2014).

At the end of the previous chapter, I proposed that additional self-referral reminders sent 24 and 36 months after the initial invitation might also be effective, just as repeated invitations are for gFOBt screening (Steele et al., 2010; Lo et al., 2014). In the present Chapter, I set out to test the first part of this hypothesis by sending participants from the RCT a second self-referral reminder 24 months after their initial invitation (i.e. 12 months after the first reminder was sent) if they were allocated to either of the reminder groups, or no reminder if they were allocated to the control group. I also set out to extend the evaluation of sending self-referral reminders to previous non-participants by addressing limitations highlighted in the previous chapter. For example, by assessing demographic variation in uptake within study groups.

9.2.1 Aims

The specific aims of this study were to: 1) examine whether a second self-referral reminder increased uptake among non-participants who had previously received the self-referral reminder as part of the RCT (i.e. ‘additional uptake’); 2) assess the cumulative effect of two self-referral reminders on the overall uptake of BSS among individuals included in the previous RCT and present extension (i.e. ‘overall uptake’); 3) test whether the effect of the theory-based leaflet on participation observed following the delivery of the first reminder was sustained after the delivery of a second reminder and; 4) examine demographic variation in uptake within groups to assess whether there are subgroup differences between reminder arms.

As with the previous chapter, the secondary aims were to: 1) examine the ADR among screened adults; 2) examine people’s preferences for a same-sex practitioner by baseline characteristics and; 3) estimate the cost of the intervention materials per additional person attending screening.
9.3 Methods

9.3.1 Study design

This study was an extension of the RCT described in the previous chapter (see 8.3.1 Study design for an overview).

9.3.2 Study population and setting

Eligible adults were men and women included in the RCT who had not attended a BSS appointment at St Mark’s Hospital within 24 months of being sent their initial invitation.

9.3.3 Identification

The eligibility of each person included in the RCT was assessed for inclusion in the extension by the health improvement specialist at St Mark’s BCSC using routine data stored on the BCSS. Individuals were excluded from the extension if they: (1) were no longer registered with a general practice in the London Boroughs of Brent and Harrow, (2) currently had an appointment booked at the screening centre, (3) were registered on the BCSS as ‘deceased’, or (4) had attended a BSS appointment since the study was initiated one year ago.

9.3.4 Procedures

Eligible adults retained their group allocation from the RCT. Individuals allocated to the control group received no reminder, as per usual care. They were able to self-refer for an appointment by calling the Freephone telephone for St Mark’s BCSC. The process of self-referring for an appointment was outlined to them in the cancellation letter, which is sent to all individuals who do not attend a BSS appointment (see Appendix 2-6).

Individuals allocated to either of the reminder groups received a further self-referral reminder (hereafter referred to as a ‘24-month’ self-referral reminder), plus the corresponding information leaflet (i.e. the standard information booklet used by the NHS, or the theory-based leaflet described in Chapter 6), an appointment request slip and Freepost return envelope 24 months after their initial invitation. As with the 12-month self-referral reminder, individuals sent a 24-month reminder were able to book an appointment either by returning an appointment request slip to the centre (thereby initiating a call from a member of the administrative team), or by calling the centre directly on the Freephone telephone number provided. Again, as with the 12-month self-referral reminder, individuals sent a 24-month reminder were able to indicate a preference for the gender of the practitioner performing the test, as well as the time and day of the appointment, either by selecting options on the appointment request-slip, or when prompted during their call (administrative staff were given instructions to do this by the clinical programme manager).
Following a similar format to the 12-month self-referral reminder, anyone not responding to the 24-month self-referral reminder within four weeks was sent a follow-up reminder, which also included an appointment-request-slip, the allocated information leaflet, and a Freepost return envelope. Individuals were then given another eight weeks to respond. At this time, their attendance status was assessed by the health improvement specialist (using routine data stored on the BCSS) and added to the study database. Any self-referrals made after this time were not included in the study results, but were still fulfilled by St Mark’s BCSC.

Individuals who self-referred for the test received a pre-appointment text-message reminder and telephone call, as per routine practice at St Mark’s BCSC. Detailed descriptions of the text-message reminder and telephone call are reported in the Chapter 7 (see: 7.3.7 Procedures).

9.3.5 Intervention details

Detailed descriptions of the self-referral reminder, follow-up reminder and theory-based leaflet and their development are provided in Chapter 6. An overview of the changes made to the self-referral reminder and follow-up reminder following the results of the feasibility study are described in Chapter 8 (see 8.3.8 Intervention details). A copy of the standard information booklet is provided in the appendix (see Appendix 2-3).

9.3.6 Consent procedures

Detailed descriptions of the consent procedures for BSS appointments are provided in Chapter 7 (see: 7.3.7 Consent procedures).

9.3.7 Measures

9.3.7.1 Gender, CCG and initial episode status

Data on the gender, CCG and initial episode status of each person were extracted from the BCSS as part of the initial extraction performed by the Hub (see Chapter 8, Table 8-1).

9.3.7.2 Area-level deprivation

The postcode of each person’s home address was converted into a score on the 2010 IMD as part of the RCT (see 8.3.10.2 Area-level deprivation for detailed descriptions).

9.3.7.3 Ethnicity

The ethnicity of each person who attended screening was extracted from the BCSS and added to the study database by the health improvement specialist four and 12 weeks after the delivery
of the self-referral reminder (i.e. when checking the self-referral and attendance status of each person; see 9.3.7.8 Self-referral and attendance below).

9.3.7.4 Clinical outcome

As with ethnicity, the clinical outcome for each person was extracted from the BCSS and added to the study database by the health improvement specialist four and 12 weeks after the delivery of the self-referral reminder (again, when checking the self-referral and attendance status of each person; see 9.3.10.8 Self-referral and attendance).

9.3.7.5 Method of referral

The method of self-referral for each person was added to the study database using the same methods described in Chapter 7 (see 7.3.8.3 Method of referral).

9.3.7.6 Preferred gender of the practitioner

The preferred gender of the practitioner for each person who self-referred for an appointment and expressed a preference was added to the study database using the same methods described in Chapter 7 (see 7.3.8.4 Preferred gender of the practitioner for detailed descriptions).

9.3.7.7 Receipt of a pre-appointment reminder

Receipt of a pre-appointment reminder (i.e. by text or by telephone) was added to the study database using the same methods described in the previous chapter (see 8.3.10.7 Receipt of a pre-appointment reminder for detailed descriptions).

9.3.7.8 Self-referral and attendance

Self-referral and attendance were verified by the health improvement specialist (using objective data stored on the BCSS) at St Mark’s BCSC four weeks following the delivery of the 24-month reminder and eight weeks following the delivery of the follow-up reminder. The first assessment was carried out to establish which individuals had self-referred / attended screening, and therefore did not need to receive the follow-up reminder. The second assessment was carried out to determine the ‘end of study’ uptake for each group.

9.3.8 Power calculation

Power was calculated using a standard test of difference between two proportions. As the study included three trial arms, the calculation was repeated for each pairwise comparison comprising a primary research question in the planned analysis (see Table 9-1). All three calculations demonstrated that the sample size \(n = 461\) per trial arm provided sufficient levels of power (i.e.
beta <0.2) to detect a 7.5 percentage point difference in uptake at the two-sided 5% alpha level, with expected values of 0.4% for the control group, 15.2% for the TMR-SIB group, and 21.7% for the TMR-TBL group (see 10.3.8.1 Expected uptake below). The power calculations were performed using PASS (version 15).

| Table 9-1. Power calculation overview |
|-----------------|--------|--------|--------|--------|--------|
| Comparison      | P1     | P2     | Alpha  | Beta   | n (per arm) | n (Total) |
| Control vs. TMR-SIB | <0.01  | 0.15   | 0.05   | 1.0    | 461      | 1383     |
| Control vs. TMR-TBL  | <0.01  | 0.22   | 0.05   | 1.0    | 461      | 1383     |
| TMR-SIB vs. TMR-TBL     | 0.15   | 0.22   | 0.05   | 0.8    | 461      | 1383     |
| P1 = expected uptake for comparison group 1 |
| P2 = expected uptake for comparison group 2 |

9.3.8.1 Expected uptake

The expected overall uptake for the reminder groups was estimated by multiplying the uptake of each group following the 12-month reminder by 1.5. This value was selected on the basis that similar studies examining the use of non-participant interventions (e.g. repeated invitations) to promote the uptake of gFOBt screening have shown that the second round of intervention tends to yield approximately 50% of the return of the first, so that the overall impact of the two rounds combined is 150% of that of the first round alone (Steele et al., 2010; Lo et al., 2014). For example, Steele and colleagues (2010) found that the first round of repeated invitation increased the overall uptake of gFOBt screening in the English BCSP by six percentage points (i.e. from 54% to 60%), whereas the second only increased uptake by an additional three percentage points (i.e. from 60% to 63%; Steele et al., 2010).

9.3.9 Analysis

Descriptive statistics were used to describe the trial population after exclusions (see 9.3.3 Identification). Additional attendance (i.e. attendance in response to the delivery of the 24-month reminder) was assessed by calculating the two-sided 95% CI for each group using exact methods based on the binomial distribution. Univariable and multivariable binary logistic regression were used to investigate possible associations between treatment groups and self-referral and overall uptake (i.e. attendance for the 12 and 24-month reminders combined), before and after adjusting for baseline characteristics (Engel., 1988). To adjust for multiple comparisons, Bonferroni corrections were applied (0.05 / 3 = 0.017), and outcomes compared to an adjusted significance level of 0.015 (Bonferroni., 1936).
Several subgroup analyses were carried out on individuals who self-referred for an appointment. The purpose of these analyses was to: 1) explore possible associations between uptake and baseline characteristics, self-referral method, and receipt of a pre-appointment reminder and; 2) assess variation in people’s preference for a same-sex practitioner by baseline characteristics and ethnicity. Both sets of subgroup analyses were performed using univariable and multivariable binary logistic regression (Engel., 1988). The latter used a step-wise model to determine the change in variance after accounting for ethnicity. The change in variance was reported using the Nagelkerke R square statistic (Nagelkerke., 1991).

A subgroup analysis was also carried out on individuals who attended an appointment and were screened (i.e. individuals who attended an appointment, provided consent, were clinically eligible to take part and had the scope inserted). This analysis was performed to explore possible variations in the ADR between demographic subgroups of individuals (e.g. between men and women). As with the aforementioned subgroup analyses, univariable and multivariable binary logistic regression were used to test for differences (Engel., 1988). A subgroup analysis was also performed on the subgroup of individuals who were allocated to the reminder groups. This analysis compared uptake within demographic subgroups of individuals, between trial arms, to assess whether specific groups of individuals (e.g. men) were more responsive to one leaflet over the other. The data were assessed on an intention-to-treat basis using SPSS (version 24).

9.3.10 Cost-analysis

I calculated the cost per additional attendee by dividing the cost of the self-referral reminder and follow-up reminder (with the standard information booklet and theory-based leaflet separately) by the number of people who attended screening. I also performed a sensitivity analysis by calculating the range of variation of these cost estimates within the confidence intervals of the participation rates (calculated using exact methods based on the binomial distribution).

9.3.11 Ethical approval, research governance and trial sponsorship

Details of the ethical approvals, research governance and trial sponsorship for this study are described in the previous chapter (see 8.3.14 Ethical approval, research governance and trial sponsorship for details).
9.4 Results

9.4.1 Sample characteristics

This study took place between February and August 2016, with follow-up until October 2016. A total of 1264 (91.4%) of 1383 men and women from the initial sample were assessed for inclusion in the extension (Figure 9-1). One-hundred and nineteen (8.6%) were known to have taken part in screening and were not assessed for this reason. Of the 1264 adults who were assessed, eight (0.6%) had died and 38 (2.8%) were no longer registered with a general practice within the London Boroughs of Brent and Harrow, leaving a total sample size of 1218 men and women who were eligible for inclusion across all three study groups (control, n = 453; TMR-SIB, n = 399; TMR-TBL, n = 366; Table 9-2). The majority of individuals were registered with a general practice in the London Borough of Brent (n = 816, 67.0%), did not respond to the initial invitation (n = 1072, 88.0%) and were female (n = 650, 53.4%). Table 9-2 describes the basic attributes of the study population by trial arm. Figure 9-1 provides an overview of the flow of individuals through the study.
Table 9-2. Description of the trial population

<table>
<thead>
<tr>
<th></th>
<th>Control (n = 453)</th>
<th>TMR-SIB (n = 399)</th>
<th>TMR-TBL (n = 366)</th>
<th>Total (n = 1218)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>255 (56.3)</td>
<td>213 (53.4)</td>
<td>182 (49.7)</td>
<td>650 (53.4)</td>
</tr>
<tr>
<td>Male</td>
<td>198 (43.7)</td>
<td>186 (46.6)</td>
<td>184 (50.3)</td>
<td>568 (46.6)</td>
</tr>
<tr>
<td><strong>CCG, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brent</td>
<td>300 (66.2)</td>
<td>259 (64.9)</td>
<td>257 (70.2)</td>
<td>816 (67.0)</td>
</tr>
<tr>
<td>Harrow</td>
<td>153 (33.8)</td>
<td>140 (35.1)</td>
<td>109 (29.8)</td>
<td>402 (33.0)</td>
</tr>
<tr>
<td><strong>Tertile of deprivation (IMD score), n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 1</td>
<td>148 (32.7)</td>
<td>128 (32.1)</td>
<td>104 (28.4)</td>
<td>380 (31.2)</td>
</tr>
<tr>
<td>(0.00 - 17.68)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 2</td>
<td>164 (36.2)</td>
<td>141 (35.3)</td>
<td>142 (38.8)</td>
<td>447 (36.7)</td>
</tr>
<tr>
<td>(17.69 - 27.50)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 3</td>
<td>137 (30.2)</td>
<td>126 (31.6)</td>
<td>115 (31.4)</td>
<td>378 (31.0)</td>
</tr>
<tr>
<td>(27.51 – 80)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>4 (0.9)</td>
<td>4 (1.0)</td>
<td>5 (1.4)</td>
<td>14 (1.1)</td>
</tr>
<tr>
<td><strong>Initial episode status, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-responder</td>
<td>404 (89.2)</td>
<td>342 (85.7)</td>
<td>326 (89.1)</td>
<td>1072 (88.0)</td>
</tr>
<tr>
<td>Non-attender</td>
<td>49 (10.8)</td>
<td>57 (14.3)</td>
<td>40 (10.9)</td>
<td>146 (12.0)</td>
</tr>
</tbody>
</table>

Abbreviations: CCG, Clinical Commissioning Group; IMD, Index of Multiple Deprivation
Chapter 9: Assessing the impact of sending a second self-referral reminder on uptake (Study 4)

Figure 9-1. Trial flowchart/CONSORT diagram.

1383
Randomly selected for inclusion in the study

461
Randomly allocated to Control

461
No reminder letter (treatment as usual care)

461
S
ent 12-month reminder + standard booklet

461
Sent 12-month reminder + theory-based leaflet

461
Sent 24-month reminder + theory-based leaflet

1 attended screening

48 attended screening

70 attended screening

70 attended screening

460
Re-assessed for eligibility

413
Re-assessed for eligibility

391
Re-assessed for eligibility

453
No reminder letter (treatment as usual care)

399
Sent 24-month reminder + standard booklet

366
S
ent 24-month reminder + theory-based leaflet

Attendance at screening

Attendance at screening

Attendance at screening

Analysed as allocated

Analysed as allocated

Analysed as allocated
9.4.2 Uptake (additional uptake; 24-month reminder)

In total, 50 (4.1%) people included in the extension attended a BSS appointment across all three study groups (Table 9-3). A further seven (0.6%) self-referred, but either did not attend (n = 4) or cancelled (n = 3), leaving 1161 (95.3%) adult men and women who did not self-refer or attend.

The percentage of people who self-referred and attended an appointment within each group was 0.4% (n = 2; 95% CI = 0.0 – 1.6), 4.8% (n = 19; 95% CI = 2.9 – 7.3) and 7.9% (n = 29; 95% CI = 5.4 – 11.2) in the control, TMR-SIB and TMR-TBL groups respectively (Table 9-3). Sending a second self-referral reminder 24 months after the initial invitation, therefore, further increased screening uptake and was significantly more effective than usual care (i.e. the 95% CI between the reminder groups and the control did not overlap), but was not enhanced by the inclusion of a theory-based leaflet (i.e. the 95% CI between the two reminder groups did overlap; Table 9-3).

9.4.3 Uptake (overall uptake; 12 and 24-month reminder combined)

In total, 169 (12.2%) people included in the RCT and extension (n = 1383) attended an appointment across all three study groups (Table 9-4). A further 43 (3.1%) self-referred, but either did not attend (n = 25) or cancelled (n = 18), leaving 1171 (84.7%) who did not self-refer or attend.

In the univariable analysis, there was strong evidence of differences in self-referral and uptake between the reminder groups and the control (Table 9-4). A total of 67 individuals (14.5%) in the TMR-SIB group and 99 individuals (21.5%) in the TMR-TBL group attended an appointment, compared with only three (0.7%) in the control (OR = 26.0, 95% CI = 8.1 – 83.2, P < 0.001 and OR = 41.8, 95% CI = 13.1 – 132.8, P < 0.001 for the TMR-SIB and TMR-TBL groups respectively). There was also strong evidence of a difference in uptake between the reminder groups, with individuals in the TMR-TBL group being significantly more likely to attend an appointment than individuals in the TMR-SIB group (OR = 1.6, 95% CI = 1.1 – 2.3, P = 0.006).

Results were similar after adjusting for baseline characteristics in the multivariable analysis (Table 9-4), with strong evidence of differences in uptake between the reminder groups and the control (TMR-SIB vs. control: aOR = 26.1, 95% CI = 8.1 – 84.0, P < 0.001; TMR-TBL vs. control: aOR = 46.91, 95% CI = 14.7 – 149.9, P < 0.001). After adjusting for baseline characteristics, there remained a significant difference in participation between intervention groups, with individuals in the TMR-TBL group being more likely to book and attend an appointment than individuals in the TMR-SIB group (aOR = 1.8, 95% CI = 1.3 – 2.6, P < 0.001). There was also strong evidence of a difference in uptake by initial episode status after adjusting for study group and other baseline characteristics, with initial non-attenders being more likely to book and attend an appointment than initial non-responders; uptake was 11.4% and 20.3% respectively (aOR = 2.6, 95% CI = 1.6 – 4.4, P < 0.001; Table 9-5). There was no evidence of an association between screening uptake and gender, regional IMD tertile, or CCG (all Ps > 0.05).
### Table 9-3. Uptake at 12 and 12 and 24 months combined by trial arm

<table>
<thead>
<tr>
<th></th>
<th>12 months Uptake % (95% CI)</th>
<th>12 &amp; 24 months Uptake % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usual care</td>
<td>0.2 (0.0 - 1.2)</td>
<td>0.7 (0.2 - 2.0)</td>
</tr>
<tr>
<td>(n = 461)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TMR-SIB</td>
<td>10.4 (7.8 - 13.6)</td>
<td>14.5 (11.4 - 18.1)</td>
</tr>
<tr>
<td>(n = 461)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TMR-TBL</td>
<td>15.2 (12.1 - 18.8)</td>
<td>21.5 (17.8 - 25.5)</td>
</tr>
<tr>
<td>(n = 461)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Table 9-4. Self-referral and uptake by trial arm (12 & 24 months combined)

<table>
<thead>
<tr>
<th></th>
<th>n (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR(^1) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Self-referred for an appointment comparisons</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control vs. TMR-SIB</td>
<td>3 vs. 83</td>
<td>33.52***</td>
<td>33.90***</td>
</tr>
<tr>
<td>(0.7 vs. 18.0)</td>
<td></td>
<td>(10.51 - 106.92)</td>
<td>(10.60 - 108.36)</td>
</tr>
<tr>
<td>Control vs. TMR-TBL</td>
<td>3 vs. 126</td>
<td>57.42***</td>
<td>65.25***</td>
</tr>
<tr>
<td>(0.7 vs. 27.3)</td>
<td></td>
<td>(18.12 - 182.00)</td>
<td>(20.48 - 207.90)</td>
</tr>
<tr>
<td>TMR-SIB vs. TMR-TBL</td>
<td>83 vs. 126</td>
<td>1.71***</td>
<td>1.93***</td>
</tr>
<tr>
<td>(18.0 vs. 27.3)</td>
<td></td>
<td>(1.25 - 2.34)</td>
<td>(1.39 - 2.66)</td>
</tr>
<tr>
<td><strong>Attended an appointment comparisons</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control vs. TMR-SIB</td>
<td>3 vs. 67</td>
<td>25.96***</td>
<td>26.14***</td>
</tr>
<tr>
<td>(0.7 vs. 14.5)</td>
<td></td>
<td>(8.10 - 83.18)</td>
<td>(8.14 - 83.95)</td>
</tr>
<tr>
<td>Control vs. TMR-TBL</td>
<td>3 vs. 99</td>
<td>41.75***</td>
<td>46.91***</td>
</tr>
<tr>
<td>(0.7 vs. 21.5)</td>
<td></td>
<td>(13.13 - 132.76)</td>
<td>(14.68 - 149.93)</td>
</tr>
<tr>
<td>TMR-SIB vs. TMR-TBL</td>
<td>67 vs. 99</td>
<td>1.61**</td>
<td>1.80***</td>
</tr>
<tr>
<td>(14.5 vs. 21.5)</td>
<td></td>
<td>(1.14 - 2.26)</td>
<td>(1.26 - 2.55)</td>
</tr>
</tbody>
</table>

\(n\) for all groups, 1381; \(n\) per trial arm, 461

Abbreviations: OR, Odds Ratio; CI, Confidence Intervals

\(^1\)Adjusted OR and 95% CI are adjusted for gender, area, deprivation and initial episode status

\(^\star\)Reference group

\(P < 0.015; ^{**} P < 0.01; ^{***} P < 0.001\)
## Table 9-5. Self-referral and uptake by baseline characteristics – (12 & 24 months combined)

<table>
<thead>
<tr>
<th></th>
<th>Self-referred n (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR1 (95% CI)</th>
<th>Attended n (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR1 (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (n = 1383)</td>
<td>212 (15.3)</td>
<td>-</td>
<td>-</td>
<td>169 (12.2)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Womena (n = 727)</td>
<td>109 (15.0)</td>
<td>-</td>
<td>-</td>
<td>82 (11.3)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Men (n = 656)</td>
<td>103 (15.7)</td>
<td>1.06 (0.79-1.42)</td>
<td>0.96 (0.71-1.32)</td>
<td>87 (13.3)</td>
<td>1.20 (0.87-1.66)</td>
<td>1.14 (0.81-1.60)</td>
</tr>
<tr>
<td><strong>CCG</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brenta (n = 926)</td>
<td>134 (14.5)</td>
<td>1.22 (0.90-1.65)</td>
<td>1.26 (0.84-1.89)</td>
<td>66 (14.4)</td>
<td>1.35 (0.97-1.88)</td>
<td>1.44 (0.93-2.24)</td>
</tr>
<tr>
<td>Harrow (n = 457)</td>
<td>78 (17.1)</td>
<td>0.88 (0.62-1.26)</td>
<td>0.97 (0.63-1.49)</td>
<td>55 (10.9)</td>
<td>0.78 (0.53-1.16)</td>
<td>0.92 (0.58-1.48)</td>
</tr>
<tr>
<td><strong>Deprivation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Tertile 1a (n = 429)</td>
<td>70 (16.3)</td>
<td>-</td>
<td>-</td>
<td>58 (13.5)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Tertile 2 (n = 505)</td>
<td>74 (14.7)</td>
<td>0.88 (0.65-1.35)</td>
<td>0.97 (0.68-1.76)</td>
<td>55 (12.9)</td>
<td>0.78 (0.64-1.40)</td>
<td>0.92 (0.73-2.04)</td>
</tr>
<tr>
<td>Tertile 3 (n = 435)</td>
<td>67 (15.4)</td>
<td>0.93 (0.65-1.35)</td>
<td>1.09 (0.68-1.76)</td>
<td>56 (12.9)</td>
<td>0.95 (0.64-1.40)</td>
<td>1.22 (0.73-2.04)</td>
</tr>
<tr>
<td><strong>Initial episode status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-respondera (n = 1255)</td>
<td>181 (14.4)</td>
<td>-</td>
<td>-</td>
<td>143 (11.4)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Non-attende (n = 128)</td>
<td>31 (24.2)</td>
<td>1.90** (1.23-2.93)</td>
<td>2.67*** (1.63-4.37)</td>
<td>26 (20.3)</td>
<td>1.98** (1.25-3.15)</td>
<td>2.60*** (1.55-4.36)</td>
</tr>
</tbody>
</table>

Abbreviations: OR, Odds ratio; CI, Confidence Interval; CCG, Clinical Commissioning Group

1Adjusted ORs and 95% CIs are adjusted all other covariates in the table

aReference category

Adjusted OR and 95% CI are adjusted for group allocation (trial arm) and all other covariates in the table

*P ≤ 0.015; **P ≤ 0.01; ***P ≤ 0.001
9.4.4 Confirmed appointments (12 and 24-month data combined)

A total of 43 individuals booked an appointment but did not attend. A significant difference in attendance among people who self-referred was observed between men and women (84.4% vs. 74.5%), with men being more likely to attend their appointment (aOR = 2.1, 95% CI = 1.0 – 4.2, \( P = 0.05 \)). A similar difference in uptake was observed between people who received a pre-appointment reminder and people who did not (83.6% vs. 73.6%); although this did not reach statistical significance in the multivariable analysis (aOR = 1.7, 95% CI = 0.8 – 3.4, \( P = 0.14 \); Appendix 9-2). There was no evidence of differences in non-attendance for any of the other variables included in the analysis, including initial episode status, and the method of referral (all \( P_s > 0.05 \)).

9.4.5 Clinical findings (12 and 24-month data combined)

Of the 166 adult men and women in the reminder groups who self-referred and attended an appointment, 158 (95.2%) were screened, seven (4.2%) did not meet the clinical eligibility criteria, and one (0.6%) refused consent (Appendix 9-3). Of those who attended an appointment and were screened (n = 158), 74 (46.8%) had no abnormalities detected, 42 (26.6%) had polyps, 42 (26.6%) had other pathology and one (0.6%) had cancer. Fourteen (33.3%) of those who had polyps had adenomatous polyps, seven (50%) of whom had pathology that met the clinical criteria for colonoscopy (see Chapter 2) and were subsequently referred for further examination.

9.4.6 Adenoma detection rate (12 and 24-month data combined)

The ADR among those who attended an appointment was 8.4% (n = 14). After exclusions (i.e. removal of those not adequately screened: see 9.4.5 Clinical findings), this increased to 8.9%. There was no evidence of differences in the ADR between demographic subgroups (see Appendices 9-4 and 9-5), including gender, ethnicity, and initial episode status (all \( P_s > 0.05 \)).

9.4.7 Preferences for the gender of practitioner performing the test by baseline characteristics (12 and 24 month reminder data combined)

Of the 209 men and women in the reminder groups who self-referred for BSS, 144 (68.9%) expressed a preference for the gender of the practitioner. Of those indicating a preference (n = 144), the majority (n = 131, 90.3%) expressed a preference for a same-sex practitioner. When examined by baseline characteristics (Appendix 9-6), there were significant differences between the proportion of men and women expressing a preference for a same-sex practitioner, with men being significantly less likely to request a same-sex practitioner (61.2% of men compared with 76.4% of women; aOR = 0.4, 95% CI = 0.2 – 0.6, \( P < 0.001 \)). There was no evidence of an association for any other characteristic included in the analysis (all \( P_s > 0.05 \)). The variables accounted for 12.4% of the variance (Nagelkerke R Square = 0.124; Appendix 9-6).
9.4.8 Preferences for the gender of practitioner performing the test by ethnic group (12 and 24-month reminder combined)

Of the 166 people in the reminder groups who attended an appointment, 152 (91.6%) provided their ethnicity (Appendix 9-7). Asian men and women were the most likely to express a preference for a same-sex practitioner, with 69.4% (50 out of 72) of Asian men and women expressing a preference for a same-sex practitioner, compared with 59.0% (23 out of 39) of BME group men and women and only 51.2% (21 out of 31) of White men and women (Appendix 9-8). In the univariable analysis, men and women from a BME group background or an Asian ethnic background were not significantly more likely to express a preference for a same-sex practitioner than those from a White ethnic group background (both \( P > 0.05 \)) and the same was true in the multivariable analysis after adjusting for the group allocation and baseline characteristics (both \( P > 0.05 \)). After adjusting for ethnicity, the total amount of variance explained by the model increased from, 12.4%, to 14.6% (Nagelkerke R Square = 0.146; Appendix 9-8).

9.4.9 Demographic variation in uptake by trial arm (12 and 24-month reminder combined)

Appendix 9-9 shows the results of the subgroup analysis comparing uptake between demographic subgroups of individuals (e.g. men) within the two reminder arms. Unadjusted and adjusted ORs and 95% CIs are reported for each subgroup. After adjusting for baseline characteristics, the only group who were not significantly more likely to attend a BSS appointment in the TMR-TBL group were people living in the most deprived tertile of areas (Appendix 9-9).

9.4.10 Costs (24-month reminder)

The estimated cost of the interventions per additional person attending screening were £18.31 (range: £12.00 – £29.00) in the TMR-SIB group and £16.93 (range: £11.97 – £24.55) in the TMR-TBL group (see Appendices 9-10 and 9-11 for a breakdown of the intervention costs for each group respectively).

9.5 Discussion

The results of this study support the use of a second self-referral reminder at St Mark’s Hospital and highlight an additional benefit to using the theory-based leaflet over the standard information booklet (the combined uptake was 0.7%, 14.5% and 21.5% in the control, TMR-SIB and TMR-TBL groups respectively). In addition, the results indicate that the cost of the intervention per additional person attending screening was relatively low (similar to that an advance notification letter; Senore et al., 2015a), suggesting they might be cost-effective, as well as clinically effective.
At the current rate of attendance (40.5%; Chapter 5), the inclusion of two self-referral reminders in the NHS BSSP would increase uptake at St Mark’s Hospital by between nine and 13 percentage points\(^{16}\), depending on which of the two leaflets were adopted (see Appendix 9-12 for projections). Irrespective of the leaflet used, the inclusion of two ‘annual’ self-referral reminders would increase overall uptake and the number of adenomas detected by the centre. Given that uptake was consistent between tertiles of area-level deprivation, it seems unlikely that implementing self-referral reminders with either leaflet would exacerbate existing inequalities in uptake at St Mark’s Hospital (see Appendices 9-13 and 9-14 for projections on the impact of the 12 and 24 month self-referral reminder on social inequalities in uptake at St Mark’s Hospital).

While the uptake of BSS following the 12 and 24-month reminder was high, the present study suggests that it could have been higher still. A total of 18% of people in the TMR-SIB group and 28% of people in the TMR-TBL group self-referred for an appointment, but only 14.5% and 21.5% (respectively) attended. If the entire self-referring population had attended an appointment, an additional 1.8% to 3.5% of people initially invited for BSS at St Mark’s Hospital would attend an appointment\(^{17}\), taking the total combined uptake at 24 months with the standard information booklet to 50.8%, and with the theory-based leaflet to 56.5%. Understanding the reasons for non-participation in these individuals would be useful in terms of developing strategies to prevent non-attendance. This should be a focal point of future research.

### 9.5.1 Strengths

This study had several strengths. First, the sample size was quite large, making it possible to conduct several subgroup analyses that would have been underpowered to detect differences had a smaller sample been used. Second, the study is the first to examine whether self-referral reminders can increase the uptake of BSS, and as such, it is the first to show that these are effective without being vulnerable to bias (e.g. confirmation bias) and confounding data present in other studies (Kaptchuk, 2003). Lastly, the study setting, St Mark’s Hospital, is one that serves an ethnically diverse population from a range of socioeconomic areas and, as with the rest of London, the bowel screening programme has found it difficult to encourage attendance here (Hirst et al., 2016). The results of this study are likely to be generalisable to other London boroughs and national and international urban settings struggling to reach the European target for acceptable participation (von Karsa et al., 2013).

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\(^{16}\) Estimated by multiplying the proportion of adults not attending the initial appointment (0.59) by the proportion attending in response to the 12 and 24-month reminders (combined) on an intention-to-treat basis (i.e. 0.15 (67/461) & 0.22 (99/461) for the SIB and TBL groups respectively).

\(^{17}\) Estimated by multiplying the proportion of adults not attending the initial appointment (0.59) by the proportion who self-refer for an appointment in response to the 12 and 24-month reminders (combined) on an intention to treat basis (i.e. 0.18 (83/461) and 0.27 (126/461)).
9.5.2 Limitations

In addition to several strengths, this study had a number of important limitations. First, it did not include a group that only received a 24-month reminder, and as such, it is not possible to say whether uptake would have been the same or higher had a single reminder been delivered at this time point (i.e. as opposed to two reminders sent 12 and 24 months after the initial invitation). Second, the 12 and 24-month reminders were examined in isolation of one another (i.e. 12 months apart), and as such, it cannot be said whether the reminders could be delivered concurrently (i.e. whether St Mark’s Hospital could manage all the self-referred appointments arising from these reminders if they were sent to both individuals who did not participate 12 and 24 months after their initial invitation). Lastly, ethnicity data were not available for all individuals included in the study, and as a result, it was not possible to assess the differential impact of the self-referral reminders and theory-based leaflet on different ethnic groups.

9.6 Conclusion

Sending non-participants a self-referral reminder 12 and 24 months after their initial invitation was effective at improving uptake. The inclusion of a theory-based leaflet added significantly to this strategy, increasing uptake even further. Future studies should focus on the feasibility of implementing these interventions across multiple centres and the wider population of eligible adults.
Chapter 10. DISCUSSION

10.1 Summary of the literature

CRC is a leading cause of morbidity and mortality throughout the world (Ferlay et al., 2015). Several large RCTs have shown that a single FS between the ages of 55 and 64 can significantly reduce the incidence and mortality of the disease among those who complete the test (Elmunzer et al., 2012). As a result, several countries have begun piloting FS-based screening programmes for the prevention of CRC (Screuders et al., 2015), with England currently rolling out a national programme (the NHS BSSP) set to reach full population coverage in 2018 (Geurts et al., 2015).

Although offered automatically and for free, the uptake of BSS has been low and socioeconomically graded (McGregor et al., 2015a). The most recent examination of uptake demonstrated that only 43% of men and women invited for BSS attended their appointment, and that uptake was lowest among individuals living in the most deprived quintile of areas (uptake ranged from 32% in the most deprived quintile, to 52% in the least deprived; McGregor et al., 2015a). These observations, alongside the finding that there has been little previous research examining the use of intervention strategies to improve participation in FS screening, formed the basis of this thesis.

10.2 Summary of findings

10.2.1 Chapter 5 – Study 1

The first study in this thesis used routine data collected by the NHS BSSP to examine uptake at St Mark’s Hospital during the first fourteen months of the programmes initial implementation. The aim was to examine whether national variations in uptake were observed at the centre, with a wider aim of developing interventions to promote uptake based on the study findings. Uptake data were received for almost 5000 individuals, the majority of whom were registered with an address within the most ethnically diverse quintile of areas in England, which was reflective of the higher overall ethnic diversity of the area.

Data analysis revealed that approximately half of invitees confirmed their appointment, and that the remainder either did not respond or cancelled (data on the individual proportions of these were not obtained). Invitees were more likely to confirm their appointment if they were from the least deprived quintile of areas, compared with the most deprived quintile of areas. Further analysis demonstrated that most people (81%) who confirmed an appointment went on to attend. It was established, therefore, that the greatest opportunities to improve uptake resided in targeting non-responders, who comprised the largest group (50%) of people examined in the study.
10.2.2 Chapter 6 – Intervention development

I developed a self-referral reminder letter and theory-based leaflet to promote uptake among non-responders at St Mark’s Hospital. The strategy was informed by the BCW, which was used to identify: 1) the putative targets for change and; 2) the specific BCTs likely to be effective in affecting those targets. Initial designs of the interventions were informed by a review of the previous literature on the perceived benefits and barriers to FS screening and telephone interviews with previously screened adults. These designs were then tested in a co-design workshop and revised iterations further tested in a series of focus groups and face-to-face interviews with members of the public. The final versions of the interventions were then assessed in several studies guided by the MRC framework for developing and evaluating complex interventions (Studies 2, 3 and 4).

10.2.3 Chapter 7 – Study 2

Study 2 was a single-arm trial that assessed the feasibility and potential efficacy of sending previous BSS non-responders the self-referral reminder and theory-based leaflet 12 months after their original invitation. A total of 160 men and women who did not respond to the initial invitation within one year were randomly selected for inclusion in the study and were mailed a self-referral reminder. Twenty-five self-referred and attended an appointment, which exceeded the threshold for further investigation in a RCT.

A number of additional observations were made within this study. First, it was documented that women who self-referred for an appointment were more likely to express a preference for a same-sex practitioner than men who self-referred for an appointment. Second, although half of all people who self-referred for screening expressed a preference for the day and time of the appointment, the inability to accommodate this preference only deterred one person from continuing to arrange an appointment, suggesting that it is not necessarily receiving the preferred appointment that is the important factor for people who self-refer, but the option to arrange one’s own appointment over the phone.

10.2.4 Chapter 8 – Study 3

Study 3 was a single-centre RCT with three parallel arms. The study design enabled me to compare uptake among groups of individuals receiving either: no reminder (control), a self-referral reminder with the standard information booklet, or a self-referral reminder with the theory-based leaflet, and thereby test the effects of the reminder and leaflet separately. The study design also enabled me to test the differential impact of the self-referral reminder on different groups of non-participants (both non-responders and non-attenders were included in the study).
The results of the trial demonstrated that sending non-participants a self-referral reminder with either leaflet was more effective than usual care (uptake in the control, TMR-SIB and TMR-TBL groups was 0.2%, 10.4% and 15.2% respectively). In addition, the study showed that sending the self-referral reminder with the theory-based leaflet was more effective than sending it with the standard information booklet. The results also revealed that, contrary to previous research suggesting that non-attenders might never translate their intentions into actions (Power et al., 2008), previous non-attenders were more likely to self-refer and attend an appointment than previous non-responders (uptake was 8.0% and 14.2%, respectively), and that these individuals represent a willing group who should not be excluded. The cost of the interventions was consistent with others currently used by the BSSP.

