A PRIMARY CARE-BASED INTERVENTION TO IMPROVE PARTICIPATION IN THE NHS BOWEL CANCER SCREENING PROGRAMME

Thesis submitted for the degree of Doctor of Philosophy

Department of Primary Health Care

University of Oxford

Hilary Term 2012

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B.A. (Hons), M.MSc.

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Abstract

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***Background*:** Currently, participation in the NHS Bowel Cancer Screening Programme (NHSBCSP) is poor, with around half of all people invited returning their (FOBT) kits. The research programme aimed to investigate whether a general practitioner's (GP) letter encouraging participation and a detailed leaflet explaining how to complete the (FOBT) included with the invitation materials would improve uptake.

***Methods*:** The research programme was divided into three phases which were designed to sequentially develop and evaluate the two interventions. The initial and second phases developed and refined the two interventions and the trial outcome measures with previous participants and stakeholder representatives. The final phase was a randomised 2x2 factorial trial conducted with people invited to screening in October 2009. Participants were randomised to either a GP's endorsement letter and/or a detailed procedural leaflet with their FOBT kit. The primary outcome was verified participation in the NHSBCSP. Questionnaires were also used to evaluate participant perceptions of CRC screening and GPs views on involvement with the NHSBCSP.

***Results*:** The factorial trial demonstrated both the GP's endorsement letter and the detailed procedural leaflet increased participation in the NHSBCSP. In the intention-to-treat analysis, participation improved by 6% for the detailed procedural leaflet and 5.8% for the GP endorsement letter 20 weeks after receipt of the FOBT kit. The random effects logistic regression model confirmed that there was no important interaction between the two interventions, and estimated an adjusted rate ratio of 1.11 (P=0.038) for the GP's letter and 1.12 (P=0.029) for the leaflet. The per protocol analysis indicated that the insertion of an electronic GP's signature on the endorsement letter was associated with increased participation (P=0.039).

***Conclusions*:** Including both an endorsement letter from each patient's GP and a detailed procedural leaflet could increase participation in the NHSBCSP by around 10%, a relative improvement of 20% on the current participation rate.. Both interventions were well-received by participants and there was minimal impact on GP workload.

Acknowledgements

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I would like to dedicate this work to the memory of Dr Joan Austoker. Joan was my boss, mentor, and occasional nightmarishly harsh critic. Without Joan's unwavering support, guidance and abuse, I would not have either an understanding of the intricacies of screening or the drive to complete this work. Joan's passing was an incalculable loss to both me and my colleagues in the PCERG; I only hope this work does, in part, reflect the importance that Joan made to my life.

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Statement of Contribution

The study, analysis and interpretation in this thesis are the original work of the author, carried out with the supervision of Professor David Mant and Dr Alison Ward in the Department of Primary Health Care at the University of Oxford. Dr Joan Austoker (deceased) and Professor Paul Glasziou also contributed to the supervision of the thesis in 2008-2009.

As author my specific contribution to this research programme included the development of the research programme, the collection and analyses of the pilot questionnaire and qualitative data, organisation and conduct of the randomised factorial trial, analyses of participation and questionnaire trial data and the interpretation and writing of the thesis.

I hereby declare that no part of this thesis has been submitted for any other degree at this or any other universities.

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Appendices

Chapter 1: Introduction

1.0 Overall Aim of the Thesis

The overall aim of the thesis is to evaluate the effectiveness of a GP endorsement letter and/or a detailed procedural leaflet for improving participation in the NHS Bowel Cancer Screening Programme (NHSBCSP). The two main hypotheses are:

a) a GP endorsement letter will improve participation in the NHSBCSP
b) a detailed procedural leaflet, providing information on how to collect, store and return the FOBT kit, will improve participation in the NHSBCSP

Colorectal cancer (CRC) is the second leading cause of cancer deaths in the United Kingdom [1], and survival rates are lower than in other European countries [2]. As screening using the faecal occult blood test (FOBT) can increase early-stage diagnosis and significantly reduces CRC mortality [3], the national NHSBCSP was introduced in spring 2006. Currently, participation in the NHSBCSP is relatively low, with around 50% of people invited to the national programme returning their FOBT kits [4, 5].

Previous research has strongly indicated the involvement of primary care practitioners can improve participation in the CRC screening [6-8]. At present, GPs in the United Kingdom are not involved in the NHSBCSP. The simplest method of involving primary care in the screening process is for the invitation to participate to include a personalised letter from the GP. The present research

sought to develop and evaluate a GP endorsement letter which could be included in the invitation process for the NHSBCSP.

Patient-specific factors, such as poor knowledge of the benefits of CRC screening, negative attitudes towards screening and perceived self-efficacy for completing the FOBT procedure, can also contribute to poor participation [8-10]. In attempting to address these difficulties, several primary care-based studies [11, 12] have suggested that providing people with more personalised information on completing the test can improve participation rates. The present research therefore also sought to develop and evaluate a detailed procedural leaflet to determine the effectiveness of this intervention for improving participation in the NHSBCSP.

1.1 Objectives of the Thesis

The specific objectives of the thesis are:

- to summarise the existing literature on participation in CRC screening and interventions for improving uptake in organised screening programmes
- to undertake systematic reviews of the effectiveness of the provision of a GP endorsement letter and specific population information for CRC screening
- to apply the MRC guidance for complex interventions [13] in the design and evaluation of the research programme
- to develop two interventions (a GP endorsement letter and detailed procedural leaflet), utilising stakeholder representative involvement and extensive pilot evaluations, for improving participation in the NHSBCSP

- to conduct a factorial randomised controlled trial of the two interventions to evaluate their effect on participation of a representative sample of people invited to the NHSBCSP

It is important to note that the thesis does not make a specific effort to address low uptake groups such as specific ethnic minorities or people from high-deprivation areas given the need for targeted research for these hard-to-reach groups and the importance of demonstrating the effectiveness of the two interventions at the population level. It is expected further research, based on the findings of this thesis, would address these groups in the near future.

1.2 Overall Structure of the Thesis

The structure of the thesis follows the development of the interventions during the formative stages of the research programme, through the pilot questionnaire and interview study used to refine the interventions, and finally, the factorial randomised controlled trial which evaluated the effectiveness of the GP endorsement letter and detailed procedural leaflet for improving participation in the NHSBCSP.

Chapter 2: Colorectal Cancer and Screening Participation. This chapter provides an overview of the health burden of CRC, the effectiveness of screening for CRC and the identified facilitators and barriers affecting CRC participation.

Chapter 3: Primary Care, Information Provision and Colorectal Cancer Screening. The results of two systematic reviews are presented in this chapter. The first review concerned the effectiveness a GP endorsement letter can have for participation in CRC screening, and the second review involved an evaluation of the content, format and presentation of information materials for people invited to CRC screening.

Chapter 4: Intervention Development. This chapter details the methodological and theoretical framework for the research programme. The chapter also describes the initial development of the interventions with the stakeholder group and the evidence informing the content of both interventions.

Chapter 5: Pilot Study – Questionnaire Results. The methodology and results of the pilot questionnaire study are reported in this chapter. The pilot study was the second stage of the research programme and performed to enhance the objectives of the final stage of the research. Respondents' views of the pilot procedural leaflet and the evaluation of the outcome measures intended for use in the factorial trial are presented.

Chapter 6: Qualitative Interview Series. This component of the pilot study explored in depth participants' perceptions of the draft procedural leaflet and their understanding of the potential facilitators and barriers for participating in CRC screening. The chapter reports previous participants' views of CRC screening, the role of GPs in the NHSBCSP and examines perceptions of knowledge and attitudes towards CRC and the FOBT kit.

Chapter 7: Initial Organisation of the Factorial Trial. This chapter briefly outlines the initial organisation required for the evaluation of the interventions within the NHSBCSP. The chapter describes initial organisation of the factorial trial (discussions with the key stakeholders to allow the trial to occur within the screening programme and the requirements for recruiting GP practices) and the changes required to the questionnaire component of the trial following the pilot study.

Chapter 8: Factorial Trial Methodology. The main aim of the research was to evaluate the effectiveness of the two interventions (GP endorsement letter and/or procedural leaflet) for improving participation in the NHSBCSP. This chapter details the rationale, recruitment and overall methodology for the factorial trial. The chapter also describes the participant and GP questionnaire components of the trial.

Chapter 9: Results of the Factorial RCT. This chapter presents the intention-to-treat and per protocol analyses for participation (primary outcome) in the factorial randomised trial. The analyses include screening participation based on the return of FOBT kits for 12 and 20 weeks, and the intention-to-treat (ITT) and per protocol (people receiving the FOBT pack) results.

Chapter 10: Trial Questionnaire Results. The results of trial participants who completed both the baseline and the follow-up questionnaires are presented in this chapter. The results of the questionnaire sent to GP practices concerning

the resource implications of the trial and general views of the NHSBCSP are also detailed.

Chapter 11: Conclusions. The final chapter of the thesis summarises the overall findings of the research programme and discusses these results in the context of the existing literature. Recommendations for alterations to the organisation of the NHSBCSP invitation process and implications for future research are discussed in detail.

1.3 Context of the Thesis

CRC screening is one of three current screening programmes delivered by the NHS Cancer Screening Programmes. Cancer screening has become a contentious issue in recent years, primarily due to debates about the effectiveness of screening [16-18], and also regarding the provision of information to enable people to make an 'informed choice' about participating or not in the programmes [19-21]. It is now widely accepted, by the NHS and international bodies [22, 23], that it is essential to provide balanced, non-coercive information to people invited to screening rather than to solely promote participation. These factors have a significant bearing on the development and conduct of the present research.

There are substantial differences between the three current screening programmes in terms of delivery, participant requirements and potential benefits and risks associated with participation. For example, the NHS Breast Screening Programme requires women aged 47-74 to attend a mammography

unit, has limited GP involvement and there is controversy concerning the benefit-risk profile of mammography [24]. The Cervical Screening Programme is completely dependent on GP involvement (for invitations and investigations), begins at the age of 23 years old and can result in significant over-detection of non-life threatening conditions [25]. Unlike these two programmes, the NHSBCSP invites both men and women, has no GP involvement and people are requested to perform the test without speaking to a clinician, or attending a specific healthcare facility. This presents a particular difficulty for both the communication or benefits and risks of participating in screening and for establishing the most effective ways of involving health professionals in enhancing participation in the programme.

The view that screening is an inherently 'good' behaviour which should be promoted is no longer acceptable. The present research sought to develop two interventions which would allow people to freely make their own choice about participating or not in the NHSBCSP, and further, explore avenues for the provision of this information via primary care and the NHSBCSP current invitation process.

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Chapter 2: Colorectal Cancer and Screening Participation

2.0 Objectives of the Chapter

The objectives of this chapter are to provide a brief overview of colorectal cancer (CRC) and a summary of the rationale and effectiveness of population screening programmes in reducing CRC incidence and mortality. The chapter also includes an overview of the facilitators and barriers to participation in CRC screening programmes.

2.1 Introduction

Reducing deaths from CRC is an important population health priority. Each year approximately 435,000 people are diagnosed with CRC in Europe, with almost half of these patients dying of the disease; this makes CRC the second leading cause of European cancer deaths [1]. Any interventions aiming to improve the effectiveness of CRC screening require an understanding of the epidemiology of the disease and appreciation of how the intervention will impact on the delivery of the screening programme.

It is important to note that cancer screening is one of several strategies currently employed in England to improve survival and decrease colorectal cancer morality. The recently introduced National Awareness and Early Diagnosis Initiative (NAEDI) is a public sector/third sector partnership between the Department of Health, National Cancer Action Team, and Cancer Research UK. The role of NAEDI is to coordinate and provide support to activities and research that promote the earlier diagnosis of cancer. Associated research also

includes efforts to reduce referral times for diagnostic procedures, increased awareness of symptoms in the general public and greater involvement of Primary Care practitioners for identifying the early warning signs of CRC in patients presenting with lower gastrointestinal disorders. Although these research efforts are complimentary to the role of CRC screening for reducing CRC morbidity and mortality presented in this chapter, and in-depth exploration of these initiatives is beyond the scope of the present research.

2.2 Pathogenesis of Colorectal Cancer

The development of CRC is thought to be a multistep process involving both genetic and environmental factors. Regardless of aetiology, the majority of CRC cases (70-95%) arise from benign, neoplastic precursor lesions called adenomatous polyps [2-4]. Adenomas can occur anywhere in the colon or rectum and are visible gland-forming projections of the mucosa; they are classified according to their attachment – polyps with a stalk (peduncaluated) versus those that are flat (sessile) [5, 6]. Adenomatous polyps are further categorised based on histological appearance: tubular (70%-85%), villous (5%-10%), or mixed tubulovillous (10%-20%) [2, 5]. Progression from an adenoma to CRC is a multistep process which is characterised by the adenoma extending into the submucosa and becoming malignant over a period of time (see Figure 1) [4-6].

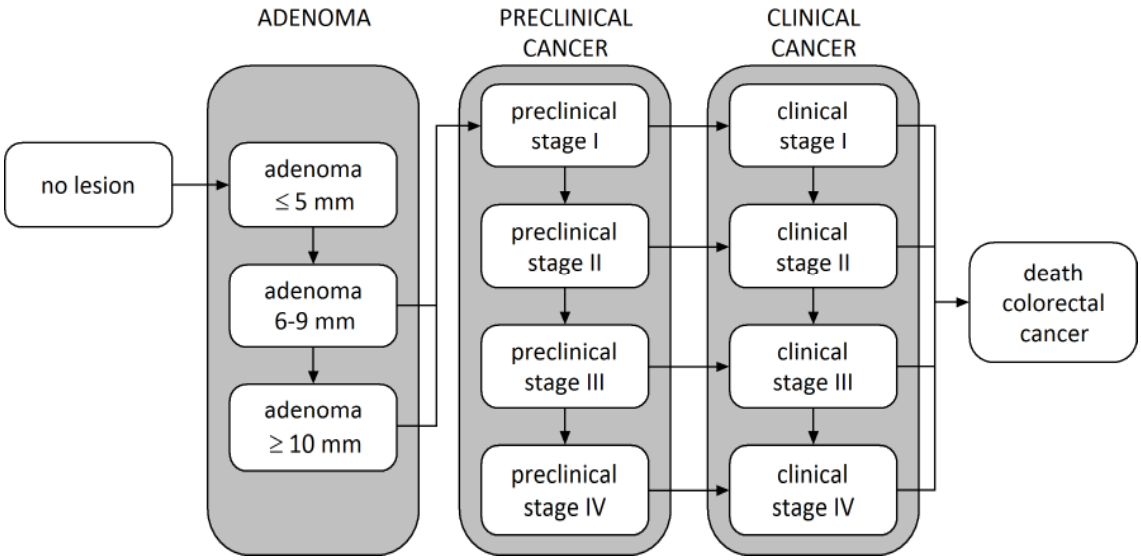

Figure 1: Schematic overview of the adenoma-carcinoma sequence [7].

The natural history of the adenoma-carcinoma sequence has been well-documented. The duration of the progression of an adenoma to CRC is around 10 to 15 years [4-6]. Approximately 40-50% of the population will develop one or more adenomas in a lifetime [8], although the majority of adenomas will not develop into CRC, with around 5-6% of the population actually developing the disease [9]. There is considerable evidence indicating that the removal of an adenoma can prevent the incidence of CRC [8-11] and that the prognosis for CRC detected at an early stage is far better than for late-stage CRC [12-14]. The long latency phase provides an opportunity for the implementation of effective methods to detect CRC and adenomas at an early stage to reduce the health burden of the disease in the population.

2.3 Risk Factors for Colorectal Cancer

The majority of people who develop CRC (approximately 75%) have no specific risk factors [15, 16]. People at increased risk of developing CRC include those with a family history of one or more close relatives with CRC (15-20% of all

cases) [17-19], people with chronic inflammatory bowel diseases (1% of cases) [20-22] and those with well-defined inherited disorders (3-6% of cases) such as hereditary non-polyposis colorectal cancer (HNPCC) and familial adenomatous polyposis (FAP) [23-25]. The primary factors associated with developing CRC include:

- Age: increasing age is the strongest predictor for the development of CRC [26, 27]; over 8 in 10 CRC cases (84%) in the UK occur in people aged 60 years or older [28]
- Gender: men have a higher incidence of CRC than women and an increased risk of advanced adenomas or neoplasia [29-31]
- Ethnicity: in the UK, people from Asian and Black ethnic groups are less likely to develop CRC than Whites, although there is a paucity of research in this area [32, 33]
- Social deprivation: socioeconomic status is inconsistently associated with an increased risk of CRC [34, 35], although a recent study in England found an 11% increase in the incidence of CRC for males from deprived areas compared to men from affluent areas [36].

Lifestyle and potentially modifiable risk factors such as Type 2 diabetes mellitus [37], diet and nutrition [38-42], physical activity [43-45], obesity [46-48], smoking [49, 50] and alcohol consumption [51, 52] are also linked to an increased risk of developing CRC. Although primary prevention of CRC can potentially reduce the incidence of CRC [53, 54], secondary prevention provides a more direct solution if pre-cancerous polyps can be detected through effective screening.

2.4 UK Colorectal Cancer Incidence and Mortality

CRC is the third most commonly diagnosed cancer in the UK with over 31,000 people in England diagnosed with the disease in 2008 [28].

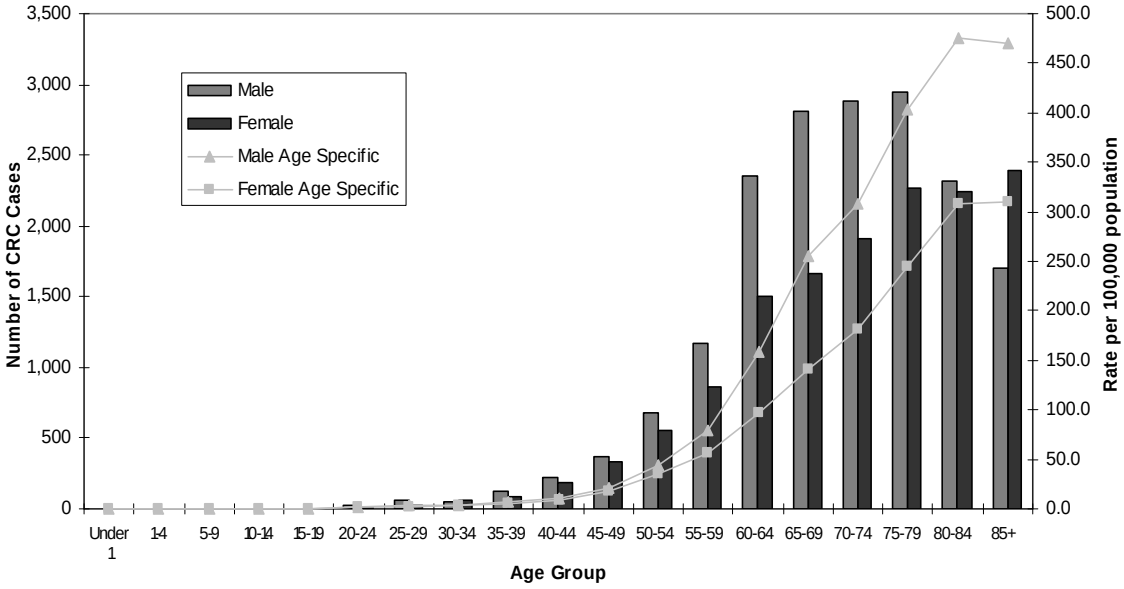

Figure 2: CRC incidence (ICD C18-20) for men and women in England [55].

As can be seen in Figure 2, the incidence of CRC increases dramatically with age and men have a higher incidence rate than women after the age of 60 years. The lifetime risk of being diagnosed with CRC is estimated to be 1 in 14 for men and 1 in 19 for women [28].

CRC is the second leading cause of all cancer deaths in the UK [56]. The number of deaths in England and Wales in 2009 from CRC was 13,677 (see Figure 3).

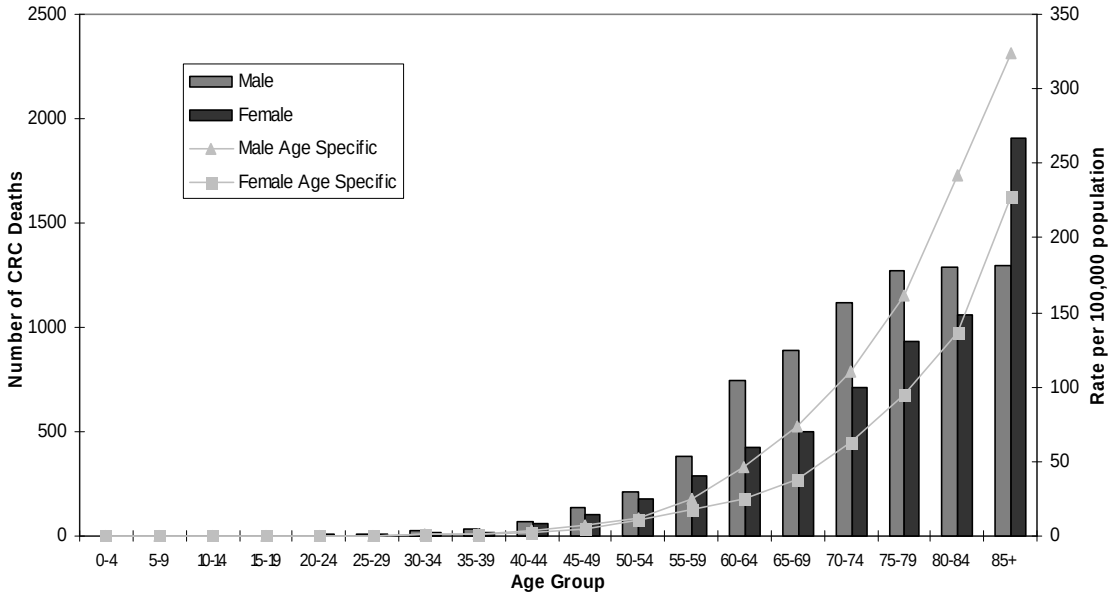

Figure 3: CRC mortality (ICD C18-20) for men and women in England and Wales [57].

CRC is the third most common cause of cancer deaths in men, following prostate and lung cancer, and the third most common cause of cancer deaths in women after breast and lung cancer [56]. The implementation of both public health and primary care interventions to reduce the impact of CRC is therefore of national importance.

2.5 Survival rates for Colorectal Cancer

As shown in Table 2.1, the overall five-year relative survival of CRC patients in England is around 50% [12]. However, there are substantial differences in survival rates based on the stage of diagnosis. People diagnosed with Duke's Stage A have over a 90% five-year survival rate in comparison to around 7% for people who are diagnosed at Duke's Stage D.

Table 2.1: Number of cases (1996-2006) and five-year survival of CRC patients (diagnosed 1996-2002) by stage of diagnosis in England [12].

Stage at Diagnosis	Number of Cases	Percentage of Cases	Percentage of Cases Unknown	5-year Relative Survival (%)	Confidence Interval (%)
Duke's A	26,727	8.7	13.2	93.2	92.5 – 93.9
Duke's B	74,784	24.2	36.9	77.0	76.4 – 77.5
Duke's C	72,806	23.6	35.9	47.7	47.1 – 48.3
Duke's D	28,377	9.2	14.0	6.6	6.1 – 7.0
Unknown	106,040	34.3	-	35.4	35.0 – 35.8
Total	308,734	100.0	100.0	50.7	50.4 – 51.0

Although there is variation in the CRC five-year survival rates between countries, overall UK survival rates remain lower than European countries with comparable health systems and the United States [58-60]. Recent analyses of the lower comparable survival rates indicate UK patients tend to present with more advanced stage of CRC than patients in Europe or the USA [13, 14], with recent evidence suggesting differences in UK survival rates are due to later diagnosis and differences in treatment [60, 61]. Increasing the proportion of people detected with early-stage CRC through population screening may have a significant effect on survival rates in the UK.

2.6 Population Screening for Colorectal Cancer

Cancer screening is defined as the systematic application of a test to individuals who have not sought medical attention because of symptoms [62]. The aim of population screening is to discover latent disease in the public in order to detect the disease in its early stages and enable it to be treated adequately before posing a threat to the individual and/or community [63]. The screening process includes identifying and inviting people to be screened, the screening test, diagnostic investigations when an abnormal result is detected, treatment of the polyp or cancer. The purpose of cancer screening is to reduce mortality and

morbidity by detecting the cancer at an early stage when treatment is more likely to be effective [65, 66]. Further benefits of cancer screening include less invasive treatment for the identified cancer, healthcare resource savings and reassurance for people receiving negative results [65, 66].

However, cancer screening differs substantially from reactive clinical practice as it is offered to people who did not request a medical investigation and who are apparently healthy. Furthermore, the screening test can cause harm as well as giving benefit [67]. The testing procedure can lead to both false-positive and false-negative results, significant adverse events may occur during diagnostic follow-up, and screening has been suggested to lead to widespread over-detection and over-treatment of inconsequential disease [68, 69]. Increasingly, there are calls for screening programmes to provide information which allows people the opportunity to weigh up the probable benefits and harms, using their own values and preferences [68, 69].

2.7 Information for Cancer Screening

Providing people with high-quality information about the benefits and risks associated with screening is an essential component of an organised programme. Traditionally, the provision of information has been to encourage involvement in the programme, although more recently, it has been acknowledged that information materials should allow an individual to decide for themselves (to make an informed choice or an informed decision) about whether or not they should participate in cancer screening [70-72]. Informed decision-making is a decision process in which individuals are expected to

make a rational and autonomous choice concerning their own health in order to protect themselves from risks and harms [73].

Concerns have been raised about the potential conflict between advocating high uptake rates and the intention to promote informed decision-making for cancer screening. The purpose of cancer screening should be to benefit the whole community, while at the same time respecting the individual's autonomy that includes the right to refuse screening [73]. Interventions aimed at increasing uptake should try to identify ways to minimise barriers to participation among those who have understanding of its likely benefits, limitations and harms [73].

2.7 Effectiveness of Screening for Colorectal Cancer

There are several modalities available for CRC screening. Until recently, high-quality research evidence for the effectiveness of the various modalities to reduce CRC mortality and morbidity was relatively sparse. Faecal occult blood testing (FOBT), either guaiac (gFOBT) or immunochemical FOBT (iFOBT), has received the greatest research attention, although evidence for effectiveness for endoscopic screening has recently been published.

2.7.1 Guaiac FOBT for Colorectal Cancer Screening

Currently, gFOBT is the only screening modality for which extensive evidence of efficacy has been established based on the analyses of several high-quality randomised controlled trials (RCTs) [74-77]. The Cochrane review (updated in 2010) [78, 79], which included four large-scale randomised controlled trials

(RCTs), reported a reduction in CRC mortality of 16% (RR 0.84, 95% CI 0.78 to 0.90). The relative risk reduction in CRC mortality for biennial screening was 15% (RR 0.85, 95% CI 0.78 to 0.92). When adjusted for screening attendance in the individual studies, there was a 25% relative risk reduction (RR 0.75, 95% CI 0.66–0.84) for those attending at least one round of screening using the gFOBT.

2.7.2 Alternative Screening Modalities

Alternative CRC screening modalities to gFOBT are currently under investigation or in use. These include immunochemical FOBT (iFOBT), flexible sigmoidoscopy (FS), and colonoscopy screening (CS). The improved accuracy and patient acceptance of iFOBT [80-82] have been suggested as reasons for adopting this modality over gFOBT for population screening [83, 84]. Ongoing trials of flexible sigmoidoscopy (FS), either alone or in combination with a FOBT test, have yielded promising findings [85-88], with more definitive results expected in several years. Colonoscopy (CS) is also advocated as a screening method due to its superiority in detecting CRC and pre-cancerous lesions compared to other modalities [89-91], although concerns about implementation, efficacy and safety have been raised [92-94].

2.7.3 Screening Modality Recommendations

Government, health professional and patient advocacy organisations have published numerous recommendations for CRC screening. Based on systematic reviews of the evidence [95, 96], North American organisations recommend screening starting at age 50 years using either annual FOBT, FS

once every 5 years (or FS once every 5 years in combination with annual FOBT) or colonoscopy every 10 years [97-99]. European guidelines recommend annual FOBT as a CRC screening strategy in 50-74 year old without any specific risk factors [100] the guidelines include advice on implementing CRC screening programmes [101].

There is an ethical imperative to base screening on the best available evidence because of the potential to harm people who are healthy [68]. In the United Kingdom, assessing the effectiveness for the introduction of a new cancer screening programme is the responsibility of the UK National Screening Committee (UK NSC). The results of the first Cochrane review [102] on the effectiveness of CRC screening led the UK NSC to commission a pilot study to determine the feasibility of introducing a CRC screening programme in the UK.

2.8 UK Colorectal Cancer Screening Pilot

The UK Colorectal Cancer Screening Pilot, which began in 2000, aimed to determine the feasibility of introducing population screening for CRC using biennial gFOBT [103]. Two regions in England and Scotland invited 478,250 residents aged 50-69 years old to complete gFOBT screening. Participation in the first round was 56.8%; however, this decreased to 51.9% in the second round for the English pilot site [104]. Although uptake varied with gender, age and level of deprivation, the pilot was deemed successful for introducing biennial gFOBT screening in the UK. CRC screening in England is predicted to reduce number of CRC deaths by 13.3% for men and 11.7% for women after 19 years [105].

Further evidence for the effectiveness of the pilot programme was demonstrated by a retrospective analysis which found a 23% reduction in the diagnosis of CRC for the English pilot site over the five-year study period [106]. There was also a significant reduction in emergency admissions for CRC in one pilot area [107]. However, hospital colonoscopy activity increased 21% in England and considerably added to the associated administrative workloads [108]. Furthermore, there was a strong perception by GP's that the introduction of a CRC screening programme would impact significantly on their primary care workload [109].

2.9 NHS Bowel Cancer Screening Programme

Following the successful pilot programme, the NHS Bowel Cancer Screening Programme (NHSBCSP) was introduced in July 2006 [110]. The NHSBCSP sends a mailed invitation to participate in screening every two years to all people in England aged 60-69 (60-74 from April 2010) who are registered with a GP practice. The invitation process occurs in two stages:

- the first stage involves sending a one-page invitation letter (briefly explaining the programme and the rationale for the invitation; see Appendix 1.1) and an evidence-based information booklet [111] to the potential participant. People receiving the invitation are given the opportunity to withdraw from CRC screening by contacting the Southern Programme Hub (SPH) in the week prior to receiving the FOBT pack
- the second stage (one week after the invitation letter) involves mailing the FOBT pack (including the 'Hema-Screen' guaiac-based FOBT, six

cardboard spatulas, an brief instruction leaflet and a return-post envelope) to people who had not withdrawn from the screening programme

People who do not return a completed FOBT within four weeks receive a reminder letter from the SPH. The screening episode is considered closed if people have not returned their FOBT 12 weeks after the FOBT pack is sent (although FOBT kits will still be processed after this time if received by the Hub). General Practitioners (GPs) are not directly involved in the delivery of the NHSBCSP but are notified when invitations are being sent out in their area and receive a copy of the results letter that is sent to their patients.

Currently, participation in the NHSBCSP is below the rates observed in the UK Colorectal Cancer Screening Pilot, with around half (49%-52%) of the eligible population returning their FOBT [112, 113]. Although these participation rates are comparable with other European screening programmes [114], increasing informed participation should result in a larger reduction in mortality [105]. Identifying the reasons for both accepting and declining the invitation to the NHSBCSP would facilitate the development of specific interventions to increase CRC screening participation.

2.10 Participation in Colorectal Cancer Screening

As the aim of cancer screening is to reduce cancer mortality, high levels of population coverage, a reliable and acceptable screening modality, and effective completion of the screening process are required to meet this goal [65]. High participation rates result in greater efficacy in regards to mortality reduction [78] and increase the cost-effectiveness of the screening programme

[115, 116]. Participation is also widely regarded as the most important factor determining the success of an organised screening programme [65, 117].

Despite the availability of effective modalities and widespread acceptance of CRC screening by governments and national organisations, public participation in screening programmes remains modest. Pilot feasibility studies for FOBT in Europe and Australia have reported participation rates ranging from 45% to 57% [104, 112, 118-120]. Even with the availability of several CRC screening modalities, approximately 70% of respondents to a recent national survey in Canada were non-adherent to CRC screening guidelines [121] with a slightly higher proportion of people in the United States (approximately 40% to 60%) reported to be up-to-date with CRC screening recommendations [122-124].

There are a myriad of organisational, socio-demographic, provider and individual factors which can positively and negatively influence participation in CRC screening. Three comprehensive systematic reviews have indicated that age, gender, physician recommendation, family history of cancer, fear of cancer, knowledge, attitudes, beliefs, availability of screening modalities and differences in personal views on preventive behaviour all impact on participation in CRC screening [125-127]. However, there is significant inconsistency concerning the relative weight these factors have in determining participation; often studies identify multiple reasons for screening uptake.

2.10.1 Organisational and Socio-Demographic Factors

Participation in CRC screening tends to be higher for organised screening programmes as opposed to opportunistic screening [65, 128]. Studies have also shown that uptake is higher when screening is facilitated by a primary care practitioner in comparison to hospital-based involvement [129]. Reminder letters have proven to be a highly effective method for increasing participation, especially within organised screening programmes [130, 131].

Numerous studies have identified older age (≥60 years) as a significant determinant of CRC screening participation [132-136], with people aged 65 or over the most likely to attend [137, 138]. Studies have also shown that screening participation increases up to the age of 75 years and then dramatically declines [134, 139, 140]. The lack of health insurance is a significant factor associated with non-participation in US-based surveys [134, 140, 142], although this is partly dependent on the type of screening tests physicians are able to order based on the available health insurance coverage [143, 144]. Higher educational attainment is also often associated with CRC screening participation [141, 145, 146], although delineating the relationship between higher education, socio-economic status, knowledge and attitudes towards CRC screening has proven difficult [134, 147].

Another important determinant predicting participation in CRC screening is socio-economic status. Higher socio-economic status is consistently associated with CRC screening participation [135, 138]. Indeed, the difference in participation between low- and high-deprivation groups has been demonstrated

to be over 30% [138, 148]. A recent evaluation of the NHSBCSP in London found that participation rates for the least deprived areas were 49% in comparison to just 32% for the most deprived areas [112]. However, as less than half of the invited population from the least deprived areas returned their FOBT kits after opting for screening, other important factors are obviously impacting on peoples' decisions not to participate in the programme.

A number of European studies have reported a higher utilisation of FOBT by women in comparison to men [103, 149-151]. However, US-based studies regularly report men are more likely to participate in screening than women [135, 136, 148]. Although there is some evidence that this discrepancy is related to the frequency of primary care visits, previous screening behaviour, preferences for screening modality and recommendations from a GP [103, 136, 151, 152], definitive explanations for gender differences in participation remain elusive.

Low uptake for CRC screening in ethnic minority groups figures prominently in the literature. Studies in the United States [132, 144, 153], Canada [154], the Netherlands [155] and Australia [145] have all shown a significantly lower participation rates for ethnic minority groups. In the UK pilot programme [156], the South Asian population were reported to return FOBT kits approximately half as often as non-Asians. Even after adjusting for deprivation level, the South Asian population continues to show low rates of screening uptake [157], with potential differential levels of knowledge and embarrassment in comparison to non-Asian populations postulated as contributing to low participation [158].

Several prospective surveys have shown that a family history of any cancer is related to intention and actual participation in CRC screening [126, 141, 159, 160]. A recent systematic review indicated that a recommendation from a health provider, a stronger family history of CRC and fewer perceived barriers to screening, were all predictors of participation for this sub-group of people [161]. This would suggest that a combination of factors, including positive attitudes towards CRC screening, have an important effect on participation even for a group of people acutely aware of the severity of the disease.

2.10.2 Provider Factors

The receipt of a physician recommendation is an extremely important determinant of participation in opportunistic screening programmes. Numerous large-scale, US-based studies have consistently reported a significant association between the receipt of a physician recommendation and screening participation [133, 143, 144]. Alternatively, the lack of a physician recommendation is often cited as the most important reason for not completing screening [162-166]. However, several studies have suggested that merely mentioning CRC screening is unlikely to motivate most people to participate and more formal, evidence-based methods of communication are required [165, 167].

Receiving health care regularly from the same source has also been identified as having a positive role in CRC screening participation [132, 135]. One study found that people were three times more likely to participate in screening if they

had a usual source of care [168]. Individuals who maintain regular doctor visits are also more likely to participate in CRC screening [134, 169]. Although infrequently evaluated, patient trust in their primary care provider has been shown to be related to both positive perceptions of CRC screening and enhanced participation [170, 171]. Clearly, there is a very important role for primary care in facilitating participation in CRC screening which merit further investigation.

2.10.3 Individual Factors

Individual factors are the most frequently investigated variables in intervention studies and population surveys [125-127]. These often include knowledge, attitudes towards screening, perceived specific barriers to participation, risk perceptions, and fear or worry associated with cancer. Unfortunately, studies do not generally include a standard set of outcome measures for the various individual-specific factors evaluated, and even when investigating the same construct (e.g. self-efficacy), different types of measures will often be employed.

Poor knowledge of CRC or of the effectiveness of CRC screening, and a limited awareness of the availability of screening, have been shown to be negatively associated with participation [136, 143, 165]. Overall, surveys of public awareness of CRC screening regularly report a poor understanding of the risk factors associated with developing CRC, symptoms of CRC, the recommended starting age for screening, and the rationale for participating in screening [172-174]. However, knowledge of CRC incidence, mortality, and screening effectiveness appear to be important psychosocial predictors of CRC screening

uptake [125, 127]. Greater knowledge and awareness of screening have also been associated with older age, higher education attainment, and more frequent contact with a primary care practitioner [135, 172, 175], suggesting that knowledge may be a mediating factor associated for socio-demographic predictors of participation. Interventions which improve the knowledge of people invited to CRC screening may potentially improve perceptions of screening and increase participation.

Positive attitudes or beliefs towards CRC screening are consistently demonstrated to enhance participation. Overall, attitudes concerning the effectiveness of screening modalities to detect CRC, positive views of the safety and convenience of the procedure, and generally favourable perceptions of the importance of preventive health care are reported as the main determinants of screening participation [125, 126, 166, 176]. In the UK Pilot, over 90% of participants were confident that screening was likely to prevent death from CRC, lead to earlier treatment and reduce worry about CRC [104]. Self-efficacy is also an important construct for participation in CRC screening. A strong sense that the individual can either perform or undergo a screening procedure has also been associated with higher rates of participation and often related to other positive attitudes towards screening [96, 127, 159, 177].

Negative attitudes towards CRC screening are equally important for understanding participation. Indeed, changing people's negative perceptions of screening is an important rationale for employing information materials in intervention studies. Negative attitudes and beliefs can range from being very

difficult barriers to overcome (such as a person's absolute fear of dying from cancer or dread associated with undertaking the screening test) to rather practical barriers for not completing testing including conflicts with work, inconvenience, lack of interest or time [126, 127, 165]. Further barriers specific to completing FOBT have been shown to include perceived embarrassment, difficulties with bowel movements (e.g. constipation or diarrhoea), concerns about storing kits and lack of specific symptoms of CRC [84, 104, 143]. Although usually incorporated into studies to explain the main reasons for non-participation, extrapolating the various individual negative attitudes which may be amenable to change is often difficult due to the diversity of attitudinal outcomes measured by the various studies.

Perceptions of risk concerning developing or dying from CRC also impact on screening behaviour. However, the findings of several studies have been inconsistent regarding how perceived risk affects CRC screening participation. For example, several studies have reported that higher perceived risk is a significant barrier to participation [178, 179], whereas other studies have found this to be a facilitator for uptake [147, 180]. Further complicating the role perceived risk may have for predicting participation is the associations between socio-demographic factors, personal health-related factors and anxiety [181]. Increasing people's ability to more accurately perceive their risk of developing CRC has been proposed as a method for encouraging greater participation in screening [180, 182].

Health literacy is increasingly recognised as a significant factor affecting non-participation in screening. People with low health literacy are less knowledgeable about CRC screening, hold more negative perceptions about the process, and report more barriers to participation [124, 183-185]. A recent study [185] reported men with lower literacy skills were more likely to believe FOBT was inconvenient or messy, and would not participate in screening even if recommended by their physician. Further problems associated with limited health literacy include poorer information processing skills, difficulties in comprehending complex vocabulary, and fewer visits to primary care practitioners [184, 185].

2.10.4 Colorectal Cancer Screening Participation Summary

There is a highly complex relationship between the organisational, socio-demographic, provider and individual factors which variously contribute to participation in CRC screening. Succinctly identifying the primary determinants of participation and non-participation is exceedingly difficult due to differences between the types of screening modalities investigated and the failure of studies to use uniform outcome measures. However, based on the overall findings of the various studies aimed towards determining factors affecting participation, it is suggested that:

- higher rates of uptake are related to higher socio-economic status and educational attainment, older age, and female gender (for FOBT screening),
- endorsement or recommendation for screening by a primary care practitioner can have a positive influence on people's perceptions of the screening test and participation in screening, and

- individual factors, such as knowledge, positive attitudes and beliefs towards screening strongly influence personal perceptions of the importance of participating in CRC screening and of the ability to complete testing.

This would indicate that interventions which are designed to improve people's understanding of CRC and the screening process, including a recommendation from a primary care practitioner, are potentially the most effective for improving participation in the NHSBCSP.

2.11 Conclusion

CRC is a significant cause of death and morbidity in the UK. The introduction of the NHSBCSP, based on the evidence for the effectiveness of gFOBT for CRC screening and the successful resolution of the UK Pilot study, is expected to have a significant impact for reducing CRC mortality in the UK. However, poor overall participation in the programme remains a concern, and interventions which target the organisational, socio-demographic, provider and individual barriers to CRC screening are required to be developed and implemented. A significant difficulty for the development of these interventions is identifying which of the myriad of barriers affecting CRC screening participation can be targeted effectively within the current invitation structure of the NHSBCSP. Based on the research evidence, indicating that a recommendation from a primary care practitioner and the provision of information materials may impact on an individual's decision to participate in screening, two targeted systematic reviews were undertaken to provide the research basis for the development of the interventions for the current research programme.

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Chapter 3: Primary Care, Information Provision and Colorectal Cancer Screening

3.0 Objectives of the Chapter

The main objectives of this chapter are to present the results of two systematic reviews. The first review was concerned with establishing if General Practitioner (GP) involvement can improve participation in CRC screening and the second review involved an evaluation of the content, format and presentation of information materials to people invited to CRC screening.

3.1 Primary Care and CRC Screening

The role of primary care in cancer screening is increasingly debated in the literature. In North America, evidence suggests primary care practitioners are highly in favour of endorsing CRC screening, although a combination of inadequate office management systems, variable screening modality recommendations and poor communication with patients impacts on participation rates [1-3]. In the UK, GP's are also enthusiastic about CRC screening using FOBT [4], but have concerns regarding the workload and resource implications of more involvement in the NHSBCSP [5, 6].

The provision of a GP endorsement letter has proven to be effective for increasing participation in both breast and cervical cancer screening [7-9]. Although there are consistent recommendations for GP's to be provided with a greater role in CRC screening, few studies have attempted to robustly evaluate the effectiveness of this intervention for screening using FOBT.

3.2 Systematic Review 1: Primary Care Involvement in CRC Screening

The previous chapter suggested that a GP recommendation was a highly influential predictor for participation in CRC screening. However, the NHSBCSP currently does not have direct primary care involvement in the invitation process. Therefore, it was important to establish the current evidence for the effectiveness of a GP endorsement letter for improving participation in CRC screening.

The review was undertaken after a brief examination of the literature indicated there were no systematic reviews published on this specific intervention. The main aims of the primary care systematic review were to i) identity publications which have evaluated the use of a GP endorsement letter for improving participation in FOBT screening; ii) to determine the effectiveness of this intervention.

3.2.1 Primary Care Review Methods

The review concentrated on identifying evidence which could be applied to the informed consent procedure of the NHSBCSP [10]. The review was undertaken based on guidance for performing systematic reviews of the literature [11, 12].

Inclusion/Exclusion Criteria

Studies which reported sending a GP endorsement letter, either prior to or with a FOBT kit, were included in the review. Only studies specifically stating that the GP letter included an endorsement of CRC screening (i.e. importance of

participating in screening, recommendation to return kit) were included in the review. Studies which did not report a control or comparison group were excluded. Studies which evaluated interventions based on primary care reminder letters, enhancing office management systems to identify non-compliant patients or GP educational interventions were excluded.

Search Strategy

A comprehensive search of medical databases was initially performed from 1990 to 2008 and was later updated in December 2010. Search strategies were devised to include search terms relating to CRC and screening, GPs (e.g. clinician, physician, practitioner, etc.), and the provision of print resources to patients (e.g. GP endorsement or advanced notification letter). Additionally, reference lists from retrieved articles were examined for relevant publications and hand-searching of pertinent journals was conducted.

Study Selection

After the removal of duplicates, each study was assessed for inclusion based on citation title and abstract. Authors of studies not describing the content of the intervention letter in sufficient detail were contacted to request further information. Further information on the content of their materials was provided by three authors.

Data Extraction Process

Study specific information (i.e. study setting and design, participant characteristics, etc.) was extracted for the included studies. The content of the

information included in the GP letter and outcomes evaluating the intervention were also extracted.

3.2.2 Primary Care Review Results

The systematic searches identified 475 potentially relevant articles. After adjusting for duplicates, 332 articles remained. Of these, 308 were excluded on the basis of the abstract. Twenty-four studies reviewed in detail; 19 of these studies were excluded due to either the lack of a comparison group, the intervention only consisting of a letter or reminder letter, the study population being restricted to high-risk people, or the study being based on a qualitative research design. Five studies were therefore included in the review [13-17] (see Appendix 3.1).

Characteristics of Included Studies

Four of the included studies [13-15, 17] were reported as randomised controlled trials (RCTs). All of the studies included average risk people over 45 years old. The number of participants ranged from 966 to 7,320 (see Table 3.1).

Table 3.1: Characteristics of included studies.

Study	*Research design*	*Setting*	*Country*	*Number of Participants*	*Age range*
Cole	RCT	Community	Australia	1,800	≥50
Courtier	RCT	Community	Spain	2,026	50-75
Federici	RCT	Community	Italy	7,320	50-75
King	Non-randomised	Community	Australia	966	45-75
Mant	RCT	Community	UK	1,588	45-64

Cole and colleagues [13] randomised participants into one of three groups: a CRC screening invitation without indicating the GP was involved, an invitation indicating support from the GP practice and an invitation on practice letterhead

supporting screening and signed by a practice partner. Courtier and colleagues [14] randomised participants to either an invitation letter from a GP with the FOBT kit (study group), or the same intervention but who also received a visit from a trained non-health professional (intervention group). Participants in the study group were required to return their completed FOBT by post, whereas participants in the intervention group could have their kit collected by the non-health professional. The non-health professional visit was very brief (averaging around 5 minutes) and included providing general information about how to compete the test. A 2x2 factorial design was employed for the Federici and colleagues trial [15]. The primary aim of the trial was to evaluate the compliance rate for two screening tests (gFOBT versus iFOBT). However, as the authors also randomised participants to either a GP letter of invitation or a hospital-based invitation, the trial was included in the present review.

King and colleagues [16] divided participants into five groups; no method of randomisation was reported for this study. The five groups included: a) GP letter, FOBT kit with dietary restriction information, b) GP letter, FOBT kit without dietary restriction information, c) GP letter, FOBT kit without dietary restriction information and a brief CRC brochure, d) GP letter without dietary restriction information but needing participant to telephone practice for a FOBT kit, and e) FOBT kit with dietary restriction information but without GP letter. The trial by Mant and colleagues [17] randomised participants to one of four groups. The first group received a FOBT kit and GP letter, but were not invited to attend the practice for a health check. The second group were posted the same materials, but were invited to the health check and asked to return the

FOBT kit prior to attending the practice. The third group were advised they would be offered the FOBT kit during after attending for their health check appointment. The final group were offered only to attend the health check at the practice.

Content of GP Endorsement Letters

Apart from a direct suggestion regarding either the importance of participating in screening or that the GP supported CRC screening, the content of the endorsement letters were fairly brief for all included studies. The endorsement letter in the Australian trial [13] was sent on the relevant practice letterhead, indicated screening was endorsed by the practice, and signed by the person's GP of most recent contact. The Courtier and colleagues [14] trial letter was sent on practice letterhead, although only included a practice partners' signature and a brief statement about the importance of participating in screening. In the Italian trial [15], the GP letter indicated the importance of testing and directed participants to attend the practice to receive their FOBT kit. This intervention also included a small monetary incentive for completing the kit. The GP letter for the King and colleagues study [16] was sent from the patient's own doctor encouraging participation and briefly described the benefits of screening for CRC. The GP letter for the Mant and colleagues study [17] was very brief and indicated the FOBT kit may help to identify CRC at an early stage.

Effectiveness of GP Endorsement Letters for Improving Participation

The participation rates for CRC screening in comparison to a control or alternative intervention group are shown in Table 3.2.

Table 3.2: Participation rates for the four included studies.

Study	Screening Modality	Intervention Group	Control Group	Significance	Time Frame for Participation
Cole	iFOBT	40.7%	32.0%	$p = 0.002$	12 weeks
Courtier	iFOBT	57.7%	36.5%	$p = 0.001$	3 months
Federici	iFOBT/gFOBT	50.2%	16.2%	RR = 3.40	6 months
King	gFOBT	54.7%	22.5%	NR	3 months
Mant	gFOBT	31.7%	20.6%	$p = 0.001$	NR

Note: NR = Not reported

Cole and colleagues [13] reported that a personalised letter of invitation from a GP achieved a higher participation rate than an invitation from a centralised screening office. A GP invitation letter coupled with visit by non-health professional who could answer general questions about completing screening was more effective than a GP invitation letter alone [14]. King and colleagues [16] reported an increase for all four groups using a GP endorsement letter, with the highest participation rate in the GP letter with no dietary restrictions group.

In the Italian trial [15], there was a dramatic difference in participation for people attending the GP practice to obtain their test kit in comparison to attending a hospital gastroenterology department. For people invited to a health check in the Mant and colleagues trial [17], people who were sent an FOBT kit before the appointment had a significantly higher participation rate than those required to complete the FOBT after the health check. However, the return of FOBT kits for participants who were not requested to attend a health check was 25.5%, which is again higher than for people required to complete the FOBT after the health check.

Associated Outcomes Assessed by the Included Studies

Cole and colleagues [13] reported 60-69 year olds were significantly more likely to return FOBT kits, although there was no evidence for a difference in participation rates between genders. Telephone interviews conducted with non-responders to the Spanish trial [14] found lack of interest, good health status and unwillingness to interfere with daily life were the most frequently reported reasons for refusing to participate. Furthermore, the 'correctness' of completing sample (as measured by adequate faecal concentration to allow testing of the sample) was significantly higher for the group receiving the non-health professional visit than only the GP letter (75% versus 68%). King and colleagues [16] reported a higher participation rate for females, with non-responders generally stating they were 'too busy' to participate in screening. A higher compliance rate was evidenced for females in the Mant and colleagues study [17], which also reported wide variation in the compliance rate between practices involved in the trial.

3.2.3 Primary Care Review Discussion

There are very few published studies which have evaluated the effectiveness of a GP letter for improving participation in CRC screening using FOBT. Although a number of studies have involved primary care practitioners as part of the invitation process, the vast majority have included either multiple information interventions or have not compared a GP endorsement letter with an alternative intervention. All of the included studies in this review demonstrated an increased participation rate for people receiving a GP endorsement letter, although there were substantial differences between the content of the letter

and the delivery of the interventions. No outcomes associated with patient perceptions of the endorsement letter were evaluated for any of the included studies.

Two of the included studies [16, 17] found the highest rates of compliance were obtained when the GP letter and FOBT kit were posted directly to participants, rather than requiring participants to obtain the kit from their primary care practice. Alternatively, when required to attend either a primary care practice or a hospital-based clinic to collect their FOBT kit, participants overwhelmingly favoured the GP option to participate in screening [15]. These results, which are similar to previously published research [7-9], indicate that GP's can have a significant influence on CRC screening behaviour, and for the current research programme, the GP intervention should be delivered as part of the postal mail-out process, rather than requiring a participant to attend at their practice.

The trial by Cole and colleagues [13] is potentially the most applicable evidence available for modifications to the NHSBCSP invitation procedure. This trial demonstrated that an invitation letter, sent and endorsed by the patients' GP, was more effective than an invitation letter sent by a centralised screening office. The trial conducted by Courtier and colleagues [14] indicated that a brief intervention aimed at explaining the procedural aspects of completing the FOBT kit in conjunction with a GP letter, can increase screening over a GP letter alone. This suggested it would be beneficial to explore the development of an intervention which addresses patient concerns about the FOBT procedure, which could also be included with the GP endorsement letter.

There was very little evidence from the reviewed studies to indicate the appropriate wording or specific informational content which should be included in GP endorsement letters. Almost all of the GP letters devoted a single sentence to endorsing patient participation in CRC screening, although two of the interventions [13, 15] also included a brief sentence highlighting mortality caused by CRC for the population and screening could detect CRC at an early stage when treatment is more effective. Only one qualitative study, identified during systematic searching [18], has suggested recommendations for the content a GP letter. This included clarifying CRC screening is for asymptomatic people and provide information on the benefits and risks in conjunction with a direct recommendation to perform the screening test. Therefore, it was imperative to identify whether previous research had identified specific information which may affect people's decision to participate in screening, and further, the outcomes used to evaluate the effectiveness of these interventions.

3.3 Systematic Review 2: Provision of Information for CRC Screening

Recently, there has been considerable interest in identifying the most effective methods for conveying information about the benefits and risks associated with cancer screening. This is primarily due to an increased recognition that the provision of high-quality information to patients will convey a greater autonomy in medical decision-making [19-21], and further, the provision of information can lead to increased knowledge, lower anxiety about treatment choices and encourage discussions with health professionals [22].