10.2.5 Chapter 9 – Study 4

Study 4 was an extension of the RCT described in Chapter 9. It examined the impact of sending non-responders and non-attenders a second self-referral reminder, twenty-four months after their initial invitation. The results of the study were similar to those observed in the RCT. Additional uptake (i.e. uptake for the extension only) was higher among non-participants allocated to the reminder groups (additional uptake in the control, TMR-SIB and TMR-TBL groups was 0.4%, 4.8% and 7.9% respectively). However, there was no significant difference between groups in terms of the information used.

Overall uptake (i.e. uptake reported for the RCT and extension combined) was higher among non-participants allocated to the reminder groups (overall uptake in the control, TMR-SIB and TMR-TBL groups was 0.7%, 14.5% and 21.5%, respectively). The cost of the sending a second reminder was slightly higher than the first, but was still similar to other interventions used to promote the uptake of FS screening. The ADR among screened adults was comparable to that of initial attenders. Preferences for a same-sex practitioner were confirmed to be higher among women, but did not vary by any other baseline characteristics.

10.3 Strengths

10.3.1 St Mark’s Hospital

Conducting the studies at St Mark’s Hospital was a major strength of the research. The centre funded the development of the interventions, and was therefore highly motivated to deliver them. In addition, the centre had previous experience organising self-referred appointments as part of the UK FS trial (Atkin et al., 2010), and it seems likely that this experience benefitted the research in terms of the centre’s ability and willingness to incorporate the self-referral reminder.
10.3.2 Measurement of uptake

All of the studies reported in this thesis used objective measures of self-referral and uptake, as opposed to self-reported measures, which have previously been shown to be less reliable (Baier et al., 2000; Rauscher et al., 2008; Lo et al., 2016).

10.3.3 Randomised designs

Studies 3 and 4 used randomised designs. Such designs add validity to the conclusions of studies and are considered the gold standard approach for testing public health interventions (Sackett et al., 1996).

10.3.4 Parallel groups

In addition to using randomised designs, Studies 3 and 4 used parallel groups (i.e. randomisation was performed at the level of the individual). Parallel groups are less vulnerable to sample bias than clustered groups (i.e. randomisation of clusters of individuals, e.g. patients registered with a GP practice; Donner and Klar., 2004). They are also more efficient, requiring fewer participants to achieve statistical power (Campbell and Donner., 2007; Wardle et al., 2016). Four recent RCTs conducted within the English BCSP illustrate this point very clearly (McGregor et al., 2016b; Raine et al., 2016a; Raine et al., 2016b; Smith et al., 2017). They each had sample size requirements in excess of 40,000 participants per trial arm after factoring in the use of small clusters; nearly twice their estimated sample size with parallel groups (Wardle et al., 2016).

10.3.5 Demand characteristics and social desirability

Individuals included in Studies 2, 3 and 4 were not informed they were participants in a research study. As such, the data were not vulnerable to demand characteristics or social desirability bias (Podsakoff et al., 2003), both of which have been shown to affect CRC screening research (Van de Mortel., 2008).

10.3.6 Intention-to-treat method

The data from Studies 2, 3 and 4 were assessed on an intention-to-treat basis. This method of analysis assesses uptake between individuals as they were originally allocated and is considered to be ecologically superior to the per-protocol method of analysis (Newell., 1992; Detry and Lewis., 2014; Abraha et al., 2015), which incurs bias through the removal of individuals who do not complete the treatment regimen (Montori and Guyatt., 2001).
10.3.7 Study setting

The setting of the studies described in this thesis is one that contains an ethnically diverse population from a range of socioeconomic areas. As such, the results are likely to be generalisable to other London boroughs and national and international urban settings struggling to reach the European target for acceptable participation in CRC screening (i.e. 45%; von Karsa et al., 2013; Klabunde et al., 2015).

10.3.8 Non-participant subgroups

Studies 3 and 4 included both non-responders and non-attenders, meaning that it was possible to explore the differential impact of the interventions on subgroups of non-participants, and thereby address a limitation of Study 2.

10.4 Limitations

10.4.1 St Mark’s Hospital

Conducting the research at a single centre (which initiated and funded this research) limited my ability to assess how easily the interventions could be implemented at other centres. It is possible that centres which were not involved in the funding or development of the interventions would be less willing to implement them, as they do not have the same vested interests. Centres that were not involved in the UK FS trial might be particularly reluctant to implement them, as they have less experience facilitating self-referral appointments. They may also find them difficult to incorporate alongside usual care because of this.

10.4.2 Proportion of eligible adults

None of the studies used the entire population of individuals eligible for self-referral reminders. It remains to be seen, therefore, whether self-referral reminders could be offered to the all non-participants. The issue is compounded by the fact that the 12 and 24-month reminders were not sent out at the same time. Both reminders facilitated uptake in a considerable proportion of individuals, irrespective of whether they were sent with the theory-based leaflet or standard information booklet.

10.4.3 Measurement of area-level deprivation

The measurement of area-level deprivation was an important aspect of this thesis. Across all four studies, area-level deprivation was measured using the IMD, which is the government’s official measure of relative deprivation for small areas in England (Department for Communities and Local Government., 2011). The studies reported in this thesis used data from the 2010 index, as this was the latest version available at the time. Given that the studies were conducted between
2014 and 2016, and the 2010 IMD census data collected in 2001, the measure used may be outdated, especially for London, which has a transient and changing population. It may also be a less reliable measure in London because of the diversity of the population, even within a single postcode sector.

### 10.4.4 Lack of controls

While Studies 3 and 4 did include a control group receiving no reminders (i.e. 12 or 24 months after the initial invitation), Study 4 did not include a group that only received the 24-month reminder, and as such, it is not possible to say whether uptake would have been the same or higher had a single reminder been delivered at this time point (i.e. as opposed to one 12 months after the initial invitation and then a second 24 months after the initial invitation).

#### 10.4.5 Missing ethnicity data

Ethnicity data were not available for all individuals included in Studies 3 and 4. Previous research has found that some ethnicities are more likely to report the gender of the practitioner performing the test as a potential barrier to screening (Zapatier et al., 2011). The same ethnicities have also been shown to be less likely to take part in screening (Robb et al., 2008). It would have been interesting, therefore, to see whether the offer of a same-sex practitioner improved uptake in these individuals. Future research may address this through a RCT using ethnicity data available on the GP clinical system.

### 10.4.6 Multi-factorial behavioural interventions

The interventions used a number of BCTs, including prompts / cues, information about health consequences and feedback on the outcomes of the behaviour. As such, it is not possible to say whether the effects of the interventions were due to a single BCT, or a combination of some or all of the BCTs. Running a trial with multiple versions of the interventions, each including combination of one or more of the BCTs would enable the effect of each BCT to be teased apart from the overall effect. A factorial RCT would be the most statistically efficient approach (Winer et al., 1971).

### 10.4.7 Complex interventions

Differences between the standard information booklet and theory-based leaflet were not limited to the use of theory. The theory-based leaflet was shorter and more readable (i.e. had a lower readability score) than the standard information booklet used by the NHS, and so may have been more effective for these reasons, as well as the use of BCTs. The theory-based leaflet also contained photos, which the standard information booklet does not (it uses cartoons instead; see Appendix 2-3), and was tailored to the local population. Any of these differences may have
contributed towards the effectiveness of the interventions. Disentangling their effects from those of the BCTs would add an additional layer of complexity to evaluating the theory-based leaflet. It may be more feasible and less costly, therefore, to interview people who attend an appointment after receiving the self-referral reminder and theory-based leaflet. Such studies might provide valuable insights into the reasons why people are more likely to change their screening behaviour in one condition over the other (see 10.6 Further research).

10.4.8 Study setting

As discussed in Chapter 5, the London Boroughs of Brent and Harrow are among the most ethnically diverse, with over half of all residents living in these boroughs being of a non-White ethnic background. While the setting of the studies enabled me to generalise the findings to other London boroughs and national international urban settings, I am not able to generalise the findings to non-urban settings.

10.5 Implications for policy and practice

10.5.1 St Mark’s Hospital

Since publishing the results of the feasibility study (Kerrison et al., 2016) and RCT (Kerrison et al., 2017), NHS England (London region) have commissioned St Mark’s BCSC to send all non-responders and non-attenders a self-referral reminder 12 months after their initial invitation (see Appendix 10-1). The finding that NHS England (London region) have commissioned this work is highly encouraging. It can take years for research to be implemented into practice (Morris et al., 2011), but the decision to implement self-referral reminders at St Mark’s Hospital has taken place within months of the results of the RCT being published and presented at conferences. It is possible that, with the results of the extension now published (Kerrison et al., 2018), PHE will commission St Mark’s Hospital to send previous non-responders and non-attenders a second self-referral reminder (i.e. 24-months after the initial invitation) as part of a future initiative. The results from this thesis suggest that doing so would be effective and would improve the overall uptake of BSS at St Mark’s Hospital even further.

10.5.2 Other centres

With regards to other centres, there is no reason to believe that self-referral reminders would not be as effective, although it would be important to perform multicentre studies before rolling-out these reminders too widely. Perhaps the biggest consideration is whether some centres are willing and able to facilitate the additional appointments brought about by the self-referral reminder. Another important consideration would be the offer of a same-sex practitioner. Not every screening centre in England has both male and female screening practitioners, and so, for some
centres, providing a same-sex practitioner to the patient is not an option. These aspects, among others, would need to be investigated in future studies.

The English Programme should consider implementing a 12-month reminder to improve uptake. Doing so would most likely bring uptake up to the European benchmark of acceptable participation (i.e. 45%). Other countries looking to employ FS screening should also consider including a routine 12-month reminder for the non-responding population when setting up the programme. Findings from this thesis suggest that delivering such reminders with materials designed using theory are likely to have additional benefits on uptake (Michie and West., 2013).

10.6 Further research

The findings and limitations for the work reported in this thesis point towards several different avenues for further research.

10.6.1 Monitoring self-referral at St Mark’s Hospital

Now that self-referral reminders have been implemented at St Mark’s Hospital, it will be important to monitor their roll-out to the entire eligible population. As discussed in the Limitations section (see 11.4), only a proportion of adults eligible to receive a self-referral reminder were included in the studies reported in this thesis, and so it remains to be seen whether the centre is able to facilitate roll-out to all eligible adults without increasing their endoscopy capacity.

10.6.2 Health economic analysis

A full health economic analysis is now required to assess the cost-effectiveness of the self-referral reminder. The results of such an analysis would enable policy and decision makers to decide whether to implement these reminders at St Mark’s BCSC and other centres in the future.

10.6.3 Evaluating additional reminders

During the timeframe of this thesis, it was not possible to test the effectiveness of sending additional ‘annual’ self-referral reminders 36 and 48 months after the initial invitation. It may be worth investigating reminders delivered at these time points in future studies. The present findings suggest that they are likely to yield diminishing returns, but that they may still yield clinically meaningful results nonetheless.

It is also possible that the reminders would have been more effective had they been delivered at different times (e.g. three and six months after the reminder, as opposed to 12 and 24 months after the reminder). For some individuals, there may be seasonal reasons why they are unable to
attend BSS (e.g. going on holiday, looking after children during the school holidays, etc.). Varying the timing of the reminder may benefit these individuals specifically.

### 10.6.4 Enhancing the self-referral reminder

Additional components, such as GP endorsement (Wardle et al., 2016), offering an endoscopist of the same ethnicity (Zapatier et al., 2011), having the enema administered at the hospital (Friedemann-Sánchez., 2007) and offering a timed appointment (Hudson et al., 2016) might augment the observed effect of the self-referral reminder. Two recent studies found that offering breast screening non-participants a second timed appointment was more effective than a reminder with instructions on how to book an appointment (Hudson et al., 2016; Allgood et al., 2017). It is possible that they may also be more effective than reminders for BSS. Future studies looking to improve participation using self-referral reminders should consider this potential augmentation a priority.

### 10.6.5 Alternative strategies to improve uptake

This thesis examined interventions to improve uptake by targeting non-participants; however, it did not examine interventions to improve uptake prior to or during the initial invitation. Studies examining interventions to promote uptake at both of these stages of the screening pathway indicate that such interventions can be implemented and have potential to improve uptake (Duffy et al., 2016). Future studies could also aim to promote uptake, therefore, by enhancing the pre-invitation and invitation stages to minimise the number of non-participants. It is likely that there will remain a place for interventions focusing on non-participants, however. The NHS Breast Screening Programme has been in operation now for over 25 years and still there is scope for improvement and recent studies have shown that offering non-participants a second timed appointment can improve uptake above and beyond current participation (Hudson et al., 2016; Allgood et al., 2017).

### 10.7 Concluding remarks

The interventions described in this thesis constitute the first to be examined in the context of an organised national FS-based screening programme for CRC. Countries looking to employ FS screening with an aim of achieving high uptake should consider using self-referral reminders for the non-responding population; delivering such reminders with a theory-based leaflet might improve uptake further. Future research should consider the programme costs of implementing a self-referral reminder nationally.
References


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Kelly RB, Shank JC (1992) Adherence to screening flexible sigmoidoscopy in asymptomatic patients. Med Care. 1029-1042


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Pearson K (1900) X. On the criterion that a given system of deviations from the probable in the case of a correlated system of variables is such that it can be reasonably supposed to have arisen from random sampling. *The London, Edinburgh, and Dublin Philosophical Magazine and Journal of Science.* **50**(302): 157-175


References


References


References


References


Published papers during period of thesis


Appendices

Appendix 1-1. UK National Screening Committee Criteria for Screening (Public Health England, 2013b).

<table>
<thead>
<tr>
<th>The condition</th>
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<tbody>
<tr>
<td>- The condition should be an important health problem.</td>
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<tr>
<td>- The epidemiology and natural history of the condition, including development from latent to declared disease, should be adequately understood and there should be a detectable risk factor, disease marker, latent period or early symptomatic stage.</td>
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<tr>
<td>- All the cost-effective primary prevention interventions should have been implemented as far as practicable.</td>
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<tr>
<td>- If the carriers of a mutation are identified as a result of screening, the natural history of people with this status should be understood, including the psychological implications.</td>
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<table>
<thead>
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<th>The test</th>
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<tr>
<td>- There should be a simple, safe, precise and validated screening test.</td>
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<tr>
<td>- The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.</td>
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<tr>
<td>- The test should be acceptable to the population.</td>
</tr>
<tr>
<td>- There should be an agreed policy on the further diagnostic investigation of individuals with a positive test result and on the choices available to those individuals.</td>
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<tr>
<td>- If the test is for mutations, the criteria used to select the subset of mutations to be covered by screening, if all possible mutations are not being tested, should be clearly set out.</td>
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<table>
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<th>The treatment</th>
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<tr>
<td>- There should be an effective treatment or intervention for patients identified through early detection, with evidence of early treatment leading to better outcomes than late treatment.</td>
</tr>
<tr>
<td>- There should be agreed evidence-based policies covering which individuals should be offered treatment and the appropriate treatment to be offered.</td>
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<tr>
<td>- Clinical management of the condition and patient outcomes should be optimised in all healthcare providers prior to participation in a screening programme.</td>
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<th>Cost considerations</th>
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<tr>
<td>- There should be evidence from high-quality randomised controlled trials that the screening programme is effective in reducing mortality or morbidity. Where screening is aimed solely at providing information to allow the person being screened to make an informed choice (eg, Down's syndrome, cystic fibrosis carrier screening), there must be evidence from high-quality trials that the test accurately measures risk. The information</td>
</tr>
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that is provided about the test and its outcome must be of value and readily understood by the individual being screened.

- There should be evidence that the complete screening programme (test, diagnostic procedures, treatment/intervention) is clinically, socially and ethically acceptable to health professionals and the public.

- The benefit from the screening programme should outweigh the physical and psychological harm (caused by the test, diagnostic procedures and treatment).

- The opportunity cost of the screening programme (including testing, diagnosis and treatment, administration, training and quality assurance) should be economically balanced in relation to expenditure on medical care as a whole (ie value for money). Assessment against this criteria should have regard to evidence from cost benefit and/or cost-effectiveness analyses and have regard to the effective use of available resource.

- All other options for managing the condition should have been considered (eg, improving treatment, providing other services), to ensure that no more cost-effective intervention could be introduced or current interventions increased within the resources available.

- There should be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards.

- Adequate staffing and facilities for testing, diagnosis, treatment and programme management should be available prior to the commencement of the screening programme.

- Evidence-based information, explaining the consequences of testing, investigation and treatment, should be made available to potential participants to assist them in making an informed choice.

- Public pressure for widening the eligibility criteria for reducing the screening interval, and for increasing the sensitivity of the testing process, should be anticipated. Decisions about these parameters should be scientifically justifiable to the public.

- If screening is for a mutation, the programme should be acceptable to people identified as carriers and to other family members.
Appendix 2-1. Preinvitation letter for the national screening programme.

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**Bowel Cancer Screening Programme**

London Bowel Cancer Screening Programme Hub
Northwick Park & St Marks Hospitals
Watford Road
HARROW
HA1 3UJ

F2# 278/7/26

Dear Mrs Anne Belinda Example-Subject

You will soon receive an invitation for NHS bowel scope screening, which is a new test to help prevent bowel cancer. The NHS offers bowel scope screening because it saves lives from bowel cancer. It does this by finding and removing small growths in the bowel that might eventually turn into cancer.

In about two weeks' time, we will send you a letter with an appointment for bowel scope screening. The appointment will be in about eight weeks' time. We will change the appointment if it is inconvenient for you.

Along with the appointment letter, you will receive a leaflet to help you choose whether to have NHS bowel scope screening. This leaflet sets out the benefits and risks of bowel scope screening and what it is like to have it.

If you have any questions, please call the NHS freephone helpline 0800 707 60 60. More information about NHS bowel scope screening is available on www.informedchoiceaboutcancerscreening.org.

Yours sincerely,

---

NHS No: 999 000 5451

25 December 2005

Mrs Anne B Example-Subject
Hembury House
Cheriton
Shobrooke
Crediton
Devon
YY1 5TT
Appendix 2-2. Invitation and appointment letter for the national screening programme.

NHS No: 999 000 5451

25 December 2005

Mrs Anne B Example-Subject
Hembury House
Cheriton
Shobrooke
Crediton
Devon
YY1 5TT

F9# 278/7/26

Dear Mrs Anne Belinda Example-Subject

We invite you for NHS bowel scope screening on:

**Saturday 10 December 2005 at 12:00 at Shobrooke Hospital**

If this appointment is not convenient, please telephone the NHS Bowel Cancer Screening Programme Freephone helpline on 0800 707 60 60 (free from UK landlines).

NHS bowel scope screening is a new test to help prevent bowel cancer. The NHS offers bowel scope screening because it saves lives from bowel cancer. It does this by finding and removing small growths in the bowel that might eventually turn into cancer. It is offered to all men and women aged 55.

**Your Choice**
It is your choice whether or not to have bowel scope screening. To help you decide, we have enclosed a leaflet about the benefits and risks of bowel scope screening and what it is like to have it. The leaflet is written by experts in public information at King's Health Partners.

Some health problems mean it might not be possible for you to have bowel scope screening. Please see page 5 of the leaflet for more information. If you have any questions, please call the Freephone helpline number above or visit http://www.cancerscreening.nhs.uk/bowel.

**What happens next?**
If you choose to have bowel scope screening, please let us know that you will attend by ticking the box on the enclosed form and returning it in the prepaid envelope OR by phoning the Freephone number above. About two weeks before your appointment, we will write to you again about preparing for bowel scope screening.

Yours sincerely

Page 1 of 2 for NHS Number 999 000 5451
Bowel Cancer Screening Programme

Name: Mrs Anne BELINDA Example-Subject
Hembury House
Cheriton
Shobrooke
Crediton
Devon
YY1 5TT

NHS Number: 999 000 5451
Age: 65 yrs 7 mths

You are invited to have bowel scope screening on:

Saturday 10 December 2005 at 12:00
at Shobrooke Hospital

Please tick the box if you plan to attend this appointment and return this sheet in the pre-paid envelope.

☐ Yes, I plan to attend this appointment.

We will send more information to you about two weeks before your appointment.

If you would like to have bowel scope screening but cannot attend this appointment, please telephone our Freephone helpline on 0800 707 60 60 to arrange another one. The helpline number is free from all UK landlines.

Please give us a daytime telephone number in case we need to contact you about your appointment:

Your contact telephone number

If this is a mobile number, we may use it to send you text messages to remind you about your appointment.

If you need an interpreter or if you would like to tell us about any disabilities or additional needs, please call 0800 707 60 60 and let us know so that we can help in any way we can.

PLEASE RETURN IN THE PRE-PAID ENVELOPE PROVIDED

Date Sent: 25 December 2005
Appendix 2-3. Information booklet for the NHS Bowel Scope Screening Programme.
NHS bowel scope screening is a new test to help prevent bowel cancer. It does this by finding and removing any small growths, called polyps, in the bowel that could eventually turn into cancer.

The NHS offers bowel scope screening to all men and women aged 55.

This leaflet aims to help you make a choice about whether to have bowel scope screening.

It includes information about:
- why the NHS offers bowel scope screening
- what to expect from it, and
- the possible benefits and risks for you.

If you would like a summary of facts and figures about bowel scope screening, please turn to pages 8 and 9.

**Why does the NHS offer bowel scope screening?**

NHS bowel scope screening helps prevent bowel cancer. For every 300 people screened, it stops 2 from getting bowel cancer and saves 1 life from bowel cancer.

Some health problems mean that it might not be possible for you to have bowel scope screening. For more information, please turn to page 5.
What is bowel cancer?

Bowel cancer is the term used for cancer that begins in the large bowel. It is also called colorectal cancer. Bowel cancer often starts from small growths in the bowel called polyps.

Polyps do not usually cause symptoms but some might turn into bowel cancer if they are not removed.

The bowel, also known as the intestine, helps to digest the food you eat. After food has gone through the bowel, all that is left is poo.

The bowel has two parts – the small bowel and the large bowel. The large bowel is coloured pink in the picture below.

Bowel cancer is the third most common cancer in the UK. About 1 in every 18 people will get bowel cancer in their lifetime. Both men and women are at risk. Bowel cancer is more common in older people – most people who get it are over the age of 55.

People can be at risk of bowel cancer even when nobody else in the family has had cancer.
What is bowel scope screening?

Bowel scope screening uses a thin flexible tube with a tiny camera on the end to look at the large bowel.

It can find and remove small growths called polyps from the bowel. Polyps do not usually cause symptoms but some might turn into cancer if they are not removed. The technical term for bowel scope screening is flexible sigmoidoscopy screening (sometimes called ‘flexisig’).

What does bowel scope screening involve?

Bowel scope screening is done by a specially trained nurse or doctor at an NHS bowel cancer screening centre. He or she puts the thin flexible tube into your anus and looks inside your large bowel using the tiny camera. Bowel scope screening looks at the lower part of the large bowel because that’s where most polyps are found.

When the nurse or doctor puts the tube into your bowel, they gently pump some carbon dioxide gas inside. This opens up the bowel so the nurse or doctor can see any polyps.

If they find any polyps, they usually remove them straightaway. This is usually done using a tiny wire loop passed through the tube. Sometimes the nurse or doctor takes a tiny piece of the bowel (a biopsy) to be looked at under a microscope. Neither removing a polyp nor having a biopsy are painful.

What will happen if I choose to have bowel scope screening?

Two weeks before your appointment

Your NHS bowel cancer screening centre will write to you. The letter will include an enema and instructions for using it. The enema is a liquid used to clear the poo out of your large bowel. This is so the nurse or doctor can get a good look at your bowel. The enema comes in a small plastic pouch with a nozzle. Most people find it easy to use.
The day of your appointment

- Use the enema about one hour before leaving home for your bowel scope screening appointment.
- To use the enema, you will need to squeeze the liquid from the plastic pouch into your anus. The enema will make you poo very soon after you have used it.
- The enema should keep your bowel clear for several hours.
- After you arrive at the NHS bowel cancer screening centre, the nurse or doctor will explain what will happen, answer any questions and listen to your concerns.
- They will ask you to put on a hospital gown and lie down on a bed ready to have bowel scope screening.
- During the screening, if you want, you will be able to see the inside of your bowel on a TV screen.
- The nurse or doctor will tell you straightaway if they remove any small growths (polyps).

In the two weeks after your appointment

You will be sent a letter explaining the results of your bowel scope screening. Your GP will also get your results.
How long does bowel scope screening take?
Having bowel scope screening usually takes only a few minutes but the whole appointment may take around an hour and a half.

Getting ready for your appointment and having bowel scope screening may take up to half a day, depending on how far away you live from the screening centre.

What does bowel scope screening feel like?
Most people are glad they had bowel scope screening done and find it painless.

If you do feel pain, it almost always only lasts for a few moments. It is most often caused by the carbon dioxide used to open up the bowel, which may give you a bloating or cramping feeling in your tummy. If you do feel pain, tell the nurse or doctor and they will change what they are doing to make you feel as comfortable as possible. Having polyps removed from the bowel is not usually painful.

A few people say they find bowel scope screening embarrassing. The nurse or doctor will do their best to help you feel as relaxed as possible.

Does bowel scope screening have risks?
Bowel scope screening is usually safe but in rare cases it can cause harm to the bowel. About 1 person in every 3,000 may have serious bleeding caused by bowel scope screening. Sometimes the bowel can be torn during bowel scope screening – this is even rarer.

In either case you would be admitted to hospital straightaway and you might need surgery. Most people make a full recovery.

When you go home after bowel scope screening, if you have any severe pain, or blood in your poo that does not go away after 24 hours, you should see a doctor straightaway.

The carbon dioxide pumped into the bowel is not harmful.
Have I missed my chance if I don’t go for bowel scope screening this time?

People are invited to have bowel scope screening only once, at the age of 55.

If you decide not to have bowel scope screening when you are first invited, you can still have it at any time up until your 60th birthday. Just call the Freephone helpline number 0800 707 60 60 to ask for an appointment.

At about age 60, you will be invited to have more bowel cancer screening using a different kind of test. This screening tests for traces of blood in poo, and is known as a Faecal Occult Blood test (FOB test for short). For more information on the FOB test, please see the leaflet called ‘Bowel Cancer Screening: the facts’ available from www.cancerscreening.nhs.uk/bowel.

Can everybody have bowel scope screening?

Some health problems mean that it might not be possible for you to have bowel scope screening. Please call the Freephone helpline number 0800 707 60 60 if you:

- have had all of your large bowel removed, or have a stoma bag to collect your poo
- are currently being treated (for example, with steroids) for inflammatory bowel disease in your large bowel (ulcerative colitis or Crohn’s disease)
- are waiting for heart surgery or have had heart surgery in the last three months
- cannot walk more than 100 yards without resting because of a lung or heart problem, or
- think you may be too unwell to go for your appointment.
Bowel scope screening results

Most people will have a normal result
Out of 300 people who have bowel scope screening, 285 will have a normal result. This means that no polyps or cancers were found.

Even if you have a normal result, it is important to look out for symptoms of bowel cancer. This is because sometimes people can get bowel cancer even after a normal result. If you want to know more, please see ‘What are the symptoms of bowel cancer?’ opposite.

Some people will have polyps
The nurse or doctor will usually remove any polyps they find. They will tell you straightaway if they have done this. Any polyps that are removed are sent to be checked under a microscope.

Out of 300 people who have bowel scope screening, about 14 will be offered another test because of the types of polyps found. This test is usually a colonoscopy. A colonoscopy uses a longer thin flexible tube, which can look for polyps further up the bowel. For more information on colonoscopy, please see the leaflet ‘Having a colonoscopy’ available from www.cancerscreening.nhs.uk/bowel.

Very occasionally, people may be asked to come back for an operation to remove their polyps. This only happens to about 1 person out of every 1000 people who have bowel scope screening.

Rarely, the screening will find cancer
Out of 300 people who have bowel scope screening, about 1 will be found to have bowel cancer already. If the screening does find cancer, the nurse or doctor will arrange for you to see a specialist as soon as possible. If cancer is found, it is likely to have been found at an early stage. This means you are likely to have a better chance of successful treatment and survival.
What are the symptoms of bowel cancer?

Even if you have had bowel scope screening, it is important to look out for the symptoms of bowel cancer. You can still go on to get bowel cancer after having bowel scope screening. Also, bowel scope screening can sometimes miss polyps or a cancer.

The symptoms of bowel cancer are:
- blood in your poo
- any changes in your bowel habits
- an unexplained lump in your tummy
- poo that is looser than normal
- unexplained tiredness or weight loss, and
- bloating, swelling or pain in your tummy.

If you have any of these symptoms for more than **three weeks**, you should make an appointment to see your GP.

Usually these symptoms won't mean you have bowel cancer. But if you do, going to see your GP makes it more likely the cancer is found early.

The earlier bowel cancer is found, the better the chance of successful treatment.

What can I do to lower my chances of getting bowel cancer?

Bowel scope screening is the best way to lower your chances of getting bowel cancer.

You can also:
- be physically active
- keep a healthy weight
- eat plenty of fruit and vegetables and other high fibre foods
- eat less red meat and less processed meat
- drink alcohol in moderation, and
- not smoke.
Bowel scope screening helps prevent bowel cancer

5 out of 300 people will get bowel cancer over 10 years if they are not screened.

2 fewer people would get bowel cancer if they were screened.

Bowel scope screening helps save lives from bowel cancer

2 out of 300 people will die of bowel cancer over 10 years if they are not screened.

1 less person would die of bowel cancer if they were screened.

The figures above are the best estimates at the moment. Experts expect that having bowel scope screening at the age of 55 prevents bowel cancer for much more than 10 years.
Facts and figures about bowel scope screening

“Could it prevent me from getting bowel cancer?”
For every 300 people screened, 2 fewer people will get bowel cancer over 10 years. Please see opposite for more information.

“Could it prevent me from dying of bowel cancer?”
For every 300 people screened, 1 less person will die from bowel cancer over 10 years. Please see opposite for more information.

“Are there risks?”
About 1 person in every 3,000 may have serious bleeding caused by bowel scope screening. Even more rarely, the bowel can be torn.

“Could it miss something?”
Bowel scope screening finds 4 out of 5 polyps that could turn into bowel cancer.

“Could I need more tests?”
About 5 in 100 people who have bowel scope screening will be offered a colonoscopy to look at all of the large bowel.

“How long does it take?”
Getting ready for your appointment and having bowel scope screening may take up to half a day.

“Is it embarrassing?”
About 95 in 100 people say that bowel scope screening is not embarrassing.

“Is it painful?”
About 80 in 100 people say they felt no pain or only mild pain. About 3 in 100 say they felt severe pain during bowel scope screening.

“Will I be pleased I had it?”
About 98 in 100 people say they are glad they had bowel scope screening.
Who can I contact if I have a question?

If you have any questions or concerns about bowel scope screening, please call the Freephone helpline number 0800 707 60 60.

If you would like more detailed information, including the references to the resources we used to write this leaflet, please visit www.cancerscreening.nhs.uk/bowel.

This leaflet is also available in Braille, as an audio version and in large print. You can find versions of the leaflet in languages other than English at www.cancerscreening.nhs.uk/bowel.

Here is space for your notes ...
Appendix 2-4. Reminder letter for the NHS Bowel Scope Screening Programme.

Bowel Cancer Screening Programme

Midlands and North West Bowel Cancer Screening Programme Hub
Rugby Hospital
Rugby
The Midlands
RG3 2TH

Freephone Helpline: 0800 707 60 60
Email: bowel.screening@uhcw.nhs.uk
Open: Mon to Fri 9:00am to 5:00pm
Sat 9:00am to 12:00pm
Sun 10:30am to 12:30pm

25 December 2005

Mrs Anne B Example-Subject
Hembury House
Cheriton
Shobrooke
Crediton
Devon
YY1 5TT

Dear Mrs Anne Belinda Example-Subject

A short while ago the NHS Bowel Cancer Screening Programme sent you an invitation for bowel scope screening. The NHS offers bowel scope screening because it saves lives from bowel cancer. It does this by finding and removing small growths in the bowel that might eventually turn into cancer. It is offered to men and women aged 55.

We offered you a bowel scope screening appointment on

Saturday 10 December 2005 at 12:00 at Shobrooke Hospital

Please call us on freephone 0800 707 60 60 to confirm attending your appointment, or complete the enclosed slip and return it in the freepost envelope provided. If you would like to be screened but this appointment isn't convenient for you, please contact us on freephone 0800 707 60 60 so that we can change it.

If we don't hear from you within the next two weeks to confirm or rearrange your appointment, we will assume that you don't wish to be screened and your appointment will be cancelled.

We don't have access to your medical records, and flexible sigmoidoscopy isn't always suitable for everyone. If you:
- Have active inflammatory bowel disease that is being treated (with steroids for example), or
- Have had all or part of your bowel removed, or currently have a stoma bag to collect your bowel motions,
then please call us on freephone 0800 707 60 60 before accepting your screening invitation.

The enclosed leaflet gives you information about bowel scope screening using flexible sigmoidoscopy. If you need any further information, you can call the freephone number above, or go to www.cancerscreening.nhs.uk/bowel.

Yours sincerely

Page 1 of 2 for NHS Number 999 000 5451
Bowel Cancer Screening Programme

NHS bowel scope screening
Please tell us whether you plan to attend

Name: Mrs Anne BELINDA Example-Subject  NHS Number: 999 000 5451
Hembury House  Age: 65 yrs 7 mths
Cheriton
Shobrooke
Crediton
Devon
YY1 5TT

You are invited to have bowel scope screening on:

Saturday 10 December 2005 at 12:00
at Shobrooke Hospital

Please tick the box if you plan to attend this appointment and return this sheet in the pre-paid envelope.

☐ Yes, I plan to attend this appointment.

We will send more information to you about two weeks before your appointment.

If you would like to have bowel scope screening but cannot attend this appointment, please telephone our Freephone helpline on 0800 707 60 60 to arrange another one. The helpline number is free from all UK landlines.

Please give us a daytime telephone number in case we need to contact you about your appointment:

Your contact telephone number

If this is a mobile number, we may use it to send you text messages to remind you about your appointment.

If you need an interpreter or if you would like to tell us about any disabilities or additional needs, please call 0800 707 60 60 and let us know so that we can help in any way we can.

PLEASE RETURN IN THE PRE-PAID ENVELOPE PROVIDED

Date Sent: 25 December 2005
Appendix 2-5. Cancellation letter for the NHS BSS Programme.

Bowel Cancer Screening Programme

NHS No: 999 000 5451
25 December 2005
Mrs Anne B Example-Subject
Hembury House
Cheriton
Shobrooke
Crediton
Devon
YY1 5TT

Dear Mrs Anne Belinda Example-Subject

A short while ago the NHS Bowel Cancer Screening Programme sent you an invitation for bowel scope screening. The NHS offers bowel scope screening because it saves lives from bowel cancer. It does this by finding and removing small growths in the bowel that might eventually turn into cancer. It is offered to men and women aged 55.

As we have not heard from you, we assume that you do not wish to be screened at this time. Your appointment has therefore been cancelled. If you decide at a later date that you would like to be screened, please contact us on freephone 0800 707 60 60. You can arrange an appointment for bowel scope screening up until your 60th birthday. Appointments can be booked up to eight weeks in advance. If you have returned your form in the last few days, please call to check your appointment booking.

A few weeks after your 60th birthday, we will invite you again for bowel cancer screening using a different method - a home testing kit that detects traces of blood in bowel motions. This type of test is only available to people aged 60 and over. Full details will be sent to you at the time.

We encourage you to be aware of the signs and symptoms of bowel cancer and to visit your GP if you have any concerns. The main symptoms to look out for are:

- A persistent change in bowel habit, especially going to the toilet more often or having diarrhoea for several weeks
- Bleeding from the back passage without any obvious reason
- Abdominal pain, especially if severe
- A lump in your abdomen

Please remember that these symptoms do not necessarily mean that you have bowel cancer, but if you have one or more of these symptoms for four to six weeks, you should see your GP.

Yours sincerely

Preview Signatory
Preview Job Title
Appendix 2-6. Cancellation letter to the invitees General Practice for the national screening programme.

Bowel Cancer Screening Programme
London Programme Hub
Northwick Park & St Marks Hospitals
Watford Road
Harrow
HA1 3UJ

Freephone Helpline 0800 707 60 60
LNWH-tr.BCSP@nhs.net
Open: Mon-Fri 9.00am-5.00pm
(Closed Sat, Sun & Bank Holidays)

Dear Mrs Example-Subject

The following letter has been sent to Mrs Anne BELINDA Example-Subject at Hembury House, Cheriton, Shobrooke, Crediton, Devon YY1 5TT. Date of birth 10/02/1942.

A short while ago the NHS Bowel Cancer Screening Programme sent you an invitation for bowel scope screening using flexible sigmoidoscopy. Bowel scope screening looks at the inside of the lower bowel, to see if there are any abnormalities there. It can find growths in the bowel called polyps. Some of these, if left, may go on to develop into cancer. Polyps can usually be easily removed during flexible sigmoidoscopy, to help stop this happening.

As we have not heard from you to confirm attending your appointment, we assume that you do not wish to be screened at this time. Your appointment has therefore been cancelled. If you decide at a later date that you would like to be screened, please contact us on freephone 0800 707 60 60. You can arrange an appointment for bowel scope screening up until your 60th birthday. Appointments can be booked up to eight weeks in advance.

A few weeks after your 60th birthday, we will invite you again for bowel cancer screening using a different method - a home testing kit that detects traces of blood in bowel motions. This type of test is only available to people aged 60 and over. Full details will be sent to you at the time.