Several publications have attempted to identify the content of information materials for cancer screening. These studies have shown materials normally do not provide information about the risks of screening and often overtly promote participation in screening [23-25]. Additionally, there is some confusion over what are the most effective methods for presenting information about the benefits and risks of screening without adversely affecting people's decisions [26, 27]. A further difficulty for this area of research is the lack of consistent outcomes used in studies evaluating information materials for decision-making [29].

To date, there has been no attempt to systematically review current publications concerning the provision of information for CRC screening. Therefore, the aim of this review was to identify and evaluate the content and presentation of information interventions about CRC screening to "average-risk" people. Additionally, the review aimed to determine the outcomes used to evaluate the effectiveness of the intervention materials.

3.3.1 Provision of Information Review Methods

The review methodology was based on recommendations for evaluating cancer screening and public health interventions developed by the Task Force on Community Preventive Services (TFCPS) [29-31]. It concentrates on three of the 12 intervention areas identified by the TFCPS as important for understanding uptake in screening. These include small media, group and one-to-one education interventions. These three intervention areas are concerned with educational, informational or motivational messages delivered to people

either through written information, DVD/video, lectures or one-to-one discussions between a patient and a health provider [29].

Inclusion/Exclusion Criteria

Studies reporting a patient information intervention (defined as verbal, written/print, video/DVD, or computerised delivery formats, either alone or in combination) about a CRC screening modality (e.g., FOBT, FS, CS, or combination) were considered for inclusion in the review. Only studies including "average-risk" patients and comparing the information intervention to a control group, or to another intervention group, were included in the review. Excluded studies were those which presented detailed information to elicit specific preferences for CRC screening, studies using reminder letters or systems, and qualitative studies. There were no restrictions on the type of quantitative study design or type of outcome measures evaluated in the study.

Search Strategy

A comprehensive search of medical databases was performed from 1990 to 2008 (updated in December 2010). Search strategies were devised to include the following search terms in combination with terms relating to CRC and screening: patient or health information, decision-making, knowledge and perceptions, and psychosocial factors. Additionally, reference lists from retrieved articles were examined for relevant publications and hand-searching of pertinent journals was conducted.

Study Selection

After the removal of duplicates, each study was assessed for inclusion based on citation title and abstract. Authors of studies not describing the content of the patient materials in sufficient detail were contacted to request further information. Further information on the content of materials was provided by 36 authors.

Data Extraction Process

The data extraction form was based on the TFCPS form [31] and modified to allow extraction of the content and presentation of information in the CRC screening materials. The modified form included study-specific categories (e.g. study setting and design, participant characteristics, etc.) and a further seven categories related to the type of information included the materials. These categories were developed from current guidance on the quality and presentation of information to enable informed decision-making for patients [32-34] and included information concerning CRC, description of screening modalities, benefits and risks of screening, and decision-making for screening.

3.3.2 Provision of Information Review Results

The systematic searches identified 7,024 potentially relevant articles. After adjusting for duplicates, 4,901 articles remained. After excluding studies not meeting the inclusion criteria on the basis of the abstract, 211 studies reviewed in detail. Of these, 165 studies were excluded due to the lack of a comparison group, the intervention only consisting of a letter or reminder letter, the study population was “high-risk” people, or that the study being based on a qualitative

research design. A further two studies were excluded as the authors failed to provide further information concerning their materials. Therefore, forty-four studies were identified for inclusion in the review.

The final 44 included studies were divided into five categories based on the modified classification used by the TFCPS [29] (see Table 3.3). The five modified categories were:

a) *National/Regional Evaluation Trials (Randomised Trials)*: three studies [35-37] included in this category were large-scale trials evaluating either the feasibility of introducing a CRC screening programme or a patient/provider intervention to improve compliance for CRC screening.

b) *Brief Educational Trials (Randomised Trials)*: 23 studies [38-60] included in this category evaluated one or more interventions presenting information on CRC screening and required participants to only view the intervention materials once.

c) *Brief Educational Studies (Non-Randomised Studies)*: 10 studies [61-65] included in this category were one or more interventions presenting information about CRC screening, required participants to only view the intervention materials once and were non-randomised studies or pilot designs.

d) *Extended Educational Studies*: five studies [66-75] in this category included several interventions presenting information over prolonged time-period, required participants to view the intervention materials more than once and were based on randomised study designs.

e) *Endoscopy Educational Studies*: three studies [76-78] in this category provided intervention materials concerned with endoscopic screening modalities and required participants to only view the intervention materials once.

Twenty-six studies were conducted in primary care settings (see Table 3.3). Nearly all of the studies included participants over the age of 50; two studies included people aged 45 years or older and two studies reported presenting information to people aged younger than 45 years. The number of participants in the studies ranged from 49 to 26,682.

The format of patient materials, the type of screening tests included in the materials, and the stated aims of the study are shown in Table 3.4. Around half of the studies employed only one format for the intervention materials, with approximately the same number including two formats. The majority of the included studies presented information concerning one to three screening tests, with 8 studies including information on four or more modalities. 28 studies stated the aim of the research was to improve compliance.

Table 3.3: Overview of included studies.

Type	*Study*	*Research design*	*Setting*	*Country*	*Number of Participants*	*Age range*
Eval	Segnan[35]	RCT	PC/Community	Italy	26,682	55-64
Eval	Sequist[36]	RCT	PC	USA	21,860	50-80
Eval	van Rossum[37]	RCT	Community	Netherlands	20,623	50-75
RCT	Basch[38]	RT	HBF	USA	456	52-79
RCT	Braun[39]	RT	Civic Clubs	USA	121	65†
RCT	Cole[40]	RT	Community	Australia	2,400	50-74
RCT	Dolan[41]	RCT	PC (IM)	USA	95	50-83
RCT	Friedman[42]	RCT	OCC	USA	160	≥ 50
RCT	Hart[43]	RCT	PC	UK	1,571	61-70
RCT	Jerant[44]	RCT	PC	USA	49	≥ 50
RCT	Makoul[45]	RCT	PC	USA	270	50-80
RCT	Meade[46]	RCT	PC	USA	1,100	≥ 50
RCT	Menon[47]	RCT	PC	USA	199	≥ 50
RCT	Miller Jnr[48]	RT	PC (IM)	USA	194	50-86
RCT	Myers[49]	RCT	HMO	USA	2,201	50-74
RCT	Myers[50]	RCT	PC	USA	1,546	50-74
RCT	Pignone[51]	RCT	PC	USA	249	50-75
RCT	Robb[52]	RT	PC	UK	1,945	45-66
RCT	Ruffin[53]	RCT	Community	USA	174	50-70
RCT	Smith[54]	RCT	Community	Australia		
RCT	Stokamer[55]	RCT	PC	USA	788	≥ 50
RCT	Tilley[56]	RCT	Worksites	USA	5,088	NR
RCT	Trevena[57]	RCT	PC	Australia	271	50-74
RCT	Tu[58]	RCT	PC	USA	210	50-78
RCT	Wolf[59]	RCT	PC	USA	402	≥ 65
RCT	Zapka[60]	RCT	PC	USA	938	50-74
EE	Campbell[61]	RT	Churches	USA	587	≥ 18
EE	Costanza[62]	RCT	PC	USA	2,448	50-75
EE	Marcus[63]	RCT	Community	USA	4,014	≥ 50
EE	Powe[64]	RT	SCC	USA	134	50-94
EE	Walsh[65]	RT	PC	USA	7,993	50-79
BE	Geller[66]	Survey	PC	USA	319	50-80
BE	Griffith[67]	Survey	Community	USA	106	50-81
BE	Griffith[68]	RT	Community	USA	62	48-75
BE	Lasser[69]	Survey	PC	USA	183	52-80
BE	Lewis[70]	CT	PC	USA	237	50-75
BE	Plaskon[71]	Survey	PC	USA	81	50-70
BE	Powe[72]	Survey	SCC	USA	70	52-92
BE	Powe[73]	Survey	SCC	USA	106	50-94
BE	Weinrich[74]	2 x 2 Survey	CMS	USA	211	72†
BE	Weinrich[75]	2 x 2 Survey	CMS	USA	171	72†
EES	Brotherstone[76]	Survey	PC	UK	65	60-64
EES	Denburg[77]	RCT	PC	USA	781	≥ 50
EES	Wardle[78]	RT	PC	UK	2,966	55-64

Note: RCT = Randomised controlled trial; RT = Randomised trial; CT = Controlled trial; PC = Primary Care or Internal Medicine; SCC = Senior Citizens Centres; OCC = Outpatient Community Clinic, IM = Internal Medicine; CMS = Congregate Meal Sites; HBF = Health benefit fund; HBRCPP = Health Behaviour Research Centre Participant Panel; RCL = Duke University Medical Center Risk Communication Lab; HMO = Health Maintenance Organisation; NR = not reported; † = reported mean age

Four publications aimed to improve knowledge, four publications aimed to improve decision-making, and seven studies were concerned with study-specific objectives ranging from evaluating a particular theoretical model to assessing the psychosocial impact of the materials. Seven separate categories

addressed pertinent areas of information about CRC background information, CRC screening tests, the benefits and risks associated with screening, patient decision-making and information that encouraged participation in CRC screening (see Tables 3.5 and 3.6).

Table 3.4: Format, type of screening information provided and stated aims of the included studies.

Type	*Reference*	*Format of materials*	*Screening Information*	*Stated aims of study*
Eval	Segnan[35]	Print	FOBT, FS	Increase compliance†
Eval	Sequist[36]	Print	FOBT, FS, COL	Increase compliance
Eval	van Rossum[37]	Print	FOBT, COL	Evaluate test performance
RCT	Basch[38]	Telephone, Print	FOBT, FS, COL, BE	Increase compliance
RCT	Braun[39]	Verbal, Print	FOBT	Increase compliance
RCT	Cole[40]	Print	FOBT	Increase compliance
RCT	Dolan[41]	Verbal, Print	FOBT, FS, COL, BE	Improve decision-making
RCT	Friedman[42]	Verbal, Video, Print	FOBT	Increase compliance
RCT	Hart[43]	Print	FOBT	Increase compliance
RCT	Jerant[44]	Computer	FOBT, FS, COL	Improve TTM constructs
RCT	Makoul[45]	Multimedia	FOBT, FS, COL	Improve knowledge/intention
RCT	Meade[46]	Video, Print	FOBT, FS, COL	Improve knowledge
RCT	Menon[47]	Computer	FOBT, FS, COL	Efficacy of materials
RCT	Miller Jnr[48]	Computer, Verbal	FOBT	Increase compliance
RCT	Myers[49]	Telephone, Print	FOBT	Improve compliance
RCT	Myers[50]	Telephone, Print	FOBT, FS	Improve compliance
RCT	Pignone[51]	Video, Print	FOBT, FS	Increase compliance
RCT	Robb[52]	Print	FOBT, FS	Evaluate psychosocial impact
RCT	Ruffin[53]	Computer	FOBT, FS, COL, BE	Preference and increase compliance
RCT	Smith[54]	Print, DVD	FOBT, COL	Improve decision-making
RCT	Stokamer[55]	Verbal, Print	FOBT	Increase compliance
RCT	Tilley[56]	Verbal, Print	FOBT, FS, DRE	Increase compliance
RCT	Trevena[57]	Print	FOBT, COL	Improve decision-making
RCT	Tu[58]	Verbal, Video, Print	FOBT, FS, COL, BE	Increase compliance
RCT	Wolf[59]	Verbal	FOBT, FS, COL	Improve decision-making
RCT	Zapka[60]	Video	FOBT, FS	Improve compliance
EE	Campbell[61]	Verbal, Video, Print	FOBT, FS, COL	Improve healthy behaviours
EE	Costanza[62]	Verbal, Print	FOBT, FS, COL	Increase compliance
EE	Marcus[63]	Print	FOBT, FS, COL	Increase compliance
EE	Powe[64]	Video, Print	FOBT	Increase compliance/knowledge
EE	Walsh[65]	Print	FOBT, FS, COL	Increase compliance
BE	Geller[66]	Computer	FOBT, FS, COL	Interest in screening
BE	Griffith[67]	Video	FOBT, FS, COL, BE, CT	Evaluate decision-making
BE	Griffith[68]	DVD	FOBT, FS, COL, BE	Interest in screening/preferences
BE	Lasser[69]	Verbal, Print	FOBT, FS, COL, BE	Increase compliance
BE	Lewis[70]	Video/DVD, Print	FOBT, FS, COL, BE, VC	Increase compliance
BE	Plaskon[71]	Verbal, Print	FOBT	Increase compliance
BE	Powe[72]	Video, Print	FOBT	Increase compliance*
BE	Powe[73]	Video, Print	FOBT	Increase compliance
BE	Weinrich[74]	ST, Verbal	FOBT	Improve knowledge
BE	Weinrich[75]	ST, Verbal	FOBT	Increase compliance*
EES	Brotherstone[76]	Print	FS	Improve knowledge
EES	Denburg[77]	Print	FOBT, FS, COL	Increase compliance
EES	Wardle[78]	Print	FS	Increase compliance

Note: FOBT = faecal occult blood test, FS = flexible sigmoidoscopy, COL = colonoscopy, BE = Double contrast barium enema, CT = computer tomography, DRE = digital rectal examination, ST = Slide-tape TTM = Transtheoretical Model
* = Also cancer fatalism and knowledge; † = Also acceptability and safety of proposed tests and detection rates.

Background information about CRC included statements about the incidence, mortality and development of the disease. Also included in this category was associated information about the numerical risk of developing or dying from CRC, visual representations of risk and a diagram or illustration of the colon/rectum. Almost all studies (41/44) included information about how CRC develops and mortality information (36/44). Few of the materials presented numerical information about developing or dying from CRC and were usually confined to materials described as decision-aids.

CRC specific information concerned the potential risk factors for developing CRC, symptoms of CRC, asymptomatic nature of CRC and the recommendations for CRC screening. Risk factors associated with CRC were included in most materials (35/44), and although information about symptoms (30/44) ranged from very brief to detailed. The asymptomatic nature of CRC was described by the majority of materials (38/44), with decision-aids often linking this to the rationale for screening.

Table 3.5: Content of information materials.

		CRC Background Information						CRC Specific Information				Test Specific Information			
	Reference	CRC Incidence	CRC Mortality	How CRC Develops	Diagram / Illustration	Numerical Risk	Visual Rep. of Risk	CRC Risk Factors	CRC Symptoms	No Symptoms	Scrn Age / Interval	Rationale for Test	How Test Performed	Meaning of Results	Further Diagnostic
Eval	Segnan[35]	✓		✓	✓			✓			✓	✓	✓	✓	✓
Eval	Sequist[36]			✓		✓		✓		✓	✓	✓	✓	✓	✓
Eval	van Rossum[37]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
RCT	Basch[38]	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓		
RCT	Braun[39]		✓	✓	✓			✓	✓		✓	✓	✓		
RCT	Cole[40]	✓		✓				✓	✓	✓	✓	✓	✓		
RCT	Dolan[41]	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
RCT	Friedman[42]		✓	✓	✓			✓	✓	✓	✓	✓	✓		
RCT	Hart[43]	✓	✓	✓		✓		✓	✓	✓	✓	✓	✓	✓	✓
RCT	Jerant[44]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
RCT	Makoul[45]		✓	✓	✓		✓	✓	✓	✓	✓	✓	✓		✓
RCT	Meade[46]		✓	✓		✓		✓	✓	✓	✓	✓	✓		
RCT	Menon[47]	✓		✓				✓		✓		✓	✓		
RCT	Miller Jnr[48]	✓	✓	✓	✓	✓	✓				✓	✓	✓		
RCT	Myers[49]	✓	✓	✓				✓	✓	✓	✓	✓	✓		
RCT	Myers[50]	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓		
RCT	Pignone[51]	✓	✓	✓	✓			✓		✓	✓	✓	✓	✓	✓
RCT	Robb[52]		✓	✓		✓	✓	✓	✓	✓	✓	✓	✓		
RCT	Ruffin[53]	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓
RCT	Smith[54]			✓	✓	?		✓	✓	✓		✓	✓	✓	✓
RCT	Stokamer[55]		✓	✓								✓	✓	✓	✓
RCT	Tilley[56]	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓		
RCT	Trevena[57]	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
RCT	Tu[58]	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓
RCT	Wolf[59]	✓	✓	✓		✓	✓			✓	✓	✓	✓	✓	✓
RCT	Zapka[60]	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓
EE	Campbell[61]		✓	✓				✓	✓	✓	✓	✓			
EE	Costanza[62]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
EE	Marcus[63]			✓	✓			✓	✓	✓	✓	✓	✓	✓	✓
EE	Powe[64]		✓	✓				✓	✓	✓		✓	✓		
EE	Walsh[65]	✓	✓					✓	✓	✓	✓	✓	✓	✓	✓
BE	Geller[66]		✓	✓				✓	✓	✓	✓	✓	✓	✓	✓
BE	Griffith[67]	✓	✓	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓
BE	Griffith[68]	✓	✓	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓
BE	Lasser[69]											✓	✓	✓	✓
BE	Lewis[70]	✓	✓	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓
BE	Plaskon[71]		✓						✓			✓	✓		
BE	Powe[72]		✓	✓				✓	✓	✓		✓	✓		
BE	Powe[73]		✓	✓				✓	✓	✓		✓	✓		
BE	Weinrich[74]		✓	✓	✓			✓	✓	✓	✓	✓	✓		
BE	Weinrich[75]		✓	✓	✓			✓	✓	✓	✓	✓	✓		
EES	Brotherston[76]	✓		✓	✓			✓		✓		✓	✓	✓	
EES	Denburg[77]	✓	✓	✓				✓		✓	✓	✓	✓	✓	✓
EES	Wardle[78]	✓		✓						✓		✓	✓	✓	

Test-specific information primarily concerned an overview of the screening test, how the test was performed, the meaning of test results, and for materials presenting information about FOBT or FS, the potential need for further diagnostic testing (CS) in the case of a positive result. All of the materials

included an overview of one or more screening modalities. This could be very brief information to quite extensive sections providing detailed information about the rationale for the test, an explanation for how the test detects CRC and potential costs associated with the screening modality. Around half of all materials (24/44) explained the meaning of test results.

All of the materials included information about the benefits of early detection and treatment (see Table 3.6), although this ranged from very brief statements to detailed explanations.

Table 3.6: Content of Information Materials.

		Benefits of Screening				Risks of Screening				Decision-Making Information				Encouraging Participation		
	Reference	Early Detection	Early Treatment	Prevent CRC	Reliability of Test	False-Positive	False-Negative	Pain / Embarrass.	Bleeding / Perforation	Speak to Physician	Values Clarification	No Screening	Further Information	Promote Scrn	Overcoming Barriers	Patient Narrative
Eval	Segnan[35]	✓	✓	✓				✓	✓	✓			✓	✓		
Eval	Sequist[36]	✓	✓	✓	✓					✓			✓	✓		
Eval	van Rossum[37]	✓	✓	✓	✓					✓			✓			
RCT	Basch[38]	✓	✓	✓						✓				✓		
RCT	Braun[39]	✓	✓							✓			✓	✓	✓	✓
RCT	Cole[40]	✓	✓		✓								✓	✓		✓
RCT	Dolan[41]	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓			✓	
RCT	Friedman[42]	✓	✓	✓						✓				✓	✓	✓
RCT	Hart[43]	✓	✓	✓									✓	✓	✓	
RCT	Jerant[44]	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓		✓	✓
RCT	Makoul[45]	✓	✓	✓						✓				✓		
RCT	Meade[46]	✓	✓							✓				✓	✓	✓
RCT	Menon[47]	✓	✓							✓				✓	✓	
RCT	Miller Jnr[48]	✓	✓	✓						✓				✓	✓	
RCT	Myers[49]	✓	✓							✓			✓	✓	✓	✓
RCT	Myers[50]	✓	✓	✓						✓			✓	✓		
RCT	Pignone[51]	✓	✓							✓			✓	✓	✓	✓
RCT	Robb[52]	✓	✓	✓									✓			
RCT	Ruffin[53]	✓	✓	✓		✓		✓	✓	✓	✓		✓	✓	✓	
RCT	Smith[54]	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓			
RCT	Stokamer[55]	✓	✓							✓			✓		✓	
RCT	Tilley[56]	✓	✓	✓						✓			✓	✓		
RCT	Trevena[57]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
RCT	Tu[58]	✓	✓	✓						✓			✓	✓	✓	✓
RCT	Wolf[59]	✓	✓		✓	✓	✓	✓		✓		✓				
RCT	Zapka[60]	✓	✓	✓				✓		✓			✓	✓	✓	✓
EE	Campbell[61]	✓	✓										✓	✓	✓	✓
EE	Costanza[62]	✓	✓	✓	✓			✓		✓			✓	✓	✓	
EE	Marcus[63]	✓	✓	✓						✓			✓	✓	✓	✓
EE	Powe[64]	✓	✓							✓				✓	✓	✓
EE	Walsh[65]	✓	✓							✓			✓	✓	✓	
BE	Geller[66]	✓	✓	✓		✓	✓	✓	✓	✓				✓	✓	✓
BE	Griffith[67]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓
BE	Griffith[68]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓
BE	Lasser[69]	✓	✓			✓		✓	✓	✓			✓			
BE	Lewis[70]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓
BE	Plaskon[71]	✓	✓							✓				✓	✓	
BE	Powe[72]	✓	✓							✓				✓	✓	✓
BE	Powe[73]	✓	✓							✓				✓	✓	✓
BE	Weinrich[74]	✓	✓							✓			✓	✓	✓	✓
BE	Weinrich[75]	✓	✓							✓			✓	✓	✓	✓
EES	Brotherston[76]	✓	✓		✓	N/A	✓	✓	✓				✓	✓		✓
EES	Denburg[77]	✓	✓	✓		✓		✓	✓	✓			✓	✓		
EES	Wardle[78]	✓	✓	✓		N/A		✓		✓			✓	✓	✓	✓

Over half of the materials (27/44) also included statements about how removing polyps can prevent CRC from developing. Very few studies (12/44) addressed the reliability of the screening modality or provided any information concerning

the risks associated with screening. Those that did provide information were generally described as decision-aids.

The decision-information category was concerned with statements about patient decision-making for CRC screening. Nearly all the materials (40/44) included a statement about speaking with their primary care provider or physician and most (33/44) provided references or descriptions for where people could receive further information about CRC screening. Only decision-aid materials included value-clarification exercises or provided information about the potential consequences of not participating in screening.

The final category for the content of materials was concerned with information included in the material that directly encouraged participation in CRC screening. The majority of materials (32/44) explicitly endorsed or promoted CRC screening. These statements tended to emphasise the importance of starting screening, that CRC screening can save lives, or directly stated that the patient should participate in screening. Over half (24/44) of the materials provided statements about how to overcome potential barriers to CRC screening. Often, this was associated with alleviating potential concerns about screening procedures (e.g. time required to complete FOBT, perceived safety of FS, etc.), although some materials included statements addressing concerns people may hold about a diagnosis of cancer (e.g. most people will not have cancer but will have peace of mind after the test). Approximately half of the materials (21/44) incorporated patient testimonials or narratives (previously screened individuals or people who have been diagnosed with CRC after screening).

Outcomes Evaluated by Included Studies

The most frequently reported outcomes are shown in Table 3.7. Sixteen studies included intention to screen as an outcome; 10 of these studies included one question to determine screening intention (generally a Likert response format) while the remainder included multiple items. Seventeen studies reported using a knowledge scale. There was significant variation in regards to the number of items included in the knowledge scales (from 3 to 16 items), the method of data collection (written questionnaire responses versus verbal responses) and the reporting of the psychometric properties of the knowledge scale (validity and reliability). A minority of studies (7/17) provided specific information on the items included in the knowledge scale [45, 47, 48, 52, 54, 57, 76] or detailed the development, reliability and validity of the scale [42, 47, 54, 72-74]. Three studies employed a verbal or open-ended response format where responses were coded by the researchers to determine the level of knowledge [45, 54, 57, 76] and one study based knowledge on the manufacturer's instructions for completing FOBT [48].

Table 3.7: Outcomes evaluated in the included studies.

	Reference	Test Compliance	Intention to Screen	CRC Knowledge	Attitudes / Values	Self-efficacy	Decision Process	Anxiety / Worry	Risk Perceptions	Preference for Test	Physician Discussion	Evaluation of Materials	Cost of Intervention	Theoretical Basis	Pilot Devel of Materials
Eval	Segnan[35]	✓													
Eval	Sequist[36]	✓													
Eval	van Rossum[37]	✓													
RCT	Basch[38]	✓													
RCT	Braun[39]	✓	✓	✓	✓	✓						✓			
RCT	Cole[40]	✓													
RCT	Dolan[41]	✓		✓			✓			✓		✓			
RCT	Friedman[42]	✓	✓	✓		✓			✓		✓				
RCT	Hart[43]	✓										✓			
RCT	Jerant[44]			✓	✓	✓				✓		✓		✓	
RCT	Makoul[45]		✓	✓						✓	✓	✓			✓
RCT	Meade[46]			✓								✓			✓
RCT	Menon[47]			✓	✓	✓	✓		✓			✓		✓	
RCT	Miller Jnr[48]	✓	✓	✓	✓				✓			✓			
RCT	Myers[49]	✓													
RCT	Myers[50]	✓			✓	✓	✓	✓	✓	✓				✓	
RCT	Pignone[51]	✓	✓				✓			✓	✓			✓	✓
RCT	Robb[52]		✓	✓				✓				✓			
RCT	Ruffin[53]	✓	✓							✓	✓			✓	
RCT	Smith[54]	✓	✓	✓	✓	✓	✓	✓				✓		✓	✓
RCT	Stokamer[55]	✓											✓		
RCT	Tilley[56]	✓												✓	
RCT	Trevena[57]	✓	✓	✓	✓	✓	✓	✓				✓		✓	
RCT	Tu[58]	✓													✓
RCT	Wolf[59]		✓						✓			✓			✓
RCT	Zapka[60]	✓									✓	✓		✓	
EE	Campbell[61]	✓										✓		✓	
EE	Costanza[62]	✓	✓											✓	
EE	Marcus[63]	✓										✓		✓	
EE	Powe[64]	✓		✓								✓		✓	
EE	Walsh[65]	✓													
BE	Geller[66]		✓								✓	✓		✓	✓
BE	Griffith[67]		✓	✓			✓			✓	✓	✓			✓
BE	Griffith[68]		✓	✓			✓			✓	✓	✓	✓		✓
BE	Lasser[69]	✓			✓					✓					
BE	Lewis[70]	✓	✓									✓	✓		
BE	Plaskon[71]	✓							✓					✓	
BE	Powe[72]	✓		✓										✓	
BE	Powe[73]	✓									✓			✓	
BE	Weinrich[74]	✓		✓											
BE	Weinrich[75]	✓													
EES	Brotherston[76]	✓		✓											✓
EES	Denburg[77]	✓													✓
EES	Wardle[78]	✓	✓		✓	✓		✓	✓			✓			

The most commonly reported outcome for the included studies (35/44) was self-reported or verified compliance with CRC screening. Participation rates for FOBT studies were highly variable; the proportion of people participating in screening ranged from 5.2% to 93% for the intervention groups and 6.6% to 84.6% for the control groups (see Table 3.8). Many of the included studies

reported significant increases in participation, although this difference rarely exceeded an increase of over 15% between the intervention and comparison group.

Table 3.8: Participation rates for included studies using FOBT.

Study	Screening Modality	Intervention Group	Control Group	Significance	Time Frame for Participation
Segnan[35]	FOBT	30.1% (Mail)	28.1% (GP)	NS	24 months
Sequist[36]	FOBT	25.4%	20.4%	$p < 0.001$	15 months
van Rossum[37]	FOBT	59.6% (iFOBT)	46.9% (gFOBT)	$p < 0.01$	12 months
Braun[39]	FOBT	66.7%	84.6%	NS	16 weeks
Cole[40]	FOBT	48.3% (Adv Not)	39.7%	RR = 1.23	12 weeks
Friedman[42]	FOBT	43.6%	36.0%	NS	3 months
Hart[43]	FOBT	35.7%	29.4%	NS	NR
Miller Jnr[48]	FOBT	62.4%	63.4%	NS	30 days
Myers[49]	FOBT	48.1% (TIP)	27.4%	$p < 0.01$	90 days
Smith[54]	FOBT	59%	75%	$p < 0.001$	3 months
Stokamer[55]	FOBT	65.9%	51.3%	$p < 0.01$	6 months
Trevena[57]	FOBT	5.2%	6.6%	NS	1 month
Tu[58]	FOBT,	69.5%	27.6%	OR = 6.38	6 months
Campbell[61]	FOBT	36.8% (TPV)	21.7%	NS	1 year
Powe[64]	FOBT	61% (CSE)	15% (Trad)	$p < 0.013$	12 months
Walsh[65]	FOBT	58.9%	64.8%	$p = 0.05$*	2 years
	FOBT	38.0%	27.8%	$p < 0.01$*	5 years
Plaskon[71]	FOBT	51%	0%	$p < 0.001$	1 week
Powe[72]	FOBT	60%	68%	NS	1 week
Powe[73]	FOBT	63% (CSE)	7%	$p < 0.0001$	1 year
Weinrich[75]	FOBT	93% (EE/AAC)	56%	$p < 0.000$	6 days

Note: TIP = Tailored Information plus Phone-call Group; CSE = Cultural Self-Empowerment Group; EE/AAC = Elderly Educator, Adaption for Aging Method Group; CSE = Cultural and Self-Empowerment Group; Trad. = Traditional/Control group; NR = Not reported; * = significance based on change in compliance between baseline and 2 years

Studies including multiple screening modalities (FOBT, FS, COL, BE) also demonstrated highly inconsistent rates of participation; ranging from 14.6% to 84.1% for the intervention groups and 4.0% to 79.9% for the control groups (see Table 3.9). The time-frame for verified or self-reported completion of screening varied greatly between studies. In regards to FOBT compliance, the time-frame for return of the kits ranged from six days to five years. For compliance with multiple screening modalities, the time-frame ranged from two months to five years.

Table 3.9: Participation rates for included studies using multiple screening modalities.

Study	Screening Modality	Intervention Group	Control Group	Significance	Time Frame for Participation
Segnan[35]	FS	28.1% (+FOBT)	28.1% (FS only)	NS	24 months
Sequist[36]	FOBT, FS, COL	44.0%	38.1%	$p < 0.001$	15 months
Basch[38]	FOBT, FS, COL, BE	27.0%	6.1%	RR = 4.4	6 months
Dolan[41]	FOBT, FS, COL, BE	48.7%	51.9%	NS	2-3 months
Myers[50]	FOBT, FS	48.5%	32.6%	$p < 0.001$	24 months
Pignone[51]	FOBT, FS	36.8%	22.6%	NR	3 months
Ruffin[53]	FOBT, FS, COL	64.4%	37.9%	$p < 0.035$	24 weeks
Tilley[56]	FOBT, FS, DRE	47%	44%	$p < 0.001$	2 years
Zapka[60]	FOBT, FS	55.1%	55.3%	NS	4-6 months
Costanza[62]	FOBT, FS, COL	44%	46%	NS	3 months
Marcus[63]	FOBT, FS, COL	51% (MT)	42% (SU)	$p < 0.03$	14 months
Walsh[65]	FOBT, FS, COL	77.2%	77.6%	NS	2 years
		84.1%	79.9%	NS	5 years
Lasser[69]	FOBT, FS, COL, BE	31.2%	8.9%	$p < 0.0002$	6 months
Lewis[70]	FOBT, FS, COL, BE	14.6%	4.0%	$p < 0.01$	5 months
Brotherstone[76]	FS	68.3% (Illust)	67.5% (Text)	NS*	6 months
Denburg[77]	FOBT, FS, COL	70.7%	59.0%	$p < 0.001$	4 months
Wardle[78]	FS	53.5%	49.9%	$p < 0.05$	3 months

Note: *Brotherstone indicated that the study was not powered to address compliance.

3.3.3 Provision of Information Review Discussion

Overall, there was significant variation in the content, format, presentation and types of outcomes used to evaluate the provision of patient information for CRC screening. Even after categorising studies according to the primary characteristics of the intervention, there was still substantial disparity between what information was included, the way information was presented and how the interventions were evaluated. Probable reasons for this variation include differences between the specified aims of the individual studies (e.g. promote participation in screening in comparison to encouraging an informed decision) and the range of alternative formats employed (e.g. computerised formats allow more information to be included in the materials than do print or verbal interventions).

There was some communality between the materials in regards to content. Consistently, the materials included general information about the development of CRC and highlighted mortality associated with CRC. The reviewed materials also usually described risk factors and the asymptomatic nature as well as symptoms of CRC. All of the materials provide at least a brief rationale for CRC screening, how testing occurs, and the benefits of early detection and treatment. However, very few studies included information about the potential risks of screening and generally directly promoted participation in screening. Materials which did include information about the risks of screening were either decision aids or only concerned with endoscopy screening modalities. The most frequently included information about decision-making for CRC was the suggestion or recommendation that patients speak to their physician to clarify any uncertainties they may hold regarding their participation. These results replicate previous reviews of the content of cancer screening materials which found that risks were rarely included in the information materials and directly encouraged participation in screening [23-25].

The primary outcome used to demonstrate the effectiveness of an intervention was either self-reported or verified compliance with CRC screening. However, there was considerable variation in the time-frame used to define compliance with screening. Furthermore, there were also large differences between the baseline participation rates for the comparison groups (range 0% to 85%) and the participation rates in the intervention groups (range 5% to 93%). Coupled with the differences between the content and format of the included materials, this effectively makes comparisons between the interventions extremely difficult.

The majority of studies reported a statistically significant increase in participation rates. However, for most of the studies reporting a significant increase, the proportional difference was often modest (e.g. around 5% to 15%). Only nine studies [38, 49, 53, 58, 64, 69, 71, 73, 75] reported an increase in participation of greater than 15%, although in six of these studies the time-frame for compliance was in excess of 6 months. Indeed, a minority of studies actually reported a decrease in participation between the intervention and control groups [39, 41, 48, 57, 60, 62, 65, 72]; however, this was small, and usually for studies with shorter compliance time-frames or studies which described the intervention as a decision-aid. The reasons for the variability in compliance rates between studies are related to differences in the time frame for assessing compliance, structural barriers (e.g., availability of FOBT or endoscopy services [71]), compliance not being the primary outcome of the study [57], and the number of times screening was offered to participants (i.e., single versus multiple times).

The lack of consistency between reported outcomes for the included studies was similar to previous research concerning informed decision-making in cancer screening [28]. The present review demonstrated this problem was related to all studies evaluating information materials for CRC screening and not only to those concerned with informed decision making. Although around half of the included studies attempted to evaluate patient perceptions of the materials, this ranged from single item questions to more thorough investigations of participant views of the content, format and functional aspects

of the materials. Around a third of the studies reported employing one or more theoretical frameworks for the development or evaluation of the materials, which is similar to previous reviews [79, 80]. The general lack of the inclusion of a theoretical framework for the development and evaluation of materials impacts on the ability of studies to provide a rationale for the reasons the information have an effect on participants, and further, limits the types of outcomes available for measuring changes in participation and associated outcomes.

3.4 Conclusion

The two systematic reviews revealed several important considerations for the development and design of the present research programme. Firstly, the review of GP endorsement letters for improving participation in CRC screening exposed a paucity of research in this area. Even though the review demonstrated this intervention can improve participation, very few studies have directly evaluated the effectiveness of GP involvement in the invitation process for CRC screening and none in conjunction with the NHSBCSP. As GP's are not currently involved in the NHSBCSP, the potential for improving participation in the programme was an obvious area requiring further investigation based on the results of the review.

Secondly, the review of patient information for CRC screening found most interventions used materials which directly promote participation. This is incompatible with the NHSBCSP procedure for providing information with the invitation to screening to encourage informed choice [10]. However, the review also identified few studies which have attempted to evaluate non-promotional

materials (e.g. decision-aids) and studies which used materials aimed at providing advice and assistance with the procedural aspects of completing CRC screening [14, 39, 42, 48]. Based on the quite extensive requirements for developing a decision-aid, and given the general lack of research for interventions targeting functional aspects of CRC screening, it was decided that the present research should concentrate on the development and evaluation of a brief intervention aimed at providing advice on how to complete FOBT screening.

Finally, it was clear CRC screening participation should be the primary outcome measure used for evaluating the interventions in the research programme. Nearly all studies included in both reviews employed participation as the primary outcome measure. However, few studies attempted to investigate the reasons surrounding observed changes in participation or attempted to comprehensively investigate participants' views of the intervention materials. This suggested that a questionnaire component should also be included in the trial to ascertain participant's view of the interventions, and potentially, changes in knowledge, attitudes, and autonomous decision-making.

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Chapter 4: Intervention Development

4.0 Objectives of the Chapter

The main objectives of this chapter are to outline the design of the three year research programme and the development of the two interventions with the stakeholder representatives. The chapter also provides an overview of the theoretical foundations for design and evaluation of the interventions.

4.1 Overview of the Research Programme

The main objective of the three-year research programme was to develop and evaluate a primary care-based intervention to improve participation in the NHSBCSP (see Appendix 1.1). The two proposed interventions were a detailed procedural leaflet and a GP endorsement letter. The programme was divided into three main phases:

a) Phase 1: Intervention Development (organisation and consultation with key stakeholders to assist in the development of the two interventions).
b) Phase 2: Pilot Evaluation (quantitative and qualitative evaluation of the intervention materials and questionnaire outcomes for the factorial trial).
c) Phase 3: Factorial Randomised Trial (prospective investigation of the interventions for improving participation in the NHSBCSP and investigating the impact of the interventions for both invited participants and primary care practices involved in the trial).

4.2 MRC Framework for Complex Interventions

The design and methodology of the present research programme was based on the original Medical Research Council (MRC) framework for complex interventions [1, 2]. Primarily concerned with randomised controlled trials, the framework identifies a step-wise approach to the evaluation of interventions with multiple components or outcomes [1]. The five sequential phases of the guidance are:

1) Pre-Clinical phase ('Theory'): exploration of relevant theory and current evidence to ensure the most appropriate choice of intervention and hypotheses
2) Phase I ('Modelling'): identifying the components of the intervention and outcomes to provide evidence of effectiveness
3) Phase II ('Exploratory Trial'): describing the components of a replicable intervention based on feasible protocol and comparison of the intervention to an appropriate alternative
4) Phase III ('Definitive RCT'): comparison of a fully-defined intervention to an appropriate alternative using a theoretically defensible protocol which is reproducible, adequately controlled and with appropriate statistical power
5) Phase IV ('Long-Term Implementation'): determine whether the results of the intervention can be replicated by others in uncontrolled settings over a longer period of time [1, 2]

Although the updated MRC documentation [3-5] conceptualises the evaluation of complex interventions as a less linear process than the previous guidance, the iterative nature of systematically developing the theoretical basis and

assessing pertinent outcomes prior to an evaluation of the intervention remains essentially the same. The focus for the present research programme was on the first three phases of the original MRC guidance. Particular attention was attached to the development of the initial two phases of the guidance ('Pre-clinical' and 'Modelling' phases) to provide a comprehensive basis for the final phase of the research, a factorial randomised trial ('Exploratory Trial').

4.3 Intervention Development

The aim of the first phase of the research programme was to develop the two interventions (procedural leaflet and GP endorsement letter) for the factorial trial. The development of the two interventions was based on theoretical models of behaviour change, informed by previous research in this field, and additionally, refined through discussion with representatives from a stakeholder group specifically organised for this project. The current interventions were defined as written population information materials which aimed to enhance decision-making and improve participation in the NHSBCSP. The materials were designed to be balanced, non-coercive and complement the current information resources provided by the NHSBCSP.

4.4 Overview of Theoretical Models for Cancer Screening Research

Studies developing or evaluating information materials for cancer screening should adopt theoretical models of health behaviour to formulate the relative influence of factors affecting participation [6]. The theoretical models which are most frequently investigated include the Health Belief Model (HBM), Theory of Reasoned Action (TRA), Theory of Planned Behaviour (TPB), Transtheoretical

Model (TTM), and the Precede-Proceed Model [7, 8]. However, only around a third of publications evaluating either information materials or health behaviour interventions report being informed by one or more the available theories [6, 8, Chapter 3]. There is increasing evidence suggesting theory-based interventions are more effective and can contribute to a larger effect on behaviour change than generic interventions, and further, strategies combining multiple concepts can have a greater effect than approaches using a single theory [9-12].

4.4.1 Health Behaviour Theories Informing the Research Programme

The present research incorporated components of three prominent health behaviour theories. Two of these theories have been used extensively in cancer screening research, whilst the third has not previously been evaluated in this context.

Theory of Planned Behaviour (TPB)

In TPB, the proximal determinant of behaviour is the person's intention to engage in that behaviour [12-13]. The theory postulates that there are three main components affecting a person's intention to engage in a given behaviour. These are:

a) attitude towards behaviour: refers to the degree to which a person has a favourable or unfavourable evaluation of the behaviour
b) subjective norms: perceived social pressure will affect a person's decision to engage in the behaviour

c) perceived behavioural control: refers to the perception of the ease or difficulty of performing the behaviour of interest and whether they have the necessary skills to perform the behaviour [13-15]

Therefore, people are likely to follow a particular health action if they believe the behaviour will lead to outcomes they favour or value, believe significant others will see this behaviour as positive and feel the action is under their control [13, 14].

TPB is an attractive theory for cancer screening research as surveys examining the reasons for participation often fail to incorporate individual-level determinants of the behaviour [16]. Meta-analyses of studies utilising TPB account for around one-third of the variance for the components of the theory [17-19]. However, criticisms of the model include the necessity to include additional explanatory variables, the conceptual similarity of perceived behavioural control to self-efficacy in social cognitive theory and difficulties and the relatively small amount of variance explained by intention or perceived behavioural control for a particular behaviour [18, 19].

For the purposes of the present research, TPB primarily informed the content of the interventions through improving participants' perceived behaviour control of completing the FOBT kit and challenging negative attitudes towards completing the test. The primary components of the theory (intention, attitudes, subjective norms and perceived behavioural control or self-efficacy) were also included in the design of the questionnaire components of the research.

Social Cognitive Theory (SCT)

SCT is one of the major theories and most commonly used in combination with other health behaviour models. According to this approach, the two key determinants of engaging in a behaviour are perceived self-efficacy and outcome expectancies [20-22]. Self-efficacy is the confidence a person holds about performing a specific behaviour, and includes the self-belief the person has to overcoming the barriers associated with performing the behaviour [20, 21]. Outcome expectancies are a set of core determinants that predict engaging in a particular behaviour which include:

- knowledge: of the health benefits and risks of a behaviour
- outcome expectations: the expected benefits and costs for engaging in a behaviour
- perceived facilitators and impediments: personal, social and environmental influences which can impact on engaging in a particular behaviour [20, 23-25]

One underlying assumption of the current self-efficacy construct is that an individual's ability to perform the target behaviour rests mainly on interdependent psychological factors; such as the motivation to perform the action, awareness or knowledge of the benefits and risks of the behaviour, and a positive attitude towards the behaviour and associated outcomes [25]. These factors are strongly associated with an individual's perceived self-efficacy to participate in the behaviour, and therefore, interventions which aim to stimulate motivation, improve knowledge and instil a belief that engaging in the behaviour will lead to a desirable outcome are important for behavioural change [22, 25].

The perceived behavioural control element of TPB is highly compatible with the concept of perceived self-efficacy included in SCT [13, 19, 23]. However, TPB does not include knowledge as a component for evaluating health interventions, not does it emphasise the role of expectations of a positive outcome for behavioural change. Therefore, SCT was incorporated into the development and evaluation of the interventions to allow a comprehensive examination of individual factors which may improve participation in CRC screening.

Self Determination Theory

Self-determination theory (SDT) is a general theory of human motivation providing a framework to understand how practitioners, researchers and policy makers can improve patients' health and psychosocial outcomes [26]. The theory postulates that people have three innate psychological needs (autonomy, competence and relatedness) which are vital to supporting healthy functioning and determining behaviour [26, 27]. A central tenant of SDT is the distinction between autonomous and controlled behaviours, which are two types of motivated behaviours that involve different reasons for engaging in an action [26, 27].

According to SDT, three primary types of motivation underlie people's behaviour. These are represented along a continuum of self-determination or autonomy ranging from amotivation (least autonomous) to intrinsic motivation (completely self-determined). These are defined as:

a) Amotivation: refers to behaviours that are neither extrinsically nor intrinsically motivated. Amotivated behaviours are non-regulated and non-intentional
b) Controlled regulation: encompasses two forms of extrinsic motivation; 'External regulation' concerns behaviours that are non-autonomous and performed in order to obtain a reward or to avoid negative consequences. 'Introjected regulation' refers to activities that have been partially internalised by the person through previous experience, but are again not fully autonomous and are performed to avoid feeling guilty or gaining approval from significant others
c) Autonomous regulation: includes three forms of motivation which are considered autonomous or self-determined. 'Identification' occurs when the behaviour is positively endorsed, judged as important and chosen by the person. 'Integration' refers to performing a behaviour because it is perceived as being strongly related to other beliefs which are similar to that behaviour. 'Intrinsic motivation' represents the highest level of self-determination and concerns behaviours which people engage in for the pleasure or satisfaction derived from performing the act [26-29]

As the distinction between autonomous regulation, controlled regulation and amotivation is represented as a continuum, actions or behaviours can be evaluated to the degree they are self-determined or not [26, 28]. This led to the development of the Treatment Self-Regulation Questionnaire (TSRQ) for investigating health-related behaviours. SDT is the only theory of motivation and behaviour in which the importance of autonomous self-regulation, including

methods for assessing it, is emphasised [30]. Given the importance for autonomous decision-making emphasised by the NHS CSP [31], the assessment of self-determination was perceived to be an innovative and appropriate theoretical component for the present research.

4.5 Overview of Evidence Informing Intervention Development

The content of the both interventions was informed by previously published research conducted by the Department [32-35] in combination with the detailed systematic reviews of current research presented in the preceding chapters (see Chapters 2 and 3). Traditionally, primary care-based interventions have relied on either behavioural change strategies based on 'informational power' (presenting factual information about health consequences) or 'expert power' (using professional influence to effect behaviour change) [36]. Previous research has demonstrated the provision of information based on these two strategies can positively effect participation in CRC screening [37-40]. However, no study has attempted to evaluate these two interventions together, and further, interventions focusing on 'informational power' have not included specific procedural information aimed towards completing the enhancing peoples' abilities to perform the FOBT kit. The interventions were designed to target a selection of identified barriers to participation that were amenable to change using print materials.

4.5.1 GP Endorsement Letter

A primary objective of the present research was to evaluate the effectiveness of a GP endorsement letter for improving participation in an organised CRC screening programme. Although an area of research that has received relatively little attention, studies have demonstrated the inclusion of a GP endorsement letter with an invitation can improve participation in CRC screening [41-43]. However, no study has evaluated the effectiveness of a GP endorsement letter for improving participation in the NHSBCSP. Furthermore, information concerning the content of the endorsement letter is often unavailable or extremely brief in the reported literature. A primary aim for the present research was to develop the content of the endorsement letter in conjunction with GP's, the stakeholder group and informed by the available evidence.

4.5.2 Procedural Barriers

Very few studies have directly attempted to ascertain people's views of the procedural barriers associated with the FOBT screening. Providing specific information about alternative methods for actually performing the test should, by extension, improve people's perceptions and perceived self-efficacy for completing the test. Evidence from research studies [44-48] has shown that embarrassment, unpleasantness with collecting samples, lack of time, storing the kit, and concerns about performing the test correctly are major procedural barriers reported by people for not completing FOBT screening. The UK CRC Screening Pilot also found that irregular or loose bowel movements prevented around 1 in 5 people completing the kit [48]. A primary aim for developing the

procedural leaflet was to identify the most pertinent concerns people have about the FOBT kit and attempting to enable behavioural change by providing useful alternatives to help people complete screening.

4.5.3 Information Interventions to Compliment NHSBCSP Materials

The stated aim of the NHS Cancer Screening Programmes is to provide sufficient information about the risks and benefits of screening to enable a person to make an informed choice about participating or not in the programme [31]. Therefore, the interventions developed for the present research needed to complement this approach and provide information which was not overtly coercive, aimed to reinforce messages included in the current NHSBCSP materials and target both the ‘informational’ and ‘expert’ power strategies to effect behavioural change.

4.5.4 Effective Communication and Message Framing

The way information is presented is central to decision-making about engaging in health behaviours or for participation in preventive screening [49, 50]. Understanding the effects of message framing for participation in screening was crucial for the development of the interventions. Gain-framed messages emphasise the benefits of a behaviour; for example "Colorectal cancer screening reduces your chance of dying". Whereas loss-framed messages highlight the risks associated with a behaviour; for example "Not participating in screening decreases your chance of beating cancer". The decision to include gain-framed messages was based on the uncertainty surrounding the value of loss-framed messages for cancer screening [51, 52], research suggesting gain-

framed messages may be more easily understood by older people [53], and to avoid negative (fear inducing) or perceived coercive statements in the interventions. Therefore, gain-framed messages were included in both draft interventions.

4.5.5 Health Literacy

Health literacy also has a significant effect on participation and peoples' perceptions of CRC screening [54-56]. Furthermore, people with low levels of health literacy have very poor perceptions of their ability to complete the FOBT kit [57]. The content and wording of the interventions needed to be accessible to people with lower levels of health literacy, especially in regards to the detailed procedural leaflet. Therefore, significant consideration was given to ensuring the readability of the interventions was based on current guidance for clarity and people with low levels of literacy [58-61] in conjunction with feedback from the stakeholder representatives.

4.5.6 Knowledge, awareness and risk

Poor knowledge or awareness of CRC and CRC screening are consistently reported as barriers to participation [62-64]. Furthermore, inaccurate risk perceptions (i.e. perceiving the risk of developing CRC as very low or very high) is also associated with poor participation in CRC screening [65, 66]. The objective of the interventions was not to repeat information people already receive as part of their invitation; however, it was important to highlight the most salient aspects of screening (i.e. rationale for screening, identifying CRC early

to reduce risk of dying, invited population at highest risk of developing CRC) that are often misunderstood and affect participation.

4.5.7 Tailored information

Research has shown that tailoring information, either through personalised invitations or inclusion of highly relevant information for the person, can improve participation in CRC screening [40, 67-69]. Although it was not possible to perform individualised assessments to specific tailor the interventions for potential participants, it was especially crucial for the procedural leaflet to include targeted information concerning potential barriers to completing the test. Therefore, the interventions were designed to be personalised and aimed to include information which would be personally relevant to people invited to the NHSBCSP.

4.5.8 Perceived self-efficacy

High perceived self-efficacy has been demonstrated to be associated with CRC screening participation [70-72] and shown to significantly increase following the provision of high-quality patient information interventions [73-75]. Both interventions aimed to increase an individual's perceived self-efficacy for participating in screening through either the offer of support in the GP endorsement letter, or through the advice provided to complete the FOBT kit in the procedural leaflet.

4.6 Initial Development of the Interventions

Both interventions were developed prior to submission to the stakeholder representatives. The rationale for the content of the interventions is detailed in the following sections.

4.6.1 Initial Development of the GP Endorsement Letter

The GP endorsement letter was designed to enact behavioural change through encouragement ('expert power') to complete screening by a persons' trusted health provider (see Appendix 4.1). The letter was tailored to the individual by including their name and also being printed on their GP practice letterhead. The letter expressed the GP's support for the NHSBCSP and included information on the severity of CRC for the invited age group and the rationale for early detection of CRC. The next paragraph provided an offer of support from the GP to contact them if the person had any questions about participating in screening. The final section included information about the symptoms of CRC and urged people to contact their GP if they experienced these symptoms for more than four weeks.

4.6.2 Initial Development of the Detailed Procedural Leaflet

The procedural leaflet was designed to enact behavioural change through improving peoples' perceptions of the FOBT kit and increased self-efficacy for completing the test (see Appendix 4.2). The title ("Helping You with the Test") was non-confrontational and indicated the leaflet was aimed at providing advice on completing the FOBT kit. The first section included a tailored approach which posed questions identified to barriers that may prevent people from

participating based on potential negative views of the procedure. The next section reinforced the rationale for screening (reducing risk of dying from CRC) and key messages about the risks of CRC. The following sections ('Before you begin' and 'Tips for collecting your sample') addressed ways people could reduce the difficulties associated with the test procedure and also for people with bowel conditions (e.g. diarrhoea or constipation). The final sections included information about storing their sample or contacting the Screening Hub if they had any further questions. The procedural leaflet was primarily aimed at enhancing peoples' attitudes towards the FOBT kit and improving perceived self-efficacy for completing and returning the kit.

4.7 Involvement of Consumer and Professional Experts

The final essential component for developing and evaluating complex interventions, not specifically stated in the original MRC guidance, is the involvement of user and expert representatives in the design and conduct of the research. There has been considerable interest in promoting greater involvement of the public and service-users in the design and conduct of research studies [76, 77]. Consumer involvement in developing patient information material has been suggested to improve the clarity of information and the knowledge of people who read the material [78-80].

The inclusion of a representative group of professional and consumer stakeholders, who have a broad understanding of CRC screening, was viewed as imperative for helping to provide advice for the content of the interventions and for the potential dissemination of the materials. This required recruiting and

organising a stakeholder group to provide guidance and comments on the draft detailed information leaflet and for the content of the GP endorsement letter.