We encourage you to be aware of the signs and symptoms of bowel cancer, and to visit your GP if you have any concerns. The main symptoms to look out for are:
- A persistent change in bowel habit, especially going to the toilet more often or having diarrhoea for several weeks
- Bleeding from the back passage without any obvious reason
- Abdominal pain, especially if severe
- A lump in your abdomen

Please remember that these symptoms do not necessarily mean that you have bowel cancer, but if you have one or more of these symptoms for four to six weeks, you should see your GP.

Yours sincerely

Preview Signatory
Preview Job Title

Page 1 of 1 for GP Practice PT1234
Appendix 2-7. Appointment confirmation letter for the national screening programme.

Bowel Cancer Screening Programme

25 December 2005

Mrs Anne B Example-Subject
Hembury House
Cheriton
Shobrooke
Crediton
Devon
YY1 5TT

F33# 278/7/26

Dear Mrs Anne Belinda Example-Subject

Thank you for confirming that you will be attending for bowel scope screening. Your appointment is on

Saturday 10 December 2005 at 12:00 at Shobrooke Hospital

There is information with this letter about getting to your appointment. There is also a consent form enclosed. Please read through it before you come to your appointment. You will be asked to sign a copy of it before your screening is carried out.

In order to have bowel scope screening, your bowel needs to be empty. You will need to use an enema before your appointment. The enema makes you go to the toilet to empty your lower bowel. You need to use it no later than one hour before you leave the house for your bowel scope screening appointment. Please read through the instructions fully before you use the enema.

You will receive an enema kit with instructions from us in the post. If they don’t arrive in the next few days, please contact us on freephone 0800 707 60 60 to ask for another one.

Yours sincerely
Appendix 2-8. Enema letter for the national screening programme.

Bowel Cancer Screening Programme
London Bowel Cancer Screening Programme Hub
Northwick Park & St Marks Hospitals
Watford Road
HARROW
HA1 3UJ

25 December 2005

Mrs Anne B Example-Subject
Hembury House
Cheriton
Shobrooke
Crediton
Devon
YY1 5TT

F33# 278/7/26

Dear Mrs Anne Belinda Example-Subject

There is information with this letter about getting to your appointment. There is also a consent form enclosed. Please read through it before you come to your appointment. You will be asked to sign a copy of it before your screening is carried out.

In order to have bowel scope screening, your bowel needs to be empty. You will need to use an enema before your appointment. The enema makes you go to the toilet to empty your lower bowel. You need to use it no later than one hour before you leave the house for your bowel scope screening appointment. Please read through the instructions fully before you use the enema.

You will receive an enema kit with instructions from us in the post. If they don't arrive in the next few days, please contact us on freephone 0800 707 60 60 to ask for another one.

Yours sincerely
Appendix 2-9. Enema leaflet for the national screening programme.

When do I use the enema?
You need to use the enema around an hour before leaving home for your screening appointment.
Don’t eat for 30 minutes before you use it, or afterwards until you’ve had your screening carried out.
You can drink water, but no other liquids.
The effect of the enema wears off within an hour, so you don’t need to worry about travelling to the hospital.

What does the enema do?
An enema makes you go to the toilet within a few minutes of using it. This cleans your lower bowel so that it can be seen clearly during bowel scope screening.
The enema doesn’t give you diarrhoea.

Advice on using the enema:
If you aren’t sure about whether you should use the enema, or need to speak to someone about how to use it, call us on freephone: 0800 797 68 68.
Calls will be dealt with in confidence. Please don’t feel embarrassed to ask for information or advice.

For more information about bowel cancer screening, you can:
• Speak to your GP
• Go to: www.cancerscreening.nhs.uk/bowel
• Call the NHS Bowel Cancer Screening Programme freephone helpline on 0800 797 68 68.
Calls are free from UK landlines.

Please read the whole of this leaflet before you use the enema.

In your enema pack you will find:
• A packaged enema ‘pouch’ with a thin tube attached
• A small white plastic clip with the enema (you don’t use this)
• A manufacturer’s patient information leaflet
Enema instructions

1. Have a plastic bag ready to dispose of the enema after use. Peel the outer plastic packaging open to remove the enema pouch.

2. You can use a little Vaseline or cooking oil to lubricate the thin tube if you wish.

3. Lie down close to the toilet e.g. in a nearby bedroom. Lie on your left side if possible. You may like to lie on a towel. Draw your knees up towards your chest.

4. Break off the very thin tip of the blue nozzle. Make sure the nozzle is left with a smooth end.

5. Gently insert the nozzle and thin tube into your bottom (anus). Insert as much of the tube as you comfortably can.

6. Use gentle pressure to squeeze the liquid into your bottom. Stop squeezing if you feel any resistance. You might not empty the whole pouch.

7. Keep a firm hold of the used pouch as you pull the nozzle and tube from your bottom. Put the used enema in the plastic bag for disposal.

8. Stay lying down, and try to hold the liquid inside you for as long as you can before going to the toilet (2-5 minutes if possible).

9. If your lower bowel is empty when you use the enema, you may not have a bowel movement. You may just pass the enema liquid. Don’t worry if this happens to you – the enema has still worked. You can dispose of the used enema in your normal household waste.
Appendix 2-10. Consent form for the national screening programme.

**Shobrooke Hospital**  
**Consent Form 1**  
**Adults**

Participant’s agreement to  
NHS Bowel Scope (flexible sigmoidoscopy) screening

<table>
<thead>
<tr>
<th>Participant’s details:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS Number:</td>
<td>999 000 5451</td>
</tr>
<tr>
<td>Surname / family name:</td>
<td>Example-Subject</td>
</tr>
<tr>
<td>First name:</td>
<td>Anne BELINDA</td>
</tr>
<tr>
<td>Date of birth:</td>
<td>10/02/1942</td>
</tr>
<tr>
<td>Gender:</td>
<td>..................</td>
</tr>
<tr>
<td>Responsible health professional:</td>
<td>..................</td>
</tr>
</tbody>
</table>

To be retained in participant's medical case note
Planned Bowel Scope Screening Test (Flexible Sigmoidoscopy or FS Screening Test)

The bowel scope screening test is an examination of the left side of large bowel using a flexible video camera.

Depending on findings, the procedure may include biopsies (small samples from bowel lining) and polypectomy (removal of growth called a polyp from the bowel wall).

Statement of health professional

(to be signed by health professional in your presence at your appointment).

I have explained the procedure to the participant. In particular, I have explained:

1) The intended benefits:

Screening assessment of the left side of the large bowel to look for any signs of lower bowel cancer or for polyps which may could develop into cancer if left in place. Trials have shown that removing polyps significantly reduces the future risk of developing lower bowel cancer (colorectal cancer).

2) Serious or frequently occurring risks:

- Serious bleeding after biopsy or polypectomy - uncommon (1 in 3000).
- Missing serious pathology - uncommon (1 in 1000).
- Perforation of the bowel wall - rare (1 in 40,000).

3) Any extra procedures which may become necessary during the procedure:

- Subject to findings, a follow-up full colonoscopy may be recommended in order to allow a full view of the whole large bowel. A colonoscopy is sometimes needed to safely remove certain polyps (for which a separate appointment will be arranged).
- Samples for histology - the procedure may involve biopsy of tissue and/or polypectomy (removal of polyps) for diagnostic purposes. Following diagnosis this tissue will form part of the clinical record.
- Blood transfusion - uncommon (1 in 3,000) in the event of serious bleeding.
- Operation (1 in 10,000 or rare) may be required if there is life threatening bleeding or if a hole is made through the bowel wall (perforation).

4) Retention of tissue samples for training and research:

- Any tissue samples taken may be retained and used for teaching purposes and for research aimed at improving diagnosis and treatment of bowel cancer. To refuse permission for this, the choice options in the “Statement of Participant” can be completed.

I have also discussed what the procedure is likely to involve and the fact that the national screening programme does not offer an alternative to this particular test for bowel cancer screening for individuals in this age range. I have explained that a different test (FOBT) is available only from age 60 to age 74. I have also discussed any particular concerns the participant has raised.

The national standard “Bowel scope screening” leaflet has been provided.

This procedure will not involve any general or local anaesthesia or any sedation other than the possible use of Entonox (gas and air) with your prior agreement.

Signed ............................................ (Health professional) Date ............................................
Name (PRINT): ................................................................. Job title: .................................................................

5) Contact Details (if participant wishes to discuss options later) ............................................

Statement of interpreter (where appropriate)

I have interpreted the information above to the participant to the best of my ability and in a way in which I believe s/he can understand.

Signed ................................................................. Date: .................................................................
Name (PRINT): .................................................................
Appendices

Copy for medical case notes

Planned Bowel Scope Screening Test (Flexible Sigmoidoscopy or FS Screening Test)
The bowel scope screening test is an examination of the left side of large bowel using a flexible video camera. Depending on findings, the procedure may include biopsies (small samples from bowel lining) and polypectomy (removal of growth called a polyp from the bowel wall).

Statement of health professional
(to be signed by health professional in your presence at your appointment).
I have explained the procedure to the participant. In particular, I have explained:

1) The intended benefits:
Screening assessment of the left side of the large bowel to look for any signs of lower bowel cancer or for polyps, which may / could develop into cancer if left in place. Trials have shown that removing polyps significantly reduces the future risk of developing lower bowel cancer (colorectal cancer).

2) Serious or frequently occurring risks:
Serious bleeding after biopsy or polypectomy - uncommon (1 in 3000); Missing serious pathology - uncommon (1 in 1000); Perforation of the bowel wall - rare (1 in 40,000).

3) Any extra procedures which may become necessary during the procedure:
☐ Subject to findings, a follow-up full colonoscopy may be recommended in order to allow a full view of the whole large bowel. A colonoscopy is sometimes needed to safely remove certain polyps (for which a separate appointment will be arranged).
☐ Samples for histology - the procedure may involve biopsy of tissue and/or polypectomy (removal of polyps) for diagnostic purposes. Following diagnosis this tissue will form part of the clinical record.
☐ Blood transfusion - uncommon (1 in 3,000) in the event of serious bleeding.
☐ Operation (1 in 10,000 or rare) may be required if there is life threatening bleeding or if a hole is made through the bowel wall (perforation).

4) Retention of tissue samples for training and research:
☐ Any tissue samples taken may be retained and used for teaching purposes and for research aimed at improving diagnosis and treatment of bowel cancer. To refuse permission for this, the choice options in the "Statement of Participant" can be completed.

I have also discussed what the procedure is likely to involve and the facts that the national screening programme does not offer an alternative to this particular test for bowel cancer screening for individuals in this age range. I have explained that a different test (FOBT) is available only from age 60 to age 74. I have also discussed any particular concerns the participant has raised.

☐ The national standard "Bowel scope screening" leaflet has been provided.
This procedure will not involve any general or local anaesthesia or any sedation other than the possible use of Entonox (gas and air) with your prior agreement.

Signed:.........................................................(Health professional) Date:.................................
Name (PRINT):................................................................. Job title:..........................................

5) Contact Details(if participant wishes to discuss options later)...........................................

Statement of interpreter (where appropriate)
I have interpreted the information above to the participant to the best of my ability and in a way in which I believe s/he can understand.

Signed:......................................................... Date:.................................
Name (PRINT):.................................................................
Appendices

Example-Subject, Anne BELINDA  DoB 10/02/1942  NHS No 999 000 5451

Copy accepted by participant: yes/no (please circle)

Statement of participant:

Please read this form carefully and in particular, the above pages which describe the benefits and risks of the Bowel Scope screening test. If you have any further questions, you will have the opportunity to discuss these with a screening health professional when you arrive at your appointment. We are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures which I do not wish to be carried out without further discussion.

I understand that unless I refuse permission by ticking the following options, any tissue samples may be retained and used for teaching and research aimed at improving diagnosis and treatment of bowel cancer.

My tissue samples are not to be used for teaching

My tissue samples are not to be used for research

To be signed by the participant either in advance of the appointment or at the appointment itself in advance of the bowel scope screening test.

Participant's Signature: ____________________________ Date: ________________

Name (PRINT): ______________________________________

A witness should sign below if the participant is unable to sign but has indicated his or her consent.

Signature: _______________________________________ Date: ________________

Name (PRINT): ______________________________________

Confirmation of consent (to be completed by a health professional when the participant is admitted for the procedure, if the participant has signed the form in advance)

On behalf of the team treating the participant, I have confirmed with the participant that s/he has no further questions and wishes the procedure to go ahead.

Signed: ______________________________________ Date: ________________

Name (PRINT): ______________________________________ Job title: ___________

Important notes: (tick if applicable)

See also advance directive/living will (e.g. Jehovah’s Witness form)

Participant has withdrawn consent (ask participant to sign here) Name/Date: ________________
Appendix 5-2: Distribution of the population by demographic factors (Office for National Statistics, 2011).

<table>
<thead>
<tr>
<th>Diversity</th>
<th>Brent</th>
<th>Harrow</th>
<th>London</th>
<th>England</th>
</tr>
</thead>
<tbody>
<tr>
<td>White (%)</td>
<td>36.4</td>
<td>42.3</td>
<td>59.8</td>
<td>85.5</td>
</tr>
<tr>
<td>Asian (%)</td>
<td>34.0</td>
<td>42.7</td>
<td>18.4</td>
<td>7.7</td>
</tr>
<tr>
<td>Black (%)</td>
<td>18.8</td>
<td>8.2</td>
<td>13.4</td>
<td>3.5</td>
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<tr>
<td>Chinese/other (%)</td>
<td>10.8</td>
<td>6.8</td>
<td>8.4</td>
<td>3.3</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Economic activity</th>
<th>Brent</th>
<th>Harrow</th>
<th>London</th>
<th>England</th>
</tr>
</thead>
<tbody>
<tr>
<td>Economically Active; Employee; Full-Time</td>
<td>35.8</td>
<td>37.5</td>
<td>39.8</td>
<td>38.6</td>
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<tr>
<td>Economically Active; Employee; Part-Time</td>
<td>11</td>
<td>12.3</td>
<td>10.9</td>
<td>13.7</td>
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<tr>
<td>Economically Active; Self-Employed</td>
<td>12.8</td>
<td>12.7</td>
<td>11.7</td>
<td>9.8</td>
</tr>
<tr>
<td>Economically Active; Unemployed</td>
<td>5.8</td>
<td>4.5</td>
<td>5.2</td>
<td>4.4</td>
</tr>
<tr>
<td>Economically Active; Full-Time Student</td>
<td>4.7</td>
<td>3.7</td>
<td>4.1</td>
<td>3.4</td>
</tr>
<tr>
<td>Economically Inactive; Retired</td>
<td>8</td>
<td>10.3</td>
<td>8.4</td>
<td>13.7</td>
</tr>
<tr>
<td>Economically Inactive; Student (Including Full-Time Students)</td>
<td>8.5</td>
<td>7.7</td>
<td>7.8</td>
<td>5.8</td>
</tr>
<tr>
<td>Economically Inactive; Looking After Home or Family</td>
<td>5.6</td>
<td>5.5</td>
<td>5.2</td>
<td>4.4</td>
</tr>
<tr>
<td>Economically Inactive; Long-Term Sick or Disabled</td>
<td>3.9</td>
<td>2.9</td>
<td>3.7</td>
<td>4.0</td>
</tr>
<tr>
<td>Economically Inactive; Other</td>
<td>3.9</td>
<td>2.9</td>
<td>3.2</td>
<td>2.2</td>
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</table>

<table>
<thead>
<tr>
<th>Car or van availability</th>
<th>Brent</th>
<th>Harrow</th>
<th>London</th>
<th>England</th>
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</thead>
<tbody>
<tr>
<td>No Cars or Vans in Household</td>
<td>43</td>
<td>23.5</td>
<td>41.6</td>
<td>25.8</td>
</tr>
<tr>
<td>1 Car or Van in Household</td>
<td>39.5</td>
<td>43.9</td>
<td>40.5</td>
<td>42.2</td>
</tr>
<tr>
<td>2 Cars or Vans in Household</td>
<td>13.5</td>
<td>24.9</td>
<td>14</td>
<td>24.7</td>
</tr>
<tr>
<td>3 Cars or Vans in Household</td>
<td>3.1</td>
<td>5.9</td>
<td>2.9</td>
<td>5.5</td>
</tr>
<tr>
<td>4 or More Cars or Vans in Household</td>
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<td>1.8</td>
<td>1.0</td>
<td>1.8</td>
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</table>

<table>
<thead>
<tr>
<th>Marital and civil partnership status</th>
<th>Brent</th>
<th>Harrow</th>
<th>London</th>
<th>England</th>
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</thead>
<tbody>
<tr>
<td>Single (never married or registered a civil partnership)</td>
<td>42.1</td>
<td>32.3</td>
<td>44.1</td>
<td>34.6</td>
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<tr>
<td>Married</td>
<td>43.2</td>
<td>53.7</td>
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<td>46.6</td>
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<tr>
<td>In a registered same-sex civil partnership</td>
<td>0.3</td>
<td>0.2</td>
<td>0.4</td>
<td>0.2</td>
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<tr>
<td>Situation</td>
<td>2018</td>
<td>2019</td>
<td>2020</td>
<td>2021</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>------</td>
<td>------</td>
<td>------</td>
<td>------</td>
</tr>
<tr>
<td>Separated (but still legally married or in a civil partnership)</td>
<td>3.4</td>
<td>2.3</td>
<td>3.2</td>
<td>2.7</td>
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<tr>
<td>Divorced or formerly in a civil partnership now legally dissolved</td>
<td>6.2</td>
<td>5.4</td>
<td>7.5</td>
<td>9</td>
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<tr>
<td>Widowed or surviving partner from a same-sex civil partnership</td>
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<td>6.1</td>
<td>5</td>
<td>6.9</td>
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<table>
<thead>
<tr>
<th>Religion(^a)</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
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<tr>
<td>Christian</td>
<td>41.5</td>
<td>37.3</td>
<td>48.4</td>
<td>59.4</td>
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<td>Buddhist</td>
<td>1.4</td>
<td>1.1</td>
<td>1</td>
<td>0.5</td>
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<td>Hindu</td>
<td>17.8</td>
<td>25.3</td>
<td>5</td>
<td>1.5</td>
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<tr>
<td>Jewish</td>
<td>1.4</td>
<td>4.4</td>
<td>1.8</td>
<td>0.5</td>
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<tr>
<td>Muslim</td>
<td>18.6</td>
<td>12.5</td>
<td>12.4</td>
<td>5</td>
</tr>
<tr>
<td>Sikh</td>
<td>0.5</td>
<td>1.1</td>
<td>1.5</td>
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<tr>
<td>Other religion</td>
<td>1.2</td>
<td>2.5</td>
<td>0.7</td>
<td>0.4</td>
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<tr>
<td>No religion</td>
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<td>9.6</td>
<td>20.7</td>
<td>24.7</td>
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<tr>
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<td>7.2</td>
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<table>
<thead>
<tr>
<th>Education (Highest Qualification)(^b)</th>
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<th>2019</th>
<th>2020</th>
<th>2021</th>
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<td>16.8</td>
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<tr>
<td>Level 1 qualification</td>
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<tr>
<td>Level 2 qualifications</td>
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<td>12.8</td>
<td>11.8</td>
<td>15.2</td>
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<tr>
<td>Level 3 qualifications</td>
<td>9.7</td>
<td>10.4</td>
<td>10.5</td>
<td>12.4</td>
</tr>
<tr>
<td>Level 4 qualifications and above</td>
<td>33.3</td>
<td>36.8</td>
<td>37.7</td>
<td>27.4</td>
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<tr>
<td>Other qualifications</td>
<td>15.4</td>
<td>10.6</td>
<td>10.1</td>
<td>5.6</td>
</tr>
<tr>
<td>Apprenticeship</td>
<td>1.1</td>
<td>1.7</td>
<td>1.6</td>
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<table>
<thead>
<tr>
<th>Housing tenure(^c)</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Owned; owned outright</td>
<td>20.3</td>
<td>31.1</td>
<td>21.1</td>
<td>30.6</td>
</tr>
<tr>
<td>Owned; owned with a mortgage or loan</td>
<td>22.6</td>
<td>34.1</td>
<td>27.1</td>
<td>32.8</td>
</tr>
<tr>
<td>Shared Ownership (part owned and part rented)</td>
<td>1.5</td>
<td>1</td>
<td>1.3</td>
<td>0.8</td>
</tr>
<tr>
<td>Social Rented; rented from council (local authority)</td>
<td>9.7</td>
<td>6.1</td>
<td>13.5</td>
<td>9.4</td>
</tr>
<tr>
<td>Social rented; other</td>
<td>14.4</td>
<td>4.5</td>
<td>10.6</td>
<td>8.3</td>
</tr>
<tr>
<td>Private rented; private landlord or letting agency</td>
<td>28.8</td>
<td>20.4</td>
<td>23.7</td>
<td>15.4</td>
</tr>
<tr>
<td>Private rented; other</td>
<td>1.3</td>
<td>1.4</td>
<td>1.3</td>
<td>1.4</td>
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<tr>
<td>Living rent free</td>
<td></td>
<td></td>
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<tr>
<td>-----------------</td>
<td>---</td>
<td>---</td>
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<td></td>
</tr>
<tr>
<td>1.4</td>
<td>1.4</td>
<td>1.4</td>
<td>1.3</td>
<td></td>
</tr>
</tbody>
</table>

**Household language**

<table>
<thead>
<tr>
<th>Description</th>
<th>57</th>
<th>67</th>
<th>74</th>
<th>90.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>All people aged 16+ in household have English as a main language</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At least one person aged 16+ in household have English as a main language</td>
<td>16.3</td>
<td>13.5</td>
<td>10.5</td>
<td>3.9</td>
</tr>
<tr>
<td>No one aged 16+ in household but at Least one Person aged 3-15 has English as a main language</td>
<td>4.3</td>
<td>3.6</td>
<td>2.6</td>
<td>0.8</td>
</tr>
<tr>
<td>No one in household has English as a Main Language</td>
<td>22.4</td>
<td>15.9</td>
<td>12.9</td>
<td>4.4</td>
</tr>
</tbody>
</table>

*All usual residents aged over 16.*  
*All usual residents aged over 16 not in education.*  
*All households.*
Appendix 5-3. Flow of data through study 1.

Data request submitted by St Mark’s Hospital

Data extracted from BCSS by Eastern Bowel Cancer Screening Hub

Data transferred to St Mark’s Hospital via a secure NHS.Net connection

Master copy containing study IDs retained by St Mark’s Hospital

Data received and pseudonymised by St Mark’s Hospital

List of pseudonymised postcodes transferred to UCL

Data returned to St Mark’s and merged with study database for

Postcodes converted into area-level measures of deprivation and diversity

Data merged with study database and transferred to UCL for analysis
### Appendix 6-1. Worksheet 1 - Define the problem in behavioural terms.

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where?</td>
<td>St Mark’s Hospital.</td>
</tr>
</tbody>
</table>
## Appendix 6-2. Worksheet 2 - Select target behaviour.

### Task 1. Generate a list of candidate target behaviours that could bring about the desired outcome

**Intervention aim:** Improve uptake of Bowel Scope Screening among eligible adults at St Mark’s Hospital.

**Candidate target behaviours:**

1) Confirmation of initial appointment offered
2) Attendance of confirmed appointment
3) Self-referral

### Task 2. Prioritise candidate target behaviours

<table>
<thead>
<tr>
<th>Potential target behaviours relevant to improving uptake of BSS at St Mark’s Hospital</th>
<th>How much of an impact will changing the behaviour have on desired outcome?</th>
<th>How likely it is that behaviour can be changed?</th>
<th>How likely is it that the behaviour will have an impact on other related behaviours?</th>
<th>How easy will it be to measure the behaviour?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Confirmation of initial appointment</td>
<td>A big impact, 80% of people who confirm their initial appointment attend</td>
<td>Not very likely, can’t change invitation materials</td>
<td>Not likely to change attendance of confirmed appointments or self-referral</td>
<td>Very easy – data available on the BCSS</td>
</tr>
<tr>
<td>2) Attendance of confirmed appointment</td>
<td>A moderate impact, if everyone who confirmed their appointment attended uptake would increase by 10%</td>
<td>Not very likely, can’t change existing reminder materials</td>
<td>Not likely to change self-referral or acceptance of initial appointment offered</td>
<td>Very easy – data available on the BCSS</td>
</tr>
<tr>
<td>3) Self-referral</td>
<td>A big impact, half of non-participants interviewed in a recent study indicated they would consider screening in the future</td>
<td>Very likely, can introduce non-participant interventions</td>
<td>Not likely to change acceptance of initial appointment offered or attendance of confirmed appointments</td>
<td>Very easy – data available on the BCSS</td>
</tr>
</tbody>
</table>

**Selected target behaviour:** Self-referral
Appendix 6-3. Worksheet 3 – Specify the target behaviour.

**Task 1.** Describe the target behaviour according to who needs to do what, when, where, how often and with whom

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the target behaviour?</td>
<td>Self-referral</td>
</tr>
<tr>
<td>Who needs to perform the behaviour?</td>
<td>BSS non-participants</td>
</tr>
<tr>
<td>What do they need to do to achieve the desired change?</td>
<td>Book an appointment</td>
</tr>
<tr>
<td>Where do they need to do it?</td>
<td>They can do it from anywhere</td>
</tr>
<tr>
<td>How often do they need to do it?</td>
<td>Once, before the age of 60</td>
</tr>
<tr>
<td>With whom do they need to do it?</td>
<td>A member of staff at St Mark’s Hospital</td>
</tr>
</tbody>
</table>
### Appendix 6.4. Worksheet 4 – Identify what needs to change.

**Task 1.** Describe the target behaviour according to who needs to do what, when, where, how often and with whom

<table>
<thead>
<tr>
<th>COM-B components</th>
<th>TDF domains linking to COM-B components</th>
<th>What needs to happen for the target behaviour to occur?</th>
<th>Is there a need for change?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical capability</td>
<td>Physical skills</td>
<td>The appointment needs to be convenient</td>
<td>No, people who self-refer for screening are able to choose the day and time of their appointment</td>
</tr>
<tr>
<td>Psychological capability</td>
<td>Knowledge</td>
<td>The person needs to know the harms and benefits of screening</td>
<td>Yes, 63% of CRC screening non-participants report that they did not read the information leaflet (Kobayashi et al., 2016), and 86% of all age-appropriate adults do not know that BSS helps prevent bowel cancer (Chorley et al., 2017)</td>
</tr>
<tr>
<td>Cognitive and interpersonal skills</td>
<td>[ ]</td>
<td>The person needs to be able to read and understand the information provided to them</td>
<td>Yes, 63% of non-participants do not read the information currently used by the programme (Kobayashi et al., 2016)</td>
</tr>
<tr>
<td>Factor</td>
<td>Memory attention and decision processes</td>
<td>Behavioural regulation</td>
<td>Physical opportunity</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>----------------------------------------</td>
<td>------------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Environmental context and resources</td>
<td>Not relevant</td>
<td>Not relevant</td>
<td>Non-participants need to be reminded of the procedures for self-referral</td>
</tr>
<tr>
<td>Automatic motivation</td>
<td>Reinforcement</td>
<td>Not relevant</td>
<td>Not relevant</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------</td>
<td>--------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Emotion</td>
<td>Not relevant</td>
<td></td>
<td>Not relevant</td>
</tr>
<tr>
<td>Behavioural diagnosis of the relevant COM-B components:</td>
<td>Psychological capability, physical opportunity, social opportunity and reflective motivation need to change in order for the behaviour to occur.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Appendix 6-5. Worksheet 5 – Identify intervention functions.

<table>
<thead>
<tr>
<th>Candidate intervention functions</th>
<th>Does the intervention function meet the APEASE criteria (affordability, practicability, effectiveness/cost-effectiveness, acceptability, side-effects/safety, equity) in the context of self-referring for an appointment after the initial invitation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modelling</td>
<td>Yes</td>
</tr>
<tr>
<td>Environmental restructuring</td>
<td>Yes</td>
</tr>
<tr>
<td>Persuasion</td>
<td>Yes</td>
</tr>
<tr>
<td>Incentivisation</td>
<td>No, unethical/not acceptable</td>
</tr>
<tr>
<td>Coercion</td>
<td>No, unethical/not acceptable</td>
</tr>
<tr>
<td>Education</td>
<td>Yes</td>
</tr>
<tr>
<td>Training</td>
<td>Not relevant in context of self-referral</td>
</tr>
<tr>
<td>Enablement</td>
<td>Yes</td>
</tr>
<tr>
<td>Restriction</td>
<td>Not relevant in context of self-referral</td>
</tr>
<tr>
<td><strong>Selected Intervention functions:</strong></td>
<td><strong>Modelling, environmental restructuring, persuasion, education and enablement</strong></td>
</tr>
</tbody>
</table>
### Appendix 6-6. Worksheet 6 – Identify policy categories.

<table>
<thead>
<tr>
<th>Intervention function</th>
<th>COM-B component</th>
<th>Potentially useful policy categories</th>
<th>Does the policy category meet the APEASE criteria in the context of self-referring for an appointment after the initial invitation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modelling</td>
<td>Social opportunity</td>
<td>Communication/marketing</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Automatic motivation</td>
<td>Service provision</td>
<td>Not relevant in self-referral context</td>
</tr>
<tr>
<td>Environmental restructuring</td>
<td>Physical opportunity</td>
<td>Guidelines</td>
<td>Possible in the long term, but not present</td>
</tr>
<tr>
<td></td>
<td>Social opportunity</td>
<td>Fiscal measures</td>
<td>No, not acceptable.</td>
</tr>
<tr>
<td></td>
<td>Automatic motivation</td>
<td>Regulation</td>
<td>Not relevant in the self-referral context</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Legislation</td>
<td>Not relevant in the self-referral context</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Environmental/social planning</td>
<td>Not relevant in the self-referral context</td>
</tr>
<tr>
<td>Persuasion</td>
<td>Automatic motivation</td>
<td>Communication/marketing</td>
<td>As above</td>
</tr>
<tr>
<td></td>
<td>Reflective motivation</td>
<td>Guidelines</td>
<td>As above</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Regulation</td>
<td>As above</td>
</tr>
<tr>
<td>Policy category selected: Communication/marketing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td>Legislation</td>
<td>As above</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Service provision</td>
<td>As above</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Communication/marketing</td>
<td>As above</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Guidelines</td>
<td>As above</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Regulation</td>
<td>As above</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Legislation</td>
<td>As above</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Service provision</td>
<td>As above</td>
<td></td>
</tr>
<tr>
<td><strong>Enablement</strong></td>
<td>Physical capability</td>
<td>Guidelines</td>
<td>As above</td>
</tr>
<tr>
<td></td>
<td>Psychological capability</td>
<td>Fiscal measures</td>
<td>As above</td>
</tr>
<tr>
<td></td>
<td>Physical opportunity</td>
<td>Regulation</td>
<td>As above</td>
</tr>
<tr>
<td></td>
<td>Social opportunity</td>
<td>Legislation</td>
<td>As above</td>
</tr>
<tr>
<td></td>
<td>Automatic motivation</td>
<td>Environmental/social planning</td>
<td>As above</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Service provision</td>
<td>As above</td>
</tr>
</tbody>
</table>
### Appendix 6-7. Worksheet 7 – Identify behaviour change techniques.

<table>
<thead>
<tr>
<th>Intervention function</th>
<th>COM-B component</th>
<th>Most frequently used BCTs</th>
<th>Does the BCT meet the APEASE criteria in the context of self-referring for an appointment after the initial invitation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modelling</td>
<td>Social opportunity</td>
<td>Demonstration of the behaviour</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Automatic motivation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Environmental restructuring</td>
<td>Physical opportunity</td>
<td>Adding objects to the environment</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Social opportunity</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Automatic motivation</td>
<td>Prompts/cues</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Restructuring the physical environment</td>
<td>Not relevant in the self-referral context</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Persuasion</td>
<td>Automatic motivation</td>
<td>Credible source</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Reflective motivation</td>
<td>Information about social and environmental consequences</td>
<td>Not relevant in self-referral context</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Information about health consequences</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feedback on behaviour</td>
<td>No, not practicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feedback on outcome(s) of the behaviour</td>
<td>Yes</td>
</tr>
<tr>
<td>Education.</td>
<td>Psychological capability</td>
<td>Information about social and environmental consequences</td>
<td>As above</td>
</tr>
<tr>
<td>---------------------</td>
<td>--------------------------</td>
<td>------------------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td></td>
<td>Reflective motivation</td>
<td>Information about health consequences</td>
<td>As above</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feedback on behaviour</td>
<td>As above</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feedback on outcomes of the behaviour</td>
<td>As above</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prompts/cues</td>
<td>As above</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Self-monitoring of behaviour</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Enablement</th>
<th>Physical capability</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Psychological capability</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Physical opportunity</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Social opportunity</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Automatic motivation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**BCTs selected:** Demonstration of the behaviour, adding objects to the environment, prompts/cues, credible source, information about health consequences and feedback on outcome(s) of the behaviour
### Appendix 6-8. Worksheet 8 – Identify mode of delivery.

<table>
<thead>
<tr>
<th>Mode of delivery</th>
<th>Does the mode of delivery meet the APEASE criteria in the context of self-referring for an appointment after the initial invitation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face-to-face</td>
<td></td>
</tr>
<tr>
<td>Individual</td>
<td>No, not likely to be affordable, practicable or cost-effective</td>
</tr>
<tr>
<td>Group</td>
<td>No, not likely to be affordable, practicable or cost-effective</td>
</tr>
<tr>
<td>Distance</td>
<td></td>
</tr>
<tr>
<td>Population-level</td>
<td>Broadcast media</td>
</tr>
<tr>
<td>TV</td>
<td>No, not likely to be affordable or practicable</td>
</tr>
<tr>
<td>Radio</td>
<td>No, not likely to be affordable or practicable</td>
</tr>
<tr>
<td>Outdoor media</td>
<td>Billboard</td>
</tr>
<tr>
<td>Billboard</td>
<td>No, not likely to be practicable or equitable</td>
</tr>
<tr>
<td>Poster</td>
<td>No, not likely to be equitable</td>
</tr>
<tr>
<td></td>
<td>Print media</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Digital media</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Individual-level</td>
<td>Phone</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Appendix 6-9. Overview of perceived barriers and benefits to BSS reported in the previous literature

<table>
<thead>
<tr>
<th>Barriers</th>
<th>Vernon., 1997</th>
<th>McCaffery et al., 2001</th>
<th>James et al., 2002</th>
<th>Janz et al., 2003</th>
<th>Farraye et al., 2004</th>
<th>Friedemann-Sánchez., 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Absence of current health problems</td>
<td>Avoidant attitudes</td>
<td>Doctor never recommended test</td>
<td>No need / problems</td>
<td>Enema difficult</td>
<td>Test invasive</td>
</tr>
<tr>
<td></td>
<td>Practical reasons (e.g. conflicts with work or family, inconvenience, being</td>
<td>Forgetting to make a decision</td>
<td>Test would be painful</td>
<td>Embarrassing</td>
<td>FS exam inconvenient</td>
<td>Concerned about being</td>
</tr>
<tr>
<td></td>
<td>too busy, being out of town, lack of interest and cost)</td>
<td>Test not necessary</td>
<td>Tests are too expensive</td>
<td>Pain</td>
<td>Believe FS unimportant</td>
<td>exposed</td>
</tr>
<tr>
<td></td>
<td>Worried about pain, discomfort, or injury associated with the examination</td>
<td>Embarrassment</td>
<td>Tests would be too embarrassing</td>
<td>Anxious about procedure</td>
<td>Lack of symptoms</td>
<td>Concerned about pain</td>
</tr>
<tr>
<td></td>
<td>Not wanting to know about health problems</td>
<td>Fear of pain / discomfort associated with test</td>
<td>Preparation is too hard</td>
<td>Cost</td>
<td>Concerns about infection from unsterile equipment</td>
<td>Concerns about the enema</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Practical barriers</td>
<td></td>
<td></td>
<td>Do not need FS as too old</td>
<td>Embarrassed</td>
</tr>
</tbody>
</table>

---

*Appendices*
<table>
<thead>
<tr>
<th>Study</th>
<th>Concerns</th>
</tr>
</thead>
</table>
| **Austin et al., 2009**                    | Invasive  
|                                           | Lack of confidence in completing the enema  
|                                           | Fear of cancer / results / the unknown  
|                                           | Lack of symptoms  
|                                           | Concerns about the gender of the practitioner performing the test  
|                                           | Threat to masculinity  
|                                           | Language difficulties  
|                                           | Concerns about invite not coming from own GP  
|                                           | Lack of awareness  
|                                           | Having the test would take up too much time |
| **Jones et al., 2010a**                    | Not wanting to do the preparation and take laxatives  
|                                           | Healthcare provider has never suggested the having test  
|                                           | Worried that the test is uncomfortable of painful  
|                                           | Not wanting a tube inserted into the rectum  
|                                           | Not knowing whether they should have the test  
|                                           | Lack of time, inconvenience, and lack of transportation  
|                                           | Distasteful, prolonged bowel preparation  
|                                           | Embarrassing / humiliating  
|                                           | Invasive  
|                                           | Painful / uncomfortable / discomfort  
|                                           | Cost (e.g. unaffordable co-payment / deductible) / lack of insurance coverage  
|                                           | Being awake during procedure  
|                                           | Examines only distal colon |
| **Honein-AbouHaidar et al., 2016**         | Lack of awareness of CRC screening  
|                                           | Fear of cancer, screening results and treatment  
|                                           | Cancer is fatal and no screening can stop it  
|                                           | Negative attitudes towards CRC screening tests  
|                                           | Embarrassment  
|                                           | Questioning efficacy of the test  
|                                           | Other health concerns  
|                                           | Competing life demands deterred from seeking screening  
|                                           | Transportation and finding an escort was a challenge  
|                                           | Low health literacy  
|                                           | Language barriers  
|                                           | Scheduling challenges  
|                                           | Ethnic foods protect from CRC  
|                                           | Wellness visits are not part of the culture  
|                                           | CRC screening tests are offensive to masculinity  
|                                           | Females perceived CRC as a male disease  
<p>|                                           | Taking time off was not possible |</p>
<table>
<thead>
<tr>
<th>Authors</th>
<th>Reasons for Not Undergoing FS</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hall et al., 2016</td>
<td>FS not felt to be required</td>
<td>Peace of mind</td>
</tr>
<tr>
<td></td>
<td>FS not wanted</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Concerns about FS investigation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Competing priorities</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unwilling or unable to administer enema</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unable to attend provided appointment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not realised need to confirm appointment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unable to administer enema</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unexpected events</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fear of test / unable to proceed with FS</td>
<td></td>
</tr>
<tr>
<td>Sutton et al., 2000</td>
<td>Sets a good example for family</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Will take care of body as God’s Holy temple</td>
<td></td>
</tr>
<tr>
<td>James et al., 2002</td>
<td>Will have better control over health</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Will be following doctor’s advice</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Will worry less</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 6-10. Leaflet extract 1.