4.8 Stakeholder Recruitment

After receiving confirmation of the NIHR Award, potential representatives were approached to request their involvement in the research. The stakeholder representatives were first contacted by telephone and then sent a formal invitation letter (see Appendix 4.3) with the protocol for the research programme (see Appendix 1.1). After further discussions, 13 representatives agreed to participate in the stakeholder group. The stakeholder group (see Table 1) consisted of representatives with extensive experience in the organisation and delivery of cancer screening services, the development and evaluation of patient information materials and direct experience of providing advice to people about CRC.

Table 1: Stakeholder group representatives and affiliations.

Organisation/Role	Representative
Consumer Representative	Ms Christina Gratis (NIHR Patient Representative)
Consumer Representative	Mrs Diane McCloud (Bowel Cancer Survivor)
NHS Cancer Screening Programmes	Prof Julietta Patnick (Director) [†]
NHS Cancer Screening Programmes	Ms TJ Day (Informed Choice Coordinator)
Department of Health Cancer Policy Team	Mr Tim Elliot (Team Leader for Cancer Screening)
NHSBCSP Southern Screening Hub	Dr Stephen Halloran (Director)
NHSBCSP Southern Screening Hub	Ms Katy Reed (Hub Administrator)
Bowel Cancer UK	Charity Nurse Advisor (Lead*)
Beating Bowel Cancer	Charity Nurse Advisor (Lead*)
General Practitioner	Dr Paul Glasziou (Director – CEMB[†])
General Practitioner	Dr David Mant (Head of Department)
Cancer Screening Information Specialist	Dr Joan Austoker (Director – PCERG[‡])
Cancer Screening Information Specialist	Dr Clare Bankhead (Research Lecturer)

[†] = CEMB (Centre for Evidence-Based Medicine, University of Oxford); [‡] = PCERG (Primary Care Education Research Group, University of Oxford); * = Lead Nurse Advisor consulted with other members of their team.

Although the stakeholder group included two consumer representatives, it was extremely difficult to gain further consumer involvement in the project. This is

partly due to the lack of consumer involvement organisations for medical research in the Oxfordshire area, and further, the inability to provide financial or other incentives for lay-person involvement in research. However, the stakeholder group also included those health professionals with close ties to the community, who were well versed in the views of consumers and CRC patients concerning information materials.

4.8.1 Draft Procedural Leaflet Discussions

The draft procedural leaflet was sent to the stakeholder group members in late-February 2008. Written comments were returned from the representatives one week later. In general, stakeholder comments were very positive, although there were a number of suggested changes primarily concerning alterations to the format and wording of several sections. After collating the responses, each member of the group was sent a summary of the suggested alterations (see Appendix 4.4) and provided with an updated version of the procedural leaflet in mid-March 2008 (see Appendix 4.5). Following further email and telephone discussions with the stakeholder representatives, the finalised draft version of the leaflet was agreed.

4.8.2 Draft GP Endorsement Letter Discussions

During initial discussions, stakeholders expressed significant concerns about commenting on the content of the draft GP endorsement letter. With the exception of the GP and cancer information specialists, all other stakeholders were either apprehensive about the utility of their suggestions for the content of the letter (generally believing that GPs were better placed to make these

amendments), or indicated that any discussions should occur later in the research programme (after GPs involved in the factorial trial had the opportunity to view the draft letter). Several representatives also suggested that the available literature concerning the use of GP endorsement letters, supplemented by ascertaining GP views prior to the factorial trial, was sufficient for the purposes of developing the intervention.

After extensive discussions with both supervisors and the stakeholder group, it was decided that an evaluation of the GP endorsement letter would not be included in the pilot study. This was based on the view that the pilot should concentrate on evaluating the procedural leaflet and potential outcome measures for the factorial trial. Concerns were also raised about the validity of evaluating the intervention in a population who have already participated in CRC screening and in the absence of behavioural outcomes. Furthermore, my supervisors (and several stakeholder representatives) questioned whether the role of the stakeholder group would be weakened if we did not take into account the rather strong views of the members at such an earlier stage of the research.

4.9 Summary

The initial development of the interventions followed the MRC framework for complex interventions [1-3] which entailed a synthesis of the available evidence, the application of a coherent theoretical framework and the considerable involvement of expert representatives to refine the draft intervention materials. The preliminary work was instrumental for enabling the detailed procedural

leaflet and potential trial outcomes to be evaluated in the second phase of the research programme.

4.9 References

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Chapter 5: Pilot Study – Questionnaire Results

5.0 Objectives of the Chapter

The pilot study aimed to evaluate and refine the procedural leaflet and the outcome measures for the main trial. The objective of this chapter is therefore to describe the methodology and results of the pilot questionnaire. Respondents' views of the pilot procedural leaflet and the evaluation of the outcome measures intended for use in the factorial trial are also presented.

5.1 Design and Aims of the Pilot Phase

A mixed-methods design, including a retrospective survey and a significant qualitative component, was used for the pilot phase. It was conducted to satisfy the 'Phase 1 (modelling)' component of the MRC guidance [1-3]. The primary aims were to:

- evaluate and refine the procedural leaflet (using both questionnaire data and interviews with participants)
- develop specific outcome measures (knowledge) and evaluate previously validated measures (TSRQ, attitudinal scales) for potential inclusion as secondary outcomes in the final phase of the research
- explore people's perceptions and views of CRC and information for CRC screening

5.2 Initial Development

The two components of the pilot study were the questionnaire survey and the interview series (see Appendix 5.1). Primary considerations for the questionnaire were:

a) develop potential outcome measures (knowledge scale)

b) ascertain the utility of previously developed outcome measures (Treatment Self-Regulation Questionnaire, Negative Attitudes Towards Screening scale), and,

c) obtain specific feedback concerning the detailed procedural leaflet

A retrospective survey design was chosen to avoid difficulties with disrupting the NHSBCSP. It also had the advantage of allowing the views of previous participants and non-participants in screening to be evaluated. The information materials evaluated in the pilot study included the draft procedural leaflet (see Appendix 4.6) and the NHSBCSP information booklet [4]. After detailed consultation with the stakeholder group and my supervisors, it was agreed that it was not feasible to pilot the draft GP endorsement letter but the qualitative component of the pilot would allow investigation of the role the GP might play in screening participation in the NHSBCSP.

5.3 Population Sample

The sampling frame consisted of men and women (aged 60 to 69 years) previously invited for screening by the NHSBCSP. People who received a positive FOBT result were excluded from the study. Participants were randomly selected after stratifying according to age group (60-64, 65-69), gender and previous participation in the NHSBCSP.

5.4 Pilot Questionnaire Instrument

The 12-page pilot questionnaire (see Appendix 5.2) was divided into seven sections. Initial testing by stakeholder representatives suggested it would take

around 20 to 30 minutes to complete. It included the following scales and outcomes.

Knowledge Scale Development

A pool of 36 items was generated based on the previous qualitative and quantitative literature in CRC screening [5-12] and research conducted during the development of the NHSBCSP information materials [13-16]. After review by stakeholder representatives and experts in cancer screening research, the item pool was reduced to 24 items concerning CRC, risk factors for developing CRC, rationale and effectiveness of FOBT screening, false-positive and false-negative results, and potential consequences of participating in screening.

Traditionally, knowledge scales tend to use a "true/false/don't know" response format. However, "don't know" responses are normally not analysed in detail and can yield data that suffer systematic contamination by extraneous factors (e.g. personality factors, self-confidence, risk-taking, peoples' differential propensity to guess) [17-18]. In an effort to develop an innovative approach to the knowledge scale, a parallel scale was used for each knowledge item. Based on the 'levels of certainty' approach [19-21], respondents were requested to indicate the extent they were 'sure' about answer on a four-point response scale (from 1 'totally sure' to 4 'not sure at all'). This approach, primarily used in education research, attempts to calibrate the degree of certainty with the correctness of respondents' answers.

Self-Determination Scale

The 'Treatment Self-Regulation Questionnaire' (TSRQ) was used to evaluate autonomous motivation for participating in CRC screening. The extensively validated scale assesses the degree to which a person's motivation for engaging in a healthy behaviour is relatively autonomous or controlled [22-24]. The TSRQ is designed to assess three different forms of motivation to perform a behaviour: autonomous regulation, controlled regulation and amotivation [22-23]. The wording of items in the TSRQ was modified in accordance with previous research [22, 24-26] and suggestions from the authors of the instrument [27].

The TSRQ includes 15 items, each representing a reason for engaging in or changing specific health behaviours. The scale begins with the stem statement "The reason I would complete bowel cancer screening is…?" with responses made using a seven-point Likert scale (ranging from 1 'not at all true' to 7 'very true'). The TSRQ consists of three subscales (autonomous regulation, controlled regulation and amotivation). The responses are summed to provide the autonomous regulation score (range 6-42), the controlled regulation score (range 6-42) and the amotivation score (3-18).

The TSRQ also includes four further items concerning perceived competence (self-efficacy) to engage in the target behaviour. These items were modified to specify collecting, completing, storing and returning the FOBT card. Responses are made on a four-point Likert format (from 1 'strongly agree' to 4 'strongly disagree') with scores ranging from 4 to 16.

Negative Attitudes towards CRC Screening

The negative attitudes towards CRC screening scale, previously evaluated in a UK population [28], was included to ascertain the utility of employing the measure in the factorial trial. The measure includes six-items with respondents requested to indicate the extent they agree or disagree with each statement on a five-point response scale (from 1 'strongly agree' to 4 'strongly disagree'). Five of the items are used to generate an overall score for the scale (ranging from 5 to 20), with a higher score indicating a more positive attitude towards CRC screening.

Views of the NHS Information Materials

A nine-item 'acceptability' scale for ascertaining participant views about the NHSBCSP information booklet [4] was adapted from a validated scale for decision-aids [29-31] and previous UK-based screening research [32]. Participants views on the balance, level of detail, length of booklet, readability and amount of information about the benefits and risks of screening was assessed.

Views about the Procedural Leaflet

An eight-item scale, slightly modified from the 'acceptability' scale above, was used to assess participants' views of the procedural leaflet. This assessed the readability, balance, level of detail and amount of information in the leaflet, and if the leaflet had influenced participant's views on screening. Two open-ended

items asked if aspects of the design or layout could be changed or if any further information should be included.

Importance of Information

There is considerable controversy regarding what specific information should be included in population materials for cancer screening. Previously, several publications have indirectly attempted to identify key information which should be included in materials from the perspective of health professionals or reviews of the literature [33-36]. However, no study has directly asked respondents what information they consider important for making a decision about CRC screening. A 17-item scale was developed which asked participants to rate how important various aspects of information about CRC screening was to them. Scale items were devised to cover all potential areas and consequences of screening, and included the purpose of CRC screening, how CRC can develop, advantages and risks of FOBT and colonoscopy, and treatment for CRC. A four-point response format ranging from 1 ‘not important’ to 4 ‘extremely important’ was used for the scale.

CRC Screening Specific Characteristics

Eight items asked participants about their previous experience with CRC or CRC screening. Participants were asked if they were aware of the NHSBCSP before they received their invitations, if they had ever completed an FOBT kit before their last screening invitation, if they participated in the NHSBCSP, if they had ever discussed CRC screening with their GP and if they found it embarrassing to talk about CRC screening with their GP or family/friends.

Participants were also asked if they had a previous CRC diagnosis, a colonoscopy in the past 10 years, or if any close relatives or friends were previously diagnosed with CRC.

Perceived Risk and Worry

Two items assessed participant's subjective and comparative perceived risk for developing CRC. Participants were asked how likely it was they would develop CRC in the near future and also asked to rate their chances of developing CRC in comparison to someone like them (both on a five-point scale). Participant worry about being diagnosed with CRC was assessed by a single question (from 1 'very worried' to 4 'not worried at all').

5.5 Qualitative Interview Series

People completing the questionnaire were invited to also participate in a qualitative study. Maximum variation sampling was used to select people based on the person's age (60-64 versus 65-69 years old) and responses to the questionnaire. The methodology for the qualitative interview series is described in more detail in the following chapter.

5.6 Ethics and R&D Submission

After finalising the draft procedural leaflet with the stakeholder group, the ethics application for the pilot phase of the research programme was submitted in early April 2008 and approved in June 2008. However, delays in the NHS Research Governance Approvals process meant that the pilot questionnaire

packs were not mailed to participants until November 2008, some four months after originally anticipated (see Appendix 5.3).

5.7 Selection Procedure

Selection of participants was a two-stage process. Firstly, after receiving R&D approvals, the NHS Cancer Screening Programmes was contacted to provide an anonymised list (with study subject identifier) of all people who had been invited to the NHSBCSP from the Southern Screening Hub in the first week of June 2008. After excluding people who had received a positive result from screening (60 people; 35 male, 25 female) and those aged over 70 years old (548 people; 290 male, 258 female), the remaining 6670 people were stratified according to gender, age group and participation in screening (see Table 5.1).

Table 5.1: Stratified sample frame for pilot study.

	Previous Participants		**Previous Non-Participants**	
Age Group	***Male***	***Female***	***Male***	***Female***
60-64	1030	1157	1033	740
65-69	745	906	580	479
Total	1775	2063	1613	1219

Fifty people from each of the eight stratified groups were randomly selected (200 previous participants and 200 previous non-participants) using the 'ralloc' command in STATA Version 10. The second stage involved returning the list of randomised participants to the NHS CSP, which was then sent to the Southern Screening Hub, who matched the personal details (name and address) with the unique study number. Unfortunately, due to an administrative problem, the details for only 100 previous non-participants (25 from each stratified group) were returned. Therefore, only 300 of the intended 400 people selected could be contacted to participate in the pilot.

5.8 Sample size

The proposed psychometric analyses required a ratio of approximately five times as many respondents as items in the measurement scales [37-38]. For example, as the TSRQ has 15 items, a minimum of 75 is suggested. The sample size was therefore less optimal for detailed sub-group analysis but provided reasonable provision for comparison of gender effects.

5.9 Recruitment Procedure

All participants (200 previously screened and 100 non-attenders) were sent a pilot questionnaire pack. The pack included an invitation letter (see Appendix 5.4), study information sheet (see Appendix 5.5), questionnaire consent form (see Appendix 5.6) request for information form (see Appendix 5.7), pilot questionnaire (see Appendix 5.2), a non-participation reply slip (see Appendix 5.8), and a reply-paid envelope. People who did not respond to the questionnaire pack were sent a reminder pack including a reminder invitation letter (see Appendix 5.9) a second pilot questionnaire, consent form and reply-paid envelope three weeks after the initial mail-out. People who returned the non-participation reply slip were not sent any further materials.

Respondents indicating they would be interested in participating in the qualitative study were sent an interview invitation letter (see Appendix 5.10), interview information sheet (see Appendix 5.11), a contact consent form (see Appendix 5.12) and an interview consent form (see Appendix 5.13). After

returning the two consent forms, participants were contacted by telephone to arrange a convenient time to conduct an interview.

5.10 Statistical Analysis

Questionnaire data were double-entered and analysed using STATA Version 10. Demographic, CRC screening-specific characteristics, perceived risk and worry, and participant perceptions for the procedural leaflet and 'The Facts' booklet were analysed using the Pearson Chi-square test or Fisher's exact test if cell frequencies were below 5. The Wicoxon Mann-Whitney test was used for comparing differences between males and females for the importance of information items. Item analysis and exploratory factor analysis was performed for the knowledge scale. Item analysis, correlation and Fisher's exact test were used to investigate the negative attitudes towards screening scale.

5.11 Results of the Pilot Questionnaire

The results of the pilot questionnaire are shown below. Due to the very low response rate for the non-screened group, the focus of the analysis was restricted to screened group responders.

5.12 Response rate

300 pilot questionnaires were mailed to potential respondents. 200 were sent to previous NHSBCSP participants (screened group) and 100 to previous non-participants (non-screened group). Five people from the non-screened group were excluded after the first mail-out (one deceased, two incorrect addresses and two ineligible due to an existing medical condition).

The overall response rate (including returned questionnaires and requests for no further participation in the study) was 57% (168/295). In the screened group, 16% (32/200) responded that they did not wish to participate in the study in comparison to 14.7% (14/95) in the non-screened group. The response rate was far greater in the screened group than in the non-screened group; 61% (112/200) of people from the screened group returned the questionnaire in contrast to only 10.5% (10/95) in the non-screened group.

Ten people (8 no consent; two incomplete questionnaires) in the screened group and three people (two no consent; one incomplete questionnaire) in the non-screened group were excluded from the analysis. Therefore, the overall response rate for valid questionnaires was 36.9% (109/295); 51% (102/200) for the screened group and 7.4% (7/95) for the non-screened group.

5.13 Participant Characteristics

The demographic characteristics of the screened group are shown in Table 5.2. Significantly more men were married (p = 0.013) and more females were aware of the NHSBCSP before receiving their invitation than males (p = 0.022). Almost the entire screened group (99%) reported their ethnicity as white, although one person reported their ethnicity as ‘mixed white-Spanish’. A quarter of people reported having a previous FOBT prior to their last invitation to screening, with 14% reporting a previous colonoscopy.

Table 5.2: Demographic characteristics of screened group participants.

		Total		Male		Female	
Gender	*Total*	102	-	46	*45.1*	56	*54.9*
Age	*60-64*	53	*52.0*	23	*50.0*	30	*53.6*
	65-69	49	*48.0*	23	*50.0*	26	*46.4*
Martial Status	*Married*	76	*75.5*	38†	*82.6*	38	*67.9*
	Widowed	11	*10.8*	1	*2.2*	10	*17.9*
	Single	3	*2.9*	0	-	3	*5.3*
	Divorced	12	*11.8*	7	*15.2*	5	*8.9*
Education	*'O' Level*	21	*20.6*	6	*13.0*	15	*26.8*
	'A' Level	6	*5.9*	4	*8.7*	2	*3.6*
	Clerical	17	*16.7*	9	*19.6*	8	*14.3*
	University	21	*20.6*	11	*23.9*	10	*17.9*
	None of above	37	*36.3*	16	*34.8*	21	*37.5*
General Health	*Excellent*	17	*16.6*	9	*19.6*	8	*14.3*
	Good	66	*64.7*	28	*60.9*	38	*67.9*
	Fair	16	*15.7*	8	*17.4*	8	*14.3*
	Poor	3	*2.9*	1	*2.2*	2	*3.6*
Ethnicity	*White*	101	*99.0*	46	*100*	55	*98.2*
	White (Other)	1	*1.0*	0	-	1	*1.8*
Aware of BCSP	*Yes*	57	*55.9*	20	*43.5*	37†	*66.1*
	No	45	*44.1*	26	*56,5*	19	*33.9*
Previous FOBT	*Yes*	26	*25.5*	10	*21.8*	16	*28.6*
	No	75	*73.5*	35	*76.1*	40	*71.4*
	Don't know	1	*1.0*	1	*2.1*	0	-
Previous Colonoscopy	*Yes*	14	*13.7*	6	*13.0*	8	*14.3*
	No	88	*86.3*	40	*87.0*	48	*85.7*
Discussed with GP	*Yes*	5	*4.9*	4	*8.7*	1	*1.8*
	No	96	*94.1*	42	*91.3*	54	*96.4*
	Don't remember	1	*1.0*	0	-	1	*1.8*
Family History	*Yes*	13	*12.8*	5	*10.9*	8	*14.3*
	No	81	*79.4*	36	*78.2*	45	*80.4*
	Don't know	8	*7.8*	5	*10.9*	3	*5.3*
Know someone with CRC	*Yes*	25	*24.7*	9	*19.6*	16	*29.1*
	No	64	*63.4*	30	*65.2*	34	*61.8*
	Don't know	12	*11.9*	7	*15.2*	5	*9.1*

† denotes $p = 0.05$

Only 5% of the group reported that they had previously spoken with their GP about CRC. Approximately 1 in 8 people (13%) responded that a close family member (i.e., mother, father, brother, sister) had previously been diagnosed with CRC and a quarter had known another close relative or friend who had been diagnosed with CRC.

5.14 Views of CRC and CRC Screening

Participant views of CRC are shown in Table 5.3. There were no significant differences between age groups. Significantly more men were 'very confident'

that they could complete CRC screening in the future in comparison to females (p = 0.015). The majority of the screened group (62%) reported that their main reason for completing the CRC screening was for 'peace of mind'. 79% of respondents indicated that, in comparison to other decisions about their health, the decision to participate in CRC screening was 'very important'. 94% were 'completely' or 'very' convinced about the benefits of CRC screening. Two-thirds (66%) of the group responded that it was 'not difficult at all' to complete FOBT.

Table 5.3: CRC specific characteristics screened group

		Total		Male		Female	
Main reason for screening	*Symptoms*	2	*2.0*	2	*4.3*	0	-
	Family history	10	*9.9*	2	*4.3*	8	*14.6*
	GP recommend	4	*4.0*	2	*4.3*	2	*3.6*
	Support screening	13	*12.9*	5	*10.9*	8	*14.6*
	Peace of mind	64	*63.3*	29	*63.1*	35	*63.6*
	Advice from family	1	*1.0*	0	-	1	*1.8*
	CRC concern	7	*6.9*	6	*13.1*	1	*1.8*
Subjective risk	*Very likely*	2	*2.0*	2	*4.4*	0	-
	As likely as not	49	*49.5*	19	*42.3*	30	*55.6*
	Not very likely	48	*48.5*	24	*53.3*	24	*44.4*
Comparative risk	*Little more*	7	*7.0*	1	*2.1*	6	*11.1*
	About the same	75	*75.0*	34	*74.0*	41	*75.9*
	Little/Much less	18	*18.0*	11	*23.9*	7	*13.0*
Importance of decision	*Very important*	81	*79.4*	35	*76.1*	46	*82.1*
	Moderate important	19	*18.6*	9	*19.6*	10	*17.9*
	Slightly important	2	*2.0*	2	*4.3*	0	-
Convinced of FOBT benefits	*Completely convinced*	44	*43.1*	25	*54.4*	19	*33.9*
	Very convinced	52	*51.0*	19	*41.3*	33	*58.9*
	Slightly convinced	6	*5.9*	2	*4.3*	4	*7.2*
Worried about CRC	*Very worried*	12	*11.8*	5	*10.9*	7	*12.5*
	Moderately worried	31	*30.4*	12	*26.1*	19	*33.9*
	Slightly worried	43	*42.2*	22	*47.8*	21	*37.5*
	Not worried	16	*15.6*	7	*15.2*	9	*16.1*
Embarrassed (talk to GP)	*Very embarrassed*	2	*2.0*	0	-	2	*3.5*
	Moderately embarr.	4	*3.9*	1	*2.1*	3	*5.4*
	Slightly embarrassed	20	*19.6*	5	*10.9*	15	*26.8*
	Not embarrassed	76	*74.5*	40†	*87.0*	36	*64.3*
Embarrassed (talk to friends)	*Very embarrassed*	3	*2.9*	1	*2.2*	2	*3.6*
	Moderately embarr.	5	*4.9*	1	*2.2*	4	*7.1*
	Slightly embarrassed	22	*21.6*	7	*15.2*	15	*26.8*
	Not embarrassed	72	*70.6*	37	*80.4*	35	*62.5*
Difficult to complete FOBT	*Moderately difficult*	7	*6.8*	5	*10.9*	2	*3.6*
	Slightly difficult	28	*27.5*	11	*23.9*	17	*30.4*
	Not difficult	67	*65.7*	30	*65.2*	37	*66.0*
Confident doing FOBT	*Very confident*	95	*93.1*	46‡	*100*	49	*87.5*
	Moderately confident	7	*6.9*	0	-	7	*12.5*

† denotes p = 0.05; ‡ denotes p = 0.01

Most respondents reported that they were not embarrassed to speak to their GP (75%) or their family and friends (71%) about CRC screening. Men were less embarrassed to speak to their GP about CRC screening than women (p = 0.044). A small proportion of people (16%) reported that they were 'not worried at all' about being diagnosed with CRC. Three-quarters of people reported that, in comparison to people like them, their chance of developing CRC was 'about the same'. Around half of respondents (48%) reported that their risk of developing CRC was 'not very likely' in comparison to 2% of people who indicated that it was 'very likely'.

5.15 Views on the 'Help with the Test' leaflet

Responses concerning screened group participants' views of the intervention leaflet "Help with the Test" are shown in Table 5.4. There were no significant differences between males and females or between age groups. Almost all participants indicated that the leaflet contained the right amount of detail (98%) and was easy to read (95%). The majority of people (81%) reported that the leaflet would be 'very useful' for completing CRC screening, although this was somewhat higher in females (86%). Approximately three-quarters of respondents indicated the suggestions for collecting (76%) and storing samples (75%) were 'very useful'. Just over half of respondents (52%) reported that they were more positive about CRC screening after reading the leaflet, 48% reported that their views had not changed and one person (1%) was not sure if their views had changed.

Table 5.4: Pilot respondents' views of the 'Help with the Test' leaflet.

		Total		Male		Female	
Useful for decision	*Very useful*	83	*81.4*	35	*76.1*	48	*85.7*
	Somewhat useful	18	*17.6*	10	*21.7*	8	*14.3*
	Not very useful	1	*1.0*	1	*2.2*	0	-
Readability	*Easy to read*	97	*95.1*	43	*93.5*	54	*96.4*
	Slightly difficult	5	*4.9*	3	*6.5*	2	*3.6*
Detail	*About right*	100	*98.0*	44	*95.6*	56	*100*
	Not enough	2	*2.0*	2	*4.6*	0	-
Collecting samples	*Very useful*	77	*75.5*	33	*71.7*	44	*78.6*
	Somewhat useful	24	*23.5*	12	*26.1*	12	*12.4*
	Not really useful	1	*1.0*	1	*2.2*	0	-
Storing samples	*Very useful*	76	*74.5*	32	*69.6*	44	*78.6*
	Somewhat useful	22	*21.6*	12	*26.1*	10	*17.9*
	Not really useful	3	*2.9*	2	*4.3*	1	*1.8*
	Not at all useful	1	*1.0*	0	-	1	*1.8*
Influenced views	*More positive*	53	*52.0*	27	*58.7*	26	*46.4*
	Views same	48	*47.0*	19	*41.3*	29	*51.8*
	Don't know	1	*1.0*	0	-	1	*1.8*
Further information	*Yes*	82	*5.0*	37	*6.5*	2	*3.6*
	No	5	*81.2*	3	*80.4*	45	*81.8*
	Not sure	14	*13.8*	6	*13.1*	8	*14.6*

Two people suggested changing the design to stress that piles cause bleeding or emphasise that the FOBT spatulas are disposable. The other three responses concerned correcting a typographical error in the leaflet. Five people each provided a single suggestion for improving the leaflet by including further information about piles, diet to prevent CRC, diverticulitis, a persons' next screening date, and what to do if you have large stools.

5.16 Views of 'The Fact's booklet

Respondents' views of the NHSBCSP "Bowel cancer Screening: The Facts" booklet are shown in Table 5.5. There were no significant differences between males and females in the screened group regarding their perceptions of the booklet.

Table 5.5: Pilot respondents' views of the 'The Facts' booklet.

		Total		Male		Female	
Amount read	*All*	86	*84.3*	36	*78.3*	50	*89.3*
	Most	15	*14.7*	9	*19.6*	6	*10.7*
	A little	1	*1.0*	1	*2.1*	0	*-*
Readability	*Easy to read*	100	*98.0*	44	*95.7*	56	*100*
	Slightly difficult	2	*2.0*	2	*4.3*	-	*-*
Detail	*About right*	101	*99.0*	46	*100*	55	*98.2*
	Not enough	1	*1.0*	0	*-*	1	*1.8*
Amount of information	*About right*	100	*98.0*	45	*97.8*	55	*98.2*
	Not enough	2	*2.0*	1	*2.2*	1	*1.8*
Useful for decision	*Very useful*	94	*86.2*	43	*84.3*	51	*87.9*
	Somewhat	14	*12.9*	7	*13.7*	7	*12.1*
	Not very useful	1	*0.9*	1	*2.0*	0	*-*
Presentation	*Balanced*	102	*100*	46	*100*	56	*100*
Benefits of screening	*Too much*	2	*2.0*	0	*-*	2	*3.6*
	Right amount	97	*95.1*	45	*97.8*	52	*92.9*
	Too little	3	*2.9*	1	*2.2*	2	*3.6*
Downsides of screening	*Too much*	4	*3.9*	1	*2.2*	3	*5.4*
	Right amount	95	*93.1*	43	*93.5*	52	*92.9*
	Too little	3	*3.0*	2	*4.4*	1	*1.8*
Further information	*Yes*	4	*3.9*	2	*4.4*	2	*3.6*
	No	79	*77.5*	36	*78.3*	43	*77.8*
	Not sure	19	*18.6*	8	*17.4*	11	*19.6*

A majority of participants (84%) reported reading the entire booklet. Almost all participants reported the booklet contained the right amount of information (99%), was easy to read (98%) and included the right amount of information (99%). All participants indicated that the booklet was balanced. Participants also reported that the booklet included the right amount of information on the benefits (95%) and downsides (93%) of CRC screening. 86% of participants reported that the information in the booklet would be 'very useful' for making a decision to participate or not in CRC screening. Four (4%) people reported that they would like further information concerning diet (two people), the relationship between smoking and CRC (one person) and more information on sedation during colonoscopy (one person) included in the booklet.

5.17 Views of the relative importance of information

Respondents' rating of the relative importance for including particular information in population materials about CRC screening is shown in Table 5.6. None of the items were normally distributed. The majority of items showed a median of four, indicating that a large majority of people responded that it was 'extremely important' to include this information in a booklet about CRC screening. The three highest rated items for the entire sample were the benefits of treatment, the symptoms of CRC and the purpose of CRC screening, respectively. The three least endorsed items were the location/function of the bowel, what and how a colonoscopy is performed (colonoscopy explained) and where to obtain further information about CRC, respectively.

Table 5.6: Mean (rating average) and standard deviation of respondents concerning the importance of information to include in patient materials.

	Total		**Male**		**Female**	
Importance of Information Item	*Mean*	*SD*	*Mean*	*SD*	*Mean*	*SD*
A. Purpose of CRC screening	3.67	0.55	3.65	0.60	3.67	0.51
B. Risk of developing CRC	3.58	0.55	3.48	0.62	3.66	0.48
C. Symptoms of CRC	3.70	0.58	3.57	0.69	3.80†	0.44
D. Location/function of bowel	3.00	0.74	2.89	0.68	3.01	0.77
E. How CRC develops	3.51	0.63	3.37	0.71	3.63	0.52
F. Reliability/accuracy of FOBT	3.59	0.57	3.41	0.65	3.73‡	0.44
G. How to complete FOBT	3.60	0.57	3.45	0.66	3.71†	0.46
H. Benefits of CRC screening	3.64	0.50	3.61	0.49	3.66	0.51
I. Risks of CRC screening	3.50	0.69	3.44	0.58	3.54	0.76
J. Meaning of results	3.65	0.54	3.52	0.62	3.75†	0.44
K. Receiving test results	3.39	0.63	3.22	0.66	3.54†	0.57
L. Colonoscopy explained	3.34	0.68	3.09	0.69	3.55‡	0.60
M. Benefits of colonoscopy	3.46	0.59	3.28	0.58	3.61‡	0.56
N. Risks of colonoscopy	3.46	0.66	3.24	0.67	3.68‡	0.58
O. Benefits of treatment	3.74	0.49	3.70	0.47	3.77	0.50
P. Risks of treatment	3.53	0.59	3.28	0.62	3.73‡	0.49
Q. Further information on CRC	3.34	0.67	3.15	0.66	3.50‡	0.63

† denotes $p < 0.05$, ‡ denotes $p < 0.001$

There were a number of significant differences between males and females regarding the importance of information to include in a booklet about CRC screening. The rating average for ten of the seventeen items was significantly

higher for females than males in the screened group. Females rated the reliability/accuracy of FOBT, the risks of treatment, the risks of colonoscopy, the benefits of colonoscopy, colonoscopy explained and further information about CRC as significantly more important to include in an information booklet about CRC screening in comparison to males. Other items that were significantly more important to females in comparison with males included the symptoms of CRC, the meaning of test results, how to complete FOBT and receiving test results.

5.18 Psychometric Performance of the Knowledge Scale

Responses to the 24 pilot knowledge items are presented in Table 5.7. The table shows the item difficulty (proportion of correct responses) and the median, mean and standard deviation for the level of certainty reported by respondents. No differences between males or females in the proportion of correct answers or certainty of responses to the knowledge items were observed. The results of the knowledge scale were analysed based on item difficulty, item discrimination and internal consistency.

Table 5.7: Proportion of correct responses and the median, mean and standard deviation for the degree of certainty for each of the knowledge items.

Item	% Correct	Median	Mean	SD	Item	% Correct	Median	Mean	SD
Item A	82.80	8	6.55	2.33	*Item M*	87.10	7	6.75	1.90
Item B	94.62	8	7.27	1.46	*Item N*	97.85	8	7.57	0.93
Item C	89.25	8	6.87	1.88	*Item O*	100.00	8	7.74	0.52
Item D	90.32	8	7.04	1.60	*Item P*	90.32	7	6.91	1.60
Item E	97.85	8	7.39	1.48	*Item Q*	93.55	8	7.10	1.65
Item F	93.55	8	7.09	1.56	*Item R*	64.52	7	5.36	2.89
Item G	84.95	7	6.60	2.17	*Item S*	77.42	7	5.92	2.35
Item H	84.95	7	6.58	2.00	*Item T*	86.02	8	6.68	2.18
Item I	98.92	8	7.41	1.02	*Item U*	95.70	8	7.30	1.36
Item J	81.72	8	6.55	2.27	*Item V*	97.85	8	7.74	0.87
Item K	89.25	7	6.74	1.65	*Item W*	87.10	8	6.98	1.76
Item L	82.80	7	6.44	2.00	*Item X*	55.91	6	4.82	2.77

Item Difficulty

Clearly, almost all of the items were not difficult for respondents to answer correctly. Ideally, a knowledge scale should contain items with a wide range of difficulty levels to effectively measure knowledge among a diverse group of individuals [39]. According to accepted convention, items are not useful if answered by more than 80%, or fewer than 20% of respondents [38, 40]. Only three knowledge items, Item R ('no side effects associated with a colonoscopy'), Item S ('bowel cancer most commonly diagnosed cancer in UK') and Item X ('change in bowel habit for 6 weeks is symptom of CRC') fell within this range. However, other researchers have inflated the cut-off indices by 10% if significant skewness associated with the individual item responses was observed [41]. Although this potentially reduces the number of items for retention to 11, given the high proportion of correct responses to the items, this arbitrary cut-off point for inclusion was considered insufficient for the purposes of constructing the final scale.

The degree of certainty for respondents answers (how sure the answer was correct) for each of the knowledge items demonstrated a similar problem as evidenced for the item-difficulty analysis. More than half of the items (13) recorded a median of 8 (indicating the majority of respondents' answers were correct and they were 'totally sure' their answer was correct). Indeed, the relatively high mean and low standard deviation for the items also suggests that respondents' correctly answered the items with a high degree of certainty. This indicates that the majority of items were not difficult for the respondents, with only Items R, S and X posing problems for how sure respondents were that their answers to these items were correct.

Item Discrimination

The ability of each item to discriminate between people with different levels of knowledge was measured by the correlation between the score on each item with the overall knowledge score (see Table 2, Appendix 5.14). An item-to-total score correlation of 0.2 is regarded as the cut-off point below which items should be discarded [38, 40]. Three items (Items I, S and V) would be eligible for exclusion from the scale based on the low item-test correlation.

Internal Consistency

The KR20 analysis for the knowledge scale was 0.68. However, this represents the internal consistency if all items were included in the scale. The item-rest correlation (the correlation between the item and all other items on the scale was poor for six of the knowledge questions (Items E, I, S, T, U, and V); indicating these should be removed from scale. As STATA does not provide a

KR20 value for each item if removed from the scale, a surrogate analysis using the 'Cronbach's alpha' command was employed (see Appendix 5.14). Based on the results of the alpha analysis, three items (Items I, S and V) would be eligible for exclusion from the scale based on the subsequent increase in the total Cronbach's alpha score if these items were removed.

Factor Analysis

Originally, a principle components analysis was to be undertaken using a tetrachoric matrix (as the knowledge scale was binary). However, this was not possible as the correlation between almost all of the binary knowledge variables was -1 due to participants answering the vast majority of items correctly. Therefore, it was not possible to perform the exploratory factor analysis for the true/false component of the knowledge scale.

Comments on the Analysis of the Knowledge Scale

The preceding analyses demonstrates that respondents correctly answered almost all of the knowledge pilot items, and further, the level of certainty in their answers reflects a very high degree of knowledge of the subject area. This is cause for considerable consternation for the development of a valid and reliable knowledge scale. Ideally, a core set of items with varying levels of difficulty would have emerged, allowing for a robust scale to be developed for the final phase of the research. Instead, few items would be eligible for removal based on the analyses, requiring greater analysis of the qualitative results and pertinent research literature to determine the items that should be retained for the secondary outcomes in the randomised trial.

5.19 Negative Attitudes to CRC Screening

The responses of the screening group to the negative attitudes towards CRC screening scale [28] are shown in Table 5.8. There were no differences between males and females or age group for the individual scale items.

Table 5.8: Responses to the individual items in the negative attitudes towards CRC screening scale.

	Strongly Agree		Agree		Disagree		Strongly Disagree	
	N	*%*	*N*	*%*	*N*	*%*	*N*	*%*
Too afraid	5	*4.9*	24	*23.5*	53	*52.0*	20	*19.6*
Too embarrassed	3	*3.0*	11	*10.8*	44	*43.1*	44	*43.1*
Know soon as possible	56	*54.9*	7	*6.9*	10	*9.8*	29	*28.4*
Rather not know	4	*3.9*	1	*1.0*	20	*19.6*	77	*75.5*
Know only at the end	1	*1.0*	1	*1.0*	13	*12.7*	87	*85.3*
Thought scares me	27	*26.5*	59	*57.8*	10	*9.8*	6	*5.9*

The majority of previously screened respondents were not embarrassed about completing FOBT, not afraid to think about CRC, and would prefer to know they had CRC, especially agreeing with wanting to know before the very end. However, most respondents reported being scared of the thought of CRC. There were notable differences between the responses of the pilot participants and previously published research (see Appendix 5.15).

In accordance with previous research [28], the total score for the negative attitude scale was based on five of the six items ('know as soon as possible' removed from the scale). Although consistent with previous research, the internal consistency of the scale was poor ($\alpha = 0.57$) and significantly skewed ($p = 0.002$). The median for the overall scale score was 16 (mean = 15.56, SD = 2.16, range 7 to 20). Respondents were categorised as having 'high' (score 16-

20; positive), ‘medium’ (score 14-16) or ‘low’ (score 6-13; negative) attitudes toward screening (see Table 5.9).

Table 5.9: Categories for respondents based on the negative attitudes towards CRC screening scale.

	Total		Males		Females	
	N	***%***	***N***	***%***	***N***	***%***
High (positive)	56	*54.9*	29	*63.1*	27	*48.2*
Medium	33	*32.3*	14	*30.4*	19	*33.9*
Low (negative)	13	*12.8*	3	*6.5*	10	*12.9*

Although more males were categorised as ‘positive’ about CRC screening, bivariate analyses indicated there were no differences between gender or age group. Unlike previously published research utilising this scale, the total scale score was not significantly correlated with pertinent variables such as knowledge, self-efficacy, importance of decision or convinced of the benefits of CRC screening. Furthermore, the proportion of pilot respondents in ‘positive’ and ‘negative’ categories was considerably different to this previous research (see Appendix 5.15).

5.20 Treatment Self Regulation Questionnaire (TSRQ)

The results for the TSRQ are shown in Table 5.10. The mean autonomous regulation score was 35.60 (SD = 5.87, median = 37, range 6 to 42), indicating that respondents believed they had made an autonomous decision about completing or continuing CRC screening. The mean controlled regulation score was 16.36 (SD = 8.73, median = 15, range 6 to 42), suggesting respondents did not feel overtly pressured by external factors to complete or continue screening. The mean amotivation score was 6.56 (SD = 4.13, median = 6, range 3 to 21) indicating completing or continuing screening was viewed as an intentional act.

There were no significant differences between males and females for scores on the subscales.

Table 5.10: Mean, SD, median and range of the TSRQ subscales.

Individual Items and Total	Mean	SD	Median	Range
Autonomous regulation subscale	35.60	5.87	37	6 to 42
Controlled regulation subscale	16.36	8.73	15	6 to 42
Amotivation subscale	6.56	4.13	6	3 to 21

The internal consistency for the two subscales was very good (autonomous = 0.78, controlled = 0.84), and adequate for the amotivation subscale ($\alpha = 0.66$). The internal consistency of the subscales is consistent with previously reported research using the TSRQ [42-44]. The subscales were not significantly correlated with the TSRQ self-efficacy subscale; however, the autonomous and controlled subscales were significantly correlated with single item self-efficacy question used in the pilot questionnaire (see Table 5.11). Furthermore, the TSRQ subscales were also negatively correlated with the single item worry question, indicating the autonomous and controlled subscales were negatively associated with negative health outcomes. This replicates previous research findings for the validity of the questionnaire which postulate the autonomous and controlled subscales should be positively correlated with self-efficacy and negatively correlated with negative (worry) health outcomes [22].

Table 5.11: Correlation between TSRQ subscales and selected variables.

	Self-efficacy subscale		Single item self-efficacy		Single item worry	
	r^2	*p-value*	r^2	*p-value*	r^2	*p-value*
Autonomous	0.12	0.25	0.23	0.02	-0.28	0.01
Controlled	0.11	0.28	0.31	0.01	-0.21	0.03
Amotivation	0.05	0.60	0.13	0.18	-0.05	0.64

Self-Efficacy Subscale

The results of the four item self-efficacy scale are shown in Table 5.12. The mean total score for the self-efficacy scale was 14.96 (SD = 1.71, median 16, range 11 to 16).

Table 5.12: Results for the individual and total self-efficacy subscale.

Individual Items and Total	Mean	SD	Median	Range
Confident can collect sample	3.74	0.44	4	3 to 4
Confident can smear sample on kit	3.72	0.45	4	3 to 4
Confident can store test card correctly	3.71	0.48	4	2 to 4
Confident can return test card	3.78	0.41	4	3 to 4
Total	14.96	1.71	16	11 to 16

Although the internal consistency for the scale was extremely high (α = 0.97), this is primarily due to the significant negative skewness of total score (skewness p = 0.011, kurtosis p = 0.004) and the median equalling the highest potential score for the scale (indicating the majority of respondents 'strongly agreed' with each self-efficacy item). The results are indicative of a very poor scale to measure self-efficacy.

5.21 Non-Screened Participant Characteristics

There were a total of seven participants in the non-screened group (see Table 5.13). Five out of seven were aged 65-69 years and all of the non-screened group were married. Four reported their general health as 'good' and the entire non-screened group reported their ethnicity as 'white'. Five were aware of the NHSBCSP before receiving their invitation and four had previously completed FOBT and a colonoscopy.

Table 5.13: Demographic characteristics of non-screened group participants.

		Total	Male	Female
Gender	*Total*	7	5	2
Age	*60-64*	2	1	1
	65-69	5	4	1
Martial Status	*Married*	7	5	2
Education	*'O' Level*	4	3	1
	'A' Level	-	-	-
	Clerical	-	-	-
	University	2	1	1
	None of above	1	1	-
General Health	*Excellent*	-	-	-
	Good	4	2	2
	Fair	1	1	-
	Poor	2	2	-
Ethnicity	*White*	7	5	2
	White (Other)	-	-	-
Aware of BCSP	*Yes*	5	4	1
	No	2	1	1
Previous FOBT	*Yes*	4	3	1
	No	3	2	1
Previous Colonoscopy	*Yes*	4	2	2
	No	3	3	-
Discussed with GP	*Yes*	1	1	-
	No	5	4	1
	Don't remember	1	-	1
Family History	*Yes*	2	1	1
	No	5	4	1
Know someone with CRC	*Yes*	3	1	2
	No	2	2	-
	Don't know	2	2	-

One person reported previously speaking to their GP about CRC screening. Two reported that a family member had been diagnosed with CRC and three reported knowing either another close relative or friend who had been diagnosed with CRC. CRC specific characteristics of the non-screened group are shown in Table 5.14. Three people reported that their main reason for completing the CRC screening was for 'peace of mind'.

Table 5.14: CRC specific characteristics non-screened group participants.

		Total	Male	Female
Main reason for screening	*Symptoms*	1	1	0
	Family history	1	0	1
	GP recommend	1	1	0
	Support screening	1	1	0
	Peace of mind	3	2	1
Subjective risk	*As likely as not*	4	3	1
	Not very likely	3	2	1
Comparative risk	*Little more*	3	2	1
	About the same	3	2	1
Importance of decision	*Very important*	3	2	1
	Moderate important	3	2	1
	Slightly important	1	1	0
Convinced of FOBT benefits	*Completely convinced*	2	1	1
	Very convinced	2	2	0
	Slightly convinced	3	2	1
Worried about CRC	*Moderately worried*	3	2	1
	Slightly worried	3	2	1
	Not worried	1	1	0
Embarrassed (talk to GP)	*Moderately embarr.*	1	1	0
	Slightly embarrassed	1	0	1
	Not embarrassed	5	4	1
Embarrassed (talk to friends)	*Very embarrassed*	1	1	0
	Moderately embarr.	1	0	1
	Slightly embarrassed	2	2	0
	Not embarrassed	2	2	0
Difficult to complete FOBT	*Moderately difficult*	2	1	1
	Slightly difficult	2	2	-
	Not difficult	2	2	-
Confident doing FOBT	*Very confident*	2	1	1
	Moderately confident	3	3	0
	Slightly confident	2	1	1

Five non-screened respondents reported that they were ‘not embarrassed’ to talk to their GP about CRC screening, but were less inclined to speak to their friends. Five were either ‘very’ (2) or ‘moderately’ (3) confident of completing CRC screening in the future.

5.21 Discussion

The main aim of the pilot questionnaire was to evaluate the draft procedural leaflet with people previously invited to screening and investigate potential outcomes measures for the main factorial trial. The results indicated that the draft procedural leaflet was well-received by previous screening participants

and required few modifications for the main factorial trial. However, the results for the inclusion of outcome measures in the factorial trial were somewhat mixed. The TSRQ questionnaire performed well and was consistent with previous research concerning autonomous decision-making [22, 24-26], although the perceived competence (self-efficacy) subscale was not shown to be particularly useful. Responses to the knowledge items provided a good foundation for developing the knowledge scale, however, required further examination in the qualitative component of the pilot study. The negative attitudes to CRC screening scale [28] did not demonstrate psychometrically sound properties and the results indicated it should be excluded as an outcome in the main trial.

Although there were initial difficulties with the organisation of the pilot questionnaire mail-out, the response rate for previous non-participants in screening was still very poor (7%). This meant that meaningful comparisons between the two groups (screened versus not screened) were not possible. This was a particular concern for attempting to compare participants and non-participants, given it was highly unlikely the questionnaire response rate for non-participants would be very poor. This also highlighted the need to retain participation in CRC screening as the primary outcome factor for the trial.

Participants' perceptions of the draft procedural leaflet were extremely encouraging. Almost all people reported the leaflet was easy to read and contained the right amount of detail. Around three-quarters of participants also reported information about collecting and storing samples was very useful.

Around half of the participants indicated they were more positive about screening and almost all thought it would be very or somewhat useful for the decision to participate or not in CRC screening. The results strongly indicated the draft procedural leaflet was an appropriate and well received population information material likely to enhance decision-making and potentially improve participation in CRC screening.

There was relatively little information to indicate the potential effect of including a GP endorsement letter may have for improving participation. Very few participant's (5%) had previously discussed CRC screening with their GP and even less (4%) had previously returned their FOBT kits because of a recommendation form their GP. This was a particular limitation of the pilot study. However, it was planned that the qualitative interviews conducted as part of the pilot would provide further information regarding the role of the GP in decision-making about participating or not in CRC screening.

An important finding for the pilot questionnaire was the very strong interest in specific information which participants' felt should be included in population information materials. No study has attempted to quantitatively evaluate the specific information which should be included in screening information materials, and the results demonstrated there was both a strong interest in receiving comprehensive information and that there were some differences between genders in regards to the perceived importance of screening information.

The results for the views of the NHSBCSP materials are very similar to reported views of information materials used in other European programmes [42]. Crucially, respondents valued the inclusion of information about both the benefits and risks associated with screening, rather than just information promoting the benefits. This reinforced the notion that any information interventions implemented in the NHSBCSP should provide balanced information about CRC screening without being overtly promotional in nature.

The results for the pilot knowledge scale were less satisfactory than hoped. A significant limitation for identifying items which could be retained for a reliable knowledge scale was the very high rate of correct responses for almost all items. The primary reason for the low level of item difficulty and lack of variation between items is due to the methodology of the pilot study. Although it was anticipated that the proportion of correct answers would be greater than expected in the general population (given respondents received information at the time of completing the questionnaire), the results were far higher and more uniform than anticipated. The results of the qualitative phase coupled with further examination of the literature were required to develop the knowledge scale for the purposes of the main factorial trial.

A further difficulty for the identifying the inclusion of outcome measures for the questionnaire component of the main factorial trial was the negative attitudes to CRC screening scale [28] and the self-efficacy subscale of the TSRQ [27]. The current analysis for the negative attitudes scale did not replicate previously published research and the results strongly suggested it would be inappropriate

for inclusion in the main trial. The results for the self-efficacy subscale were equally concerning. These results demonstrated the self-efficacy subscale was significantly skewed, not correlated with the other TSRQ subscales, and did not discriminate between people with different levels of self-efficacy.

There are some concerns that the number of scales and items included in the pilot questionnaire may have been overly burdensome for participants. Although it was necessary to include a large number of items in the knowledge scale in order to develop a psychometrically sound measure, coupled with exploring the appropriateness of previously validated scales and associated items significantly increased the length of the questionnaire. It is uncertain what effect this may have had for participants, however, it is reasonable to assume this decreased the participation rate for the questionnaire. In hindsight, it would have been beneficial if the pilot questionnaire contained more targeted or specific items to decrease the overall length of the questionnaire.

Overall, the pilot questionnaire achieved the objectives of satisfying the MRC guidance for the initial development of outcomes for the factorial trial, although modifications to two scales were required and further evidence-gathering was required during the pilot qualitative phase to formulate the GP endorsement letter.

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Chapter 6: Qualitative Interview Series

6.0 Objectives of the Chapter

The objectives of this chapter are to describe the background, methodology and results for the qualitative component of the pilot study. The interview series explored participants' perceptions of the draft procedural leaflet, and their understanding of the potential facilitators and barriers for participating in CRC screening. The study also attempted to ascertain the external validity of selected outcomes (knowledge scale, negative attitudes towards screening, TSRQ) and the role of GP's in the NHSBCSP.

6.1 Overview of Qualitative Research

A considerable amount of qualitative research has been published exploring factors affecting participation in CRC screening. The majority tends to focus on the reasons for non-participation in CRC screening or identifying the barriers associated with low uptake in minority or socially disadvantaged groups. More recently, a number of research projects have attempted to evaluate people's perceptions of decision-making and the role that information materials can have for improving participation in CRC screening programmes.

The most frequently reported reason for not participating in screening identified by previous qualitative research is the lack of a recommendation from a primary care physician. Participants in both focus group and interview studies consistently state that the failure of their primary care provider to recommending a CRC screening modality [1-5], the lack of communication or counselling

regarding the importance of screening [6, 7] or the perceived failure to adequately discuss screening concerns with their GP [8-10] are significant barriers to participation. This was especially evident for participants from ethnic minorities or studies conducted in socially deprived areas [5-7, 11, 12].

Qualitative studies have also characterised a number of other important barriers to participation in CRC screening. Primary among these is respondents' poor general knowledge of CRC and screening [3-6, 10, 13]. Specific deficits include misconceptions about risk factors for developing CRC [9, 14], doubts about the effectiveness of screening modalities [5, 11, 13], misunderstanding of the rationale for screening [4, 7, 15], and being unaware of the high incidence and mortality of CRC [6, 12]. Patient perceptions of 'feeling well' or not having any CRC symptoms are also reported as contributing to poor participation rates [3, 11, 14, 15]. Other important barriers include fear of being diagnosed with CRC or the test modality, embarrassment associated with the test procedure, lack of information, time constraints (especially for currently employed people), limited access to tests, and lack of insurance or high financial costs required for testing (primarily from US-based studies) [1, 2, 6-11, 13, 14].

Very few studies have attempted to identify the facilitators for FOBT testing or investigated specific participant concerns regarding the procedural aspects of FOBT screening. Facilitators for completing FOBT include a positive attitude towards preventive health and screening, the expectation of reassurance ('peace of mind') from completing testing, knowing someone with any form of cancer, support from family members or friends, perceived benefits of early

detection, ease of use or the convenience of completing the test at home, and receiving a recommendation from their primary care practitioner [1, 2, 11, 14-18]. Studies focusing on patient preferences for particular screening modalities support these findings, having demonstrated that FOBT is regarded as more convenient, less invasive, and less fear provoking in comparison to endoscopic screening [19-21]. However, screening non-participants often report concerns about collecting and storing FOBT kits, disgust related to handling stools, misunderstanding instructions and significant difficulties associated with their perceived ability to complete the kit correctly [15-18, 22-24].

It is essential to conduct formative research with participants to understand the unique characteristics affecting the interpretation or relevance of the intervention materials for improving participation in CRC screening. Studies which have investigated the role of information provision and decision-making have found participants have a very positive attitude towards screening, a poor understanding of potential screening risks and often have great difficulty understanding the role of informed choice for CRC screening [16, 17, 24-26]. Participants have voiced their support for information which encourages participation and minimises or omits negative information about screening, leading several authors to suggest there are significant discrepancies between the views health professionals and the public in regards to the notion of informed choice [17, 24, 25]. Two studies have also shown that people invited to screening feel they have a moral obligation or civic responsibility to participate in screening if invited by the NHS [15, 17].