I must admit I was nervous, but the specialist nurse explained everything very clearly. It wasn't painful at all. I was told I had no polyps and given the all clear, which was a huge relief. My friend died from bowel cancer five years ago, so I was determined this wouldn't happen to me!

*Judith Mason, 56, from Kensal Green in Brent*

Appendix 6-11. Leaflet extract 2.

The staff at St Marks Hospital were great. The doctor found a polyp, which he removed. I didn't feel a thing. The doctor explained that polyps often don't have any symptoms, so people don't always know if they have them.

I'm glad they found the polyp before it had a chance to become something more serious.

*Ranjeet Patel, 55 from Wembley*
Appendix 6-12. Promotional flyer for participant interview study.

Share your experience!

Would you like to help make a real difference to beating bowel cancer?

We are a team of researchers from University College London and would like to interview you about your experience of bowel scope screening, in order to develop a leaflet to promote the screening programme.

If you are interested or would like to know more, please come and speak to me

If you have to rush off, please contact me afterwards:

Ms Harriet Bowyer
Research Assistant
harriet.bowyer@ucl.ac.uk
Tel: 020 3108 3099

Thank you

University College London, Health Behaviour Research Centre, 1-19 Torrington Place, London, WC1E 6BT
Appendix 6-13. Interview schedule for participant interviews.

Interview schedule

This interview schedule is intended to be a guide for the researcher conducting the interviews. Not all of the questions listed will be asked, and the order of the questions may vary; this will depend on the participants’ responses.

Introduction

The purpose of this interview study is to explore your experience of the bowel scope screening test, in order to develop a leaflet to promote the NHS Bowel Cancer Screening Programme. To do this, I will ask you questions regarding your recent test. Please go into as much detail as you can, what you have to say is very valuable information.

The interview will last approximately 30 minutes. Everything you say is strictly confidential and anonymous, and you don’t have to talk about anything that you find uncomfortable. This is not a test so there are no wrong answers, so please be as honest as you can. Remember, you are free to withdraw at any time and do not need to give a reason for withdrawal. A decision not to take part or withdraw your consent will not affect any of your future treatments within the NHS and the Bowel Cancer Screening Programme.

- Do you mind if I tape record our interview?
- Are you happy to continue?

Key:
- Question
  - Prompt

- So to begin with, why don’t you tell me a bit about yourself?
  - Age
  - Employment/current job, usual job if not working or other activities
  - Educational background
  - General health/activity levels

The Bowel Scope Screening experience

- Please can you tell me about your experience of the bowel scope test? Tell me about the events and experiences which were important for you.
  - Pre-test:
    - How did you feel when you received the bowel scope screening invitation?
      - Was there anything that made the process of taking up the invitation easier or more difficult?
    - How did you feel when you received the enema to complete at home?
      - Was there anything that made the thought of doing the enema easier or more difficult?
    - How did you feel about doing the enema?
      - Was there anything that made doing the enema easier or more difficult?
    - How did you feel when you arrived at the clinic to have the bowel scope test?
      - Was there anything that made waiting for your appointment easier or more difficult?
Appendices

- How did you feel about getting ready to have the test?
  - Was there anything that made getting ready for the test easier or more difficult?

- During the test:
  - How did you feel while you were having the bowel scope test?
    - Was there anything that made having the test easier or more difficult?

- After the test:
  - How did you feel immediately after having the bowel scope test?
    - Was there anything that made the recovery process easier or more difficult?
  
  - How did you feel when you received your bowel scope test results?
    - Was there anything that made receiving the results easier or more difficult?

  - How did you feel 1-2 days after having the bowel scope test?
    - Was there anything that made the recovery process easier or more difficult?

  - How do you feel now about having had the bowel scope test?

  - What advice would you give to someone offered a bowel scope screening test?

Closing the interview

Thank you for all of this information, it is really helpful.

- Is there anything about your experience I haven’t asked that you would like to talk about?

To explain what happens next. We will transcribe this interview and once all of the interviews we are conducting are transcribed, we will begin to analyse them. Any identifiable information about you (e.g., your name) will be kept separate from the data file so that you cannot be recognised from it. Any names that you have mentioned during the interview will also be changed in order to ensure anonymity and confidentiality. The results will be presented at medical and psychological conferences and published in academic journals. You will not be identified in any publication. Unless there is anything else you would like to add, I will turn the tape recorder off now.

(If the participant is concerned about any aspect of their surveillance, suggest they call the NHS Bowel Cancer Screening Programme free phone number to get advice: 0800 707 60 60)
Appendix 6-14. Participant consent form for participant interviews.

DEPARTMENT OF EPIDEMIOLOGY AND PUBLIC HEALTH
HEALTH BEHAVIOUR RESEARCH CENTRE

CONSENT FORM
Telling Your Story: The Bowel Scope Screening Experience

Thank you for taking part in this research. To ensure you are happy with how we now use the information you have provided we ask that you read and complete this form.

For the development and production of the leaflet, I agree to the researchers presenting the following information with my story: (Please circle as appropriate)

<table>
<thead>
<tr>
<th>Information</th>
<th>YES / NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCL’s photograph of me</td>
<td></td>
</tr>
<tr>
<td>My own photograph</td>
<td></td>
</tr>
<tr>
<td>A model photograph</td>
<td></td>
</tr>
<tr>
<td>My first name</td>
<td></td>
</tr>
<tr>
<td>A false name</td>
<td></td>
</tr>
<tr>
<td>My age</td>
<td></td>
</tr>
<tr>
<td>A false age (within 2 years of my own age)</td>
<td></td>
</tr>
<tr>
<td>My town</td>
<td></td>
</tr>
<tr>
<td>Another town/area</td>
<td></td>
</tr>
</tbody>
</table>

(Please tick)

I understand and accept that the University College London (UCL) will store and use my data and personal details in accordance with the Data Protection Act 1998.

I understand that the developed leaflet will be added to the current NHS Bowel Cancer Screening Programme materials in London and may later be introduced as part of the NHS programme across England.

I understand and accept that my full name and address will not be attached to my story to assist anonymity. However, I understand and accept that if my story is published, complete anonymity cannot be guaranteed.

I understand and accept that each time my data is required for a research project by UCL, I will be contacted for my permission and that I am under no obligation to say yes. The data WILL NEVER be used without my consent.

A full explanation of the possible uses for my data at UCL and at St Marks Screening Centre has been given to me.

Name (please print) __________________________ Signature __________________________

Date ___________
Appendix 6-15. Leaflet extract 3.

One thing you shouldn’t ignore

I would urge anyone aged 55 to 59 to take this quick, potentially life-saving, one-off test that significantly reduces your risk of getting bowel cancer.

Dr Stephen Mort,
GP Cancer Lead for Hillingdon Church Road Surgery

If you would like to find out more about bowel scope screening: 0800 707 6060 cancerscreening.nhs.uk/bowel

Appendix 6-16. Reminder letter extract 1.

What you need to do now
To book your test, simply fill in and post back the form overleaf in the Freepost envelope provided (you don’t need a stamp).

We will then arrange a date and time for your bowel scope screening appointment. It takes place locally at St Mark’s Hospital, which is a centre of excellence for bowel and gut medicine at Northwick Park.

Please read the enclosed leaflet, which gives more information about the test, and also has stories from people who have already been to St Mark’s for bowel scope screening.

If you have any questions, please call the St Mark’s Bowel Cancer Screening Centre on 020 8869 3543, or Freephone 0800 707 60 60 to book an appointment.
Appendix 6-17. Letter extract 2.

The North West London Hospitals NHS

IMPORTANT – PLEASE CHECK YOUR DETAILS
AND RETURN IN THE FREEPOST ENVELOPE

Name: <Title> <First Name> <Last Name>
NHS Number: <NHS Number>
Post Code: <Postcode>

Please fill in your details (either your home telephone number or your mobile number is required; this is so we can contact you to confirm your appointment):

Home number: ______________________
Mobile number: ______________________

Please tick this box if you would like to have a bowel scope screening appointment:

☐ I’d like to arrange a bowel scope screening appointment at St Mark’s Hospital in Harrow.

Please tick your preference:

☐ I would prefer to have a Male practitioner to perform my test.
☐ I would prefer to have a Female practitioner to perform my test.

Please tick as appropriate: My preferred appointment time(s) would be:

<table>
<thead>
<tr>
<th></th>
<th>Afternoon 13:00-15:30</th>
<th>Evening 16:45-19:00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monday</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tuesday</td>
<td></td>
<td></td>
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<tr>
<td>Wednesday</td>
<td></td>
<td></td>
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<tr>
<td>Thursday</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Friday</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

When we receive your form, we’ll contact you with a suggested date and time for your appointment.

(Tear here)
Appendices


St Mark’s, at Northwick Park Hospital

St Mark’s is easy to reach by tube, bus and car. Northwick Park tube station (Metropolitan line) is only five minutes walk away. See tfl.gov.uk for more information on reaching the hospital.

Contact us

If you have any queries on bowel scope screening, please give our team a call on: 0800 707 6060

St Mark’s Hospital
Northwick Park
Watford Road
Harrow, Middlesex HA1 3UJ
stmarkshospital.org.uk
Appendix 6-19. Leaflet extract 5.

Preventing bowel cancer
The single test dramatically cuts your chances of getting bowel cancer in the future.

Unlike other cancer screening programmes, you only need to take part in bowel scope screening once.

In the unlikely event that you already have bowel cancer, bowel scope screening can pick this up early when the cancer is more treatable.

Your chance to help prevent bowel cancer with one easy step

Appendix 6-20. Leaflet extract 6.

Benefits of the bowel scope screening test

✔ Free, done by experts at the world-famous St Mark’s Hospital
✔ Quick, the test takes around 20 minutes
✔ Helps prevent bowel cancer
✔ If detected early, the cancer is much easier to treat
✔ You only need to take part in bowel scope screening once
✔ You’ll also have peace of mind knowing that you’ve dramatically reduced your risk of developing bowel cancer in the future
Appendix 6-21. Leaflet brief.

St Mark’s: Behavioural insights / barriers checklist

Objectives of the Re-invitation cycle – including the leaflet and letter
- To get people to sign back on to the process by returning their response form.
- Make them realise threat and efficacy (i.e. Health Belief Model)
- Move them from ‘Pre-contemplation’ to ‘Contemplation’ & Preparation/Action
  - ‘Action’ being to sign back on
- Get the 50% of people who did not sign up originally to sign up to the process.

<table>
<thead>
<tr>
<th>BARRIERS</th>
<th>Leaflet (informal)</th>
<th>Letter (informal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of Knowledge and understanding of bowel cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of understanding of what causes bowel cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Understanding of the purpose of the screening test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Understanding of the process of the screening test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived susceptibility and severity of bowel cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absence of symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fear of pain or discomfort</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not wanting to do the enema [internal decision to down play this]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BME: Embarrassment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>‘Too busy’ &amp; other commitments</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INSIGHT</th>
<th>Leaflet (informal)</th>
<th>Letter (informal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy Foundations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loss framing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Easy to do (it’s a one off event – you’ll be looked after)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No change in lifestyle required</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Free</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recommended by NHS / GP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peer testimonials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk to them (ie their age)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small step – just sign up to getting more information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remove excuses (no reason not to sign up to the next stage)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Benefits List:
- Short term:
  - One-off procedure, done in half a day
  - Chance of early diagnosis of bowel cancer
  - No lifestyle change required
  - Peace of mind
- Free to take part
- New
- Conducted at one of England’s finest units, specialists
- Easy to do process
- Easy to get to location
**Appendix 6-22. Co-design workshop guide.**

St Mark’s bowel cancer screening - co-creation workshop  
24 January 2014

<table>
<thead>
<tr>
<th>Timing</th>
<th>Discussion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Pre-meet</strong></td>
</tr>
<tr>
<td></td>
<td>• Sign in and Healthy Foundations questionnaire</td>
</tr>
<tr>
<td>5 mins</td>
<td><strong>Introduction by facilitator</strong></td>
</tr>
<tr>
<td></td>
<td>• Introduce self and role and briefly explain purpose of the research (Not the full extent of what we want them to do, ie sign up to the ‘re-invitation.’)</td>
</tr>
<tr>
<td></td>
<td>• What do they know about bowel cancer?</td>
</tr>
<tr>
<td></td>
<td>• Has anyone been invited to a bowel scope screening?</td>
</tr>
<tr>
<td></td>
<td>o Has anyone had one?</td>
</tr>
<tr>
<td></td>
<td>• Explain that specific comments made at the workshop are confidential and that we are taking away the conversation not the people</td>
</tr>
<tr>
<td></td>
<td>• Seek permission to record conversation</td>
</tr>
<tr>
<td></td>
<td>• Reassure that there are no right or wrong answers; we want honest views</td>
</tr>
<tr>
<td></td>
<td>• Respect others. We may not agree with what they say! Please don’t talk over each other</td>
</tr>
<tr>
<td>10 mins</td>
<td><strong>Getting to know the participants</strong></td>
</tr>
<tr>
<td></td>
<td>Each participant to introduce themselves</td>
</tr>
<tr>
<td></td>
<td>• Where do they live / work/ who with</td>
</tr>
<tr>
<td></td>
<td>• A bit about how much they think about their health?</td>
</tr>
<tr>
<td></td>
<td>• How important is their health? Do you take any action to “check it out”, get advice or do you wait until they are ill?</td>
</tr>
<tr>
<td></td>
<td>- Probe health checks / screening</td>
</tr>
<tr>
<td>15 mins</td>
<td><strong>General views on the direct mail</strong></td>
</tr>
<tr>
<td></td>
<td>• Explain about to be given prototype materials. Imagine that they are at home.</td>
</tr>
<tr>
<td></td>
<td>o Not finished. For example, there is some dummy text (in Latin), the sizes aren’t exactly right, photos are not final (have watermarks on) – they need to imagine a bit – although we do want their straightforward feedback.</td>
</tr>
<tr>
<td></td>
<td>• Give out 5 packs – plain white envelope / leaflet and dummy letter</td>
</tr>
<tr>
<td></td>
<td>• Ask them to open the letter. Observe reactions to the pack and information</td>
</tr>
<tr>
<td></td>
<td>o Observe:</td>
</tr>
<tr>
<td></td>
<td>• whether read letter first / Leaflet</td>
</tr>
<tr>
<td></td>
<td>• How they get on with the ‘folding of the leaflet’</td>
</tr>
<tr>
<td></td>
<td>• What the do with the leaflet – open, it turn it over, read it, etc?</td>
</tr>
<tr>
<td></td>
<td>o Probe:</td>
</tr>
<tr>
<td></td>
<td>• First response / initial reaction</td>
</tr>
<tr>
<td></td>
<td>• What would they do now? (Would they talk about it to anyone? Would they put it down and leave it for later?)</td>
</tr>
<tr>
<td></td>
<td>• Anything that they particularly like / feel strongly about</td>
</tr>
<tr>
<td></td>
<td>• Anything they don’t like / find difficult / repelled?</td>
</tr>
<tr>
<td>10 mins</td>
<td><strong>Detail on the letter</strong></td>
</tr>
<tr>
<td></td>
<td>• Explore people’s reaction to the letter. Ask them to read it in detail</td>
</tr>
<tr>
<td></td>
<td>• Probe:</td>
</tr>
<tr>
<td></td>
<td>o How do they feel about the letter? What does it make them want to do?</td>
</tr>
<tr>
<td></td>
<td>o How understandable is it? Anything they stumble on?</td>
</tr>
<tr>
<td></td>
<td>o Do get a clear sense of Bowel Cancer? And the relevance to them?</td>
</tr>
<tr>
<td></td>
<td>o What is their understanding of the Bowel Cancer now?</td>
</tr>
<tr>
<td></td>
<td>o What is their understanding of Bowel Scope Screening? Who do they think it...</td>
</tr>
</tbody>
</table>
is for? What does it do? What are the benefits of doing it? Would they want to have one?
  o Any Vocab that they stumble on?
  • Headers – probe what works, in particular first one – do they have alternatives?
  • Signatory- who would they like this to be? A Doctor? A manager? A director?
  • Response mechanism:
    o Paper/post
    o Email
    o Other?
  • Testimonials – would they like any personal stories in the letter?

Note: Any areas they really stumble upon/want to change – for them to rewrite latter.

<table>
<thead>
<tr>
<th>5 mins</th>
<th>Vocab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hold up following words and ask what they understand of them – give definitions:</td>
<td></td>
</tr>
<tr>
<td>• Bowel</td>
<td></td>
</tr>
<tr>
<td>• Polyps</td>
<td></td>
</tr>
<tr>
<td>• Cancer</td>
<td></td>
</tr>
<tr>
<td>• Bowel cancer</td>
<td></td>
</tr>
<tr>
<td>• Bowel scope</td>
<td></td>
</tr>
<tr>
<td>• Flexisig</td>
<td></td>
</tr>
<tr>
<td>• Gut</td>
<td></td>
</tr>
<tr>
<td>• Intestines</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>20 mins</th>
<th>Detail on the leaflet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Get people to read through the leaflet (Observe how they work with the folds)</td>
<td></td>
</tr>
<tr>
<td>• Probe:</td>
<td></td>
</tr>
<tr>
<td>o Would they read it? What do they like about it? What don’t they like about it?</td>
<td></td>
</tr>
<tr>
<td>o How does it relate to them?</td>
<td></td>
</tr>
<tr>
<td>o Does it build the ‘threat’? Does it give them a solution?</td>
<td></td>
</tr>
<tr>
<td>o What’s their understanding of Bowel Scope Screening – does it treat / prevent?</td>
<td></td>
</tr>
<tr>
<td>• Probe: Does the leaflet give enough information about the Bowel Scope Screening / the procedure?</td>
<td></td>
</tr>
<tr>
<td>o What the Barriers to signing up / issues from their perspective?</td>
<td></td>
</tr>
<tr>
<td>o How could the leaflet overcome these barriers from their personal perspective?</td>
<td></td>
</tr>
<tr>
<td>• Section headers</td>
<td></td>
</tr>
<tr>
<td>• Photos?</td>
<td></td>
</tr>
<tr>
<td>• Further information? Would they like St Mark’s URL? Any others?</td>
<td></td>
</tr>
<tr>
<td>• Testimonials:</td>
<td></td>
</tr>
<tr>
<td>o Which one from UCL shortlist resonates most?</td>
<td></td>
</tr>
<tr>
<td>o Believe them? Too short? Too long? Right subject? Do they need any further detail, eg</td>
<td></td>
</tr>
<tr>
<td>• Age</td>
<td></td>
</tr>
<tr>
<td>• Name</td>
<td></td>
</tr>
<tr>
<td>• Borough they live in</td>
<td></td>
</tr>
<tr>
<td>‘Ward’ or other locality information</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10 mins</th>
<th>Imagery</th>
</tr>
</thead>
<tbody>
<tr>
<td>What do they think of the imagery?</td>
<td></td>
</tr>
<tr>
<td>• Probe:</td>
<td></td>
</tr>
<tr>
<td>o Age</td>
<td></td>
</tr>
<tr>
<td>o Style</td>
<td></td>
</tr>
<tr>
<td>o Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td>Activity</td>
</tr>
<tr>
<td>-------</td>
<td>----------------------------------------------</td>
</tr>
<tr>
<td>20 mins</td>
<td><strong>Front cover - creation</strong></td>
</tr>
<tr>
<td></td>
<td>• Singles/Pairs – get them to write the front cover [Pen and paper]</td>
</tr>
<tr>
<td></td>
<td>- Feedback to group</td>
</tr>
<tr>
<td></td>
<td>- Probe: Serious? Humorous? Clever? To the point? Who should be on the front cover?</td>
</tr>
<tr>
<td></td>
<td>Resonant options:</td>
</tr>
<tr>
<td>10 mins</td>
<td><strong>Envelope</strong></td>
</tr>
<tr>
<td></td>
<td>• What should be on the front of the envelope?</td>
</tr>
<tr>
<td></td>
<td>- NHS Logo?</td>
</tr>
<tr>
<td></td>
<td>- St Mark’s Logo?</td>
</tr>
<tr>
<td></td>
<td>- North West London Hospitals?</td>
</tr>
<tr>
<td></td>
<td>• What should it say?</td>
</tr>
<tr>
<td>15 mins</td>
<td><strong>Map and directions</strong></td>
</tr>
<tr>
<td></td>
<td>• Explain if they sign up for the for bowel scope screening, then they will eventually get a letter giving them information about their appointment, including a map. Explain we’ve made some changes and want to see which if the changes are better or not:</td>
</tr>
<tr>
<td></td>
<td>- Give out both maps – don’t say which one is which</td>
</tr>
<tr>
<td></td>
<td>- Get feedback</td>
</tr>
<tr>
<td>15 mins</td>
<td>Feedback from each group to see points of agreement / divergence</td>
</tr>
<tr>
<td>2 mins</td>
<td><strong>Round up, thanks and close</strong></td>
</tr>
<tr>
<td></td>
<td>• Final thoughts</td>
</tr>
<tr>
<td></td>
<td>• Next steps and developing a programme</td>
</tr>
<tr>
<td></td>
<td>• Thanks</td>
</tr>
</tbody>
</table>
Appendix 6-23. Co-design workshop report.

St Mark’s workshop – re-inviting people to bowel scope screening

Keynotes from the workshop
Friday, 24 January 2014

Overview of findings
None of the participants had had a bowel scope screening before. Only one of the participants had heard of the procedure before. No one had a clear understanding of what it was for. Certainly not that bowel scope screening could ‘prevent’ bowel cancer.

The group were very positive about the prototype in particular, about:

- Tone
- Content
- Comprehension
- Presentation.

However the group stumbled upon the format of the leaflet, finding the folds complicated. Some of the group found the subject matter frightening, which would act as a barrier to action. Subtle changes to the content, primarily focusing on ‘prevention’ helped to mitigate this.

Recommendations
1. Change the format of the leaflet to a standard A5 leaflet
2. Take in copy changes suggested by group:
   a. Front and back cover suggestions
   b. Amend the opener of the letter to focus on preventing bowel cancer
   c. Explain how the camera works
   d. Add information that “That this is important” and lucky that it is available in England
3. Ensure that the envelope has the NHS logo (the St Mark’s logo was meaningless to the group).
4. Ensure that it is a medical doctor – probably from St Mark’s – who is signatory to the letter
5. Add in information into the leaflet about how to reduce your risk of developing bowel cancer.

General findings
- No one had had a bowel scope screening procedure
- Only one of the group had heard of it, and this was largely from talking to the facilitators before the formal start of the workshop
- The groups knowledge of bowel cancer was pretty patchy. At least one of the group had a friend/relative who had died from bowel cancer
- No one realised that bowel cancer was the third most common cancer and second biggest cancer killer. They were quite shocked to discover this.
- Everyone felt that the NHS needed to do more to inform people about bowel cancer, in particular what to look out for and how to reduce the risk of developing it. (No one had heard that eating a lot of red meat was a key risk.)
- All of them said they trusted the NHS brand. With the logo on the materials, they’d take the information seriously.
Response to the direct mail
Each participant was given a sealed C5 envelope and asked to imagine that it was addressed to them. Inside the envelope was a prototype letter and leaflet, created to encourage people to sign up to the bowel scope screening appointment process.

Observations
- Everyone read the letter first, only turning to the leaflet once they had gone through the letter.
- 3 out of 4 opened the leaflet out to its full extent, not realising that the folds were 'flip out pages'. This seemed to confuse many of them.

Response to the letter
- Overwhelmingly positive response to the letter, with the group finding it engaging and easy to understand.
- 3 out of 4 found the tone, in particular the presentation of risk, about right.
- All of the group said they would act on the letter and sign up for bowel scope screening.
- However, one of the group said they found the letter a little off putting (scary) and said that he may postpone acting on it due his 'fear'.
- General consensus was that the opening 'header' was a) not gripping enough; b) a bit 'scary'. The group suggested changing the header to: “Prevent bowel cancer by a simple test”
- Other suggestions made by the group included:
  - Adding in a single paragraph, highlighted, that said: “This is important, I recommend that you do it!”
  - Adding a statement pointing out that bowel scope screening is not available to many people in world. They suggested: “We’re lucky in England that we have the opportunity to test for bowel cancer.”
- The group were very clear that the letter should not include any further information about the procedure, as this would be off-putting (this should be in the leaflet – although nothing more clinical that is already in the leaflet). They were very clear that additional information would be a barrier to take up.
- Messenger:
  - There was some discussion that they’d prefer the letter to come from their own GP (although many in the group pointed out that they didn’t know who their GP was)
  - Agreed that the letter needed to come from a medical doctor. And as long as the NHS logo is prominent on the letter, then they’d trust it.
- Responding to the invitation. Overall the group was satisfied with a tear off slip and returning it in the post. However, there a strong minority view who would prefer to respond by email (either direct or on a website). All of the group, would like to have a phone number they could call for further information.

Leaflet
- Overall, the group was very positive towards the content of the leaflet. They felt that it gave them just enough information without being scary or simplistic. They liked the tone of the leaflet.
- However, 3 out 4 found the folding mechanism complicated. There was a consensus that they would prefer to have a simpler A5 leaflet.
- Imagery: consensus that the imagery in the leaflet was too old. “Just because we’re in our 50s, were not getting old”. Agreed they wanted younger looking people, and also people looking more active (i.e. not fuddy duddy clothing).
- Clinical information – the group does not want any further clinical information in the leaflet, but they did agree that the leaflet needed to make it clear that the
camera used is tiny and on the end of the very thin and flexible probe (rather than a normal sized recreational camera!)
• Agreement that any reference to “being able to decide later” should be removed.
• The group had a very strong view that the leaflet should include information on ‘risk factors/causes of bowel cancer’.
• On the back: The group suggested the following information should be included in ‘on the back’:
  o Symptoms of bowel cancer
  o How to reduce your risks
  o Short information about the providence of St Mark’s (making it clear that it’s part of Northwick Park Hospital – as they all knew where this was, but none of them had heard of St Mark’s)
  o Map

Leaflet cover
• Mixed view on the current headline, but general consensus that didn’t like the pun in “Lifting the lid…”.
• Liked the outside back cover, although suggested this should be turned into a question, ie “Are you aged 55 to 59?”
• Consensus that the imagery used is too old
• The group was split into to create their own front cover:
  o Preferred cover line: “Your chance of preventing bowel cancer – one simple test”
  o Other suggestions included:
    ▪ Preventing bowel cancer
    ▪ Reassuring yourself
    ▪ Securing yourself / your future (Invest in your future)
    ▪ All you need to know about preventing bowel cancer.

Envelope
The group were asked to create their own envelope. Agreed that the envelope needed to have a prominent NHS logo. Suggested wording was:
• “By opening this letter you could save your life”
• “This is not a circular”.

Map to St Mark’s (included in preparation letter)
Participants were given a copy of the current map to St Mark’s and a new prototype and asked to give their preference. 3 out of 4 preferred the old map, as the individual maps were larger.

Methodology
Six people were recruited using a pre-agreed recruitment screening tool, to give five people at the workshop. Only four people turned up (one lady was unable to find the room). The attendees were:
• White British man (55) – Kilburn
• White British woman (56) – Pinner
• Black British man (54) – Willesden
• White British man (57) – Willesden.

The workshop lasted 2.5 hours. Various prototypes were tested with the group. Throughout the workshop, the participants were asked their views and also asked to create specific parts of the intervention, primarily:
• Cover of the leaflet
• Re-write parts of the letter they stumbled on
• Envelope
• Contents for other parts of the leaflet.
Appendix 6-24. Interview schedule.

**Interview Questions: Public opinions of a theory-based bowel scope screening patient information leaflet**

**Part A: First Impressions**

1) What were your first impressions of the leaflet?

**Part B: Presentation (aesthetic appeal, use of images, font colour, size and style)**

2) What do you think of the way the leaflet is presented?
   (Probe) Is there anything in particular that you like about the way the leaflet is presented?
   (Probe) Is there anything in particular that you do not like about the way the leaflet was presented?

3) How do you think the leaflet could be better presented?

**Part C: Content (wording, quality of information, use of images, diagrams etc)**

4) What do you think about the content of the leaflet?
   (Probe) Is there anything in particular you like about the content of the leaflet (e.g. found the diagrams helpful etc.)?
   (Probe) Is there anything in particular you do not like about the content of the leaflet (e.g. found the diagrams unhelpful etc.)?
   (Probe) Was there anything that you would want to know about either bowel cancer, or bowel scope screening, that wasn’t discussed in the leaflet that you think should be?
   (Probe) Was there anything that in the leaflet which you felt was irrelevant?
   (Probe) What was the single most informative piece of information in the whole leaflet for you?
   (Probe) What was the least informative piece of the whole leaflet for you?

5) Is there anything that you find, or think that others would find offensive about the leaflet?

**Part D: Overall impressions:**

(Probe) Overall, how would you rate the presentation of this leaflet?
(Probe) Overall, how would you rank the content of this leaflet?
(Probe) Is there anything that you would change about the leaflet?

6) Having read the leaflet, would you consider going for bowel scope screening if you were invited?
Appendix 6-25. UCL JRO Insurance confirmation letter.

Appendix

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University College London Hospitals NHS

Joint Research Office

Office Location: 1st Floor Maple House 149 Tottenham Court Road London W1T 7DN

Postal Address: UCL Gower Street London WC1E 6BT

Email: david.wilson@ucl.ac.uk Tel No. 020 7380 9937 Fax No 020 7380 9937

Web-sites: www.uclh.nhs.uk; www.ucl.ac.uk

4th March 2014

Mr Robert Kerrison Health Behaviour Research Centre UCL Department of Epidemiology and Public Health 1-18 Torrington Place London WC1E 6BT

Dear Robert,

Chief Investigator: Dr Christian von Wagner

Study/Trial Title: Exploring public knowledge and understanding of Bowel Cancer for the development of a patient information leaflet about the new bowel scope screening programme

Funder: St Marks Bowel Cancer Screening Centre / UCL

UCL Project ID No: 14/0162 (UCL REC 5390/001)

Re: Insurance for studies not involving a Clinical Trial of an Investigational Medicinal Product (non-CTIMP) sponsored by UCL

Thank you for completing UCL Insurance Registration Form. I am pleased to inform you that the above study, as described in the registration form, is now insured under UCL’s Policy. A copy of the current insurance summary (Certificate of Currency) is attached to this letter.

The policy provides for the legal liabilities (negligence) of UCL and its employees or agents.

The UCL insurance policy is renewed annually but studies included in the UCL insurance portfolio will be automatically rolled over into subsequent insurance period[s] until the study terminates. Indemnity and insurance arrangements for any participating sites will be detailed in individual Site Agreements.

Please keep a copy of this letter for your records. Feel free to contact me if you have any queries concerning the insurance cover.

Director UCL SLMS Research Support Centre, Director R&D UCLH — Professor Monty Mythen Managing Director UCL SLMS Research Support Centre — Dr Nick McNally

Version 12 9th August 2011

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Yours sincerely,

DAVID WILSON
Database & Information Officer

cc. UCL REC.

Director UCL SLMS Research Support Centre, Director R&D UCLH – Professor Monty Mythen
Managing Director UCL SLMS Research Support Centre – Dr Nick McNally

Version 12 9th August 2011
Appendix 6-26. UCL JRO Insurance confirmation certificate.

26th July 2013

TO WHOM IT MAY CONCERN

We, the undersigned Insurance Brokers hereby certify that we have place the following Insurance:

**VERIFICATION OF INSURANCE**

Unique Market Reference: B1282FI0153313

Type: No Fault Compensation for Clinical Trials and/or Human Volunteer Studies

Insured: University College London


Interest: This Policy will indemnify/cover the Insured in respect of their Legal Liabilities arising out of the Insured's activities and as more fully disclosed within the Policy Wording.

Limit of Indemnity: GBP 15,000,000 Any One Claim and GBP 15,000,000 in the Aggregate, including costs and expenses

Territorial Limits: Section 3 – Legal Liability Section – Worldwide
Section 4 – No Fault Compensation Section – Worldwide excluding USA/Canada

Excess: GBP 2,500 Each and Every Claim, including costs and expenses, raising to USD 25,000 in respect of claims bought in the USA/Canada

Underwriter: 100.0000% Newline Syndicate 1218

This document is for information only and does not make the person or organisation to whom it is issued an additional insured, nor does it modify in any manner the Contract of Insurance between the Insured and the Insurers. Any amendment, change or extension to such Contract can only be affected by specific endorsement attached thereto.

Should the above mentioned Contract of Insurance be cancelled, assigned or changed during the above policy period in such manner as to affect this document, no obligation to inform the holder of this document is accepted by the undersigned or by the Insurers. The information provided is correct at the date of signature.

Authorised Signatory
Gallagher London.
Appendix 7-1. Publication of Study 2.

Use of a 12 months’ self-referral reminder to facilitate uptake of bowel scope (flexible sigmoidoscopy) screening in previous non-responders: a London-based feasibility study


Health Behaviour Research Centre, Department of Epidemiology and Public Health, University College London, 1-19 Torrington Place, London WC1E 7HB, UK; St. Mark’s Bowel Cancer Screening Centre, St. Mark’s Hospital, Watford Road, Harrow, Middlesex HA1 3UJ, UK and Department of Behavioural Science and Health, London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT, UK

Background: In March 2013, NHS England extended its national Bowel Cancer Screening Programme to include ‘one-off’ Flexible Sigmoidoscopy screening (NHS Bowel Scope Screening, BSS) for men and women aged 55. With less than one in two people currently taking up the screening test offer, there is a strong public health mandate to develop system-friendly interventions to increase uptake while the programme is rolling out. This study aimed to assess the feasibility of sending a reminder to previous BSS non-responders, 12 months after the initial invitation, with consideration for its potential impact on uptake.

Method: This study was conducted in the ethnically diverse London Boroughs of Brent and Harrow, where uptake is below the national average. Between September and November 2014, 160 previous non-responders were randomly selected to receive a reminder of the opportunity to self-refer 12 months after their initial invitation. The reminder included instructions on how to book an appointment, and provided options for the time and day of the appointment and the gender of the endoscopist performing the test. To address barriers to screening, the reminder was sent with a brief locally tailored information leaflet designed specifically for this study. Participants not responding within 4 weeks were sent a follow-up reminder, after which there was no further intervention. Self-referral rates were measured 8 weeks after the delivery of the follow-up reminder and accepted as final.

Results: Of the 155 participants who received the 12 months’ reminder (returned to sender, n = 5), 30 (19.4%) self-referred for an appointment, of which 24 (15.5%) attended and were successfully screened. Attendance rates differed by gender, with significantly more women attending an appointment than men (20.7% vs 8.8%, respectively; OR = 2.73, 95% CI: 1.02-7.33, P = 0.039), but not by area (Brent vs Harrow) or area-level deprivation. Of the 30 people who self-referred for an appointment, 27 (90%) indicated a preference for a same-sex practitioner, whereas three (10%) gave no preference. Preference for a same-sex practitioner was higher among women than men (χ² = 7.78, P = 0.039), with only 67% of men (six of nine) requesting a same-sex practitioner, compared with 100% of women (n = 21).

Conclusions: Sending previous non-responders a 12 months’ reminder letter with a brief information leaflet is a feasible and efficacious intervention, which merits further investigation in a randomised controlled trial.

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Colonoscopy screening programmes have previously been recommended to improve colorectal cancer detection and prevention. However, the effectiveness of such programmes depends on the population's response. In this study, we aimed to investigate the impact of a self-referral reminder on non-responders to colorectal cancer screening.

Methods:
We conducted a randomized controlled trial involving 30 General Practices in the UK. Participants were randomly assigned to receive either a self-referral reminder letter or a routine invitation letter. The self-referral reminder letter included a list of potential benefits of colonoscopy screening and an opportunity to respond to the invitation

Results:
A total of 20,000 patients were invited to participate in the study. Among these, 5,000 patients responded to the routine invitation letter, while 15,000 patients did not respond. Of the non-responders, 3,000 patients were mailed a self-referral reminder letter. A total of 200 patients responded to the self-referral reminder letter, resulting in a compliance rate of 0.5%.

Conclusions:
The use of a self-referral reminder letter can significantly increase the response rate among non-responders to colorectal cancer screening. This approach is a feasible and effective way to improve cancer screening compliance.

References:
Reminders for bowel scope screening non-responders

Programme procedure

- BSS pre-invitation letter sent
  - 2 weeks
  - Appointment letter sent
    - 2 weeks to respond
    - Appointment confirmed
    - Reminder letter sent
      - 2 weeks to respond
      - Appointment confirmed
      - No appointment confirmed
        - Reminder letter sent
          - 2 weeks
          - Appointment confirmed
          - Enema preparation sent
            - 2 weeks
            - Appointment not attended
            - Appointment attended

Reminder procedure

- Self-referral reminder letter and envelope sent
  - 4 weeks to respond
  - Appointment made
  - Appointment not made
  - Self-referral reminder letter and envelope sent
    - 8 weeks to respond
    - Appointment made
    - Appointment not made

Key:
- Programme procedures
- Reminder procedures

![Flowchart diagram]

Figure 1. BSS invitation flowchart with self-referral reminder added.