The main aims of this component of the pilot phase of the research were to:

- evaluate participant perceptions of the draft procedural leaflet and potential ways to improve the materials provided to people invited to the NHSBCSP
- explore potential facilitators, barriers and the role of primary care for improving uptake in CRC screening, and
- investigate the constructs surrounding knowledge, attitudes and autonomous decision-making for CRC screening to inform the development or inclusion of quantitative outcomes for the main factorial trial.

6.4 Methodology

Participants could indicate their interest in participating in the interview series by returning their 'Request for Further Information' form (see Appendix 5.7) which was included with the pilot questionnaire pack. Thirty-five people who expressed an interest in the interview series were sent further information about the study (see Appendices 5.10 to 5.13) in early-November 2008; 24 people returned signed consent forms, four declined due to other commitments or illness, and no further contact was received from seven people.

Originally, the interview series was planned to offer both face-to-face or telephone interviews with participants. However, due to difficulties in securing relevant approvals for the research and the contracted time-frame available to conduct the interviews, participants were initially offered telephone interviews when contacted by the researcher. Although there is reluctance among qualitative researchers in the UK to utilise telephone interviews for research, this approach has a number of advantages over the more traditional face-to-

face methodology. Telephone interviewing allows the opportunity to collect data from geographically diverse areas, decreases cost and time constraints, and can be preferred by participants when speaking about sensitive issues [27, 28]. Participants were informed they could opt for a face-to-face interview if they preferred; however, all participants consented to the telephone interviews. Semi-structured telephone interviews were conducted with 9 men and 12 women aged 60 to 69 years old (see Table 6.1). Three people who consented to the study were unavailable to be interviewed (one due to significant illness and two others were out of the country during the interview period).

Table 6.1: Demographic characteristics of interview series participants.

		Male	Female
Age	*60-64*	3	7
	65-69	6	5
Martial Status	*Married*	7	7
	Widowed	1	2
	Divorced	1	3
	Single	-	-
Educ. Status	*Univ/College*	1	1
	Clerical/Technical	3	3
	'O' level	4	6
	None	1	2
Self-efficacy[1]	*≥13*	6	8
	≤12	3	4
Neg. Attitudes[2]	*≥15*	7	9
	≤14	2	3

[1] = based on pilot questionnaire score for the 'self-efficacy' subscale of the TSRQ;
[2] = based on pilot questionnaire score for the 'negative attitudes towards CRC screening' scale.

All participants had previously participated in the NHSBCSP. Participants were drawn from eight regions in the south-east, south-central and south-west of England. These included Dorset (6), Hampshire (4), Devon (3), Somerset (3), Gloucestershire (2), West Sussex (1), Warwickshire (1) and Berkshire (1).

All interviews were conducted by PH, audio-recorded with the participant's consent and lasted approximately 20-45 minutes. A semi-structured interview

schedule was developed and refined in the initial stages of the interview series (see Appendix 6.1). After first addressing a number of general questions regarding the participants' awareness and understanding of CRC screening, participants were then asked more specific questions concerning the draft procedural leaflet ('Help with the Test'), the current NHSBCSP information booklet ('The Facts') and a series of questions concerning their views on the role and involvement of GP's in CRC screening. The final sections of the interview schedule concerned participants views of making an informed choice about CRC screening and questions about receiving their results from the NHSBCSP. A number of the questions and prompts in the semi-structured interview schedule were included to ascertain participants' perceptions of the procedural aspects of the FOBT kit, their attitudes towards CRC screening, and the perceived autonomy of their decision to participate or not in screening. Specifically, questions were included to determine the content validity of the items used in the knowledge scale, and further, the appropriateness of including measures concerning autonomous decision-making (TSRQ) and attitudes towards CRC screening [29].

The interview series was conducted between late November and mid-December 2008. All interviews were transcribed verbatim, with the accuracy of each transcript verified by PH. Various methods of corroboration were used in the analysis and interpretation of the data to enhance consistency and reduce bias [30, 31]. An iterative, interpretive approach was used for data analysis process, combining thematic analysis with constant comparison [32, 33]. This methodology, originally developed for 'grounded theory' [32], is a general

framework which involves taking one theme and comparing this with all others which may be different or similar, to develop conceptualisations of relations between the extracted themes. The primary purpose is to generate knowledge about the common patterns and themes which emerge around the experience or behaviour.

All the data was coded initially by one person (PH). The codes were refined through discussion with my supervisors and a formative analysis was performed to review the interview schedule and the appropriateness of coding. The majority of the transcripts were analysed after data collection (summative analysis) and differences in interpretation were resolved through discussion. The qualitative software program Atlas.ti was used to facilitate the organisation and analysis of the data [34].

6.3 Results

Emergent themes derived from the interview series concerned reasons for participation in screening, knowledge and awareness of CRC and CRC screening, the role of GP's, personal concerns and worry associated with screening, opinions of the NHSBCSP process, perceptions of the information materials and views of informed choice for cancer screening.

6.3.1 Reasons for Participation

Nearly all people interviewed indicated their main reason for participating in screening was either for 'peace of mind' or because they believed it was rather obvious to engage in preventive health behaviour.

"Well I just thought it was a sensible thing to do." (P1)

"I have my regular smear tests and I have mammograms...and so anything like that I do" (P12)

"Well because my philosophy is that preventive medicine is probably better…so I'd rather have the test done and find out, than find out at the last minute." (P14)

Participants were highly supportive of taking personal responsibility for their health. However, this was often qualified as important to avoid incurring 'unnecessary' NHS costs for treatment (e.g. participants felt costs were higher if CRC was detected at a later stage) or that screening participation was important for society in general.

Almost all of the participants were aware CRC could be present without symptoms. Many equated participation in screening with their interest in controlling their own health, particularly in relation to attempting to lead an active lifestyle and improving their diet.

"Bu then you've got to take…it's your own health, so you've really got to think about doing the test I think." (P16)

"I've got that emblazoned across my mind…that as one gets older, you know, just take care to do what one can to stay healthy." (P18)

"I mean this is just hugely useful for people who are really healthy…it's not the worried well, just a question of looking after yourself and not bothering the doctor." (P1)

Around half of the participants stated the primary motivating factor for participating in screening was based on the positive outcomes associated with the early diagnosis of cancer.

"I suppose I knew that any cancer caught early is possibly treatable." (P21)

> "I wouldn't know where to start if I was diagnosed with cancer, but I really do feel you've got to get on with it and catch it as soon as you possibly can." (P7)

The belief that screening was effective was consistently expressed as instrumental for the decision to participate. A small number expressed genuine surprise of the idea that someone would not want to participate in CRC screening.

> "Well, I just can't understand anybody not taking the opportunity to check their health." (P10)

> "I can't understand why anyone wouldn't do the test…the very thing that's going to help you, I can't really imagine anybody being foolish enough not to want to do it." (P7)

Some participants felt they had a moral obligation to participate in screening, essentially because it was being offered by the NHS.

> "I sort of felt that it was duty to do it…I found it a very unexciting prospect, but I felt almost a duty, a moral duty, not just to myself, but also because I was grateful that the NHS should actually take the initiative on this." (P15)

> "I just agree with screening basically, you have to do it…and I think if it's offered, it's necessary…you're obliged to…because they don't offer something just for the sake of it." (P19)

6.3.2 Knowledge and Awareness

Knowledge and awareness of CRC and CRC screening was generally poor. Participants indicated they knew CRC was a serious disease and early detection was expected to increase the chance of treatment success. However, they also admitted to having a limited understanding of how CRC develops and an imperfect awareness of the range of CRC symptoms. One participant, who

demonstrated a greater understanding than most, suggested that CRC screening was to:

> "…check for blood to see if these little imperfections…what are they called…polyps, in your bowel system were issuing blood, which I assume is one of the signs that you could potentially end up with cancer." (P10)

Many participants were unable to offer an explanation for how CRC develops, citing either a lack of understanding of cancer or unfamiliarity with medical terminology.

> "I don't know how it develops, whether it's hereditary or whether it's something you inflict on yourself…I honestly don't know that one." (P9)

> "Well it can develop over time…it's just…I'm no good with medical words…but there's growths, cells that multiply…and you…no sorry, I can't really put it into words, but I know it's not something I want to happen to me." (P20)

However, participants who suggested they did not know how CRC develops often made an unprompted clarifying statement that they remembered reading about the development of CRC in the NHSBCSP information booklet. When asked if they remembered reading anything about 'polyps', almost all recalled hearing the word before, but were still uncertain how polyps developed into CRC or how polyps related to CRC screening.

Participants reported a very vague understanding of risk factors associated with the development of CRC. Around half suggested diet may be a significant risk factor, and around a third suggesting a hereditary or genetic component to CRC development. Only two people suggested advancing age as a potential risk factor. Participants were more aware of the symptoms of CRC. Over half of the

participants suggested a change in bowel habit (either constipation, loose bowel motions or both) as a potential symptom, as was rectal bleeding. However, very few participants equated CRC screening with the detection of blood in their stool samples. Other suggested symptoms included weight loss, stomach cramps and 'lumps' in the abdomen may be indicative of CRC.

Participants who reported having a close family member or friend diagnosed with CRC or another form of cancer were more aware of the rationale for screening, the screening procedure, and CRC symptoms. Indeed, many participants who knew a family member or friend with any form of cancer citied this as a strong influence for their decision to participate in screening. For other participants, most indicated their understanding of CRC prior to receiving the information materials was based on media reports or from brief discussions with family or friends. Participants generally suggested that specific information about CRC screening was adequately conveyed in the information materials and not necessarily knowledge they retained after participating in screening.

6.3.3 Role of GPs

Although almost all participants had few difficulties communicating with their GP about bowel problems, no-one reported receiving any information from their GP or ever discussing screening. Participants indicated that a GP endorsement letter would have reassured them more than receiving the 'anonymous' invitation letter from the NHSBCSP.

> "I think a letter…including a letter from my GP would probably put…would have put me at ease a few minutes earlier." (P11)

> "I would have thought the customer, the patient, would have been more reassured with a GP's letter, rather than just having this dumped out of the blue on them, so to speak, by an anonymous letter." (P3)

Most participants agreed it was a good idea in principle to include a GP endorsement letter, although these same participants also indicated that receiving the letter would not have any significant effect on their decision to participate or not in screening. As two participants suggested:

> "[*Receiving a GP letter*] would not have any effect, but on the other hand, if you have a 'waverer' or an 'anti', I think it wouldn't do any harm by any means" (P3)

> "Not me personally, but it would probably make someone else. I mean, because I'd already made up my mind to have it. But if your own GP endorsed it, it would probably make sure people do the test," (P14)

Participants indicated they were unaware they could discuss any potential concerns about CRC screening with their GP and felt this was an important point for programme information materials to convey. The role of the GP was perceived to be of greater importance after the receipt of a positive result. Participants generally stated they would prefer a GP discuss their potentially life-threatening results rather receive the news of a positive result from a colonoscopy nurse.

> "Then it comes back and it's positive, and they get a letter from the screening centre…and then what are they going to do? Are they going to panic? And I would have thought it was better to panic in front of a GP rather than on the end of a telephone to somebody they don't know." (P3)

Overall, participants did not view the role of the GP in CRC screening to have a significant effect on their decision-making or to alleviate potential concerns about screening.

6.3.4 Perceptions of the Information Materials

Almost all participants indicated the draft procedural leaflet would be useful, contained a sufficient amount of detail and provided constructive examples for collecting samples and returning the kit.

> "I mean the suggestions given in the leaflet as the best way to collect the samples were helpful…some hadn't crossed my mind before I read that…having more than one suggestion so you can decide was good." (P12)

> "It made things a lot clearer, I mean, than the one that came with the kit. I was only asked once before for a stool sample, and I tried in vain to remember how I did it. But these procedures would have helped, although I still managed to do it all the same." (P16)

Participants also indicated the inclusion of information about the symptoms of CRC and identifying the reasons people may be concerned about completing the kit were very useful.

Several participants were in favour of the leaflet providing strong messages promoting screening or reinforcing the importance of completing the FOBT kits. These people tended to feel it was imperative to encourage people to return their kits and minimising any adverse outcomes from screening was justified by the benefits people may experience if CRC was detected early.

> "I strongly feel that the message can't be too strong…to be put across too strongly. I can remember advertisements for smoking where they were showing you what it did to your insides. It was pretty graphic and gruesome, but by God, it made you sit up and think." (P13)

> "It's getting through to people how important it is…perhaps see your grandchildren grow up or whatever, and it's only a few days out of their life, and it might be a little bit messy, but that could mean them having a good life." (P4)

Nearly all the participants spoke in highly favourable terms about the NHSBCSP booklet. No participants suggested the booklet was overly detailed or difficult to read, and most commented on preferring to have extensive information about the screening test and colonoscopy included in the materials. Several suggested the information in the booklet provided a sense of reassurance.

> "Yes, all that information should be included, because it tells you what could happen…I'd sooner know before. But I think it's making people understand that if something is found they'll have really, really good support. Knowing what happens afterwards, if it's a bad result, well that puts people's minds at rest" (P7)

Again, some participants felt the information should more forcefully encourage participation in screening. Although a small number queried if it was necessary to put negative information at all in a booklet for a screening programme, when pressed further, these people suggested they would prefer comprehensive information for themselves, but were concerned the effect this may have on the wider population.

6.3.5 Concerns and Worry

Participants voiced some concern regarding their initial reaction to the test procedure and the anxiety generated after receiving their screening invitation. The initial reaction to receiving the test kit was often reported as surprise, as many participants were not aware that CRC screening was being offered by the

NHS. Participants indicated they were somewhat worried about collecting their samples, however, none considered this to be an insurmountable barrier.

> "My initial thoughts were 'Oh dear!'…you know when you have to take the samples, you do get a little bit worried about it, but actually, it wasn't as bad as what I thought." (P4)

In general, participants expressed greater concern about waiting for their screening results letter than completing the kit. People often suggested this concern was rather minor and more of a 'in the back of their mind' worry, rather than something which affected their day-to-day lives. Almost all participants were very satisfied with how quickly the results letter was sent after completing screening and this was a very positive component of their screening experience.

> "I think one's always a bit anxious when you do a test…it wasn't an overriding concern. I just thought if there's something wrong, it might show up." (P11)

> "I can't say that I was anxious, but it was certainly on my mind...but I was just pleased when it here so quickly. It was only a matter of days, which was impressive" (P16)

6.3.6 Views of the NHSBCSP and FOBT

Around half the participants were not aware of the NHSBCSP prior to their invitation, although few expressed concerns when receiving their invitation; indeed, the most people were thankful or highly appreciative of being included in screening. Many participants did feel it was important to improve awareness of the NHSBCSP, suggesting posters in GP offices, media campaigns or greater advertising at sporting venues. The collection of stool samples was

viewed as unpleasant by participants, but almost everyone immediately clarified this barrier was easily overcome.

> "The collection was the most unpleasant part obviously. But you sort of think, oh well, I've got to do it so just get on with it." (P4)

Others perceived few difficulties with completing the kit.

> "Catch a sample, use a little stick, take a piece, put it on the thing, post it. I don't know what the problem is." (P9)

Around half of the participants were uncertain why it was necessary to complete the kit over three separate bowel motions, and felt the reason could be more clearly stated in information. Participants reported they were confident in their abilities to complete the kit, although around half indicated they read the instruction leaflet several times to ensure they knew what was required. No participants suggested completing the kit was embarrassing and many reported speaking freely to family or close friends about their experience of screening.

6.3.7 Informed Choice

Participant views of making an informed choice about CRC screening were mixed. Although most participants were enthusiastic about receiving a balanced information booklet, this was often not viewed as affecting their decision to participate in screening. Few people were strongly in favour of providing the risks as well as the benefits of screening in the information materials.

> "I think we should be allowed to make our own decisions…I think we should be told the full risks, then make the decision ourselves." (P1)

"I'm a grown up, I can make my own decisions…so that's why you should include the bad stuff as well as the good things." (P11)

"I'd like to have full information about it. I'd like to know precisely what is going to happen next and where we go from there." (P5)

However, participants reported the booklet served more as reference source about CRC screening, rather than directly contributing to their decision-making.

"I did read the booklet but that didn't make me decide to do the test. I'd already decided yes, if the tests available…I read it more of interest, for further information, rather than to help make my mind up." (P12)

"Well, I was going to do the test anyway, but you do like to have all that information to kind of weigh up the balance and to tell you everything." (P2)

For a few people, the information materials were completely immaterial to their decision to participate in screening.

"Well to be honest I would have still done it if you hadn't sent me any of the literature...because I would have thought this is a good opportunity." (P7)

"I don't think I read it before…I read it after I'd decided." (P6)

People made a distinction between the type of information they felt was important for their own decision to participate in screening, and the type of information that should be included in materials for the general public.

"Well I'd prefer to have all the information. The risks, what happens afterwards with colonoscopy and treatment…but for the general public, I think it can be scary…so maybe only a bit about the test, and leave the rest until later…you don't want to put people off." (P18)

"It's important for me personally to know the ins and outs, so I would want it in…but for everyone else, I'm not so sure…it may well scare people in the community, and you don't want that." (P5)

A minority of interview participants experienced what may be described as 'cognitive dissonance' with the concept that screening information should be balanced.

> "I just don't understand why you can't just say 'Go to screening - It will save your life'. It should be just like breast or cervical screening…you should just go. I really don't understand why people need to be told the risks…I honestly don't." (P19)

> "Well you say it can't be coercive…but why not? It's like 'Smoking Kills'. Because if it's not found now it's going to get worse and cost the taxpayer an awful lot more money in complicated surgery...so it's important people do it and that's what you have to say." (P9)

Overall participants were supportive of the notion of informed choice, but mainly in relation to their own needs, rather than the population. Support for informed choice tended to be only in principle, as most indicated the NHSBCSP information did not have a direct effect on their decision to participate and had great difficulty in understanding why CRC screening was not vigorously promoted.

6.4 Summary of Themes and Discussion

Careful consideration of the wording and content of educational leaflets is essential and, therefore, the information materials need to be successfully piloted before use in a screening programme [24]. The results of this study highlight a number of pertinent concerns for the involvement of primary care in the NHSBCSP and the role of information materials in CRC screening. Overall, participants in this interview series were enthusiastic about participating in CRC screening and perceived relatively few barriers to completing the FOBT kit.

Furthermore, participants tended to view the provision of information materials about CRC screening as an important component of the invitation process, however, the materials had minimal influence on their decision-making and people expressed confusion about the notion of informed choice.

As shown in previous research [7, 14], participants' understanding of preventive medicine was expressed in fairly vague terms. Generally, this was explained as improving one's diet, leading an active lifestyle and participating in screening. Contrary to previous research [3, 6, 12-14], knowledge and awareness of CRC was poor and did not appear to have a significant effect on the decision to participate in screening. Few participants reported understanding how CRC develops or the rationale for screening. For almost all participants, believing CRC was a serious condition and that participating in screening may detect CRC at an early stage was sufficiently important to proceed with completing the test. Unlike previous research [5, 11, 13], participants held no doubts concerning the effectiveness of CRC screening. Therefore, the view that knowledge is a barrier to screening was not supported by this study.

The participants did not report experiencing significant negative affective reactions nor expressed feelings of anxiety associated with completing screening. The only prominent, albeit minor, concern voiced was in relation to waiting to receive the results of their screening test. However, given the relatively fast return of results letters to participants, the anxiety experienced was regarded as transitory and did not impact significantly on their daily lives.

6.4.1 Role of GP's in the NHSBCSP

Participants' failure to indicate receiving a GP endorsement letter would have an effect on their decision to participate or not in screening was unique in comparison to the previously published literature [1-10]. Only a few participants suggested the GP endorsement letter would have a positive effect on their decision-making, although the majority of people thought it was generally a good idea for the public. Overall, participants tended to view GP involvement as important only if they received a positive screening result. However, a minority of participants indicated that receiving a GP letter would have provided some reassurance about the NHSBCSP, possibly alleviating the anxiety generated when initially receiving their invitation to participate. Furthermore, the participants also felt the materials should emphasise the GP was available to discuss potential patient concerns about completing the kit. This was a particularly crucial finding for the final phase of the current research, as it suggested the GP endorsement letter should specifically include an offer of support for people who had any queries about participating in screening.

6.4.2 Procedural Concerns with the FOBT kit

Unlike previously published research [15-18, 22-24], participants did not report experiencing significant problems with collecting their samples or difficulties understanding the instructions they were given. Most participants suggested the procedure was unpleasant, but none reported a strong negative reaction to the kit or used phrases indicative of 'disgust' to describe the procedure. However, participants were highly supportive of the draft procedural leaflet and the inclusion of tips regarding collecting samples and information about the

symptoms of CRC. Some participants were in favour of including strong health promotional messages specifically encouraging people to participate in screening, although in general, most participants felt the draft procedural leaflet was sufficiently detailed and helpful to include with an invitation to the NHSBCSP.

6.4.3 Information Materials and Informed Choice

The type of information participants perceived important to understand prior to deciding to participate in screening was fairly limited. Participants expressed support for the provision of high-quality, balanced information when invited to CRC screening. However, people who were supportive of receiving this information often felt it was important for *them* to be well-informed, but not necessary for the general public. Indeed, a large proportion experienced great difficulty in appreciating the NHSBCSP view [35] that the materials should not overtly promote screening (e.g. include information about both the benefits and risks of screening). Similar to previous research [17, 25, 26, 36], many participants believed the materials should strongly promote screening as an important public health initiative and experienced difficulty understanding why the information did not specifically encourage participation. This presents a particular complexity to understanding the role of information materials for decision-making in cancer screening. Whilst it was clear that participants felt they had made an autonomous decision to participate in screening, and they should be provided with comprehensive information, they did not feel this was necessarily required for the rest of the population.

6.4.4 Knowledge, Attitudes and Autonomous Decision-Making

The interview series identified a number of deficits in participant knowledge and awareness of CRC screening which were important for informing the development of the knowledge scale. Participants' failure to appreciate that the risk of developing CRC increases with age, uncertainty surrounding the accuracy and results of FOBT testing, and the potential risks associated with screening suggested these were essential items to include in the knowledge scale. Also, it was apparent that items concerning the rationale for screening, the hereditary component for the development of CRC and the importance of detecting CRC at an early stage should be included in the scale. Participants' very positive views of screening suggested that a more procedurally-based attitude scale, as opposed to a global negative attitudes towards screening [37], may be more advantageous to include for the factorial trial to detect potential differences between participants and non-participants.

Overall, participants indicated they made an autonomous decision to participate in screening and reported feeling very confident in their ability to complete the FOBT kit. However, based on the reported reasons for completing screening, a number of participants thought screening was a mixture of personal and social responsibilities, or for a minority, there was a moral obligation to participate. This calls into question the notion of autonomous decision-making, whereby extraneous factors (i.e., participating an important social responsibility or perceived obligation to participate) may have a significant impact on a persons' choice to participate in screening [15, 25-26]. This presents a further level of

complexity for understanding decision-making for CRC screening and one which required further investigation in the factorial trial.

6.4.5 Telephone Interviews

The use of telephone interviews to conduct the qualitative component of the research was well received by the participants. Indeed, over one third (9) of participants indicated they would have not participated if the interview had been conducted face-to-face. These people suggested that although they generally felt comfortable discussing CRC screening with others, they would not have participated in the interviews if required to be present with a researcher. A potential limitation of the use of telephone interviews was that it was not always possible to ensure the participant had the draft procedural leaflet available during the discussion. However, only four participants did not have the information materials at hand for the interviews, which did not effect the overall results of the study.

6.4.6 Study Limitations

Ideally, the sample for the interview series would be based on a maximum variation sample including both previous participants and non-participants to the NHSBCSP. However, as evidenced in the questionnaire component of the pilot study, attracting people who did not participate in screening was a significant challenge. The failure to investigate views of screening non-participants does limit the results of the study. However, reasonable data saturation was achieved and the interviews identified important insights for both the development of the interventions and outcomes for the questionnaire

component of the factorial trial. The lack of generalisability of the findings is not unique and has been expressed by a number of other qualitative studies which have evaluated information materials for CRC screening [17, 22, 25-26]. As CRC screening participation is low in particular UK ethnic groups [38], further dedicated research is required to access attitudes for these hard-to-reach groups.

6.5 Implications for the Interventions and Outcomes (103)

There was limited evidence derived from the participants involved in the interview series to inform the content of the GP endorsement letter. However, participants did identify information about CRC symptoms and the offer of GP support as important to include in the endorsement letter. GP endorsement may also be more important for the non-responding population who were not represented in the sample. Interview participants suggested only minor modifications were required to the procedural leaflet. These included highlighting the rationale for completing the kit with three separate bowel movements, emphasising the importance of screening and retaining the advice for collecting and storing the samples.

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Chapter 7: Initial Organisation of the Factorial Trial

7.0 Objectives of this Chapter

As the NHSBCSP does not have active GP involvement for the invitation procedure, consultation with the various bodies responsible for delivering the programme was necessary to enable the factorial trial to be conducted. This chapter describes initial organisation of the factorial trial and the changes required to the questionnaire component of the trial following the pilot study.

7.1 Factorial Trial Organisation Requirements

An essential objective of this research programme was to determine the feasibility of conducting a primary care-based factorial trial within a screening programme that does not have direct GP involvement. This required significant consultation with various organisations responsible for delivering the NHSBCSP to ensure the conduct of the trial did not unduly effect the management of the screening programme or the quality of care for participants. The logistic and practical considerations which were addressed related to the ethical conduct of the research (ensuring that participants were not placed at risk of adverse consequences), the selection of GP practices (identifying GP practices with a sufficient number of potential participants for the trial period) and co-ordinating the mail-out of the questionnaires and interventions with the Southern Programme Hub (SPH).

7.1.1 Initial discussions and ethical considerations

The factorial trial protocol was based on consultations with the NHSBCSP, the SPH and University of Oxford staff (see Appendix 7.1). Two primary ethical concerns for the research were that:

- invitations to screening would be delayed for a proportion of participants involved in the trial
- return of a signed consent form was not appropriate for inclusion in the analysis for participation in the NHSBCSP

Delaying the invitation to screening was a significant issue for the research. There were concerns this delay may contribute to a poor prognosis for the trial participant if they were diagnosed with CRC after completing the FOBT kit. However, after reviewing the available evidence [1-3] and discussions with experts in the area, a 2-3 weeks delay was not believed to deleterious for participants involved in the trial.

A further ethical concern was related to not requiring patient consent for verification of participation in the NHSBCSP. Although cognisant of the importance of facilitating informed consent [4-6] and patient confidentiality for participants [7, 8], restricting the primary outcome of the trial to only those returning a consent form would have significant implications for evaluating the effectiveness of the interventions and the generalisability of the trial results. Based on the recruitment of non-participants in the pilot study, there were reasonable grounds to believe that selection bias (only including those returning a consent form) would have a dramatic effect on the overall aims of the trial [9].