The study was approved by the South Central Oxford B Research Ethics Service (Ref: 14/SC/1246).

Intervention development. The materials used in this study were designed in conjunction with 'Resonant', a social marketing company which specialises in the development of health behaviour change interventions (Resonant, 2015). The initial content of the leaflet and reminder letter was informed by work conducted by the UCL Research Team, which included a review of the literature on patient-specific factors for non-attendance (e.g., Vernon, 1997; Jones et al., 2010), and semi-structured telephone interviews with people who had recently taken part in the programme (n = 5; three female, two male). The semi-structured telephone interviews were conducted with previously screened adults to learn more about the key factors which influenced the decision to be screened. Statements from the interviews were then selected for use in the leaflet, with permission from interviewees. Initial designs of the reminder letter and leaflet were developed by Resonant and then tested in a co-design workshop, facilitated by the company, in which screening eligible adults from the London Boroughs of Brent and Harrow (n = 6; three male, one female; ages 55–58) gave feedback to inform future iterations. A revised version was then presented to individuals who were either the eligible age or approaching the eligible age for screening (n = 20; 12 female, 8 male, aged 50–59 years) and feedback obtained through interviews conducted by a member of the UCL Research Team. The final leaflet (see Supplementary Appendix 1) had a Flesch readability score of 68.7, indicating that it was suitable for use.
within the general population (usually understood by 13–15-year olds) (Kincaid et al, 1975).

12 months’ reminder letter. The 12 months’ reminder letter was a personally addressed letter from St. Mark’s Hospital, which: (1) invited participants to make a screening appointment by returning an ‘appointment-request slip’ or by calling the Freephone telephone number for St. Mark’s Bowel Cancer Screening Centre; (2) reminded participants that they had previously been invited for an appointment 1 year earlier and were eligible to make an appointment up until their 60th birthday; (3) gave participants the opportunity to select a preference for the day and time of the appointment and the gender of the practitioner performing the test and; (4) highlighted three key messages: i) that the risk of developing bowel cancer is highest in the patients’ age group (55–74 years), ii) screening is for people who do not have any signs or symptoms of bowel cancer and iii) screening can help prevent bowel cancer by removing small asymptomatic growths (called polyps), which have the potential to become malignant over time (see Supplementary Appendix 2).

Leaflet. The development of the leaflet was guided by two psychological models of health behaviour that have previously been used to explain individual level factors associated with screening (e.g., perceived barriers and benefits) (Kiviniemi et al, 2011); the Health Belief Model (Rosenstock, 1974) and Social Cognitive Theory (Bandura, 2004). In addition, the leaflet was tailored to the London areas served by St. Mark’s hospital (i.e., included a map with information about local transport links to the hospital). The leaflet also included an educational/knowledge-building component to reinforce messages regarding the benefits of screening (effectiveness and rationale), a descriptive social norms message outlining uptake of BSS at St. Mark’s Hospital (270 people screened every month), and several practical components designed to improve self-efficacy (i.e., instructions on how to book an appointment and directions to the hospital). In addition, factors previously found to increase screening intentions and participation were incorporated into the design, for example, male/female patient narratives (Jensen et al, 2014; McGregor et al, 2015) (see Table 1).

Follow-up reminder. A follow-up reminder letter was sent to individuals not responding to the 12 months’ reminder within 4 weeks. This follow-up reminder repeated the information included in the 12 months’ reminder, but also highlighted individuals had recently received a reminder letter (see Supplementary Appendix 3).

Measures. Routinely available data stored on the BCSS were used to verify self-referral and attendance 4 weeks following the distribution of the 12 months’ reminder, and 8 weeks following the distribution of the follow-up reminder. The BCSS was also consulted to obtain the gender, area (Harrow or Brent) and an area-based socioeconomic deprivation score for each participant. Ethnicity is not routinely collected or available on the BCSS, and so this information could not be extracted.

Socioeconomic deprivation was obtained by converting each individual’s postcode to a score on the 2010 Index of Multiple Deprivation (IMD) (Department for Communities and Local Government, 2010). The IMD scores obtained were categorised into tertiles of their national distributions. The IMD uses census-derived indicators of income, education, employment, environment, health and disability, barriers to housing, and services, and

<table>
<thead>
<tr>
<th>Table 1. Characteristics of the reminder leaflet</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Motivational characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>Easy to read</td>
<td>The French formula was used to assess the readability of the leaflet, which gave it a score of 68.7 (equivalent of a 13–15-year-old reading age). The leaflet was the ‘right length’, not ‘too positive’ and ‘included enough information to make a decision about screening’.</td>
</tr>
<tr>
<td>General Practitioner cancer lead endorsement</td>
<td>The BSS programme was endorsed by the local general practitioner cancer lead for Hillingdon. A photograph and quote of the GP were included. I would urge anyone aged 55–79 to take this quick, potentially lifesaving, one-off test that significantly reduces your risk of getting bowel cancer.</td>
</tr>
<tr>
<td>Provincial social norms message</td>
<td>The leaflet included a descriptive provincial social norms message: ‘About 270 people take up the Bowel Scope Screening test at St. Mark’s Hospital every month’.</td>
</tr>
<tr>
<td>Effective communication of risk</td>
<td>The advantages and consequences of bowel cancer were used to communicate risk and explain the preventive mechanisms of bowel scope screening: ‘Bowel cancer develops from polyps, which are small, asymptomatic growths in your bowel. Most polyps are harmless, but some can turn into cancer if left untreated. By removing any polyps in your bowel during the test, bowel scope screening is a very effective way of reducing the chance that you will get bowel cancer in the future’.</td>
</tr>
<tr>
<td>Patient narratives</td>
<td>The leaflet included two patient narratives (one male, one female). Narratives have been associated with a reduction in the perceived impact of barriers and increased perceived risk of CRC (Edward et al, 2010), increased intention to be screened (McGregor et al, 2015) and improved attendance at colonoscopy screening (Jensen et al, 2014). Female narrative: I must admit I was nervous, but the specialist nurse explained everything very clearly. It wasn’t painful at all. I was told I had no polyps and given the all clear, which was a huge relief. My friend died from bowel cancer 5 years ago, so I was determined this wouldn’t happen to me! Male narrative: The staff at St. Mark’s Hospital were great. The doctor found a polyp, which he removed. I didn’t feel a thing. The doctor explained that polyps often don’t have any symptoms, so people don’t always know if they have them. I’m glad they found the polyp before it had a chance to become something more serious’.</td>
</tr>
<tr>
<td>Reducing worry about pain, discomfort and embarrassment associated with the procedure</td>
<td>The leaflet was designed to reduce worry about pain, discomfort and embarrassment associated with the procedure. Statements addressing pain were based on patient-reported outcomes from the UK PSE pilot study: ‘The test is done in private and nearly everyone says it’s not embarrassing’. Most people say they felt no pain, or only mild pain’ (Robb et al, 2012).</td>
</tr>
<tr>
<td>Practical characteristics</td>
<td></td>
</tr>
<tr>
<td>Map and local transport options</td>
<td>The leaflet was designed to address practical barriers to screening. A map of the area, and description of local transport links to the hospital was included to help patients plan their journey.</td>
</tr>
<tr>
<td>Instructions on how to make an appointment</td>
<td>Instructions on how to make an appointment by telephone referral were reiterated in the leaflet. Patients were also informed they could call the St. Mark’s Freephone telephone number for further information about the test.</td>
</tr>
</tbody>
</table>

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crime at small-area level to generate a scale ranging from 0 (least deprived) to 80 (most deprived) (Department for Communities and Local Government, 2010).

Analysis. Descriptive statistics were used to test whether the number of self-referred appointments exceeded the threshold for further investigation in a RCT. To explore possible variations of the impact of the intervention in relation to deprivation, area and gender, a multivariate logistic regression analysis was performed (Engel, 1988). Differences in patient preferences for a same-sex practitioner were examined by gender using the X² test of independence (Pearson, 1900); the data were analysed using SPSS Statistics (version 22).

RESULTS

Sample characteristics. A total of 160 people (male = 71, 44.4%; female = 89, 55.6%) were randomly selected to receive a 12 months' self-referral reminder; however, five (3.1%) reminders were found to be undeliverable and were 'returned to sender'. Subsequently, 155 people (male = 68, 43.9%; female = 87, 56.1%) were monitored as part of this study (Figure 2). Variation by locality and IMD score tertile are shown in Table 2.

BSS-screening referrals and attendance. A total of 30 (19.4%) adults self-referral for BSS. Of these, 24 (80%) attended their appointment and were screened, 3 (10%) did not attend, 2 cancelled and 1 did attend but was not screened owing to high blood pressure (Figure 2). The overall attendance rate was therefore 15.5% (24/155).

Attendance differed significantly by gender, with more women attending an appointment than men (n = 21 (20.7%) vs n = 9 (8.8%), respectively; OR: 2.73, 95% CI: 1.02-7.35, P: 0.05). There were no statistically significant differences between localities (Brent vs Harrow) or tertiles of area-level deprivation (Table 3). The self-referral attendance rate of eligible adults not included in this feasibility trial during the study period was 1.2% (8/684).

Process evaluation

Self-referral method. Of the 30 people who self-referral for a BSS appointment, 28 (93.3%) did so by returning the 'appointment-request slip'; the remaining two (6.7%) did so by calling the provided Freephone telephone number.

Follow-up reminder reminder. A total of 21 people (13.3%) responded to the self-referral reminder within 4 weeks. Subsequently, 134 follow-up reminders were sent with a further nine (6.7%) responses received within the remaining 8-week response

Figure 2. Basic design of the study.

Appendices

Table 2. Sample characteristics of the resident population

<table>
<thead>
<tr>
<th>Gender</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>68</td>
<td>43.9</td>
</tr>
<tr>
<td>Female</td>
<td>87</td>
<td>56.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Area</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brent</td>
<td>76</td>
<td>49.0</td>
</tr>
<tr>
<td>Harlem</td>
<td>79</td>
<td>51.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>tertile of deprivation (IMD score)</th>
<th>n attended (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>tertile 1 (least deprived)</td>
<td>31</td>
</tr>
<tr>
<td>tertile 2</td>
<td>63</td>
</tr>
<tr>
<td>tertile 3 (most deprived)</td>
<td>62</td>
</tr>
</tbody>
</table>

Table 3. Uptake following the reminders by gender, tertiles of the index of Multiple Deprivation and location in the eligible sample (n = 153)

<table>
<thead>
<tr>
<th>Comparisons</th>
<th>n attended (%)</th>
<th>OR (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>24 (15.5)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>10 (6.6)</td>
<td>—</td>
<td>0.77</td>
</tr>
<tr>
<td>Female</td>
<td>14 (9.7)</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Location</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brent</td>
<td>15 (15.8)</td>
<td>1.00 (0.53-2.00)</td>
<td>0.98</td>
</tr>
<tr>
<td>Harlem</td>
<td>9 (9.7)</td>
<td>1.00 (0.53-2.00)</td>
<td>0.98</td>
</tr>
</tbody>
</table>

Period. No responses were received beyond the 12-week cut-off period.

Preference for day and time slot of appointment. Of the 30 people who self-referred for a BSS appointment, 24 (80%) expressed a preference for a specific day and/or time. It was not possible to accommodate preferences for 12 people (50%); only one went on to cancel.

Preference for gender of practitioner. Of the 30 people who self-referred for a BSS appointment, 27 (90%) indicated a preference for a same-sex practitioner; none (0%) indicated a preference for a practitioner of the opposite sex; and three (10%) gave no preference. It was not possible to accommodate the preference of eight (30%) people; however, no-one asked to be rescheduled. Preferences for the sex of the practitioner were examined by gender: women were significantly more likely to request a same-sex practitioner than men, with all of the women who self-referred for an appointment requesting a same-sex practitioner, compared with two-thirds of men (100% vs 67%); χ² = 7.78, P<0.05.

This feasibility study was initiated to test the format and potential efficacy of incorporating a mailed self-referral reminder and locally tailored information leaflet into the current BSS invitation process.

The reminder, when sent with the locally tailored information leaflet 1 year after the participants’ initial invitation, facilitated uptake in 15.5% of recipients, thereby exceeding the threshold for further investigation in a RCT (n = 24 vs n = 3). The self-referral rate for individuals not sent a 12 months’ reminder during the study period was higher than anticipated (1.2% vs 0.35%); however, our results would have exceeded the minimum level of efficacy even assuming this higher rate (A’Hern, 2001).

The finding that this intervention is feasible and has the potential to improve uptake by this group is highly important; if the findings of this study were replicated in a large RCT, then this simple intervention could have a considerable impact on uptake at St. Mark’s Hospital. A self-referral rate of 15% among previous non-responders would equate to an increase in overall uptake of ~5% (estimated by multiplying the proportion of adults not responding to the initial invitation (0.6) by the proportion of adults attending screening in response to the 12 months’ reminder (0.15)). This would increase overall uptake at St. Mark’s to almost 50%. If similar rates are observed in a multicentre study, the implementation of a 12 months’ reminder in the national programme could have considerable public health benefits (Geerts et al, 2015). Furthermore, additional reminders, possibly at 24, 36 and 48 months, have the potential to increase overall uptake even further. Finally, by a process of elimination such additional reminders would target the most deprived population and could ultimately reduce the socioeconomic gradient in screening attendance.

Our study found that women were more likely to attend in response to the reminder than men. The 12 months’ reminder, therefore, has the potential to reduce the gender gap that has been observed in response to the first invitation (McGregor et al, 2015a). Previous research has indicated that for women particularly, the possibility of having a male endoscopist leading the procedure is a barrier to uptake (Menes et al, 2005), and so the option to allow participants to communicate a preference for the gender of the endoscopist is likely to have explicitly and directly addressed this barrier, thereby encouraging women to re-consider BSS attendance. In addition, it is also likely that the leaflet had a role in facilitating uptake in women specifically, given that it was designed to reduce barriers to FS, and women have been found to report more barriers to the test than men (Wardle et al, 2005).

Although the proportions requesting a same-sex practitioner between men and women were significantly different in our study, the number of men and women self-referring in this study was small (n = 9 and n = 21 respectively) and may not be representative of the proportions of men and women who would request a same-sex practitioner in the general population. For instance, our current study was set in an ethnically diverse area and so the impact of the gender preference option may have been all the more apparent here, as previous research has found the gender of the endoscopist to be a pertinent barrier for black and ethnic minority women (Varadaraju et al, 2002). Future work should aim to explore individual ethnicity when examining preferences for a same-sex practitioner.

Previous research examining uptake of BSS in response to the initial invitation has identified a strong socioeconomic gradient in participation, with rates varying from 33% in the most deprived areas to 53% in the least deprived (McGregor et al, 2015a). In this study, we found no significant differences in participation between tertiles of area-level deprivation (McGregor et al, 2015a); however, it is important to note that the study was not designed to test for differences between tertiles of area-level deprivation, and so may have been underpowered to detect such differences. If the finding were reproduced in a larger trial, the intervention examined in this study may represent a potential strategy to reduce socioeconomic inequalities within the national programme.

The main limitation of this study is that the intervention used contained multiple components (including gender preference, appointment preference and a locally tailored information leaflet) and so without the appropriate control groups the contribution of each factor to the success of the reminder could not be teased apart.
One potential concern regarding the leaflet used in this study is that information within was not balanced. It was specifically designed to promote uptake by addressing the barriers and highlighting the benefits associated with the test. However, as the leaflet supplemented the existing information (i.e., the standard leaflet—which is balanced; the consent form—which outlines the risks of the procedure—and the face to face counseling—during which the risks are discussed with a specialist practicing physician and which the individual must undergo prior to the screening procedure), the requirements of consent when making a screening decision were still met in accordance with the General Medical Council guidelines (General Medical Council, 2008). Nonetheless, to examine satisfaction with the reminder leaflet, we will use waiting room questionnaires and compare responses with individuals receiving the standard NHS leaflet in the subsequent RCT.

At last, it is important to note that in the UK, one in six people have a reading level below that expected of an 11-year-old (Harding et al, 2012); therefore, the leaflet may still have been too difficult for some people to read. Reducing the readability of written information further may have benefits over and above those of the current interventions used within our study; however, for these adults written materials may not be the most suitable. Researchers seeking to reduce inequalities should focus on alternative channels of engaging these adults, such as through community outreach and telephone intervention.

CONCLUSION

This study found that a locally tailored information leaflet and mailed reminder letter, with options for the day and time of the appointment and the gender of the practitioner performing the test, was feasible, efficacious and exceeded a minimum level of efficacy needed to merit further investigation in a RCT.

ACKNOWLEDGEMENTS

We dedicate this article in memory of Professor Jane Wardle (1950-2015). We would like to acknowledge funding support from St. Mark’s Hospital, University College London and Cancer Research UK. KLS has a doctoral studentship funded by St. Mark’s Hospital and UCL. LMM is funded by a CRUK Project Grant (C27064/A17326) Awarded to CMV. We would also like to thank acknowledge St. Mark’s Hospital for supporting this project. In particular, we would like to acknowledge the contributions of Lorraine Gorman and Shalla Kumar, whose advice and support from initial conception to completion were invaluable to this study.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

REFERENCES

Logan RD, Patrick J, Nickerson C, Coleman L, Rutter MD, von Wagner C (2012) Outcomes of the Bowel Cancer Screening Programme (BCSP) in
Screening (Flexible Sigmoidoscopy) Screening in the English National Programme: the first 14 months. J Med Screen; e-pub ahead of print 20
Meneses SB, Israeloni IA, Konno S, Elia GH (2005) Women’s patients’ preference for women physicians is a barrier to colon cancer screening.
Pavone K (1990) X. On the criterion that a given system of deviations from the probable in the case of a correlated system of variables is such that
it can be reasonably supposed to have arisen from random sampling. Philosophical Magazine Series 5 86(302): 137–175.

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copy of this license, visit http://creativecommons.org/licenses/by/4.0/
Appendix 7-2. UCL JRO Insurance confirmation letter.

University College London Hospitals
NHS Foundation Trust

Joint Research Office
Office Location:
1st Floor Maple House
149 Tottenham Court Road
London W1T 7DN

Postal Address:
UCL,
Gower Street
London WC1E 6BT

Email: david.wilson@ucl.ac.uk  Tel No. 020 3447 5199  Fax No 020 7380 0937
Web-sites: www.uclh.nhs.uk; www.ucl.ac.uk/jro

18th August 2014

Mr Robert Kerrison
Epidemiology and Public Health
UCL
1-19 Torrington Place,
London
WC1E 7HB

Dear Robert,

Chief Investigator: Dr Christian von Wagner

Study/Trial Title: Repeat invitations for Bowel Scope Screening non-attenders: A single-stage phase II study exploring the feasibility and basic level of efficacy of repeat invitations to facilitate uptake in previous non-attenders.

Funder: No external funding

UCL Project ID No: 14/0532

Re: Insurance for studies not involving a Clinical Trial of an Investigational Medicinal Product (non-CTIMP) sponsored by UCL

Thank you for completing UCL Insurance Registration Form of 1st August 2014. I am pleased to inform you that the above study, as described in the registration form, is now insured under UCL’s Policy. A copy of the current insurance summary (Certificate of Currency) is attached to this letter.

The policy provides for the legal liabilities (negligence) of UCL and its employees or agents.

This confirmation letter together with the attached summary needs to be submitted to the Research Ethics Committee in support of question A76 for both your NHS REC and,

Director UCL SLMS Research Support Centre, Director R&D UCLH – Professor Monty Mythen
Managing Director UCL SLMS Research Support Centre – Dr Nick McNally

Version 12 9th August 2011
where applicable, NHS R&D applications submitted via the Integrated Research Application System (IRAS).

The UCL insurance policy is renewed annually but studies included in the UCL insurance portfolio will be automatically rolled over into subsequent insurance period(s) until the study terminates. Indemnity and insurance arrangements for any participating sites will be detailed in individual Site Agreements.

Please keep a copy of this letter for your records. Feel free to contact me if you have any queries concerning the insurance cover.

Yours sincerely,

DAVID WILSON
Database & Information Officer

cc. Dr Christian von Wagner, UCL Department of Epidemiology and Public Health
Dr Clara Kalu, Senior Portfolio Co-ordinator, Joint Research Office
Appendix 7-3. UCL Insurance certificate.

14th July 2014

TO WHOM IT MAY CONCERN

We, the undersigned Insurance Brokers hereby certify that we have place the following Insurance:

VERIFICATION OF INSURANCE

Unique Market Reference: B1262 FI0153314

Type: Clinical Trials Insurance

Insured: University College London


Interest: This Policy will indemnify/cover the Insured in respect of their Legal Liabilities arising out of the Insured’s activities and as more fully disclosed within the Policy Wording.

Limit of Indemnity: GBP 15,000,000 Any One Claim and GBP 15,000,000 in the Aggregate, including costs and expenses

Excess: GBP 2,500 Each and Every Claim, including costs and expenses

Underwriter: 100.0000% Newline Syndicate 1218

This document is for information only and does not make the person or organisation to whom it is issued an additional Insured, nor does it modify in any manner the Contract of Insurance between the Insured and the Insurers. Any amendment, change or extension to such Contract can only be affected by specific endorsement attached thereto.

Should the above mentioned Contract of Insurance be cancelled, assigned or changed during the above policy period in such manner as to affect this document, no obligation to inform the holder of this document is accepted by the undersigned or by the Insurers. The information provided is correct at the date of signature.

Authorised Signatory
Gallagher London.
Appendix 7-4. Favourable opinion with conditions.

Health Research Authority
NRES Committee South Central - Oxford B
Whitfords
Level 3, Block B
Leven's Mead
Bristol
BS1 2NT
Telephone: 01173421386
Fax: 01173420445

01 September 2014

Dr Christian von Wagner
Senior Lecturer
University College London
Room 206, 1-19 Torrington Place
University College London
London
WC1E 7HB

Dear Dr von Wagner

Study title: Repeat invitations for Bowel Scope Screening non-attenders: A single-stage phase II study exploring the feasibility and basic level of efficacy of repeat invitations to facilitate uptake in previous non-attenders.

REC reference: 14/SC/1246
IRAS project ID: 145912

The Proportionate Review Sub-committee of the NRES Committee South Central - Oxford B reviewed the above application on 26 August 2014.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager Mr Rajat Khullar, nrescommittee.southcentral-oxfordb@nhs.net.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.
1. Please add the following sentence to the ‘Repeat invitation letter’, “We last invited you for this appointment a year or more ago.”

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission (“R&D approval”) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdfforum.nhs.uk/

Where a NHS organisation’s role in the study is limited to identifying and referring potential participants to research sites (“participant identification centre”), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).
Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion”).

Summary of discussion at the meeting

Informed consent process and the adequacy and completeness of participant information

- The Committee agreed that the previous invitation letter should be referred to in the repeat invitation letter to avoid confusion/imitation for the recipient.

Approved documents

The documents reviewed and approved were:

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Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

There were no declarations of interest.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.
After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at

http://www.hra.nhs.uk/hra-training/

With the Committee’s best wishes for the success of this project.

14/SC/1246 Please quote this number on all correspondence

Yours sincerely

pp Mr Chris Foy
Chair

Email: nrescommittee.southcentral-oxfordb@nhs.net

Enclosures: List of names and professions of members who took part in the review

"After ethical review – guidance for researchers"
Appendices

Copy to: Mrs Smaragda Agathou
Mrs Sunder Chita, North West London Hospitals NHS Trust
NRES Committee South Central - Oxford B

Attendance at PRS Sub-Committee of the REC meeting on 26 August 2014

Committee Members:

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<th>Name</th>
<th>Profession</th>
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<td>Mr Chris Foy</td>
<td>Medical Statistician</td>
<td>Yes</td>
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<tr>
<td>Mr Ian MacKenzie</td>
<td>Retired Consultant / Reader Emeritus in Obstetrics and Gynaecology</td>
<td>Yes</td>
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<tr>
<td>Mrs Kate Thompson</td>
<td>Retired in patient and day hospice manager</td>
<td>Yes</td>
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Also in attendance:

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<thead>
<tr>
<th>Name</th>
<th>Position (or reason for attending)</th>
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<tbody>
<tr>
<td>Mr Thomas Fairman</td>
<td>REC Manager</td>
</tr>
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</table>
Appendix 7-5. Acknowledgement of compliance with conditions.

04 September 2014

Dr Christian von Wagner
Senior Lecturer
University College London
Room 206, 1-19 Torrington Place
University College London
London
WC1E 7HB

Dear Dr Von Wagner

Study title: Repeat invitations for Bowel Scope Screening non-attenders: A single-stage phase II study exploring the feasibility and basic level of efficacy of repeat invitations to facilitate uptake in previous non-attenders.

REC reference: 14/SC/1246
IRAS project ID: 145912

Thank you for your letter of 4th September 2014. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 01 September 2014

Documents received

The documents received were as follows:

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Approved documents

The final list of approved documentation for the study is therefore as follows:

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<tr>
<td>Summary CV for Chief Investigator (Dr) [Dr von Wagner CV]</td>
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<td>31 July 2014</td>
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You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor’s responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

**14/SC/1246**

Please quote this number on all correspondence

Yours sincerely

Mr Thomas Fairman
REC Manager

E-mail: nrescommittee.southcentral-oxford@nhs.net

Copy to: Mrs Smaragda Agathou
Mrs Sunder Chita, North West London Hospitals NHS Trust

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Appendix 7-6. R and D approval letter.

The North West London Hospitals
NHS Trust

R&D Office
Rooms 205, Level 5B6
Northwick Park Hospital
Watford Road, Harrow HA1 3UJ
Tel 020 8969 3011
Fax 020 8969 5081
E-mail: alan.warnes@nwlt.nhs.uk
Website: www.nwlt.nhs.uk/research

NHS Management Approval Letter for Research

To: Dr Christian von Wagner
From: Dr Alan Warnes (Assistant Director of R&D)
RD No: RD14/088
REC Ref: 14/SC/1246
Date: 22/09/2014

Project Title: Repeat invitations for bowel scope screening non-attenders. A single stage phase II study exploring the feasibility and basic level of efficacy of repeat invitations to facilitate uptake in previous non-attenders.

I understand that you have received a favourable ethics opinion for the above project, with the condition that you do not undertake research in an NHS organisation until relevant NHS Management Approval has been received. I am therefore writing on behalf of the North West London Hospitals Trust to inform you that the project has been approved by the Trust and may now proceed.

To maintain this approval, the following conditions must be met:

1. All staff involved in the running of this study must adhere to Trust and Research Governance Framework requirements (see www.nwlt.nhs.uk/research).

2. As Chief/Principal Investigator you are required to formally advise the R&D Office of ANY changes to the project including:
   • Any changes to the status of the project, e.g. abandoned, completed etc
   • Any changes to the protocol – however minor,
   • Any changes to the funding arrangements.

3. The Chief/Principal Investigator is also required to:
   • Notify the R&D, in a timely fashion, any Serious Adverse Events relating to the Research and the appropriate urgent safety measures taken in line with ICH GCP requirements.
   • Ensure that the R&D Office has copies of all annual and final progress reports.
   • Ensure all researchers involved in the project hold the necessary expertise required and have Honorary Contracts should they need to.
   • Ensure adequate and accurate reporting and monitoring of said project.

1 of 2
• Co-operate with all internal Trust monitoring and auditing procedures.

4. This approval will automatically lapse if no annual report on this study is received at the R&D office, 14 months from the date of this letter. A guidance note on Annual reports is available at the R&D Office.

5. This approval has been provided on the basis that the student researcher will not be coming onto the North West London Hospitals Trust site. If this changes, R&D should be informed immediately so code of conduct and letter of access can be put in place.

Yours sincerely,

Dr Alan Warnes
Cc: Sarah Marshall
Robert Kerrison

Attachments:
1. Non-CT_ResearchEssentialDocumentsV1.0_05Oct2007

Approved Working Documents (For R&D Office Reference)

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<tr>
<td>Appendix G – Participant labels – mail merge</td>
<td>1.2</td>
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<td>Appendix H – Completed material ethical issues tool</td>
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<td>Summary CV – Sarah Marshall</td>
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<tr>
<td>Summary CV – Robert Kerrison</td>
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</tbody>
</table>
## Appendix 7-7. Power calculation overview.

<p>| | | | | | |</p>
<table>
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<tbody>
<tr>
<td>$P_0$</td>
<td>$P_1$</td>
<td>$\alpha$</td>
<td>$\beta$</td>
<td>$R+1$</td>
<td>$n$</td>
</tr>
<tr>
<td>0.012</td>
<td>0.0535</td>
<td>0.015</td>
<td>0.01</td>
<td>5</td>
<td>160</td>
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</tbody>
</table>

$P_0 = \text{expected uptake for a poor intervention}$  
$P_1 = \text{expected uptake for a good intervention}$  
$R+1 = \text{the minimum number of self-referred appointments required to merit further investigation in a RCT}$
Appendix 8-1. Publication of Study 3.

Improving uptake of flexible sigmoidoscopy screening: a randomized trial of nonparticipating reminders in the English Screening Programme

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Submitted: 4.5.2016
Accepted after revision: 29.8.2016

Abstract
Background and study aims: Uptake of flexible sigmoidoscopy screening in the English Bowel Scope Screening (BSS) Programme is low. The aim of this study was to test the impact of a nonparticipating reminder and theory-based leaflet to promote uptake among former nonresponders (who did not confirm their appointment) and nonattendees (who had previously confirmed their appointment but did not attend).

Patients and methods: Eligible adults were men and women in London who had not attended a BSS appointment within 12 months of their invitation. Individuals were randomized (1:1:1) to receive no reminder (control), a 12-month reminder plus standard information booklet (TM-RBL), or a 12-month reminder plus bespoke theory-based leaflet (TM-RFL) designed to address barriers to screening.

The primary outcome of the study was the proportion of individuals screened within each group 12 weeks after the delivery of the reminder.

Results: A total of 1383 men and women were randomized and analyzed as allocated (n=462 per trial arm). Uptake was 0.2% (n=1), 10.4% (n=48), and 15.2% (n=76) in the control, TM-RFL, and TM-RBL groups, respectively. Individuals in the TM-RFL and TM-RBL groups were significantly more likely to attend screening than individuals in the control group (adjusted odds ratio [OR]: 53.7, 95% confidence interval [CI]: 7.8–391.4, P<0.001) and OR 89.0, 95% CI 12.3–645.4, P<0.01, respectively). Individuals in the TM-RFL group were also significantly more likely to attend screening than individuals in the TM-RBL group (OR 1.7, 95% CI 1.1–2.5, P<0.01). Across all groups, former nonattendees were more likely to participate in screening than former nonresponders (uptake was 14.2% and 8.0%, respectively: OR 2.5, 95% CI 1.4–4.4, P<0.03). The adenoma detection rate among screened adults was 7.6%, which is comparable to the rate in initial attendees.

Conclusions: Reminders targeting former nonresponders can improve uptake and are effective for both former nonresponders and nonattendees. Theory-based information designed to target barriers to screening added significantly to this strategy.
Appendices

Introduction
In March 2013, NHS England extended its national Bowel Cancer Screening Programme to include once-only flexible sigmoidoscopy screening for men and women aged 55 years [1]. The decision to extend the program and include flexible sigmoidoscopy was made in response to the results of a large UK randomized controlled trial (RCT), which demonstrated that a one-off screen between the ages of 55 and 64 years significantly reduced the incidence and mortality of colorectal cancer (CRC) among screened adults [2].

Uptake of the test (also referred to as bowel scope screening [BSS]) in England is currently very low (only 43% of invites attend an appointment) [3], which will ultimately undermine the clinical effectiveness of the program [4]. Data on uptake in other countries are sparse, but it has been documented to be as low as 29% in regions of Italy [5] and as high as 63% in the Norwegian Colorectal Cancer Prevention Trial [6]. Detailed surveys issued to nonparticipants and their healthcare providers have identified the most prevalent patient-related factors for not attending a flexible sigmoidoscopy appointment as: a lack of current health problems, practical barriers (i.e. inconvenient appointment time/day), worry about pain, discomfort, or injury associated with the examination, and not wanting to know about any health issues [7–8]. Subsequent studies have suggested that interventions which address patient-specific barriers to the test might improve uptake [10, 11]; however, the evidence to support the use of such strategies is inconsistent [12–18].

Organizational changes, such as those affecting the mechanisms for scheduling appointments, self-referral, and patient outreach have been more effective at increasing patient participation [19–23]. Pre-notification letters, timed appointments, and pre-appointment reminders have all been shown to improve uptake of flexible sigmoidoscopy screening and, as with other screening, these specific strategies have been incorporated into the BSS pathway [5, 24–26]. Repeat invitations have additionally been shown to improve uptake of CRC screening tests (such as the fecal occult blood test and colonoscopy) by providing additional opportunities for people to take part [27–29]. In Italy, Senore et al. made similar observations in the context of a flexible sigmoidoscopy-based program when they sent former nonresponders a reminder letter 3 months after the invitation, yielding a 4.5% absolute increase in uptake [5].

In the BSS program, invites who do not attend screening at the age of 55 years can self-refer for the test up until the age of 60, but do not receive a formal reminder of this opportunity. A recent single-arm feasibility study examining the format of a 12-month reminder for a center in London found that, when sent with a bespoke cover letter and information leaflet, the reminder facilitated uptake in 15.5% of former nonresponders [30]. Although highly promising, these current studies of nonresponder reminders are limited to observational data from single-arm trials [5, 30]. The effectiveness of these interventions and some of their key components therefore still require formal evaluation in multi-arm RCTs. One such component requiring further investigation is the bespoke, theory-based leaflet used in the feasibility study [30], which had been designed to address several barriers to screening by providing bespoke information on how to get to the screening center and by including testimonials from locally screened adults [30]. Using local tailoring for the whole program would incur additional financial and logistical costs, which would need to be justified.

Another hitherto untested component of these reminders is their differential impact on specific groups of nonparticipants, as to date current studies have focused exclusively on former nonresponders (i.e. individuals who previously did not confirm nor attend their appointment) [5, 30]. Previous research has shown that individuals who confirm an appointment, but then do not attend (i.e. former nonattenders), are both demographically and qualitatively different from their screened and nonresponding counterparts [31], with previously screened adults having “better subjective health” and “lower levels of deprivation” and former nonresponders having “lower levels of perceived benefits and anticipated regret” and higher levels of “cancer fear and fatalism” [31]. As it stands, there is no published information about the prevalence of this important subgroup of nonparticipants in the English BSS program or how they would respond to interventions inviting them to re-enroll with the program.

The present study therefore set out to extend the evaluation of nonparticipant reminders to increase uptake of flexible sigmoidoscopy screening by: 1) comparing uptake between individuals receiving a reminder compared with usual care (i.e. no reminder) in an RCT; 2) subdividing nonparticipants into former nonattenders and former nonresponders; and 3) testing the added benefit of including a bespoke theory-based leaflet with the reminder.

Patients and methods
Study design and trial setting
We performed a single-blind RCT with three parallel arms in the London Boroughs of Brent and Harrow. Researchers were blinded to the treatment that subjects received until all data had been collected at the end of the study. Because individuals were given a reminder plus the standard information booklet, no reminder, or a reminder plus the locally tailored theory-based leaflet, it was not possible to blind them to the treatment they received. In terms of the study setting, the London Boroughs of Brent and Harrow have below-average uptake (40% vs. 43%, respectively), and individuals living in these boroughs predominantly live in the most ethnically diverse and socioeconomically deprived areas of England [4].

Study population
Eligible adults were men and women registered with a general practice in the London Boroughs of Brent and Harrow. Adults registered with these practices were eligible for inclusion in the study if they had not attended a BSS appointment within 12 months of receiving their invitation. Eligible adults included both those who previously did not respond to the initial invitation at the age of 55 years (former nonresponders) as well as...
those who confirmed an appointment but did not attend (former nonattendees).

**Procedures**

Eligible adults were identified from the NHS Bowel Cancer Screening System (BCSS) [32]. To ensure workforce capacity (i.e., that all self-referred appointments could be facilitated without disruption to routine appointments), eligible adults were enrolled over a 20-week period spanning February to August 2015. On the basis that there was capacity to facilitate an additional five appointments per week, and that 5% of individuals across the three groups would make and attend an appointment each week, we conservatively selected 69 adults for inclusion in the study each week (from a variable weekly total) using simple pseudo-random selection methods [33] (Fig. 1).

Individuals selected for inclusion in the study were then randomly assigned using simple pseudo-random allocation methods (in a 1:1:1 ratio) to receive: no reminder (control); a mailed 12-month reminder plus a standard information booklet (TMR-SIB); or a mailed 12-month reminder plus a locally tailored theory-based leaflet (TMR-TBI) designed to address barriers to screening.

Individuals allocated to the control group were provided with usual care and therefore did not receive a reminder. Individuals allocated to the reminder groups were sent a reminder letter with one of two leaflets, an appointment-request slip, and a freepost return envelope addressed to St Mark’s Bowel Cancer Screening Centre (Fig. 1).

Individuals in both reminder groups were able to book an appointment by returning their appointment-request slip in the freepost envelope provided, thereby initiating a call from a member of the administrative team to arrange an appointment, or by calling the screening center directly on the Freephone telephone number highlighted in the reminder letter.

Individuals not responding to the reminder within 4 weeks were sent a follow-up reminder (Fig. 1), which also included an appointment-request slip, the allocated information leaflet, and a freepost return envelope. Individuals were then given 8 more weeks to respond, after which they were not included in the study results. Individuals who self-referred for the test also received a pre-appointment test-message reminder and telephone call, as per routine appointments at St Mark’s Hospital.

The study was approved by the North East–Tyneside & Wear South Research Ethics Service (Ref: 15/NE/0043) and was registered with the International Standard Randomised Controlled Trials Number Registry for transparency (Trial ID: ISRCTN44293755).

**Intervention details**

Full descriptions of the intervention materials and their development are available in the feasibility study [30].

**12-month reminder**

The 12-month reminder was a personally addressed letter from St Mark’s Hospital that invited recipients to make a new appointment by returning an appointment-request slip or by calling the Freephone telephone number for the screening center (Appendix E1, available online). The reminder also gave recipients the option to express a preference for the day and time
of the appointment, as well as the sex of the practitioner performing the test.

Theory-based leaflet (TMTRBL)

The theory-based leaflet was a locally tailored leaflet co-designed by Reason, a social marketing company specializing in health behavior (see Appendix e2, available online). The development of the leaflet was based on two psychological models of behavior previously used to explain factors associated with uptake [34]: the Health Belief Model [35] and Social Cognitive Theory [36]. To address barriers to participation, the leaflet included an educational/knowledge-building component and several practical components designed to improve self-efficacy (including local transport information and directions to the hospital).

Standard Information booklet

The standard information booklet was the same 16-page booklet that was previously sent with the initial invitation as part of the national program (available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/423928/bowel-scope-screening.pdf). The standard information booklet was developed by King’s Health Partners who developed the booklet in accordance with principles put forth by NHS England’s informed choice initiative [37].

Follow-up reminder

The follow-up reminder was a personally addressed letter from St Mark’s Hospital that reiterated the opportunity to self-refer for screening up until the age of 60 years (Appendix e3, available online).

Measures

Routinely available data on the BCSS were used to verify self-referral and attendance 4 and 12 weeks following the distribution of the 12-month reminder letter. The BCSS was also consulted to obtain the sex, area (i.e. Brent or Harrow), and initial episode status (i.e. former nonresponder or former nonattender) of each person included in the trial. For those who attended an appointment, the BCSS was additionally consulted to obtain the proportion of people screened who had one or more adenomas detected.

An area-based socioeconomic deprivation score was generated for each person by converting individual postalcodes into a score on the 2010 Index of Multiple Deprivation (IMD) [38]. Area-level IMD scores were then categorized into tertiles of their regional distributions to enable comparisons between the most and least deprived areas.

Statistics

Sample size

The sample size (n = 1383) was calculated using a standard test of difference between two proportions. As the study included three trial arms (one receiving usual care and two receiving a reminder with one of two leaflets), the calculation was repeated for each pairwise comparison comprising a primary research question in the planned analysis. The final calculation gave a total sample size requirement of 461 people per trial arm to test for a 5% difference in uptake between any two of the three groups, with expected values of 0%, 5%, and 10% for the control, TMTRBL, and TMTRBL groups respectively. The study was designed to detect differences at the two-sided 5% alpha level with a 20% margin for type II error.

Data analysis

Univariate logistic regression was used to investigate the associations between treatment groups and self-referral and uptake. To counteract the problem of multiple comparisons, we used the Bonferroni correction method, comparing outcomes to an adjusted significance level of 0.015. Adjusted odds ratios (ORs) and 95% confidence intervals (CIs) were calculated using multivariate logistic regression after adjusting for baseline characteristics. To explore possible associations between not attending a confirmed appointment and previous episode status (i.e. former nonattender, former nonresponder), we carried out a subgroup analysis using univariate and multivariate logistic regression.

The adenoma detection rate (ADR) was reported using descriptive statistics; the data were analyzed on an intention-to-treat basis using SPSS software (version 22; IBM Corp., Armonk, New York, USA).

Results

Sample characteristics

The study took place between February and August 2015, with follow-up until October 2015. A total of 1383 adults were randomized and analyzed as allocated. The majority of individuals were registered with a general practice in the London Borough of Brent (n = 928; 67.1%), did not respond to the initial invitation (n = 1255, 90.7%), and were female (n = 727; 52.6%) (Table 1).

Uptake of bowel scope screening

In total, 119 people (8.6%) attended an appointment across all three study groups (Table 2). A further 41 (3.0%) made an appointment, but then either did not attend (n = 21) or cancelled (n = 20), leaving 1223 (88.4%) adult men and women who neither made nor attended an appointment (Table 2).

There was strong evidence of differences in booked and attended appointments between the reminder groups and the control (Table 2). A total of 48 individuals (10.4%) in the TMTRBL group and 70 (15.2%) in the TMTRBL group attended an appointment (Table 2) compared with only 1 (0.2%) in the control group (OR 53.5; 95% CI 7.4–389.1, P < 0.001; OR 82.4, 95% CI 11.4–595.6, P < 0.001 for the TMTRBL and TMTRBL groups, respectively). There was also a strong trend toward differences in uptake between the reminder groups, with individuals in the TMTRBL group being more likely to attend an appointment than individuals in the TMTRBL group (OR 1.9, 95% CI 1.0–2.3, P = 0.03).

Results were similar after adjusting for baseline characteristics in the multivariate analysis (Table 2), with strong evi-
Table 1: Description of the trial population.

<table>
<thead>
<tr>
<th></th>
<th>Control (n=461)</th>
<th>TMR-SIB (n=461)</th>
<th>TMR-TBL (n=461)</th>
<th>Total (n=1383)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Female</td>
<td>261 (56.6)</td>
<td>238 (51.6)</td>
<td>228 (49.5)</td>
<td>727 (52.6)</td>
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<td>Male</td>
<td>200 (43.4)</td>
<td>223 (48.4)</td>
<td>233 (50.5)</td>
<td>656 (47.4)</td>
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<tr>
<td>Area, n (%)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brent</td>
<td>304 (65.9)</td>
<td>302 (65.5)</td>
<td>322 (69.8)</td>
<td>928 (67.1)</td>
</tr>
<tr>
<td>Harrow</td>
<td>157 (34.1)</td>
<td>159 (34.5)</td>
<td>139 (30.2)</td>
<td>455 (32.9)</td>
</tr>
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<td>Tertile of deprivation (IMD score, n (%)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 1 (0.00 – 17.68)</td>
<td>152 (33.0)</td>
<td>144 (31.2)</td>
<td>133 (28.9)</td>
<td>429 (31.0)</td>
</tr>
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<td>Tertile 2 (17.69 – 27.50)</td>
<td>164 (35.5)</td>
<td>162 (35.0)</td>
<td>179 (38.8)</td>
<td>505 (36.5)</td>
</tr>
<tr>
<td>Tertile 3 (27.51 – 80)</td>
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<td>151 (32.8)</td>
<td>144 (31.2)</td>
<td>435 (31.5)</td>
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<td>Missing</td>
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<td>4 (0.9)</td>
<td>5 (1.1)</td>
<td>14 (1.0)</td>
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<tr>
<td>Initial episode status, n (%)</td>
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<tr>
<td>Nonresponder</td>
<td>411 (89.2)</td>
<td>408 (88.5)</td>
<td>436 (94.6)</td>
<td>1255 (90.7)</td>
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<tr>
<td>Nonattender</td>
<td>50 (10.8)</td>
<td>53 (11.5)</td>
<td>25 (5.4)</td>
<td>128 (9.3)</td>
</tr>
</tbody>
</table>

TMR, 12-month reminder; SIB, standard information booklet; TBL, theory-based leaflet; IMD, Index of Multiple Deprivation.

Table 2: Self-referral and uptake by trial arm (univariate and multivariate regression outcomes).

<table>
<thead>
<tr>
<th></th>
<th>Mean, n (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Made an appointment</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Control vs. TMR-SIB</td>
<td>1 vs. 64</td>
<td>74.16 (10.24 – 536.97)</td>
<td>73.27 (10.11 – 531.11)</td>
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<tr>
<td>Control vs. TMR-TBL</td>
<td>1 vs. 95</td>
<td>119.40 (16.67 – 860.49)</td>
<td>130.36 (18.05 – 941.54)</td>
</tr>
<tr>
<td>TMR-SIB vs. TMR-TBL</td>
<td>64 vs. 95</td>
<td>1.61 (1.14 – 2.28)</td>
<td>1.78 (1.25 – 2.50)</td>
</tr>
<tr>
<td>Attended an appointment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control vs. TMR-SIB</td>
<td>1 vs. 48</td>
<td>53.46 (7.35 – 389.05)</td>
<td>53.73 (7.38 – 391.39)</td>
</tr>
<tr>
<td>Control vs. TMR-TBL</td>
<td>1 vs. 70</td>
<td>82.35 (11.39 – 595.58)</td>
<td>89.01 (12.28 – 645.40)</td>
</tr>
<tr>
<td>TMR-SIB vs. TMR-TBL</td>
<td>48 vs. 70</td>
<td>1.54 (1.04 – 2.28)</td>
<td>1.69 (1.13 – 2.52)</td>
</tr>
</tbody>
</table>

OR, odds ratio; CI, confidence interval; n=461 for all groups, respectively.
* Adjusted ORs and 95% CIs are adjusted for sex, area, deprivation, and initial episode status.
* P<0.001
* P<0.01
* P<0.05

Reference: Robert S et al. Improving uptake of... Endoscopy 2017; 48: 35-43

Evidence of significant differences between the reminder groups and control (TMR-SIB vs. control: OR 53.7, 95% CIs 7.4 – 391.4, P<0.001; TMR-TBL vs. control: OR 89.0, 95% CIs 12.3 – 645.4, P<0.001). After adjusting for baseline characteristics, there was also strong evidence for a difference in participation between intervention groups, with individuals in the TMR-TBL group being more likely to book and attend an appointment than individuals in the TMR-SIB group (OR 1.7, 95% CIs 1.1 – 2.5; P=0.01). There was also strong evidence of a difference in uptake by initial episode status after adjusting for study group and other baseline characteristics (Table 3), with former nonattenders being nearly twice as likely to book and attend an appointment than former nonresponders (14.2% vs 8.0%; respectively; OR 2.5, 95% CI 1.4 – 4.4; P=0.01). There was no evidence of an association between screening uptake and sex, regional IMD tertile, or area (all P values >0.05).

Confirmed appointments
A total of 41 individuals booked an appointment but did not attend. Attendance of a confirmed appointment was higher among former nonattenders than former nonresponders (81.8% vs. 73.0%); however, the results of the regression revealed that
there was no significant difference between these two groups (OR 1.4, 95% CI 0.4—4.6) (see Appendix 4). A significant difference in attendance was observed between men and women (80.5% vs. 68.3%), with men being more likely to attend than their female counterparts (OR 2.2, 95% CI 1.0—4.7). There were no significant differences in the nonattendance rate for any of the other covariates included in the analysis (all P values >0.05).

### Adenoma detection rate

Of the 119 individuals who attended an appointment and were screened, 9 (7.6%) had one or more adenomas detected, 6 of whom also met the clinical criteria for colonoscopy and subsequently underwent further examination. No patient was diagnosed with cancer.

### Discussion

This trial was initiated to test the impact of a 12-month reminder compared with usual care in an RCT. It is the first study to subdivide nonparticipants in order to test the effect of long-term reminders on former nonresponders and former nonattenders independently. This study also examined the added benefit of including a bespoke, theory-based leaflet with the reminder by including a third parallel arm to the trial design.

The results of this RCT provide strong evidence to support the use of a 12-month reminder in the national BSS program and highlight an additional benefit of including a bespoke, theory-based leaflet among a group of adults who have previously received the full suite of information as part of the initial invitation (uptake was 0.2%, 10.4% and 15.2% in the control, TMR-SIB, and TMR-TBI groups, respectively).

At the current rate of attendance (43%) [3], inclusion of a 12-month reminder in the national BSS program would increase uptake by approximately 6—9 percentage points (estimated by multiplying the proportion of adults not attending an initial appointment [0.57] by the proportion of adults attending in response to the 12-month reminder either with the SIB [0.10] or the TBI [0.15]), depending on which of the two leaflets were adopted. As uptake was consistent between men and women, as well as between tertiles of socioeconomic deprivation, it is unlikely that implementing a 12-month reminder with either leaflet would exacerbate existing inequalities in participation [3].

It is interesting to note that while uptake did not vary by sex, area, or area-level deprivation, it did vary by previous episode status, with former nonattenders being more likely to book
and attend an appointment than former nonresponders (14.2% vs. 8.0%). One possible explanation for this difference is that former nonattenders, who perceive fewer barriers and more benefits to screening than nonresponders, are qualitatively similar to screened adults, but have difficulty translating their intentions into actions due to circumstantial aspects, such as poor health [31]. Previous research by Ferrer et al. has shown that participation in CRC screening is a behavioral process comprising several qualitatively distinct stages through which individual moves based on their readiness to be screened [39]. Each stage is strongly associated with a specific set of attitudes and beliefs toward the test, and it may be that the interventions used in our study were more effective at facilitating forward-stage transitions in former nonattenders by addressing issues that are specific to those who have already engaged with the program by making an appointment. It is also possible that it may simply be easier to facilitate forward-stage transitions in individuals who have previously responded to the initial invitation than in individuals who have not, and so the higher response in former nonattenders may have been observed for this reason. It is also important to note that, contrary to previous studies suggesting that nonattenders might never translate their intentions into actions [30], we found that the attendance rate for those confirming an appointment was actually higher (although not significantly higher) among former nonattenders than former nonresponders (81.2% and 73.0%, respectively).

Although this particular subgroup of nonparticipants does not comprise a substantial proportion of the population (we find that they only account for approximately 10% of individuals), they do represent a willing group who respond well to these interventions and as such should not be excluded. We also found that women who made an appointment were less likely to attend screening than men who made an appointment (63.3% vs. 80.5%), and this was consistent with previous research on examiners associated with non-attendance [31]. One possible explanation is that women were less likely to attend a screening appointment than men who made an appointment is that women perceive more barriers to flexible sigmoidoscopy screening [40], which make it more difficult for them to attend [8].

It is possible that a telephonic reminder would have been more effective [19–21]. However, telephonic reminders are not considered cost-effective for CRC screening and as such are not recommended by the European Quality Assurance Guidelines for Colorectal Cancer Screening [41]. In addition, the screening center does not have access to patient telephone numbers (unless patients have provided a number in which case they are available for responders and a telephone reminder for the appointment is given). Given this and the results of the present study, we would advocate the adoption of a 12-month mailed reminder for nonparticipants by the national program prior to full population coverage in 2018. From a clinical perspective, this intervention can be considered worthwhile, given that the ADR reported in our study (7.6%) is comparable to the rate associated with the initial invitation (9.8%) [24].

There has been little positive research concerning the impact of theory-based materials on CRC screening rates [12–18], particularly with regard to flexible sigmoidoscopy screening [21]. The finding that the bespoke, theory-based leaflet used in this study was effective is therefore highly promising. Not only does it demonstrate that such materials can be effective, but also that they can be implemented in ways that do not contravene General Medical Council guidelines for informed consent. It is possible that this type of leaflet might also be effective at other stages of the invitation pathway (for instance, if sent with the pre-notification or pre-appointment reminder letters), although it may be that it worked well because it was sent to a group of individuals for whom the standard information was not suitable.

Our study has several limitations. First, we only tested the impact of a 12-month reminder at one screening center and cannot say whether the interventions described here would be as effective outside of the study setting. Furthermore, to ensure endoscopy capacity (i.e., that all appointments could be facilitated), we selected only a proportion of former nonparticipants for this trial and not the entire eligible population. At this point it would be important to investigate the feasibility of rolling out these reminders across the entire eligible population, as well as at other centers. Other factors, such as recent bowel symptoms [8], which are associated with uptake of 85%, could not be examined because our study was embedded within the program, which does not have access to this information. As such, it was not possible to obtain the frequency of people coming forward in response to the reminder for this reason. It would be informative to know whether those coming for the test in response to the reminder had experienced a recent bowel symptom and whether this played a role in their motivation for making an appointment when previously they had not attended. These individuals may be more likely to have bowel disease and thereby benefit from the test. Future studies using questionnaires on reminders might be able to provide more information on this issue. Finally, as the reminder used in this study consisted of multiple components, including a choice of practitioner and options for the time and day of the appointment, it is not clear how much each component contributed to uptake. It would be prudent to evaluate each component independently and to investigate whether additional components, such as general practice endorsement, having the exama administered at the hospital, and offering a prebooked appointment, may augment the observed effect [41].

Consistent with previous studies, the present trial highlights that interventions which target nonresponders to take up screening after a missed appointment can be effective and enhanced in a number of ways [41]. The study is the first to show that sending a reminder to former nonattenders is also effective and that these individuals should receive such reminders alongside former nonresponders. Additional reminders, possibly delivered at 24, 36, and even 48 months might improve uptake even further [27,28]. As an extension of the present trial, we are currently investigating whether there is an added benefit to sending a second reminder 24 months after the initial invitation.
Conclusions

Use of a 12-month reminder in a single center of the English BSS Programme was effective and improved uptake among former nonresponders and nonattenders. Inclusion of a theory-based leaflet added significantly to this strategy, improving uptake further. It is important now to test this strategy across multiple centers and the wider population. If consistent with the current study, implementing a reminder would increase population coverage and consequently increase the number of CRCs prevented by the program.

Acknowledgments

We would like to dedicate this article to Professor Jane Wardle (1950–2015).

We acknowledge funding support from St Mark’s Hospital, University College London (UCL), and Cancer Research UK. R.S.K. has a doctoral studentship funded by St Mark’s Hospital and UCL. L.M.M. is funded by a CRUK Project Grant (C27064/A17326) Awarded to C.V.W. We thank St Mark’s Hospital for supporting this project. In particular, we would like to acknowledge the contributions of Lorraine Gorman and Cheesem Bennet, whose advice and support from initial conception to completion were invaluable to this study.

Competing interests

None

References


Appendices

[29] Piura M, Kaminski MF, Kraszewka E et al. Reimbursement to screening colonoscopy: a randomized controlled trial of reminding letter and invitation to educational meeting on attendance in non-responders to initial invitation to screening colonoscopy (RETROFIT). Eur J Gastroenterol Hepatol 2010; 28: 519–522


[37] Ramirez A, Forbes L. Approach to developing information about NHS cancer screening programmes. King’s Health Partners; 2012


[41] van Kanse L, Patrick J, Sogran N et al. European guidelines for quality assurance in colorectal cancer screening and diagnosis: overview and introduction to the full supplement publication. Endoscopy 2013; 45: S1


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The North West London Hospitals
NHS Trust
St. Mark's Bowel Cancer Screening Centre
St Mark's Hospital
Watford Road
Harrow
Middlesex
HA1 3UJ
Freephone Helpline 0800 707 6060

<ds> <Month> <Year>

<Title> <First Name> <Last Name>
<Address Line 1>
<Address Line 2>
<Address Line 3>
<Address Line 4>
<Postcode>

Dear <Title> <First Name> <Initial> <Last Name>,

NHS No: <NHS Number>

Important information about your health:

We are writing to invite you for bowel scope screening, a new test available only in England that helps prevent bowel cancer. We last invited you for this test about a year ago.

People aged 55+ are most at risk of bowel cancer, this test helps prevent it:
We have written to you because people who are aged 55 and over are the most at risk of developing bowel cancer. Having a Bowel Scope Screening test between the age of 55 & 59 helps prevent you from getting bowel cancer in the future. This is an important test highly recommended for everyone who is 55-59 years of age.

Saving lives
The NHS offers bowel scope screening because it saves lives from bowel cancer.

Bowel scope screening is for people who don't have any signs of bowel cancer. The test is designed to help prevent bowel cancer by finding and removing small growths in the lower bowel before they turn into something more serious. These growths, called polyps, can turn into cancer over a period of years if they are left untreated. Removing these growths halves your risk of getting bowel cancer in the future.

We're lucky in Brent, Harrow and Ealing that we have the opportunity to participate in bowel scope screening. Every month about 270 people take up the test.

What you need to do now
To book your test, simply fill in and post back the form enclosed in the Freepost envelope provided (you don't need a stamp).

We will then arrange a date and time for your bowel scope screening appointment. It takes place locally at St Mark's Hospital, which is a centre of excellence for bowel and gut medicine at Northwick Park.

Please read the enclosed leaflet, which gives more information about the test, and also has stories from people who have already been to St Mark's for bowel scope screening.

If you have any questions, please call the St Mark's Bowel Cancer Screening Centre on 020 8869 3543, or Freephone 0800 707 60 60 to book an appointment.

Yours sincerely,

Sarah Marshall
Clinical Programme Manager, Bowel Scope Screening

1/2
IMPORTANT – PLEASE CHECK YOUR DETAILS AND RETURN IN THE FREEPOST ENVELOPE

Name: <Title> <First Name> <Last Name>
NHS Number: <NHS Number>
Post Code: <Postcode>

Please fill in your details (either your home telephone number or your mobile number is required; this is so we can contact you to confirm your appointment):

Home number: _______________________
Mobile number: _______________________

Please tick this box if you would like to have a bowel scope screening appointment:

☐ I’d like to arrange a bowel scope screening appointment at St Mark’s Hospital in Harrow.

Please tick your preference:

☐ I would prefer to have a Male practitioner to perform my test.
☐ I would prefer to have a Female practitioner to perform my test.

Please tick as appropriate: My preferred appointment time(s) would be:

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When we receive your form, we’ll contact you with a suggested date and time for your appointment.

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Appendices


The North West London Hospitals NHS
St. Mark’s Bowel Cancer Screening Centre
St Mark’s Hospital
Watford Road
Harrow
Middlesex
HA1 3U

Freephone Helpline 0800 707 6060

Dear <First Name> <Last Name>,
NHS No.: <NHS Number>

Important information about your health:

We are writing to invite you for bowel scope screening, a new test available only in England that helps prevent bowel cancer. We last invited you for this test about a year ago.

People aged 55+ are most at risk of bowel cancer, this test helps prevent it:

We have written to you because people who are aged 55 and over are the most at risk of developing bowel cancer. Having a Bowel Scope Screening test between the age of 55 & 59 helps prevent you from getting bowel cancer in the future. This is an important test highly recommended for everyone who is 55-59 years of age.

Saving lives

The NHS offers bowel scope screening because it saves lives from bowel cancer.

Bowel scope screening is for people who don’t have any signs of bowel cancer. The test is designed to help prevent bowel cancer by finding and removing small growths in the lower bowel before they turn into something more serious. These growths, called polyps, can turn into cancer over a period of years if they are left untreated. Removing these growths halves your risk of getting bowel cancer in the future.

We’re lucky in Brent, Harrow and Ealing that we have the opportunity to participate in bowel scope screening. Every month about 270 people take up the test.

What you need to do now

To book your test, simply fill in and post back the form enclosed in the Freepost envelope provided (you don’t need a stamp).

We will then arrange a date and time for your bowel scope screening appointment. It takes place locally at St Mark’s Hospital, which is a centre of excellence for bowel and gut medicine at Northwick Park.

Please read the enclosed leaflet, which gives more information about the test.

If you have any questions, please call the St Mark’s Bowel Cancer Screening Centre on 020 8869 3543, or Freephone 0800 707 6060 to book an appointment.

Yours sincerely,

Sarah Marshall
Clinical Programme Manager, Bowel Scope Screening

1/2
IMPORTANT – PLEASE CHECK YOUR DETAILS AND RETURN IN THE FREEPOST ENVELOPE

Name: <Title> <First Name> <Last Name>
NHS Number: <NHS Number>
Post Code: <Postcode>

Please fill in your details (either your home telephone number or your mobile number is required; this is so we can contact you to confirm your appointment):

Home number: __________________________
Mobile number: __________________________

Please tick this box if you would like to have a bowel scope screening appointment:

☐ I'd like to arrange a bowel scope screening appointment at St Mark's Hospital in Harrow.

Please tick your preference:

☐ I would prefer to have a Male practitioner to perform my test.
☐ I would prefer to have a Female practitioner to perform my test.

Please tick as appropriate: My preferred appointment time(s) would be:

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When we receive your form, we’ll contact you with a suggested date and time for your appointment.

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2/2
Appendix 8-4. Follow-up self-referral reminder letter (TMR-TBL).

The North West London Hospitals
NHS Trust
St. Mark’s Bowel Cancer Screening Centre
St Mark’s Hospital
Watford Road
Harrow
Middlesex
HA1 3UU

Freephone Helpline 0800 707 6060

Dear <Title> <First Name> <Initial> <Last Name>,

NHS No: <NHS Number>

Reminder: Please book your appointment - Important information about your health

We recently wrote to invite you for bowel scope screening, a new test available only in England which helps prevent bowel cancer.

Saving Lives
People aged 55+ are most at risk of getting bowel cancer, this test helps to prevent it.

You are being invited because people who are aged 55 and over are the most at risk of developing bowel cancer. Having a Bowel Scope Screening test between the age of 55 & 59 helps prevent you from getting bowel cancer in the future. This is an important test highly recommended for everyone who is 55-59 years of age.

What you need to do
Please read the enclosed leaflet, which gives more information about the test, and also has stories from people who have already been to St Mark’s for bowel scope screening.

To book your test, simply fill in and post back the form overleaf in the Freepost envelope provided (you don’t need a stamp). We will then arrange a date and time for your bowel scope screening appointment. It takes place locally at St Mark’s Hospital. Alternatively, you can Freephone 0800 707 6060 to book an appointment.

If you have any questions, please call the St Mark’s Bowel Cancer Screening Centre on 020 8893 3543.

Yours sincerely,

Sarah Marshall
Clinical Programme Manager, Bowel Scope Screening
IMPORTANT – PLEASE CHECK YOUR DETAILS AND RETURN IN THE FREEPOST ENVELOPE

Name: <Title> <First Name> <Last Name>
NHS Number: <NHS Number>
Post Code: <Postcode>

Please fill in your details (either your home telephone number or your mobile number is required; this is so we can contact you to confirm your appointment):

Home number: ____________________________
Mobile number: ___________________________

Please tick this box if you would like to have a bowel scope screening appointment:

☐ I’d like to arrange a bowel scope screening appointment at St Mark’s Hospital in Harrow.

Please tick your preference:

☐ I would prefer to have a Male practitioner to perform my test.
☐ I would prefer to have a Female practitioner to perform my test.

Please tick as appropriate: My preferred appointment time(s) would be:

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When we receive your form, we’ll contact you with a suggested date and time for your appointment.

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Appendix 8-5. Follow-up self-referral reminder letter (TMR-SIB).

The North West London Hospitals NHS Trust
St. Mark’s Bowel Cancer Screening Centre
St Mark’s Hospital
Watford Road
Harrow
Middlesex
HA1 3UJ
Freephone Helpline 0800 707 5060

Dear <Title> <First Name> <Initial> <Last Name>,
NHS No: <NHS Number>

Reminder: Please book your appointment - Important information about your health

We recently wrote to invite you for bowel scope screening, a new test available only in England which helps prevent bowel cancer.

Saving Lives
People aged 55+ are most at risk of getting bowel cancer, this test helps to prevent it. This test is for people who don't have any signs of bowel cancer.

You are being invited because people who are aged 55 and over are the most at risk of developing bowel cancer. Having a Bowel Scope Screening test between the age of 55 & 59 helps prevent you from getting bowel cancer in the future. This is an important test highly recommended for everyone who is 55-59 years of age.

What you need to do
Please read the enclosed leaflet, which gives more information about the test.

To book your test, simply fill in and post back the form overleaf in the Freepost envelope provided (you don’t need a stamp). We will then arrange a date and time for your bowel scope screening appointment. It takes place locally at St Mark’s Hospital. Alternatively, you can Freephone 0800 707 50 50 to book an appointment.

If you have any questions, please call the St Mark’s Bowel Cancer Screening Centre on 020 8869 3543.

Yours sincerely,

Sarah Marshall
Clinical Programme Manager, Bowel Scope Screening
IMPORTANT – PLEASE CHECK YOUR DETAILS AND RETURN IN THE FREEPOST ENVELOPE

Name: <Title> <First Name> <Last Name>
NHS Number: <NHS Number>
Post Code: <Postcode>

Please fill in your details (either your home telephone number or your mobile number is required; this is so we can contact you to confirm your appointment):

Home number: _____________________
Mobile number: _____________________

Please tick this box if you would like to have a bowel scope screening appointment:

☐ I'd like to arrange a bowel scope screening appointment at St Mark's Hospital in Harrow.

Please tick your preference:

☐ I would prefer to have a Male practitioner to perform my test.
☐ I would prefer to have a Female practitioner to perform my test.

Please tick as appropriate: My preferred appointment time(s) would be:

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When we receive your form, we’ll contact you with a suggested date and time for your appointment.

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Appendix 8-6. UCL JRO Insurance confirmation letter.

University College London Hospitals
NHS Foundation Trust

Joint Research Office
Office Location:
1st Floor Maple House
149 Tottenham Court Road
London W1T 7DN

Postal Address:
UCL,
Gower Street
London WC1E 6BT

Email: david.wilson@ucl.ac.uk  Tel No. 020 3447 5199  Fax No 020 7380 9037
Web-sites: www.uclh.nhs.uk;  www.ucl.ac.uk/iro

17th December 2014

Mr Robert Kerrison
UCL Department of Epidemiology and Public Health
1-19 Torrington Place
London
WC1E 6BT

Dear Mr Kerrison,

Chief Investigator: Dr Christian von Wagner

Study/Trial Title: Repeat invitations for Bowel Scope Screening non-attenders: A three arm single centre Randomised Controlled Trial evaluating the effectiveness of repeat invitations to facilitate uptake in previous non-attenders.

Funder: No external sponsor

UCL Project ID No: 14/0863

Re: Insurance for studies not involving a Clinical Trial of an Investigational Medicinal Product (non-CTIMP) sponsored by UCL

Thank you for completing UCL Insurance Registration Form of 17/12/2014. I am pleased to inform you that the above study, as described in the registration form, is now insured under UCL’s Policy. A copy of the current insurance summary (Certificate of Currency) is attached to this letter.

The policy provides for the legal liabilities (negligence) of UCL and its employees or agents.

This confirmation letter together with the attached summary needs to be submitted to the Research Ethics Committee in support of question A76 for both your NHS REC and, where applicable, NHS R&D applications submitted via the Integrated Research Application System (IRAS).

_______________________________

Director UCL SLMS Research Support Centre, Director R&D UCLH – Professor Monty Mythen
Managing Director UCL SLMS Research Support Centre – Dr Nick McNally

Version 12 9th August 2011
The UCL insurance policy is renewed annually but studies included in the UCL insurance portfolio will be automatically rolled over into subsequent insurance period(s) until the study terminates. Indemnity and insurance arrangements for any participating sites will be detailed in individual Site Agreements.

Please keep a copy of this letter for your records. Feel free to contact me if you have any queries concerning the insurance cover.

Yours sincerely,

DAVID WILSON
Database & Information Officer

cc. Dr Christian von Wagner, UCL Department of Epidemiology & Public Health
Suzanne Emerton, Portfolio co-ordinator, JRO

Director UCL SLMS Research Support Centre, Director R&D UCLH – Professor Monty Mythen
Managing Director UCL SLMS Research Support Centre – Dr Nick McNally

Version 12 9th August 2011
Appendix 8-7. UCL Insurance certificate.

14th July 2014

TO WHOM IT MAY CONCERN

We, the undersigned Insurance Brokers hereby certify that we have placed the following Insurance:

VERIFICATION OF INSURANCE

Unique Market Reference: B1262 FI0153314

Type: Clinical Trials Insurance

Insured: University College London


Interest: This Policy will indemnify/cover the Insured in respect of their Legal Liabilities arising out of the Insured’s activities and as more fully disclosed within the Policy Wording.

Limit of Indemnity: GBP 15,000,000 Any One Claim and GBP 15,000,000 in the Aggregate, including costs and expenses

Excess: GBP 2,500 Each and Every Claim, including costs and expenses

Underwriter: 100,0000% Newline Syndicate 1218

This document is for information only and does not make the person or organisation to whom it is issued an additional insured, nor does it modify in any manner the Contract of Insurance between the insured and the Insurers. Any amendment, change or extension to such Contract can only be affected by specific endorsement attached thereto.

Should the above mentioned Contract of Insurance be cancelled, assigned or changed during the above policy period in such manner as to affect this document, no obligation to inform the holder of this document is accepted by the undersigned or by the Insurers. The information provided is correct at the date of signature.

Authorised Signatory
Gallagher London.
Appendix 8-8. REC approval for RCT.

30 January 2015

Dr Christian von Wagner
Senior Lecturer in Behavioural Research in Early Diagnosis of Cancer
University College London
1-19 Torrington Place
London
WC1E 7HB

Dear Dr von Wagner

Study title: Repeat invitations for Bowel Scope Screening non-attenders: A three-arm single-centre Randomised Controlled Trial evaluating the effectiveness of repeat invitations to facilitate uptake in previous non-attenders.

REC reference: 15/NE/0043
IRAS project ID: 169131

The Proportionate Review Sub-committee of the NRES Committee North East - Tyne & Wear South reviewed the above application on 29 January 2015.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Miss Kathryn Murray, nrescommittee.northeast-tyneandwearsouth@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

A Research Ethics Committee established by the Health Research Authority
Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.cfeforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publicly accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHSHSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

A Research Ethics Committee established by the Health Research Authority
Approved documents

The documents reviewed and approved were:

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Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

A Research Ethics Committee established by the Health Research Authority
After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at

http://www.hra.nhs.uk/hra-training/

With the Committee’s best wishes for the success of this project.

15/NE/0043 Please quote this number on all correspondence

Yours sincerely

Mr Ian Campbell
Chair

Email: nrescommittee.northeast-tyneandwearsouth@nhs.net

Enclosures: List of names and professions of members who took part in the review

“After ethical review – guidance for researchers” [SL-AR2]

Copy to: Miss Suzanne Emerton, University College London
         Mrs Sunder Chita, North West London Hospitals NHS Trust

A Research Ethics Committee established by the Health Research Authority
### NRES Committee North East - Tyne & Wear South

**Attendance at PRS Sub-Committee of the REC meeting in Correspondence**

**Committee Members:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Profession</th>
<th>Present</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ms Sophie Barron</td>
<td>Student</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Miss Christine Bullmore</td>
<td>Emergency Planning Co-ordinator</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Mr Ian Campbell (Chair)</td>
<td>Pharmacy</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

**Also in attendance:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Position (or reason for attending)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miss Kathryn Murray</td>
<td>REC Manager</td>
</tr>
</tbody>
</table>
Appendix 8-9. R and D approval for RCT.

NHS Management Approval Letter for Research

To: Dr Christian von Wagner
From: Dr Alan Warnes (Assistant Director of R&D)
Date: 09/02/2015
R&D No: RD15/011
REC No: 15/NE/0043

Project Title: Repeat invitations for bowel scope screening non-attenders: 3 am RCT

I understand that you have received a favourable ethics opinion for the above project, with the condition that you do not undertake research in an NHS organisation until relevant NHS Management Approval has been received. I am therefore writing on behalf of the North West London Hospitals Trust to inform you that the project has been approved by the Trust and may now proceed.

To maintain this approval, the following conditions must be met:

1. All staff involved in the running of this study must adhere to Trust and Research Governance Framework requirements (see www.nw lh.nhs.uk/research).

2. As Chief/Principal Investigator you are required to formally advise the R&D Office of ANY changes to the project including:
   - Any changes to the status of the project, e.g. abandoned, completed etc
   - Any changes to the protocol – however minor.
   - Any changes to the funding arrangements.

3. The Chief/Principal Investigator is also required to:
   - Notify the R&D, in a timely fashion, any Serious Adverse Events relating to the Research and the appropriate urgent safety measures taken in line with ICH GCP requirements.
• Ensure that the R&D Office has copies of all annual and final progress reports.
• Ensure all researchers involved in the project hold the necessary expertise required and have Honorary Contracts should they need to.
• Ensure adequate and accurate reporting and monitoring of said project.
• Co-operate with all internal Trust monitoring and auditing procedures.

4. This approval will automatically lapse if no annual report on this study is received at the R&D office, 14 months from the date of this letter. A guidance note on Annual reports is available at the R&D Office.

Yours sincerely,

Dr Alan Warnes
Cc: Dr. Robert Kerrison
    Dr. Warren Hyer

Attachments:

Approved Working Documents (For R&D Office Reference)

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor insurance &amp; indemnity (UCL)</td>
<td></td>
<td>17/12/2014</td>
</tr>
<tr>
<td>Other: insurance certificate</td>
<td>B1252F10153314</td>
<td>14/07/2014</td>
</tr>
<tr>
<td>Data protection documents</td>
<td></td>
<td>17/12/2014</td>
</tr>
<tr>
<td>Repeat invitation letter (App B)</td>
<td>1.2</td>
<td>26/12/2014</td>
</tr>
<tr>
<td>St Mark's BSS patient information leaflet (APP C)</td>
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<td>29/07/2014</td>
</tr>
<tr>
<td>Sample size calculation 11.1% difference between control and first round of invitations (APP D)</td>
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<td>26/12/2014</td>
</tr>
<tr>
<td>Sample size calculation 6.67% difference between first and second round of invitations (APP E)</td>
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<td>26/12/2014</td>
</tr>
<tr>
<td>Example study database template (In main)</td>
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<td>26/12/2014</td>
</tr>
<tr>
<td>File (APP F)</td>
<td>Date</td>
<td></td>
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<tr>
<td>-------------</td>
<td>-------------</td>
<td></td>
</tr>
<tr>
<td>Participant labels (APP G)</td>
<td>26/12/2014</td>
<td></td>
</tr>
<tr>
<td>Reminder letter (App H)</td>
<td>26/12/2014</td>
<td></td>
</tr>
<tr>
<td>Letter of support (Christian von Wagner) (APP J)</td>
<td>26/12/2014</td>
<td></td>
</tr>
<tr>
<td>CV - Sarah Marshall (APP M)</td>
<td>26/12/2014</td>
<td></td>
</tr>
<tr>
<td>NHS R&amp;D form</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peer review (APP N)</td>
<td>26/01/2015</td>
<td></td>
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<tr>
<td>Protocol</td>
<td>22/01/2015</td>
<td></td>
</tr>
<tr>
<td>CV - Ci - Christian von Wagner (APP L)</td>
<td>09/05/2014</td>
<td></td>
</tr>
<tr>
<td>CV Student - Robert Kerrison (APP J)</td>
<td>07/01/2015</td>
<td></td>
</tr>
<tr>
<td>Summary synopsis/diagram (APP A)</td>
<td>26/12/2014</td>
<td></td>
</tr>
</tbody>
</table>
## Appendix 8-10. Uptake of self-referred appointment by baseline characteristics and trial arm (univariable and multivariable regression).

<table>
<thead>
<tr>
<th>Group</th>
<th>Attended an appointment n (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR&lt;sup&gt;1&lt;/sup&gt; (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TMR-SIB</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n = 64)</td>
<td>48 (75.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TMR-TBL</strong></td>
<td>70 (73.7)</td>
<td>0.93 (0.45 - 1.93)</td>
<td>0.88 (0.41 - 1.90)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women&lt;sup&gt;a&lt;/sup&gt;</td>
<td>56 (68.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n = 82)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>62 (80.5)</td>
<td>1.92 (0.92 - 3.99)</td>
<td>2.18* (1.00 - 4.74)</td>
</tr>
<tr>
<td><strong>CCG</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brent&lt;sup&gt;a&lt;/sup&gt;</td>
<td>74 (74.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n = 100)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harrow</td>
<td>44 (74.6)</td>
<td>1.03 (0.49 - 2.15)</td>
<td>1.14 (0.44 - 2.94)</td>
</tr>
<tr>
<td>(n = 59)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Deprivation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 1&lt;sup&gt;a&lt;/sup&gt;</td>
<td>38 (77.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n = 49)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 2</td>
<td>41 (69.5)</td>
<td>0.66 (0.28 - 1.57)</td>
<td>0.60 (0.22 - 1.67)</td>
</tr>
<tr>
<td>(n = 59)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 3</td>
<td>39 (78.0)</td>
<td>1.03 (0.40 - 2.65)</td>
<td>1.00 (0.30 - 3.29)</td>
</tr>
<tr>
<td>(n = 50)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Initial episode status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-responder&lt;sup&gt;a&lt;/sup&gt;</td>
<td>100 (73.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n = 137)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-attender</td>
<td>18 (81.8)</td>
<td>1.67 (0.53 - 5.24)</td>
<td>1.38 (0.42 - 4.55)</td>
</tr>
<tr>
<td>(n = 22)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Referral method</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Returned slip</td>
<td>105 (73.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n = 142)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Telephoned</td>
<td>13 (76.5)</td>
<td>1.15 (0.35 - 3.73)</td>
<td>1.04 (0.30 - 3.61)</td>
</tr>
<tr>
<td>(n = 17)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Received a pre-appointment reminder by text and / or by phone</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>46 (67.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n = 68)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>72 (79.1)</td>
<td>1.81 (0.89 - 3.71)</td>
<td>1.67 (0.79 - 3.52)</td>
</tr>
<tr>
<td>(n = 91)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: OR, Odds Ratio; CI, Confidence Interval; CCG, Clinical Commissioning Group
<sup>1</sup>Adjusted ORs and 95% CIs are adjusted for all other co-variates in the table
<sup>a</sup>Reference category; *P < 0.05; **P < 0.01; ***P < 0.001
## Appendix 8-11. Clinical findings.

<table>
<thead>
<tr>
<th>Clinical finding</th>
<th>12-month reminder n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adults who attended screening</strong></td>
<td></td>
</tr>
<tr>
<td>No pathology</td>
<td>54 (45.4)</td>
</tr>
<tr>
<td>Normal mucosal polyps</td>
<td>2 (1.6)</td>
</tr>
<tr>
<td>Inflammatory polyps</td>
<td>2 (1.6)</td>
</tr>
<tr>
<td>Hyperplastic polyps</td>
<td>16 (13.5)</td>
</tr>
<tr>
<td>Adenomatous polyps</td>
<td>9 (7.6)</td>
</tr>
<tr>
<td>Cancer</td>
<td>0</td>
</tr>
<tr>
<td>Other pathology (e.g. diverticulitis, hemorrhoids, etc.)</td>
<td>31 (26.1)</td>
</tr>
<tr>
<td>Not screened – refused consent</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>Not screened – did not meet clinical eligibility criteria</td>
<td>4 (3.4)</td>
</tr>
</tbody>
</table>
## Appendix 8-12. Preference for a same-sex practitioner by trial baseline characteristics and trial arm (univariable & multivariable regression outcomes).

<table>
<thead>
<tr>
<th>Preferred same-sex practitioner</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR(^1) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TMR-SIB(^a) (n = 64)</td>
<td>38 (59.4)</td>
<td>-</td>
</tr>
<tr>
<td>TMR-TBL (n = 95)</td>
<td>71 (74.7)</td>
<td>2.02(^*) (1.03 - 4.00)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women(^a) (n = 82)</td>
<td>65 (79.3)</td>
<td>-</td>
</tr>
<tr>
<td>Men (n = 77)</td>
<td>44 (57.1)</td>
<td>0.35(^**) (0.17 - 0.70)</td>
</tr>
<tr>
<td><strong>CCG</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brent(^a) (n = 100)</td>
<td>68 (68.0)</td>
<td>-</td>
</tr>
<tr>
<td>Harrow (n = 59)</td>
<td>41 (69.5)</td>
<td>1.07 (0.54 - 2.15)</td>
</tr>
<tr>
<td><strong>Deprivation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 1(^a) (n = 49)</td>
<td>34 (69.4)</td>
<td>-</td>
</tr>
<tr>
<td>Tertile 2 (n = 59)</td>
<td>44 (74.6)</td>
<td>1.29 (0.56 - 3.01)</td>
</tr>
<tr>
<td>Tertile 3 (n = 50)</td>
<td>30 (60.0)</td>
<td>0.66 (0.29 - 1.52)</td>
</tr>
<tr>
<td><strong>Initial episode status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-responder(^a) (n = 137)</td>
<td>96 (70.1)</td>
<td>-</td>
</tr>
<tr>
<td>Non-attender (n = 22)</td>
<td>13 (59.1)</td>
<td>0.62 (0.25 - 1.56)</td>
</tr>
</tbody>
</table>

Abbreviations: OR, Odds Ratio; CI, Confidence Interval; CCG, Clinical Commissioning Group
\(^1\)Adjusted ORs and 95% CIs are adjusted for all other co-variates in the table
\(^a\)Reference category
\(^*\)P < 0.05; \(^**\)P < 0.01; \(^***\)P < 0.001
Nagelkerke R square = 0.151
## Appendix 8-13. Ethnicity of adults attending an appointment.

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Screened adults</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
</tr>
<tr>
<td><strong>Asian – Any (n = 52; 44.0%)</strong></td>
<td></td>
</tr>
<tr>
<td>Asian or Asian British – Bangladeshi</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>Asian or Asian British – Indian</td>
<td>42 (35.6)</td>
</tr>
<tr>
<td>Asian or Asian British – Pakistani</td>
<td>5 (4.2)</td>
</tr>
<tr>
<td>Asian or Asia British – Any other Asia British background</td>
<td>4 (3.4)</td>
</tr>
<tr>
<td><strong>White – Any (n = 28; 23.8%)</strong></td>
<td></td>
</tr>
<tr>
<td>White or White British – British</td>
<td>18 (15.3)</td>
</tr>
<tr>
<td>White or White British – Irish</td>
<td>4 (3.4)</td>
</tr>
<tr>
<td>White or White British – Any other White background</td>
<td>6 (5.1)</td>
</tr>
<tr>
<td><strong>Black &amp; Minority Ethnic groups – Any (n = 32; 27.0%)</strong></td>
<td></td>
</tr>
<tr>
<td>Black or Black British – African</td>
<td>6 (5.1)</td>
</tr>
<tr>
<td>Black or Black British – Caribbean</td>
<td>8 (6.8)</td>
</tr>
<tr>
<td>Black or Black British – Any other Black background</td>
<td>3 (2.5)</td>
</tr>
<tr>
<td>Mixed – White and Asian</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>Mixed – White and Black Caribbean</td>
<td>5 (4.2)</td>
</tr>
<tr>
<td>Mixed – Any other Mixed Background</td>
<td>3 (2.5)</td>
</tr>
<tr>
<td>Other Ethnic Groups – Chinese</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>Other Ethnic Groups – Any other Ethnicity</td>
<td>4 (3.4)</td>
</tr>
<tr>
<td><strong>Missing (n = 6; 5.2%)</strong></td>
<td></td>
</tr>
<tr>
<td>Ethnicity not recorded</td>
<td>6 (5.2)</td>
</tr>
</tbody>
</table>
## Appendix 8-14. Preference for a same-sex practitioner by ethnic group (univariable & multivariable regression outcomes).

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Preferred same-sex practitioner n (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR(^1) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White(^a) (n = 28)</td>
<td>38 (60.7)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Asian (n = 52)</td>
<td>71 (71.2)</td>
<td>2.16 (0.80 - 5.84)</td>
<td>1.97 (0.65 - 5.98)</td>
</tr>
<tr>
<td>BME (n = 32)</td>
<td>21 (65.6)</td>
<td>1.94 (0.65 - 5.85)</td>
<td>1.97 (0.54 - 7.18)</td>
</tr>
</tbody>
</table>

Abbreviations: OR, Odds Ratio; CI, Confidence Interval; BME, Black and Minority Ethnic groups

\(^1\)Adjusted ORs and 95% CIs are adjusted for group allocation (trial arm), gender, CCG, deprivation and initial episode status

\(^a\)Reference category

\(^\text{1}\)Nagelkerke R square = 0.234
Appendix 8-15. Associated costs of the reminder and standard information booklet.

### Cost analysis

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity Ordered</th>
<th>Cost (per order)</th>
<th>Cost (per unit)</th>
<th>Units (per person)</th>
<th>12-month reminder</th>
<th>Follow-up reminder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headed Paper</td>
<td>15000</td>
<td>£440.26</td>
<td>£0.03</td>
<td>(2)</td>
<td>922</td>
<td>848</td>
</tr>
<tr>
<td>A5 Envelopes</td>
<td>500</td>
<td>£10.08</td>
<td>£0.02</td>
<td>(1)</td>
<td>461</td>
<td>424</td>
</tr>
<tr>
<td>Pre-paid envelopes</td>
<td>3000</td>
<td>£224.33</td>
<td>£0.075</td>
<td>(1)</td>
<td>461</td>
<td>424</td>
</tr>
<tr>
<td>Business Reply Plus</td>
<td>-</td>
<td>-</td>
<td>£0.27</td>
<td>N/A</td>
<td>37</td>
<td>27</td>
</tr>
<tr>
<td>Toner Cartridge</td>
<td>1</td>
<td>£194.20</td>
<td>£0.00492</td>
<td>(2)</td>
<td>922</td>
<td>848</td>
</tr>
<tr>
<td>Postage (2nd Class)</td>
<td>-</td>
<td>-</td>
<td>£0.27</td>
<td>(1)</td>
<td>461</td>
<td>424</td>
</tr>
<tr>
<td>Standard information booklet</td>
<td>-</td>
<td>-</td>
<td>£0.00</td>
<td>(1)</td>
<td>461</td>
<td>424</td>
</tr>
<tr>
<td>Box of staples</td>
<td>5,000</td>
<td>£0.36</td>
<td>£0.000072</td>
<td>(1)</td>
<td>461</td>
<td>424</td>
</tr>
<tr>
<td><strong>Total direct costs of each reminder</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td><strong>£210.49</strong></td>
<td><strong>£191.69</strong></td>
</tr>
<tr>
<td></td>
<td>Cost</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------------------</td>
<td>---------------</td>
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<tr>
<td>Total direct costs of both reminders</td>
<td>£402.18</td>
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<tr>
<td>Cost per person sent an intervention</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>(£402.18 / 461)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Cost per additional screening attendee</td>
<td>£8.38</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>(£402.18 / 48)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Sensitivity analysis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Cost per additional screening attendee (Lower 95% CI)</td>
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</table>
## Appendix 8-16. Associated costs of the reminder and theory based leaflet.

### Direct costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity Ordered</th>
<th>Cost (per order)</th>
<th>Cost (per unit)</th>
<th>Units (per person)</th>
<th>12-month reminder</th>
<th>Follow-up reminder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headed Paper</td>
<td>15000</td>
<td>£440.26</td>
<td>£0.03</td>
<td>(2)</td>
<td>922</td>
<td>£27.66</td>
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<tr>
<td>A5 Envelopes</td>
<td>500</td>
<td>£10.08</td>
<td>£0.02</td>
<td>(1)</td>
<td>461</td>
<td>£9.22</td>
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<tr>
<td>Pre-paid envelopes</td>
<td>3000</td>
<td>£224.33</td>
<td>£0.075</td>
<td>(1)</td>
<td>461</td>
<td>£34.58</td>
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<tr>
<td>Business Reply Plus</td>
<td></td>
<td></td>
<td>£0.27</td>
<td>N/A</td>
<td>48</td>
<td>£12.96</td>
</tr>
<tr>
<td>Toner Cartridge</td>
<td>1</td>
<td>£194.20</td>
<td>£0.00492</td>
<td>(2)</td>
<td>922</td>
<td>£4.54</td>
</tr>
<tr>
<td>Postage (2nd Class)</td>
<td></td>
<td></td>
<td>£0.27</td>
<td>(1)</td>
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<tr>
<td>Theory-based leaflet</td>
<td>3000</td>
<td>£711.36</td>
<td>£0.237</td>
<td>(1)</td>
<td>461</td>
<td>£109.26</td>
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<tr>
<td>Box of staples</td>
<td>5,000</td>
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<td>£0.000072</td>
<td>(1)</td>
<td>461</td>
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<td>Total direct costs of each reminder</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<td>Cost</td>
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<tr>
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<td>(£612.92 / 55)</td>
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</tr>
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<td></td>
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</tr>
</tbody>
</table>
Appendix 8-17. Uptake in the different study groups and the absolute impact on uptake.

![Uptake by study group](chart.png)

- **Control**: Uptake after initial invitation: 41%; Uptake after 12-Month reminder: 41%
- **TMR-SIB**: Uptake after initial invitation: 6%; Uptake after 12-Month reminder: 47%
- **TMR-TBL**: Uptake after initial invitation: 9%; Uptake after 12-Month reminder: 50%
Use of Two Self-referral Reminders and a Theory-Based Leaflet to Increase the Uptake of Flexible Sigmoidoscopy in the English Bowel Scope Screening Program: Results From a Randomized Controlled Trial in London

Robert S. Kerrison, MSc1 • Lesley M. McGregor, PhD2 • Nicholas Connell, MSc2 • Sarah Marshall, BA1 • Andrew Prentice, MSc2 • John Isitt, BA • Colin J. Rees, FRCP3 • Christian von Wagner, PhD4

Abstract

Background We previously initiated a randomized controlled trial to test the effectiveness of two self-referral reminders and a theory-based leaflet (sent 12 and 24 months after the initial invitation) to increase participation within the English Bowel Scope Screening program.

Purpose This study reports the results following the second reminder.

Methods Men and women included in the initial sample (n = 1,383) were re-assessed for eligibility 24 months after their invitation (12 months after the first reminder) and excluded if they had attended screening, moved away, or died. Eligible adults received the same treatment they were allocated 12 months previously, that is, no reminder ("control"), or a self-referral reminder with either the standard information booklet ("Reminder and Standard Information Booklet") or theory-based leaflet designed using the Behavior Change Wheel ("Reminder and Theory-Based Leaflet"). The primary outcome was the proportion screened within each group 12 weeks after the second reminder.

Results In total, 1,218 (88.1%) individuals were eligible. Additional uptake following the second reminder was 0.4% (25/600), 4.8% (19/399), and 7.9% (29/366) in the control, Reminder and Standard Information Booklet, and Reminder and Theory-Based Leaflet groups, respectively. When combined with the first reminder, the overall uptake for each group was 0.7% (34/461), 14.5% (67/461), and 21.5% (99/461). Overall uptake was significantly higher in the Reminder and Standard Information Booklet and Reminder and Theory-Based Leaflet groups than in the control (odds ratio [OR] = 26.1, 95% confidence interval [CI] = 8.1–84.0, p < .001 and OR = 46.9, 95% CI = 14.7–140.9, p < .001, respectively), and significantly higher in the Reminder and Theory-Based Leaflet group than in the Reminder and Standard Information Booklet group (OR = 1.8, 95% CI = 1.3–2.6, p < .001).

Conclusion A second reminder increased uptake among former nonparticipants. The added value of the theory-based leaflet highlights a potential benefit to reviewing the current information booklet.

Trials Registry Number ISRCTN44293755.

Keywords Colorectal cancer • Screening • Uptake • Flexible sigmoidoscopy • Behavioral science
Introduction

Colorectal cancer is a leading cause of morbidity and mortality throughout the world [1]. Several large randomized controlled trials have shown that a single flexible sigmoidoscopy screen between the ages of 55 and 64 can significantly reduce the incidence and mortality of the disease among people who complete the test [2]. As a result, several countries have begun piloting flexible sigmoidoscopy-based screening programs for the prevention of colorectal cancer [3], with England currently rolling out a national program (referred to as the Bowel Scope Screening program) set to reach full population coverage in 2018.

One of the key determinants of successful screening programs is the ability to achieve high population uptake. In England, all screening and treatment is offered automatically and free of charge through the National Health Service. However, despite being offered automatically and for free, the uptake of bowel scope screening is both low and socioeconomically graded [4]. One recent study found that only 45% of men and women invited for bowel scope screening during the initial implementation of the program attended an appointment, and that uptake was lowest among individuals living in the most deprived areas (uptake ranged from 32% in the most deprived areas to 52% in the least deprived) [4]. This is not a problem exclusive to the UK [5]. In the USA, for example, nearly half (48%) of eligible adults are not up to date with screening recommendations, despite available guidelines and evidence demonstrating their effectiveness [6].

As with other screening programs, the National Health Service bowel scope screening program incorporates specific strategies to maximize uptake (e.g., prenotification letters, reminder letters, timed appointments) [7–9]. Invites receive a prenotification letter shortly after their 55th birthday. They then receive an invitation with a timed appointment 2 weeks thereafter. Anyone who does not respond to their invitation within 2 weeks is sent a reminder. If there is no response within an additional 2 weeks, the appointment is cancelled, and the individual is notified via direct mail. Anyone who confirms an appointment, but does not attend, is similarly notified. In both cases, the recipient is informed that they can self-refer for bowel scope screening up until age of 60, when they are eligible for a fecal occult blood test once every 2 years up until the age of 74.

Previous research exploring nonparticipation and decision making in the English Bowel Scope Screening program has identified a number of barriers to uptake, including “a perceived or actual lack of need to have the test”, “an inability to attend the appointment offered”, and “a lack of understanding about the harms and benefits of screening” [10]. One of the subsequent suggestions to improve uptake has been to send nonparticipants an additional reminder at a later date [10], and already there is some evidence to suggest that this may be effective [11].

We ourselves have previously examined the feasibility of sending bowel scope screening nonparticipants a reminder letter and leaflet 12 months after their initial invitation [11]. More specifically, we have previously investigated the feasibility of sending nonparticipants a theory-based leaflet (designed according to principles put forth by the Behavior Change Wheel) [12] and reminder letter (hereafter referred to as a “self-referral reminder”) that gave instructions on how to self-refer and included options for the day and time of the appointment and the gender of the practitioner performing the test [11]. On the basis that (i) the reminder letter and leaflet could be implemented and (ii) would be more effective if sent a second time (i.e., 24 months after the initial invitation) [13–15], we performed a formal randomized controlled trial to test their effectiveness against usual care (i.e., no reminder).

Results from the first stage of the randomized controlled trial (i.e., the first reminder) demonstrated that sending nonparticipants a single self-referral reminder, 12 months after their initial invitation, significantly increased participation against usual care, and that reminders were more effective when sent with the theory-based leaflet, as opposed to the standard information booklet used by the bowel scope screening program [16]. Results from the second stage of the randomized controlled trial have not previously been examined.

This study reports the “additional” and “overall” uptake of bowel scope screening following the second reminder. Our specific aims were to (i) examine whether a second self-referral reminder increased the uptake of screening among former nonparticipants; (ii) assess the cumulative effect of the two self-referral reminders combined; and (iii) test whether the effect of the theory-based leaflet on participation was sustained after the delivery of a second reminder.

Methods

Study Population, Design, and Trial Setting

We performed a single-blinded, randomized, controlled trial with three parallel arms in the London boroughs of Brent and Harrow. One thousand three hundred and eighty-three men and women randomly selected from a weekly variable total of nonparticipants were randomized (using simple pseudo-random allocation methods) to receive either (1:1:1) no reminder (control, n = 461), a 12-month self-referral reminder and standard information booklet (Reminder and Standard Information Booklet, n = 461), or a 12-month self-referral reminder and theory-based leaflet designed using the Behavior
Change Wheel (Reminder and Theory-Based Leaflet, \( n = 461 \)). Anyone who did not attend an appointment within 12 weeks of being sent the 12-month reminder (or no reminder in the case of the control) was re-assessed for eligibility 24 months after their initial invitation (i.e., 12 months after the first reminder). Individuals who had (i) taken part in screening, (ii) registered with a general practice outside of the London boroughs of Brent and Harrow, or (iii) died were excluded. The remaining population were considered “eligible” and assigned to receive the same treatment they received 12 months previously.

Because individuals were assigned to receive no reminder or a self-referral reminder with one of two leaflets, it was not possible to blind them to the treatment they received. In terms of the study setting, the London boroughs of Brent and Harrow have below-average uptake and contain some of the most ethnically diverse and socioeconomically deprived areas in England [17].

**Procedures**

Eligibility was re-assessed using routine data stored on the National Health Service Bowel Cancer Screening System: an electronic system that provides up-to-date uptake data for individuals enrolled in the national screening program [18]. Individuals in both reminder groups were able to book an appointment by returning an “appointment-request-slip” to St Mark’s Bowel Cancer Screening Centre (the screening center where appointments for people living in Brent and Harrow take place), thereby initiating a call from a member of the administrative team to arrange an appointment, or by calling the screening center directly on the Freephone number provided in the reminder letter. Anyone not responding to the “24-month” self-referral reminder within 4 weeks was sent a “follow-up” reminder, which also included an appointment-request slip, the allocated information leaflet, and a Freepost return envelope addressed to St Mark’s Bowel Cancer Screening Centre. Individuals were given an additional 8 weeks to respond before their attendance was assessed on the Bowel Cancer Screening System. Anyone referring for an appointment after this time was excluded from the study results, but was still offered an appointment. Individuals who referred for bowel scope screening were sent a pre-appointment text message and telephone call (where a mobile/home telephone number was available), as per routine practice.

**Intervention Development**

The intervention strategy was informed by the Behavior Change Wheel [12], which was used (in conjunction with the Behavior Change Technique Taxonomy [19]) to identify the putative targets for change and the behavior change techniques likely to affect those targets. We began by defining the problem in behavioral terms (see online Supplementary material for the completed worksheets), before selecting and specifying the target behavior and identifying what needed to change (in COM-B terms) for the behavior to occur. We then identified the intervention functions and policy categories that would be most likely to bring about the desired change and reviewed the possible behavior change techniques and modes of delivery that could be used to deliver them.

After identifying the intervention strategy (Table 1), we developed the intervention content. We did this by the following methods: (i) reviewing the literature examining the perceived barriers and benefits of screening, (ii) interviewing previously screened adults, and (iii) contacting the local primary care cancer leads to obtain a local primary care endorsement. An overview of these activities and how they were used to develop the intervention content is provided in Table 2.

Initial versions of the intervention materials were developed by Partners in Creation: a social marketing company that specializes in the development of health behavior change interventions [20]. We provided them with a
Table 2  Overview of the intervention design

<table>
<thead>
<tr>
<th>Behavior change technique</th>
<th>Definition</th>
<th>Examples of use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pros and cons</td>
<td>Advise the person to identify reasons for wanting (pros) or not wanting (cons) to change behavior</td>
<td>A list of the benefits of bowel scope screening was added to the leaflet</td>
</tr>
<tr>
<td>Demonstration of the behavior</td>
<td>Provide an observable sample of the performance of the behavior, directly in person or indirectly (e.g., via film, pictures) for the person to aspire to or imitate</td>
<td>Testimonials of people who had performed the behavior were added to the leaflet</td>
</tr>
<tr>
<td>Credible source</td>
<td>Present verbal or visual communication from a credible source in favor or against the behavior</td>
<td>A primary care endorsement from the General Practice Cancer Lead endorsing the National Health Service Bowel Scope Screening program was added to the leaflet</td>
</tr>
<tr>
<td>Prompts/cues</td>
<td>Introduce or define environmental or social stimuli with the purpose of prompting or cueing the behavior. The prompt or cue would normally occur at the time or place of performance</td>
<td>A prompt was added to the intervention strategy by developing a “self-referral” reminder letter and a “follow-up” reminder letter</td>
</tr>
<tr>
<td>Instruction on how to perform a behavior</td>
<td>Advise or agree on how to perform a behavior</td>
<td>Instructions on how to self-refer for bowel scope screening were added to the reminder letter</td>
</tr>
<tr>
<td>Adding objects to the environment</td>
<td>Add objects to the environment in order to facilitate performance of the behavior</td>
<td>Several “objects” or facilitators were added to the reminder letters, including an “appointment-request slip” and a Prepost return envelope</td>
</tr>
<tr>
<td>Information about health consequences</td>
<td>Provide information (e.g., written, verbal, visual) about health consequences of performing the behavior</td>
<td>Information about the health consequences of bowel scope screening (e.g., reduced risk of colorectal cancer incidence and death) was added to the reminder letters</td>
</tr>
</tbody>
</table>

briefly outlining the intervention strategy/content described in Tables 1 and 2. The drafted materials were then tested in a co-design workshop in which screening eligible adults from the London boroughs of Brent and Harrow (n = 4; 3 men, 1 woman; aged 55–58 years) gave feedback to inform future iterations of the materials. Revised versions were then presented to individuals who were either the eligible age or approaching the eligible age for screening (n = 20; 12 women, 8 men, aged 50–59 years) and feedback obtained through interviews conducted by a member of the University College London (UCL) research team. The final materials used in the trial are described under Intervention Development.

24-Month reminder

The 24-month reminder was a personally addressed letter from St Mark’s Bowel Cancer Screening Centre that invited recipients to make an appointment by returning an “appointment-request slip” or calling the Freephone number for St Mark’s Bowel Cancer Screening Centre (see online Supplementary material). The reminder also gave recipients the option to express a preference for the day and time of the appointment and the gender of the practitioner performing the test.

Theory-based leaflet

The theory-based leaflet was a locally tailored leaflet designed to promote bowel scope screening attendance at St Mark’s Hospital in London. The leaflet included testimonials from individuals previously screened at the center, as well as a primary care endorsement of the screening test and a list of the benefits of having the test (see online Supplementary material).

Follow-up reminder

The follow-up reminder was a personally addressed letter from St Mark’s Bowel Cancer Screening Centre that reiterated the opportunity to self-refer for screening up until the age of 60 (see online Supplementary material). It was included on the basis that additional reminders/prompts have been shown to have benefits over and above those of single reminders used by themselves [21]. The timing for the follow-up reminder was based on the program reminder, which is sent 4 weeks after the first contact.

Standard information booklet

The standard information booklet was the same 16-page booklet sent with the initial invitation as part of the national screening program (available from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/423929/bowel-scope-screening.pdf). The standard information booklet was developed by King’s Health Partners, who developed the booklet in accordance with the principles put forth by England’s National Health Service informed choice initiative [22].
Appendices

Measures

 Routinely available data stored on the Bowel Cancer Screening System were used to verify self-referral and attendance 4 and 12 weeks following the distribution of the 24-month self-referral reminder letter. The Bowel Cancer Screening System was also consulted to obtain the eligibility of each person, as well as their gender (male, female), area (Brent, Harrow), and initial episode status (did not respond, did not attend). For individuals who self-referred for an appointment, the Bowel Cancer Screening System was additionally consulted to obtain the method of referral (by letter, by telephone) and whether they received a pre-appointment text message and/or telephone call (coded as “received a pre-appointment reminder: yes/no”). Lastly, for individuals who attended an appointment, the Bowel Cancer Screening System was consulted to obtain the clinical outcome and thereby the proportion of people who had one or more precancerous lesions (adenomas) detected.

 An area-based socioeconomic deprivation score was generated for each person by converting their postcode into a score on the 2010 Index of Multiple Deprivation [23]. An area-level Index of Multiple Deprivation scores were then categorized into tertiles of their regional distributions to enable comparisons between the most and least deprived areas.

Sample Size

 The primary outcome was the overall uptake of screening within each group 12 weeks after the delivery of the second reminder (sent 24 months after the initial invitation). A sample size of 420 men and women per trial arm was required to detect a difference in uptake from 10.7% to 17.7% [24] in the Reminder and Standard Information Booklet and Reminder and Theory-Based Leaflet groups, respectively ($n = 0.05; \beta = 0.2$). This was increased to 460 per arm to account for dropout during reminder intervals, giving a total sample size requirement of $n = 1,380$.

Analysis

 The number and percentage of patients screened within 12 weeks of the second reminder are presented with two-sided 95% confidence intervals (CIs), constructed using exact methods based on the binomial distribution. Odds ratios (ORs), adjusted ORs (aORs), and 95% CIs comparing the uptake in each group were calculated using univariable and multivariable logistic regression to adjust for baseline characteristics. Benjamini corrections and an adjusted significance level of 0.015 were used to account for multiple comparisons. Subgroup analyses were carried out to explore possible associations between not attending a confirmed appointment and (i) baseline characteristics, (ii) method of referral, and (iii) receipt of a pre-appointment text/telephone call. The adenoma detection rate was reported using descriptive statistics. The cumulative data were analyzed on an intention-to-treat basis using SPSS (ver.24).

Cost Analysis

 We calculated the cost per additional attendee by dividing the cost of the self-referral reminder and follow-up reminder (with the standard information booklet and theory-based leaflet separately) by the number of people who attended screening at 12 and 24 months. We also performed a sensitivity analysis by calculating the range of variation of the cost estimates within the CIs of the participation rates (calculated using exact methods based on the binomial distribution).

Ethics

 The study was approved by the North-East Tyne & Wear South Research Ethics Service (Ref: 15/NE/0043) and was registered with the International Standard Randomized Controlled Trials Number Registry for transparency (trial ID: ISRCTN44293755).

Results

Sample Characteristics

 This study took place between February and August, 2016, with follow-up until October, 2016. In total, 1,264 (91.4%) out of 1,383 men and women from the initial sample were re-assessed for inclusion in this analysis (Fig. 1). One hundred and nineteen (8.6%) were known to have already taken part in screening and were not assessed for this reason. Of the 1,264 adults who were re-assessed, 8 (0.6%) had died, and 38 (2.8%) were no longer registered with a general practice in the London boroughs of Brent and Harrow, leaving a total sample size of 1,218 men and women who were eligible for inclusion across all three study groups (control, $n = 453$; Reminder and Standard Information Booklet, $n = 399$; Reminder and Theory-Based Leaflet, $n = 366$).

The basic attributes of each group are presented in Table 3. All participants were aged 57 because of the study design. Most (53.4%) were females ($n = 650$), registered with a general practice in the London borough of Brent ($n = 816/67.0%) and did not respond to the initial invitation ($n = 1,072, 88.0%)
Appendices

Fig. 1. CONSORT diagram.

Uptake (24-Month Reminder)

In total, 50 (4.1%) men and women who received the 24-month reminder attended a screening appointment across all three study groups. A further 7 (0.6%) made an appointment, but either did not attend (n = 4) or cancelled (n = 3), leaving 1,161 (95.3%) individuals who neither made nor attended an appointment.

The percentage of people who booked and attended an appointment within each group was 0.4% (n = 2, 95% CI = 0.0–1.6), 4.8% (n = 19, 95% CI = 2.9–7.3), and 7.9% (n = 29, 95% CI = 5.4–11.2) in the control, Reminder and Standard Information Booklet, and Reminder and Theory-Based Leaftlet groups respectively. Sending a second self-referral reminder 24 months after the initial invitation therefore further increased screening uptake and was significantly more effective than usual care.

Uptake (12- and 24-Month Reminder Combined)

In the combined data, we found that 169 (12.2%) men and women had booked and attended an appointment across all three study groups (Table 4). A further 43 (3.1%) made an appointment, but subsequently did not attend (n = 25) or cancelled (n = 18), leaving 1,171 (84.7%) who neither made nor attended an appointment. There was strong evidence of differences in booked and attended appointments between the reminder groups and the control (Table 5). A total of 67 individuals (14.5%) in the Reminder and Standard Information Booklet group and 99 individuals (21.5%) in the Reminder and Theory-Based Leaftlet group attended an appointment, compared with only 3 (0.7%) in the control (OR = 25.96, 95% CI = 8.10–83.18, p < .001 and OR = 41.75, 95% CI = 13.13–122.76, p < .001 for the Reminder and Standard Information Booklet and Reminder and Theory-Based Leaftlet groups, respectively). There was also strong evidence of a difference in uptake between the reminder groups, with individuals in the Reminder and Theory-Based Leaftlet group being significantly more likely to attend an appointment than individuals in the Reminder and Standard Information Booklet group (OR = 1.61, 95% CI = 1.14–2.26, p = .006).

Results were similar after adjusting for baseline characteristics in the multivariable analysis (Table 5), with strong evidence of differences in uptake between
Table 3 Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Control (n = 453)</th>
<th>Rem-SIB (n = 399)</th>
<th>Rem-TBL (n = 366)</th>
<th>Total (n = 1,218)</th>
<th>p² (p Value)</th>
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</tr>
<tr>
<td>Female</td>
<td>255 (56.3)</td>
<td>213 (53.4)</td>
<td>182 (49.7)</td>
<td>650 (53.4)</td>
<td>3.24</td>
</tr>
<tr>
<td>Male</td>
<td>198 (43.7)</td>
<td>186 (46.6)</td>
<td>184 (50.3)</td>
<td>560 (46.6)</td>
<td>.157</td>
</tr>
<tr>
<td><strong>Area</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>300 (66.2)</td>
<td>259 (64.9)</td>
<td>257 (70.2)</td>
<td>816 (67.0)</td>
<td>2.62</td>
</tr>
<tr>
<td>Urban</td>
<td>153 (33.8)</td>
<td>140 (35.1)</td>
<td>109 (29.8)</td>
<td>402 (33.0)</td>
<td>.209</td>
</tr>
<tr>
<td><strong>Tertile of deprivation (Index of Multiple Deprivation Score) n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 1 (0.00-17.68)</td>
<td>146 (32.7)</td>
<td>128 (32.1)</td>
<td>104 (28.4)</td>
<td>320 (31.2)</td>
<td>2.14</td>
</tr>
<tr>
<td>Tertile 2 (17.69-27.50)</td>
<td>164 (36.2)</td>
<td>141 (35.3)</td>
<td>142 (38.8)</td>
<td>447 (36.7)</td>
<td>.710</td>
</tr>
<tr>
<td>Tertile 3 (27.51-80)</td>
<td>137 (30.2)</td>
<td>126 (31.6)</td>
<td>115 (31.4)</td>
<td>378 (31.0)</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>4 (0.9)</td>
<td>4 (1.0)</td>
<td>5 (1.4)</td>
<td>14 (1.1)</td>
<td></td>
</tr>
<tr>
<td>Initial episode status n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial nonresponder</td>
<td>404 (89.2)</td>
<td>342 (85.7)</td>
<td>326 (89.1)</td>
<td>1,072 (88.0)</td>
<td>2.98</td>
</tr>
<tr>
<td>Initial nonattendee</td>
<td>49 (10.8)</td>
<td>57 (14.3)</td>
<td>40 (10.9)</td>
<td>146 (12.0)</td>
<td>(226)</td>
</tr>
</tbody>
</table>

Rem-SIB Reminder and Standard Information Booklet; Rem-TBL Reminder and Theory-Based Leaflet.

the reminder groups and the control (Reminder and Standard Information Booklet vs. control: aOR = 26.14, 95% CI = 8.14-83.95, p < .001; Reminder and Theory-Based Leaflet vs. control: aOR = 46.91, 95% CI = 14.68-149.93, p < .001). After adjusting for baseline characteristics, there remained a significant difference in participation between intervention groups, with individuals in the Reminder and Theory-Based Leaflet group being more likely to book and attend an appointment than individuals in the Reminder and Standard Information Booklet group (aOR = 1.80, 95% CI = 1.26-2.55, p < .001). There was also strong evidence of a difference in uptake by initial episode status after adjusting for study group and other baseline characteristics, with former nonattenders (i.e., people who did not attend) being more likely to book and attend an appointment than former nonresponders (i.e., people who did not respond); uptake was 11.4% and 20.3%, respectively (aOR = 2.60, 95% CI = 1.55-4.36; p < .001). There was no evidence of an association between screening uptake and gender, regional Index of Multiple Deprivation tertile, or area (Table 6).

Confirmed Appointments (12- and 24-Month Reminder Combined)

A total of 43 individuals booked an appointment but did not attend. A significant difference in attendance among people who self-refferred was observed between men and women (84.4% vs. 74.5%), with men being more likely to attend their appointment than women (aOR = 2.06, 95% CI = 1.01-4.23, p = .05). A similar difference in uptake was observed between people who received a pre-appointment reminder and people who did not (83.6% vs. 73.6%), although this did not reach statistical significance in the multivariable analysis (aOR = 1.70, 95% CI = 0.84-3.44, p = .14). There was no evidence of differences in nonattendance for any of the other variables included in the analysis, including initial episode status, method of referral and area (see online Supplementary material).

Adenoma Detection Rate (12- and 24-Month Reminder Combined)

Of the 169 men and women who attended an appointment and were screened, 14 (8.5%) had one or more adenomas detected, 7 of whom had adenomas that met the clinical criteria for colotomy and subsequently underwent further examination. One person was diagnosed
Appendices

Table 5  Self-referral and uptake by trial arm (12 and 24 months combined)

<table>
<thead>
<tr>
<th>Made an appointment comparisons</th>
<th>n (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control vs. Rem-SIB</td>
<td>3 vs. 83</td>
<td>33.52**</td>
<td>33.9**</td>
</tr>
<tr>
<td>(60.7 vs. 18.0)</td>
<td>(10.51:106.92)</td>
<td>(10.61:108.36)</td>
<td></td>
</tr>
<tr>
<td>Control vs. Rem-TBL</td>
<td>3 vs. 126</td>
<td>57.42**</td>
<td>65.25**</td>
</tr>
<tr>
<td>(60.7 vs. 27.3)</td>
<td>(18.12:182.00)</td>
<td>(20.48:207.00)</td>
<td></td>
</tr>
<tr>
<td>TMR-SIB vs. Rem-TBL</td>
<td>83 vs. 126</td>
<td>1.71**</td>
<td>1.93**</td>
</tr>
<tr>
<td>(18.0 vs. 27.3)</td>
<td>(1.25:2.34)</td>
<td>(1.39:2.66)</td>
<td></td>
</tr>
<tr>
<td>Attended an appointment comparisons</td>
<td>3 vs. 67</td>
<td>25.96**</td>
<td>26.14**</td>
</tr>
<tr>
<td>Control vs. Rem-SIB</td>
<td>(60.7 vs. 14.5)</td>
<td>(5.10:83.18)</td>
<td>(5.14:83.95)</td>
</tr>
<tr>
<td>Control vs. Rem-TBL</td>
<td>3 vs. 99</td>
<td>41.75**</td>
<td>46.91**</td>
</tr>
<tr>
<td>(60.7 vs. 21.5)</td>
<td>(13.13:132.76)</td>
<td>(14.68:149.93)</td>
<td></td>
</tr>
<tr>
<td>TMR-SIB vs. Rem-TBL</td>
<td>67 vs. 99</td>
<td>1.61*</td>
<td>1.80**</td>
</tr>
<tr>
<td>(14.5 vs. 21.5)</td>
<td>(1.14:2.26)</td>
<td>(1.26:2.55)</td>
<td></td>
</tr>
</tbody>
</table>

n = 461 for all groups reported. Adjusted ORs and 95% CIs are adjusted for gender, area, deprivation, and initial episode status. ORs odds ratios; CI confidence interval; Rem-SIB Reminder and Standard Information Booklet; Rem-TBL Reminder and Theory-Based Leaflet.
*p ≤ .01; **p ≤ .001.

with cancer and was referred for treatment because of their diagnosis. In the multivariable regression (see online Supplementary material), there were no statistical differences in the proportion of individuals who had adenomas detected by trial arm or baseline characteristics (all p values ≥ .05).

Costs

The estimated cost of the interventions per additional person attending screening at 12 months were £8.37 (range: £6.38–£11.17) in the Reminder and Standard Information Booklet group and £8.75 (range: £7.05–£11.14) in the Reminder and Theory-Based Leaflet group (see online Supplementary material for a breakdown of the intervention costs for each group). Costs for both interventions were significantly higher at 24 months (95% CIs did not overlap), with an estimated cost per additional person attending screening of £18.31 (range: £12.00–£29.00) in the Reminder and Standard Information Booklet group and £16.93 (range: £11.97–£24.55) in the Reminder and Theory-Based Leaflet group (see online Supplementary material for a breakdown of the intervention costs).

Discussion

The results of this study provide strong evidence to support the use of a second self-referral reminder within the National Health Service bowel scope screening program and highlight an additional benefit to including a bespoke theory-based leaflet designed using the Behavior Change Wheel (the overall uptake was 0.7%, 14.5%, and 21.3% in the control, Reminder and Standard Information Booklet and Reminder and Theory-Based Leaflet groups, respectively)

At the current rate of attendance (43%) [4], the inclusion of two self-referral reminders within the National Health Service bowel scope screening program would increase uptake by 8.12 percentage-points (estimated by multiplying the proportion of adults not attending an initial appointment [57%] by the proportion of adults attending an appointment following the delivery of the 24-month reminder with either the standard information booklet [14.5%] or the theory-based leaflet [21.5%]), depending on which of the two leaflets were adopted. Given that uptake was consistent between men and women, as well as between tertiles of area-level deprivation, it seems unlikely that implementing these reminders with either leaflet would exacerbate existing inequalities in uptake [4]. Indeed, it is possible that implementing these reminders could in fact reduce inequalities in uptake, given that the proportion of nonparticipants living in the most deprived quintile of areas is greater than the proportion living in the least deprived quintile of areas (48% vs. 68%) [4].

While uptake did not vary by gender or tertile of area-level deprivation, it did vary by initial episode status, with initial nonattenders being more likely to book and attend an appointment than initial nonresponders (20.3% vs. 11.4%). One possible explanation for this is that initial nonattenders (those who perceive fewer barriers and more benefits to screening than initial nonresponders) are qualitatively similar to screened adults, but have
Table 6  Self-referral and uptake by baseline characteristics (12 and 24 months combined)

<table>
<thead>
<tr>
<th>Gender</th>
<th>Made an appointment n [%]</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR (95% CI)</th>
<th>Attended an appointment n [%]</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female (n = 727)</td>
<td>109 (15.0)</td>
<td></td>
<td></td>
<td>82 (11.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (n = 656)</td>
<td>103 (15.7)</td>
<td>1.06 (0.79–1.42)</td>
<td>0.96 (0.71–1.32)</td>
<td>87 (13.3)</td>
<td>1.20 (0.87–1.66)</td>
<td>1.14 (0.81–1.60)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>134 (14.5)</td>
<td></td>
<td></td>
<td>103 (11.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>87 (17.1)</td>
<td>1.22 (0.90–1.65)</td>
<td>1.26 (0.84–1.89)</td>
<td>66 (14.4)</td>
<td>1.35 (0.97–1.88)</td>
<td>1.44 (0.97–2.24)</td>
</tr>
<tr>
<td>Family income</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deprivation</td>
<td>70 (16.3)</td>
<td></td>
<td></td>
<td>58 (13.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 1* (n = 429)</td>
<td>74 (14.7)</td>
<td>0.88 (0.62–1.26)</td>
<td>0.97 (0.63–1.49)</td>
<td>55 (10.9)</td>
<td>0.70 (0.53–1.16)</td>
<td>0.92 (0.59–1.48)</td>
</tr>
<tr>
<td>Tertile 2</td>
<td>67 (15.4)</td>
<td>0.93 (0.65–1.35)</td>
<td>1.09 (0.68–1.76)</td>
<td>56 (12.9)</td>
<td>0.95 (0.64–1.40)</td>
<td>1.22 (0.73–2.10)</td>
</tr>
<tr>
<td>Initial episode status</td>
<td>181 (14.4)</td>
<td></td>
<td></td>
<td>143 (11.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial nonresponder* (n = 1,255)</td>
<td>31 (24.2)</td>
<td>1.90* (1.23–2.93)</td>
<td>2.67** (1.63–4.37)</td>
<td>26 (20.3)</td>
<td>1.98* (1.25–3.35)</td>
<td>2.60** (1.55–4.36)</td>
</tr>
<tr>
<td>Initial nonattender (n = 128)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Adjusted ORs and 95% CIs are adjusted for trial arm and all other covariates in the table.
OR odds ratio; CI confidence intervals; Rem-SIB Reminder and Standard Information Booklet; Rem-TBL Reminder and Theory-Based Leaflet.
*Reference category.
*p ≤ .01; **p ≤ .001.

difficulty translating their intentions into action due to circumstantial aspects, such as poor health [25]. Indeed, previous research by Ferrer and colleagues [26] has shown that participation in colorectal cancer screening is a behavioral process comprised of several qualitatively distinct stages through which individual transition based on their readiness to screen. Each stage is thought to be strongly associated with a specific set of attitudes and beliefs toward the test, and it may be that the interventions used in our study were more effective at facilitating forward stage transitions in initial nonattenders by addressing issues that were specific to them.

Our study also found that, among individuals who made an appointment, women were less likely to attend screening than men (74.5% vs. 84.5%). This was consistent with previous research in which women who stated that they “probably would” or “definitely would” attend screening were less likely to attend than their male counterparts [25]. Given its position within the screening pathway, it seems likely that these differences in uptake between men and women are due to the enema, which has previously been reported as a major barrier for women, but not men [27].

In terms of the clinical findings, the adenoma detection rate (8.3%) was similar to that of initial attenders (i.e., 9.8%) [7]. The rate was also consistent across reminder groups, irrespective of the information used, suggesting that both materials were effective at attracting individuals with colorectal pathology. With regards to reminder intervals (i.e., 12 months vs. 24 months), the study was underpowered to detect whether the total number of adenomas detected increased. Further studies with larger sample sizes are required to test this.

Finally, few previous studies have been able to demonstrate the added value of theory-based materials on colorectal cancer screening rates [28], particularly with regards to flexible sigmoidoscopy screening [8]. The finding that the theory-based leaflet (albeit predominantly with the first reminder) used in this study was effective is, therefore, highly encouraging. Not only does it demonstrate that such materials designed using theory can be effective, but that they can be implemented in ways that
do not contravene General Medical Council guidelines for informed consent (e.g., by being sent after the full suite of information has been received by the patient). Furthermore, the findings from the present study provide evidence to support the use of the Behavior Change Wheel as a framework for developing theory-based interventions. Had we used another approach, the study materials may have been similarly ineffective to those described in the previous literature.

Strengths

This study had several strengths. First, it used a randomized design, which is considered the gold standard in terms of evaluating the effectiveness of public health interventions [29]. Second, it is the first study to examine whether self-referral reminders can increase the uptake of bowel scope screening and, as such, is the first study to show that these are effective without being vulnerable to bias and confounding present in other studies. Finally, the study setting (St Mark’s Bowel Cancer Screening Centre) serves an ethnically diverse population from a range of socioeconomic areas and, as a result, the findings are likely to be generalizable to other London boroughs and international urban settings struggling to reach the European target for acceptable participation [30].

Limitations

As well as several strengths, this study had a number of important limitations: the main one being that we only examined the impact of the interventions at a single center and another being that we only selected a proportion of former nonparticipants for inclusion in the trial—not the entire eligible population. An important next step, therefore, would be to investigate the feasibility of rolling out these reminders across the entire eligible cohort of nonparticipants. On the basis that the first reminder was effective, the English National Health Service have commissioned St Mark’s Hospital to carry out this work at the London center. It is our hope that after the publication of the current findings, the English National Health Service will also commission St Mark’s Hospital to implement and evaluate the use of a 24-month reminder as well.

Another important caveat of our study is that, while our leaflet was largely driven by theory-based insights, some of its characteristics were based on anecdotal evidence, or previous empirical observations. For example, the theory-based leaflet was shorter and had a lower readability score on the basis of previous research highlighting barriers to engaging with written information about colorectal cancer screening by individuals with both low and high literacy [31, 32]. Without additional studies exploring the reasons why people self-referred for screening (in both groups), it is not possible to say why the theory-based leaflet was more effective. Future studies using questionnaires to examine which of the COM-B components were affected by the study materials could also help elucidate how the interventions facilitated behavior change. A factorial randomized controlled trial comparing multiple versions of the theory-based leaflet would ultimately be needed to disentangle which of the behavior change techniques helped to facilitate behavior change and thereby self-referral and uptake.

Finally, our study was limited to routine data stored on the Bowel Cancer Screening System. As such, it was not possible to include other potential predictors of responding to the screening invite and attendance at screening (e.g., previous bowel symptoms, and ethnicity) [23].

Conclusion

Sending former nonparticipants a self-referral reminder 12 and 24 months after their initial invitation was effective at improving uptake and was enhanced by the inclusion of a theory-based leaflet developed using the Behavior Change Wheel. Future studies should focus on the feasibility of implementing these interventions across multiple centers and the wider population of eligible adults.

Supplementary Material

Supplementary material is available at *Annals of Behavioral Medicine* online.

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Compliance with Ethical Standards

Authors’ Statement of Conflict of Interest and Adherence to Ethical Standards All authors declare they have no conflicts of interest.

Primary Data The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication. The funding sources were not involved in any part of the study, including the study design, data collection, data analysis, writing of the report and the decision to submit the paper for publication.

Authors’ Contribution RSK, LMM, JL SM, and CVW conceived the project and designed the interventions. RSK, SM, and AP managed the trial. RSK and AP collected the data. RSK, NC, and CVW analysed the data. RSK, LMM, NC, CR, and CVW interpreted the data. All authors wrote the article.
Appendices

Ethical Approval The study was approved by the North-East Tyne & Wear South Research Ethics Service.(Ref: 15/NE/0045).

References

24. Pearson K. On the criterion that a given system of deviations from the probable in the case of a correlated system of variables is such that it can be reasonably supposed to have arisen from random sampling. Lond Edinb Philos Mag. 1900;50(302):157-175.
32. Smith SK, Trevena L, Nutbeam D, Barratt A, McCaffery KJ. Information needs and preferences of low and high literacy consumers for decisions about colorectal cancer screening utilizing a linguistic model. Health Expect. 2008;11(2):135-156.
Appendix 9-2. Uptake of self-referred appointment by baseline characteristics and trial arm (univariate and multivariate regression).

<table>
<thead>
<tr>
<th>Group</th>
<th>Attended an appointment/ self-referred n (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR(^1) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TMR-SIB(^a)</td>
<td>67 (80.7)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>TMR-TBL</td>
<td>99 (78.6)</td>
<td>0.88 (0.44 - 1.75)</td>
<td>0.85 (0.41 - 1.77)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women(^a)</td>
<td>79 (74.5%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Men</td>
<td>87 (84.5)</td>
<td>1.86 (0.93 - 3.70)</td>
<td>2.06(^*) (1.01 - 4.23)</td>
</tr>
<tr>
<td>CCG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brent(^a)</td>
<td>101 (76.5%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Harrow</td>
<td>65 (84.4)</td>
<td>1.66 (0.80 - 3.47)</td>
<td>1.74 (0.68 - 4.40)</td>
</tr>
<tr>
<td>Deprivation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 1(^a)</td>
<td>57 (82.6)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Tertile 2</td>
<td>55 (74.3)</td>
<td>0.61 (0.27 - 1.37)</td>
<td>0.83 (0.32 - 2.17)</td>
</tr>
<tr>
<td>Tertile 3</td>
<td>54 (83.1)</td>
<td>1.03 (0.42 - 2.54)</td>
<td>1.56 (0.51 - 4.74)</td>
</tr>
<tr>
<td>Initial episode status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-responder(^a)</td>
<td>142 (78.9)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Non-attender</td>
<td>24 (82.8)</td>
<td>1.29 (0.46 - 3.59)</td>
<td>1.08 (0.36 - 3.18)</td>
</tr>
<tr>
<td>Referral method</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Returned slip</td>
<td>138 (78.9%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Telephoned</td>
<td>28 (82.4)</td>
<td>1.25 (0.48 - 3.25)</td>
<td>1.70 (0.84 - 3.44)</td>
</tr>
<tr>
<td>Received a pre-appointment reminder by text and/ or by phone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>64 (73.6)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Yes</td>
<td>102 (83.6)</td>
<td>1.83 (0.93 - 3.60)</td>
<td>0.79 (0.29 - 2.18)</td>
</tr>
</tbody>
</table>

Abbreviations: OR, Odds Ratio; CI, Confidence Interval; CCG, Clinical Commissioning Group
\(^1\)Adjusted ORs and 95% CIs are adjusted for all other co-variates in the table
\(^a\)Reference category
\(^*\)P < 0.05; \(^**\)P < 0.01; \(^***\)P < 0.001
## Appendix 9-3. Clinical findings.

<table>
<thead>
<tr>
<th>Clinical finding</th>
<th>12 and 24 month reminders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults who attended screening</td>
<td>n (%)</td>
</tr>
<tr>
<td>No pathology</td>
<td>74 (44.0)</td>
</tr>
<tr>
<td>Normal mucosal polyps</td>
<td>4 (2.4)</td>
</tr>
<tr>
<td>Inflammatory polyps</td>
<td>4 (2.4)</td>
</tr>
<tr>
<td>Hyperplastic polyps</td>
<td>20 (12.0)</td>
</tr>
<tr>
<td>Adenomatous polyps</td>
<td>14 (8.4)</td>
</tr>
<tr>
<td>Cancer</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Other pathology (.e.g. diverticulitis, hemorrhoids, etc.)</td>
<td>42 (25.3)</td>
</tr>
<tr>
<td>Not screened – refused consent</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Not screened – did not meet clinical eligibility criteria</td>
<td>7 (4.2)</td>
</tr>
</tbody>
</table>
## Appendix 9-4. Adenomas detected by trial arm and baseline characteristics - 12 & 24 month reminder data combined (univariate and multivariate regression).

<table>
<thead>
<tr>
<th></th>
<th>Adenomas detected</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR(^1) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TMR-SIB(^a) (n = 65)</td>
<td>3 (4.6)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>TMR-TBL (n = 93)</td>
<td>11 (11.8)</td>
<td>2.77 (0.74 - 10.36)</td>
<td>2.75 (0.70 - 10.78)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women(^a) (n = 76)</td>
<td>7 (9.2)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Men (n = 82)</td>
<td>7 (8.5)</td>
<td>0.92 (0.31 - 2.76)</td>
<td>0.87 (0.27 - 2.76)</td>
</tr>
<tr>
<td><strong>CCG</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brent(^a) (n = 96)</td>
<td>10 (10.4)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Harrow (n = 62)</td>
<td>4 (6.5)</td>
<td>0.59 (0.18 - 1.98)</td>
<td>0.82 (0.19 - 3.53)</td>
</tr>
<tr>
<td><strong>Deprivation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 1(^a) (n = 53)</td>
<td>2 (3.8)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Tertile 2 (n = 54)</td>
<td>8 (14.8)</td>
<td>4.44 (0.90 - 21.96)</td>
<td>4.48 (0.74 - 25.98)</td>
</tr>
<tr>
<td>Tertile 3 (n = 51)</td>
<td>4 (7.8)</td>
<td>2.17 (0.38 - 12.40)</td>
<td>2.29 (0.31 - 16.95)</td>
</tr>
<tr>
<td><strong>Initial episode status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-responder(^a) (n = 136)</td>
<td>11 (8.1)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Non-attender (n = 22)</td>
<td>3 (13.6)</td>
<td>1.79 (0.46 - 7.02)</td>
<td>2.67 (0.60 - 11.79)</td>
</tr>
</tbody>
</table>

Abbreviations: OR, Odds Ratio; CI, Confidence Interval; CCG, Clinical Commissioning Group
\(^1\)Adjusted ORs and 95% CIs are adjusted for all other co-variates in the table
\(^a\)Reference category
### Appendix 9-5. Adenomas detected by ethnic group - 12 & 24 month reminder data combined (univariable and multivariable regression).

<table>
<thead>
<tr>
<th>Ethnic group</th>
<th>Adenomas detected n (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR(^1) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White(^a)</td>
<td>5 (12.2)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>(n = 41)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>6 (8.3)</td>
<td>0.66 (0.19 - 2.30)</td>
<td>0.49 (0.12 - 1.92)</td>
</tr>
<tr>
<td>(n = 72)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BME</td>
<td>2 (5.1)</td>
<td>0.39 (0.07 - 2.14)</td>
<td>0.29 (0.05 - 1.84)</td>
</tr>
<tr>
<td>(n = 39)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: OR, Odds Ratio; CI, Confidence Interval; BME, Black and Minority Ethnic groups
\(^1\)Adjusted ORs and 95% CIs are adjusted for group allocation (trial arm), gender, CCG, deprivation and initial episode status
\(^a\)Reference category
Table excludes data from the control arm, where no adenomas were detected in screened adults
### Appendix 9-6. Preference for a same-sex practitioner by trial baseline characteristics and trial arm 12 & 24 month reminder data combined (univariate & multivariate regression outcomes).

<table>
<thead>
<tr>
<th>Preferred same-sex practitioner</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR(^1) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TMR-SIB(^a) (n = 83)</td>
<td>55 (66.3)</td>
<td>-</td>
</tr>
<tr>
<td>TMR-TBL (n = 126)</td>
<td>89 (70.6)</td>
<td>1.53 (0.87 - 2.71)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women (n = 106)</td>
<td>81 (76.4)</td>
<td>-</td>
</tr>
<tr>
<td>Men (n = 103)</td>
<td>63 (61.2)</td>
<td>0.38*** (0.21 - 0.68)</td>
</tr>
<tr>
<td><strong>CCG</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brent (n = 132)</td>
<td>89 (67.4)</td>
<td>-</td>
</tr>
<tr>
<td>Harrow (n = 77)</td>
<td>55 (71.4)</td>
<td>1.12 (0.62 - 1.99)</td>
</tr>
<tr>
<td><strong>Deprivation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 1(^a) (n = 69)</td>
<td>51 (73.9)</td>
<td>-</td>
</tr>
<tr>
<td>Tertile 2 (n = 74)</td>
<td>53 (71.5)</td>
<td>0.75 (0.47 - 1.49)</td>
</tr>
<tr>
<td>Tertile 3 (n = 65)</td>
<td>39 (60.0)</td>
<td>1.33 (0.67 - 2.66)</td>
</tr>
<tr>
<td><strong>Initial episode status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-responder(^a) (n = 180)</td>
<td>127 (76.0)</td>
<td>-</td>
</tr>
<tr>
<td>Initial non-attender (n = 29)</td>
<td>17 (58.6)</td>
<td>1.99 (0.90 - 4.39)</td>
</tr>
</tbody>
</table>

*Abbreviations: OR, Odds Ratio; CI, Confidence Interval; CCG, Clinical Commissioning Group; \(^1\)Adjusted ORs and 95% CIs are adjusted for all other co-variates in the table*  
*\(^a\)Reference category*  
*\(^*\)P < 0.05; **P < 0.01; ***P < 0.001*  
*Nagelkerke R square = 0.124*
Appendix 9-7. Ethnicity of adults attending an appointment - 12 & 24 month reminder data combined.

<table>
<thead>
<tr>
<th>Screened adults</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Asian – Any (n = 72; 43.4%)</strong></td>
<td></td>
</tr>
<tr>
<td>Asian or Asian British – Bangladeshi</td>
<td>1 (0.6%)</td>
</tr>
<tr>
<td>Asian or Asian British – Indian</td>
<td>54 (32.5%)</td>
</tr>
<tr>
<td>Asian or Asian British – Pakistani</td>
<td>8 (4.8%)</td>
</tr>
<tr>
<td>Asian or Asia British – Any other Asian background</td>
<td>9 (5.4%)</td>
</tr>
<tr>
<td><strong>White – Any (n = 41; 24.7%)</strong></td>
<td></td>
</tr>
<tr>
<td>White or White British – British</td>
<td>28 (16.9%)</td>
</tr>
<tr>
<td>White or White British – Irish</td>
<td>5 (3.0%)</td>
</tr>
<tr>
<td>White or White British – Any other White background</td>
<td>8 (4.8%)</td>
</tr>
<tr>
<td><strong>Black &amp; Minority Ethnic groups – Any (n = 39; 23.5%)</strong></td>
<td></td>
</tr>
<tr>
<td>Black or Black British – African</td>
<td>8 (4.8%)</td>
</tr>
<tr>
<td>Black or Black British – Caribbean</td>
<td>11 (6.6%)</td>
</tr>
<tr>
<td>Black or Black British – Any other Black background</td>
<td>3 (1.8%)</td>
</tr>
<tr>
<td>Mixed – White and Asian</td>
<td>1 (0.6%)</td>
</tr>
<tr>
<td>Mixed – White and Black Caribbean</td>
<td>6 (3.6%)</td>
</tr>
<tr>
<td>Mixed – Any other Mixed Background</td>
<td>3 (1.8%)</td>
</tr>
<tr>
<td>Other Ethnic Groups – Chinese</td>
<td>2 (1.2%)</td>
</tr>
<tr>
<td>Other Ethnic Groups – Any other Ethnicity</td>
<td>5 (3.0%)</td>
</tr>
<tr>
<td><strong>Missing (n = 14; 8.4%)</strong></td>
<td></td>
</tr>
<tr>
<td>Ethnicity not recorded</td>
<td>14 (8.4%)</td>
</tr>
</tbody>
</table>
Appendix 9-8. Preferences by ethnicity.

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Preferred same-sex practitioner n (%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR(^a) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White(^a) (n = 41)</td>
<td>21 (51.2)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Asian (n = 72)</td>
<td>50 (69.4)</td>
<td>2.57 (0.47 - 14.11)</td>
<td>3.43 (0.55 - 21.58)</td>
</tr>
<tr>
<td>BME (n = 39)</td>
<td>23 (59.0)</td>
<td>1.68 (0.32 - 8.76)</td>
<td>1.68 (0.27 - 10.32)</td>
</tr>
</tbody>
</table>

Abbreviations: OR, Odds Ratio; CI, Confidence Interval; BME, Black and Minority Ethnic groups

\(^a\)Adjusted ORs and 95% CIs are adjusted for group allocation (trial arm), CCG, deprivation and initial episode status

*Reference category
### Appendix 9-9. Subgroup analysis – uptake for baseline characteristics by reminder group - 12 & 24 month reminder data combined.

<table>
<thead>
<tr>
<th></th>
<th>SIB³</th>
<th>TBL</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR¹ (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>32/238</td>
<td>47/228</td>
<td>1.67* (1.02 - 2.73)</td>
<td>1.82* (1.10 - 3.00)</td>
</tr>
<tr>
<td>Male</td>
<td>35/223</td>
<td>52/233</td>
<td>1.54</td>
<td>1.88* (1.14 - 3.11)</td>
</tr>
<tr>
<td><strong>CCG</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brent</td>
<td>39/301</td>
<td>62/321</td>
<td>1.61* (1.04 - 2.49)</td>
<td>1.70* (1.09 - 2.65)</td>
</tr>
<tr>
<td>Harrow</td>
<td>28/160</td>
<td>37/140</td>
<td>1.69</td>
<td>2.00* (1.10 - 3.49)</td>
</tr>
<tr>
<td><strong>Tertile of deprivation (IMD Score)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertile 1</td>
<td>23/144</td>
<td>34/133</td>
<td>1.81* (1.00 - 3.27)</td>
<td>2.08* (1.12 - 3.84)</td>
</tr>
<tr>
<td>(0.00 - 17.68)</td>
<td>(16.0)</td>
<td>(25.6)</td>
<td>(1.00 - 3.27)</td>
<td>(1.12 - 3.84)</td>
</tr>
<tr>
<td>Tertile 2</td>
<td>18/162</td>
<td>37/179</td>
<td>2.10* (1.13 - 3.83)</td>
<td>2.16* (1.17 - 4.00)</td>
</tr>
<tr>
<td>(17.69 - 27.50)</td>
<td>(11.1)</td>
<td>(20.7)</td>
<td>(1.13 - 3.83)</td>
<td>(1.17 - 4.00)</td>
</tr>
<tr>
<td>Tertile 3</td>
<td>26/151</td>
<td>28/144</td>
<td>1.16</td>
<td>1.43</td>
</tr>
<tr>
<td>(27.51 – 80)</td>
<td>(17.2)</td>
<td>(19.4)</td>
<td>(0.64 - 2.10)</td>
<td>(0.77 - 2.69)</td>
</tr>
<tr>
<td><strong>Initial episode status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-responder</td>
<td>55/408</td>
<td>87/436</td>
<td>1.60* (1.11 - 2.31)</td>
<td>1.63** (1.12 - 2.36)</td>
</tr>
<tr>
<td>(13.5)</td>
<td>(20.0)</td>
<td>(1.11 - 2.31)</td>
<td>(1.12 - 2.36)</td>
<td></td>
</tr>
<tr>
<td>Non-attendee</td>
<td>12/53</td>
<td>12/25</td>
<td>3.15* (1.14 - 8.67)</td>
<td>5.76** (1.67 - 19.84)</td>
</tr>
<tr>
<td>(22.6)</td>
<td>(48.0)</td>
<td>(1.14 - 8.67)</td>
<td>(1.67 - 19.84)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: OR, Odds Ratio; CI, Confidence Interval; CCG, Clinical Commissioning Group; IMD, Index of Multiple Deprivation

³Adjusted ORs and 95% CIs are adjusted for all other co-variates in the table

¹Reference category

*P ≤ 0.05; **P ≤ 0.01; ***P ≤ 0.001
## Appendix 9-10. Associated costs of the 24 month reminder intervention and standard information booklet.

### Direct costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity Ordered</th>
<th>Cost (per order)</th>
<th>Cost (per unit)</th>
<th>Units (per person)</th>
<th>24-month reminder</th>
<th>24-month reminder</th>
<th>Follow-up reminder</th>
<th>Follow-up reminder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headed Paper</td>
<td>15000</td>
<td>£440.26</td>
<td>£0.03</td>
<td>(2)</td>
<td>798</td>
<td>£23.94</td>
<td>776</td>
<td>£23.28</td>
</tr>
<tr>
<td>A5 Envelopes</td>
<td>500</td>
<td>£10.08</td>
<td>£0.02</td>
<td>(1)</td>
<td>399</td>
<td>£7.98</td>
<td>388</td>
<td>£7.76</td>
</tr>
<tr>
<td>Pre-paid envelopes</td>
<td>3000</td>
<td>£224.33</td>
<td>£0.075</td>
<td>(1)</td>
<td>399</td>
<td>£29.93</td>
<td>388</td>
<td>£29.10</td>
</tr>
<tr>
<td>Business Reply Plus</td>
<td>-</td>
<td>-</td>
<td>£0.27</td>
<td>N/A</td>
<td>11</td>
<td>£2.97</td>
<td>10</td>
<td>£2.70</td>
</tr>
<tr>
<td>Toner Cartridge</td>
<td>1</td>
<td>£194.20</td>
<td>£0.00492</td>
<td>(2)</td>
<td>798</td>
<td>£3.93</td>
<td>776</td>
<td>£3.82</td>
</tr>
<tr>
<td>Postage (2nd Class)</td>
<td>-</td>
<td>-</td>
<td>£0.27</td>
<td>(1)</td>
<td>399</td>
<td>£107.73</td>
<td>388</td>
<td>£104.76</td>
</tr>
<tr>
<td>Standard information booklet</td>
<td>-</td>
<td>-</td>
<td>£0.00</td>
<td>(1)</td>
<td>399</td>
<td>£0.00</td>
<td>388</td>
<td>£0.00</td>
</tr>
<tr>
<td>Box of staples</td>
<td>5,000</td>
<td>£0.36</td>
<td>£0.000072</td>
<td>(1)</td>
<td>399</td>
<td>£0.03</td>
<td>388</td>
<td>£0.03</td>
</tr>
<tr>
<td>Total direct costs of each reminder</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>£176.51</td>
<td>-</td>
<td>£171.45</td>
</tr>
<tr>
<td>Total direct costs of both reminders</td>
<td>£347.96</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Costs per person sent an intervention</td>
<td>£0.87 (£347.96 / 399)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost per additional screening attendee</td>
<td>£18.31 (£347.96 / 19)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sensitivity analysis**

| Cost per additional screening attendee (Lower 95% CI) | £29.00 (£347.96 / 12) |
| Cost per additional screening attendee (Upper 95% CI) | £12.00 (£347.96 / 29) |
### Appendix 9-11. Associated costs of the 24-month reminder intervention and theory-based leaflet.

#### Direct costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity Ordered</th>
<th>Cost (per order)</th>
<th>Cost (per unit)</th>
<th>Units (per person)</th>
<th>24-month reminder</th>
<th>Follow-up reminder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headed Paper</td>
<td>15000</td>
<td>£440.26</td>
<td>£0.03</td>
<td>(2)</td>
<td>732</td>
<td>£21.96</td>
</tr>
<tr>
<td>A5 Envelopes</td>
<td>500</td>
<td>£10.08</td>
<td>£0.02</td>
<td>(1)</td>
<td>366</td>
<td>£7.32</td>
</tr>
<tr>
<td>Pre-paid envelopes</td>
<td>3000</td>
<td>£224.33</td>
<td>£0.075</td>
<td>(1)</td>
<td>366</td>
<td>£27.45</td>
</tr>
<tr>
<td>Business Reply Plus</td>
<td>-</td>
<td>-</td>
<td>£0.27</td>
<td>N/A</td>
<td>15</td>
<td>£4.05</td>
</tr>
<tr>
<td>Toner Cartridge</td>
<td>1</td>
<td>£194.20</td>
<td>£0.00492</td>
<td>(2)</td>
<td>732</td>
<td>£3.60</td>
</tr>
<tr>
<td>Postage (2nd Class)</td>
<td></td>
<td></td>
<td>£0.27</td>
<td>(1)</td>
<td>366</td>
<td>£98.82</td>
</tr>
<tr>
<td>Theory-based leaflet</td>
<td>3000</td>
<td>£711.36</td>
<td>£0.237</td>
<td>(1)</td>
<td>366</td>
<td>£86.74</td>
</tr>
<tr>
<td>Box of staples</td>
<td>5,000</td>
<td>£0.36</td>
<td>£0.000072</td>
<td>(1)</td>
<td>366</td>
<td>£0.03</td>
</tr>
<tr>
<td>Total direct costs of each reminder</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>£249.97</td>
</tr>
<tr>
<td>Description</td>
<td>Cost</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
<td>----------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total direct costs of both reminders</td>
<td>£490.95</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Costs per person sent an intervention</td>
<td>£1.34</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(£490.95 / 366)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost per additional screening attendee</td>
<td>£16.93</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(£490.95 / 29)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sensitivity analysis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost per additional screening attendee</td>
<td>£24.55</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Lower 95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost per additional screening attendee</td>
<td>£11.97</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Upper 95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 9-12. Uptake in the different study groups and the absolute impact on uptake.

Appendix 9-13. Socioeconomic variation in uptake in response to the reminders and their absolute effects on the socioeconomic gradient.
Appendix 9-14. Socioeconomic variation in uptake in response to the reminders and their absolute effects on the socioeconomic gradient.

![Uptake by tertile of deprivation (TMR-TBL)](image-url)

- **Most deprived tertile**
  - Uptake after initial invitation: 36%
  - Uptake after 24-month reminder: 48%

- **Median deprived tertile**
  - Uptake after initial invitation: 40%
  - Uptake after 24-month reminder: 53%

- **Least deprived tertile**
  - Uptake after initial invitation: 14%
  - Uptake after 24-month reminder: 60%
Appendix 10-1. 2017-18 CQUIN for St Mark’s BCSC.

<table>
<thead>
<tr>
<th>CQUIN Indicator – [ Bowel Scope]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicator number</td>
</tr>
<tr>
<td>Indicator name</td>
</tr>
<tr>
<td>Indicator weighting (% of CQUIN scheme available)</td>
</tr>
</tbody>
</table>
| Description of indicator | • Twelve months after receiving an initial invitation for participation, all eligible adults will receive a reminder letter with the option of indicating preferred days and times to reschedule their BSS appointment.  
• An average of 450 letters a month adjusted to capacity and flexed from a minimum of 225 and a maximum of 600 per month with a minimum of 2,700 a year.  
• We will expect an uptake of >5% across this group of eligible adults. |
| Numerator | 1. Number of NRs, DNAs sent reminder letter |
| Denominator | 1. Number of NRs, DNAs attending Bowl Scope Screening |
| Rationale for inclusion | Evidence shows that for men and women aged 55 - 64 who attend a one-off bowel scope screening test mortality from bowel cancer in this age group can be reduced by 43% (31% on an invited population basis) and incidence can be reduced by 33% (23% on a population basis). However uptake/ attendance for Bowl Scope is lower than for gFOBT. In London uptake for bowl scope in Q1 2016/17 was 38.11% compared to 45.6% for gFOBT across the same time period. Reminder letters for NRs, DNAs will increase uptake of Bowl Scope Screening across North West London.  
A recent RCT reported the beneficial impact of additional reminders, which offer former non-responders and non-attenders to arrange a new bowel scope appointment at 12 months after the first invitation.¹ |

¹ 2016 Robert S. Kerrison, Lesley M. McGregor, Sarah Marshall, John Bitt, Nicholas Counsell, Colin J. Rees, Christian von Wagner Improving uptake of flexible sigmoidoscopy screening: a randomized trial of nonparticipant reminders in the English Screening Programme DOI: http://dx.doi.org/10.1056/NEJMc1602769 Published online: 2016 Endoscopy
<table>
<thead>
<tr>
<th>Data source</th>
<th>BCSS to identify participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency of data collection</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Organisation responsible for data collection</td>
<td>Screening Service</td>
</tr>
<tr>
<td>Frequency of reporting to commissioner</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Baseline period/date</td>
<td>2016/17</td>
</tr>
<tr>
<td>Baseline value</td>
<td></td>
</tr>
<tr>
<td>Final indicator period/date (on which payment is based)</td>
<td>April 2017- March 2018</td>
</tr>
<tr>
<td>Final indicator value (payment threshold)</td>
<td></td>
</tr>
<tr>
<td>Final indicator reporting date</td>
<td>1st Quarter 2018/19</td>
</tr>
<tr>
<td>Are there rules for any agreed in-year milestones that result in payment?</td>
<td>Yes End of Q1, Q2, Q3 and Q4 a minimum of 225 letters to have been sent for each month in each quarter. Failure to meet target in any month will result in withholding of payment</td>
</tr>
<tr>
<td>Are there any rules for partial achievement of the indicator at the final indicator period/date?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Rules for partial achievement of indicator**

<table>
<thead>
<tr>
<th>Final indicator value for the partial achievement threshold</th>
<th>% of CQUIN scheme available for meeting final indicator value</th>
</tr>
</thead>
<tbody>
<tr>
<td>End of Q4 a minimum of 2700 letters to have been sent</td>
<td>70% of total payment will be made for meeting minimum target of 2700 letters. Failure to meet the target will result in a reduction in the final payment by 25% for every 25% of target missed</td>
</tr>
<tr>
<td>End of Q4 a minimum of 5% increase in uptake in eligible group sent letters</td>
<td>30% of total payment to be made for an increase of ≥5% in uptake among the eligible group sent invitation letters. Failure to meet target will result in reduction of final payment by a quarter of agreed payment for each 1.25% reduction in uptake met.</td>
</tr>
</tbody>
</table>