After discussions with the NHSBCSP and the SPH, the trial invitation letter and study information sheet were structured to ensure participants were aware that consenting to participate in the trial was distinctly separate from their decision to participate in screening. Furthermore, participants were informed the verification of participation in screening would be performed only by NHSBCSP staff and no personal identifiable information would be available to the research team for people who did not consent to the questionnaire component of the study.

7.1.2 Changes to the automated NHSBCSP invitation procedure

The NHSBCSP automated mail-out (call/recall) procedure for sending invitations to the public is organised by Connecting for Health (CfH). 'Batches' of invitations, based on the persons' age, GP practice registration and geographical region where screening will occur are sent to the SPH twice a week (over 8,000 invitations per week). The NHS Cancer Screening Programmes, in conjunction with the SPH, co-ordinated with CfH to make the necessary changes to the automated mail-out procedure. This allowed a trial-specific batch of invitations, based on the potential participants' registration with a GP practice involved in the research, to be sent to the SPH in October 2009.

7.1.3 NHSBCSP agreement for trial procedure

After extensive discussions with the SPH, the NHSBCSP, and the Director of the NHS Cancer Screening Programmes, the following stipulations for the conduct of the research were agreed:

- the trial period could not be in excess of one month (to reduce disruption to the NHSBCSP and staff at the SPH)
- the one month trial period would ensure any delay between when some trial participants would usually receive their invitation (i.e. in the first week of the month) and when they would actually receive their invitation as part of the research study (i.e. last week of the month) would be minimal and not effect their quality of care
- the changes required to the automated mail-out procedure (allowing for all trial participants to receive their invitations from the NHSBCSP at the same time) could not have a significant impact on the organisation tasked with delivering this service (CfH)

Based on these agreed requirements, the next stage in organising the trial involved ascertaining the most efficient way for the selection of GP practices to ensure a sufficient number of participants could be recruited to the trial.

7.2 Selection of GP Practices

As recruitment of participants for the trial was based on their registration with a GP practice, it was essential to determine the number of people who would be offered screening during the trial intervention period (October 2009), and specifically, the number of people per GP practice who would be invited to the NHSBCSP. This would enable the targeted recruitment of GP practices dependent on the number of patients who would be offered screening within that Practice. Based on the sample size calculation (see Appendix 7.1), 775 participants were required for the trial. After contacting the NHSBCSP Central Office, a preliminary (anonymised) list of all people invited to the NHSBCSP for

October 2009 was obtained in March 2009. A total of 25,246 people from 920 GP Practices in the south of England would be invited to the NHSBCSP during the trial period (mean per practice = 23.27, sd = 18.26; range 1 to 123). Table 7.1 shows the number of patients invited to screening per GP practice and the number of GP practices in each category.

Table 7.1: Number of patients per GP Practice and number of GP Practices involved in CRC screening in October 2009.

No. patients invited to CRC screening	No. of GP Practices	Percentage of GP Practices	Cumulative Percentage
1 to 15 patients	269	29.24%	29.24%
16 to 30 patients	297	32.28%	61.52%
31 to 45 patients	216	23.48%	85.00%
46 to 60 patients	97	10.54%	95.54%
61 to 75 patients	29	3.15%	98.70%
76 to 90 patients	8	0.87%	99.57%
91 to 105 patients	1	0.11%	99.67%
106 to 120 patients	2	0.22%	99.89%
121 or more patients	1	0.11%	100%
Total	*920*	*100%*	

Based on the above data, the majority of GP practices (85%) would have 45 patients or less invited to screening in October 2009. Given that the trial could only occur for a one month period, the decision was taken to approach practices with above 46 patients to participate in the trial. This meant that 138 GP Practices from 16 Primary Care Trusts (PCTs) would have a sufficient number of patients invited to screening in October 2009 to ensure recruit the required sample size for the trial. After further inspection, 20 GP practices from 7 PCTs were removed from the potential recruitment list due to the PCT having fewer than three GP practices available, or in two cases, the PCT not currently having an operational R&D office. 118 GP Practices from 9 PCTs were therefore identified for recruitment to the trial.

It is important to note that the decision to target those GP practices with more than 45 patients potentially introduced selection bias to the recruitment process (i.e. not all people invited to screening in October 2009 would have the opportunity to participate in the trial). This may have been avoided by employing a cluster randomisation procedure whereby practices were the unit of randomisation, rather than individual participants. However, this would have required a stratified randomisation procedure (based on size of practice) and a far greater number of GP practices recruited to the trial (logistically difficult given the scope of the funding and resources available to the trial). Furthermore, the primary aim of the trial was to establish the interventions for individual participants; randomisation by practice may well have introduced extraneous practice-specific variables which would confound the primary objectives of the trial.

7.3 Coordinating the questionnaire and intervention mail-out

The baseline questionnaire would be mailed to potential participants six weeks prior to their screening invitation letter. Therefore, GP practices needed to be recruited by early September 2009 to allow the NHSBCSP Central Office to:

- organise the trial 'batch' of invitations with the CfH (based on participating GP Practices)
- send the names and addresses of trial participants to the SPH for the mail-out of the baseline questionnaire

7.4 Stakeholder Group Agreement for the Interventions

Stakeholder group representatives were sent a summary of the results of the pilot study and asked to make comments regarding potential changes to the detailed procedural leaflet or the GP endorsement letter (see Appendix 7.2). After discussions with the representatives, there were no modifications suggested for the detailed procedural leaflet. With the exception of the GP and cancer screening specialist representatives, stakeholder members again voiced their concern about providing comments for the inclusion of information in the GP endorsement letter, and indicated this should be discussed with the GP practices involved in the trial.

7.5 Modifications to Trial Questionnaire Outcomes

The results of the pilot questionnaire and qualitative studies indicated several modifications were required to specific scales which were to be included in the trial questionnaire. Primarily this concerned finalising the items for the knowledge scale, but further, also required alterations to the attitude component of the questionnaire.

Knowledge Scale

Based on the results of the pilot study, the choice of items to include in the trial knowledge scale was somewhat complex. Although the item analysis for the pilot scale indicated six items should be removed, this still left 18 potential items for inclusion. The qualitative study identified some areas which participants felt were important for decision-making and should be included in the information materials; however, these lacked the necessary specificity for identifying items

for inclusion in the knowledge scale. As 18 items was judged to be an excessive number of questions for evaluating public understanding of CRC screening, several steps were undertaken to reduce the number of items in the knowledge scale. These steps involved reviewing the knowledge scales from previous CRC screening studies, consideration of the items in relation to recommendations about information for patient decision-making materials and discussion with stakeholder representatives.

Based on the systematic review of information materials for CRC screening (see Chapter 3), seven publications provided specific information on the items included in their study knowledge scale [10-17]. These were of limited utility given the studies used different response formats (verbal versus written response), a variable number of knowledge items in each scale and were often specific to the information included in the study materials. However, commonly employed items across studies included understanding of the accuracy of the screening test, potential for developing CRC (age-related and family history) and the potential for effective treatment if CRC is diagnosed at an early stage.

Recommendations concerning the specific content for information included in population materials [18-21] were reviewed. This was to ensure the current knowledge scale included the necessary range of items to evaluate whether or not people had a comprehensive understanding of the benefits and risks associated with participation in CRC screening. Ten items were included for the trial questionnaire knowledge scale. The items covered the majority of pertinent areas which are forwarded as important components for informed decision-

making in cancer screening [18-21]. The areas included the severity of CRC, potential for effective treatment, age-related and family history risk of developing CRC, effectiveness of screening, possible false-positive results, and the effectiveness and risks associated with the diagnostic procedure (see Table 7.2).

Table 7.2: Pilot questionnaire items, corresponding trial questionnaire item and the pertinent area for informed decision-making.

	Pilot Questionnaire	Trial Questionnaire	Pertinent area for IDM
No Changes	Item A	Item B	Severity of CRC
	Item D	Item E	Understanding of results
	Item R	Item I	Risks of diagnostic procedure
	Item W	Item F	Accuracy of diagnostic procedure
Clarification of wording	Item C	Item D	Accuracy of screening test; F/P
	Item H	Item J	Aim of screening
	Item L	Item A	Asymptomatic nature of CRC
	Item Q	Item H	Potential of effective treatment
Reversed Item	Item F	Item G	Family history risk
	Item G	Item C	Risk of developing CRC

Note: F/P denotes 'false-positive' result

Four items required no changes for inclusion in the trial knowledge scale questionnaire. Four other items required changes to the wording to improve the clarity of the question. Two further items were reversed (i.e. wording changed to a 'false' statement) given the number of 'true' items included in the scale. The scale was reviewed by both stakeholders and cancer screening specialists to ensure clarity and relevance.

Attitude and Self-Efficacy Scales

The main alterations between the pilot questionnaire and the trial questionnaire were the removal of the negative attitudes towards screening scale [22] and the omission of the self-efficacy subscale from the TSRQ [23]. The poor performance of the negative attitudes scale [22] was indicative of a

methodological difficulty inherent in a number of screening studies. Primarily, this concerns the use of scales where items are based on general attitudes towards a behaviour, as opposed to specific attitudes towards the behaviour [24, 25]. Items previously used to evaluate procedural attitudes towards FOBT screening [26-28] were reviewed and selected items were included as a scale in the trial questionnaire.

Perceived Health Competence and Health Literacy

After discussions with my supervisors, it was suggested the trial questionnaire also evaluate the utility of several measures which may prove useful for exploring differences between participants and non-participants in future research studies. These included a previously validated measure to evaluate perceived competence for performing health-related activities [29, 30] and a brief instrument to ascertain the level of health literacy in the questionnaire sample [31-33].

7.6 Ethical and R&D Submissions

The ethics application for the trial was submitted in early May 2009 and approved in June 2009. After significant delays in the NHS Research Governance Approvals process, seven PCT approvals for the trial were granted in late-July 2009 (two PCTs failed to provide approval until after the commencement of the trial). The trial was registered with the UK Clinical Research Network Study Portfolio (UKCRN ID: 6103) and the International Standard Randomised Controlled Trial Number Register (ISRCTN84055957).

7.7 Summary

Communicating with the providers of the NHSBCSP was an important consideration for ensuring the factorial trial could be successfully conducted. It was also necessary to establish the most advantageous strategy for recruiting GP practices with sufficient numbers of people invited to screening in October 2009. Based on the results of the pilot studies, the modifications to the trial questionnaire were expected to enhance the results of this component of the trial.

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Chapter 8: Factorial Trial Methodology

8.0 Objectives of this Chapter

The final phase of the research programme was the factorial randomised controlled trial (RCT). The trial aimed to evaluate the effectiveness of the two interventions (GP endorsement letter and/or procedural leaflet) for improving participation in the NHSBCSP. The trial also included participant and GP practice questionnaire components. The main objectives of this chapter are to:

- report the rationale, methodology and recruitment of GP practices and participants for the factorial RCT
- describe the participant and GP practice questionnaire components of the trial

8.1 Design of the Final Phase of the Research Programme

This study was a phase II (exploratory) 2x2 factorial randomised controlled trial (see Appendix 7.1). The design and methodology of this phase of the research programme was based on the MRC framework [1-3], satisfying the 'Phase 2 (exploratory trial)' component of the guidance. The decision to employ a factorial RCT design for the final phase of the research was based on several factors. While recognising certain limitations of the design, the factorial RCT enabled the simultaneous evaluation of the two interventions by including all participants in both analyses (reducing the sample size required) and also allowed for an investigation of the potential interaction between the interventions [4-6]. Furthermore, the design allowed for an investigation of a potential interaction between the two interventions [4-6], which would inform the

design of future research studies for primary care-based interventions for improving participation in CRC screening.

8.2 Aims of the Factorial RCT

The primary aim of the trial was to evaluate the effectiveness of a GP endorsement letter and/or a procedural leaflet for improving participation in the NHSBCSP. The secondary aims were based on the participant questionnaire and GP practice questionnaire components of the trial. Briefly, the secondary aims of the participant questionnaire concerned patient perceptions of the intervention materials, patient perceptions of bowel cancer screening and the NHS information materials, autonomy and self-efficacy for completing screening, knowledge and attitudes about bowel cancer and bowel cancer screening, and patient decision-making. The GP questionnaire aimed to evaluate the impact of the trial on participating practices (e.g. workload implications, trial participants contacting the practice) and GP perceptions of the NHSBCSP.

8.3 Interventions

Two interventions were used in the factorial RCT. These were:

- GP endorsement letter - a letter from the persons' GP Practice that was included in the FOBT pack (see Appendix 8.1)
- detailed procedural leaflet - the leaflet provided detailed information and advice concerning methods for the collection, storage and return of the FOBT kit (see Appendix 8.2)

The content of the GP endorsement letter was agreed with participating practices after ethical approvals were granted; none of the practices requested any changes to the wording of the letter. The GP endorsement letter was a personally addressed letter from each patient's GP which: (1) recommended the patient complete FOBT, (2) offered support if the patient had any questions about screening, and (3) emphasised the importance of being aware of CRC symptoms. Several key messages were included in the letter, based on the views of respondents in the pilot phase, pertinent factors identified from the overview of the research literature and phrased using the 'gain-frame' approach, which has been identified as important when targeting detection behaviours [7]. The key messages indicated the risk of developing CRC was highest in the patients' age group, highlighted CRC was often asymptomatic and screening can detect CRC at an early stage when treatments are likely to be more effective. The GP endorsement letter was written on practice letterhead, and whenever possible, included an electronic signature from one of the practice partners.

The second intervention was the detailed procedural leaflet. The A4 leaflet aimed to provide trial participants with advice about collecting samples, storing samples and returning the FOBT kit. The leaflet addressed potential barriers to CRC screening identified from the pilot phase of the programme and previous research [8-11]. The leaflet incorporated several theoretical approaches which focused on emphasising the importance of self-efficacy [12-14], potential barriers for participation in CRC screening [10, 15, 16] and effective methods for improving risk communication [17]. The leaflet included an educational or

knowledge-building component (reinforcing messages regarding the effectiveness and rationale for screening) and motivational components designed to enhance self-efficacy (advice on how to collect samples, concerns about the time required to complete the test, and what people with loose or irregular bowel movements should do).

8.4 Recruitment of GP Practices

Of the 118 GP practices identified from NHSBCSP Central Office invitation list, 95 were contacted by five Primary Care Research Networks (PCRNs) operating across 9 PCTs. 39 GP practices expressed an interest in becoming involved in the research after the relevant PCRN sent preliminary information to the practices (see Appendix 8.3). After further information was provided to the practices (see Appendix 8.4), 20 GP practices were recruited to the trial. One PCT (Dorset) did not provide data on the number of GP practices contacted as R&D approval was not available at the start of the study. One PCT (Bournemouth and Poole) was unable to recruit interested practices due to R&D approval not being available by the commencement of the study (Table 8.1).

Table 8.1: Recruitment process for GP practices in the RCT.

South-East PCTs	**Identified**	**Contacted**	**Interest**	**Recruited**
East Berkshire[1]	4	4	4	1
West Berkshire[1]	10	10	7	0
West Sussex[2]	11	7	2	2
Surrey[2]	20	10	5	3
Total	*45*	*31*	*18*	*6*
South-West PCTs	**Identified**	**Contacted**	**Interest**	**Recruited**
Hampshire[3]	34	34	10	8
Bournemouth & Poole[3]	7	7	3	0 – No R&D
Dorset[4]	9	Unknown	Unknown	0 – No R&D
Devon[4]	9	9	4	2
Somerset[5]	14	14	4	4
Total	*73*	*64*	*21*	*14*
Total	**118**	**95**	**39**	**20**

Note: 1 = South-East PCRN (Central); 2 = South-East PCRN (East); 3 = South-West PCRN (Central); 4 = South-West PCRN (West); 5 = South-West PCRN (North)

8.5 Inclusion Criteria

Inclusion criteria for participants were men or women who were registered with a GP practice in the south of England and who would be sent an invitation to the NHSBCSP in October 2009. People who accept or decline the invitation to screening were eligible for inclusion. People who specifically requested to be withdrawn from the NHSBCSP or who are currently ineligible for invitation to the programme (i.e. current bowel cancer patients, people currently in bowel cancer surveillance programmes, etc) were excluded from the research. Although the NHSBCSP invites people aged 60-69 to screening, one PCT region (Devon) was involved in piloting the age extension to the programme. Therefore, the age range for inclusion in the trial was 60 to 75 years. The inclusion criteria for the questionnaire component of the trial were the same, although participants were required to return both questionnaires and a signed consent form to be eligible.

8.6 Sample Size

The sample size calculation was based on detecting a difference in main effects between the two factorial groups (e.g., GP endorsement letter versus no GP endorsement letter or leaflet versus no leaflet), not a difference between the four intervention groups [4, 6]. Currently, the approximately half (49%-52%) of people invited to the NHSBCSP participate in screening [18-20]. The sample size calculation for the factorial RCT was based on the expectation that there would be a 10% difference between either intervention group (GP endorsement letter or procedural leaflet) in comparison to usual care (either no GP endorsement letter or no procedural leaflet). The two interventions were not

posited to have a combined effect (interaction) on participation in CRC screening for the following reasons:

- the GP endorsement letter was expected to effect a subjects' decision to participate or not in cancer screening (influence decision-making)
- the procedural leaflet was expected to effect a subjects' ability to perform the FOBT (influence self-efficacy)

Assuming a completion rate of 70% in either the procedural leaflet and/or GP endorsement group (marginal total 70%) and 50% in the usual care group (marginal total 60%), 387 participants per factorial group (total 775) would be required to detect an absolute difference of 10% at a power of 80% and a two-tailed α of 0.05.

8.7 Randomisation Procedure

Two participant electronic 'batches' of invitations were generated by the NHSBCSP Central Office. These files were anonymised and linked to the Southern Programme Hub (SPH) mail-out files. An anonymised list of participants registered with a GP practice recruited to the trial was then sent to the research team. The anonymised list was used for the randomisation of participants; SPH staff were able to match the intervention with each participant (based on the SPH mail-out file).

Trial participants were randomised to one of four intervention groups using a block randomisation procedure. The randomisation sequence, involving allocation of participants to an intervention group using randomly varying block sizes of one to four, was performed using the 'ralloc' command in STATA

Version 10. If more than one person per household would be invited during the trial period, one person would be randomly selected to participate in the trial and the other(s) in that household would be excluded. Randomisation occurred six weeks before potential participants were invited to the NHSBCSP. Ideally, the randomisation of participants would have occurred after people had indicated to the NHSBCSP they had 'opted-out' of screening (i.e. they did not wish to receive a FOBT kit). This would mean that only those people receiving a FOBT kit would have received the interventions. However, due to significant procedural difficulties with Connecting for Health, this was not possible.

8.8 Allocation Concealment and Blinding

The allocation sequence was not concealed from the research team, although the research team was not aware of individual participant's group assignment.

8.9 Primary Outcome: Participation in Screening

The primary outcome of the trial was verified participation in the NHSBCSP 12 weeks after the FOBT kit was sent to the participant. Secondary outcomes included verified participation at 20 weeks and the per-protocol analyses. Per protocol analyses were performed for verified participation at 12 weeks and 20 weeks for people sent the FOBT kit. Verification of participation was conducted by NHSBCSP staff to ensure patient confidentiality.

8.10 Secondary Outcomes

Secondary outcomes were concerned with the participant and GP practice questionnaire components of the trial.

8.10.1 Participant questionnaire outcomes

Two questionnaires (baseline and follow-up) were used in the participant questionnaire component of the trial. The before-and-after design allowed a comparison of participants' perceptions, knowledge and attitudes towards CRC screening prior to receiving the screening invitation (baseline) and after receiving the FOBT kit (follow-up). The main outcomes for the participant questionnaire component were:

a) participant perceptions of the GP letter and/or procedural leaflet
b) knowledge of bowel cancer and bowel cancer screening (overall scores for the knowledge scale and changes between baseline and follow-up)
c) autonomy of decision-making and attitudes towards bowel cancer screening (TSRQ)
d) participant views of the FOBT kit and participating in screening
e) Perceived Health Competency (PHC) scale and self-efficacy
f) views of the NHSBCSP information materials
g) health literacy

8.10.2 GP practice questionnaire outcomes

The main outcomes of the GP practice questionnaire component concerned the impact that the trial had for the GP practice (in regards to extra workload or additional resources due to patient inquiries about the trial or CRC screening) and GP opinions about the NHSBCSP.

8.10.3 Participant questionnaire instrument

Participant Perceptions of the GP Letter and/or Procedural Leaflet

The perceived effectiveness of including a GP endorsement letter with the FOBT pack was assessed by two questions in both questionnaires. Participants were asked to rate how important their GPs opinion was for them to participate or not in screening (from 1 'very important' to 4 'not important at all') and if receiving a GP letter endorsing CRC screening would have any effect on their decision. Further questions asked if participants had spoken to their GP about CRC screening, number of visits to their GP in the past year, confidence in their GP and if it was embarrassing to speak to their GP about CRC screening. Participants were also asked if they had contacted their GP or the Screening Hub about their invitation to screening during the trial period.

Participant perceptions of the detailed procedural leaflet were assessed by a six item 'acceptability' scale developed during the pilot phase of the research. Items included participant views of the utility of suggestions about completing the test, the amount of information in the leaflet, how helpful the information was for making a decision about screening and if the leaflet influenced their views on participating in screening.

Knowledge

The knowledge scale included ten items developed from the pilot phase of the research and previously published research [21-25]. A 'true/false/don't know' response format was used for six true and four false statements included in the scale. The aim of the knowledge measure was to assess the conceptual

understanding of CRC and CRC screening. All items in the scale were based on information presented in the NHSBCSP booklet ('Bowel Cancer Screening: The Facts'). Overall scores could range from 0 to 10, with a higher score indicating greater knowledge.

Autonomy and attitudes towards CRC screening

The 'Treatment Self-Regulation Questionnaire' (TSRQ) was used to evaluate autonomy and attitudes towards participating in CRC screening. The scale assesses the degree to which a person's motivation for engaging in a healthy behaviour is relatively autonomous or controlled by external factors [26-29; see Chapter 5 for further information].

Perceived Health Competency, Self-Efficacy and Intention

The 'Perceived Health Competency Scale' (PHCS) measures the degree to which an individual perceives they are capable of effectively managing or controlling their health outcomes [30]. The PHCS was recently validated for UK primary care populations [31] and has been previously used to predict psychosocial health outcomes related to information provision for breast cancer patients [32], predict quality-of-life outcomes for hypertension patients [33], and to predict adherence in renal dialysis [34]. The scale consists of eight items to which responses are chosen from a 5-point Likert scale ranging from 'strongly agree' to 'strongly disagree'. The score from each item are averaged to produce an overall score (1-5), with a higher score indicating a stronger perception of health competence.

The utility of employing a single-item self-efficacy question instead of a multi-item scale has been forwarded as an effective and economical approach to assessing participants' beliefs about their ability to perform particular health behaviours [35, 36] and has been extensively used in decision making research [37]. A single-item self-efficacy question was also included in the baseline questionnaire to as a comparative measure to the PHCS. Participants were asked to indicate how confident they were that they could complete screening on a four-point Likert scale (from 1 'very confident' to 4 'not confident at all'). Intention to participate in screening was assessed by a single question in the baseline questionnaire, and intention to participate in screening if invited in two years time was assessed in the follow-up questionnaire.

Participant Views of FOBT screening

Participant views about specific aspects FOBT screening were assessed by a 10-item scale in the baseline questionnaire and an 11-item scale in the follow-up questionnaire. Scale items were derived from previous research regarding participant satisfaction with FOBT screening [38-40]. Participants were asked to indicate on a five-point Likert scale from 1 ('strongly agree') to 5 ('strongly disagree') positive and negative statements about FOBT screening. Eight of the items were presented in both questionnaires. These items concerned participant views on the importance of receiving information, difficulty in collecting samples, perception that screening would be disgusting or embarrassing, concern about doing test correctly, inconvenience of collecting several samples, confidence in screening results and understanding the reason for being asked to do the test. Two items in the baseline questionnaire asked

participants if they felt screening would be messy or unhygienic. Three items in the follow-up questionnaire evaluated kit-specific perceptions (instructions and spatulas provided with the kit were easy to use) and if their overall experience with screening was positive.

Decision-making, Perceived Risk and Worry

Four questions concerning decision-making and the perceived benefits/barriers to CRC screening were included in both questionnaires. These questions related to the importance of the decision and the importance of knowing the benefits and risks of screening (from 1 'very important' to 4 'not important at all'), how convinced the participant was about the benefits of participating in screening (from 1 'very convinced' to 4 'not convinced at all'), and if the participant was concerned about the risks of participating in screening (from 1 'very concerned' to 4 'not concerned at all'). One question included in the baseline questionnaire asked how important it was to receive an information booklet with their invitation to screening (from 1 'very important' to 4 'not important at all').

Perceived risk of developing CRC can be a strong determinant for participation in screening [41-43]. Participant's perceived risk of developing CRC was based on two questions. Participants were asked how likely it was they would develop CRC in the near future (subjective risk from 1 'definitely will' to 5 'definitely will not') and also asked to rate their chances of developing CRC in comparison to someone like them (comparative risk from 1 'much more' to 5 'much less'). Participant concerns (worry) about being diagnosed with CRC following

participation in screening was assessed by a single question (from 1 ‘very worried’ to 4 ‘not worried at all’).

Health Literacy

Adequate literacy is an essential factor for participation in screening as both interventions and the NHSBCSP invitation process are based on written materials. Inadequate health literacy has also been shown to be associated with non-participation in CRC screening [44-46]. A three question scale, previously validated in primary care populations [47-49], was used to ascertain the general health literacy of participants. Scale items asked participants if they needed help reading patient education materials, their confidence in filling out medical forms and any difficulty in understanding written health information. Each question was based on a 5-point response scale, summed to provide a score from 0-12, with a score of ≤11 indicating inadequate health literacy.

Views of the NHS Information Materials

Participants’ views of the information booklet (‘Bowel Cancer Screening: The Facts’) were evaluated by an eight item ‘acceptability scale’ developed in the pilot phase of the research and based on previous patient decision-aid research [50-52]. Participant’s views on the balance, length of booklet, readability and amount of information about the benefits and risks of screening were assessed.

Previous Experience and Reasons for Participating

Previous experience with CRC screening or colonoscopy, personal/family history of CRC or significant bowel conditions and awareness of the NHSBCSP

was assessed in the baseline questionnaire. The main reason people would consider participating in screening was asked in both questionnaires. The follow-up questionnaire asked if people had completed screening (and if not, if they intended to return the FOBT kit), if they had received a GP letter and/or the procedural leaflet and if they had any difficulties in completing the test.

Demographic Information

Demographic information about participants was based on seven questions (included in the baseline questionnaire) relating to gender, age group, current marital and employment status, general health, highest educational qualification and ethnicity.

8.10.4 GP practice questionnaire instrument

The four-page questionnaire was divided into four sections (see Appendix 8.5). The first section (three items) asked if any patients had contacted the GP practice during the trial period, how patients preferred to resolve queries about the NHSBCSP invitation and if patient queries had any significant impact of staff time or resources. The second section (8 items) listed potential reasons for patients contacting the GP practice about CRC screening. A response scale from 1 ('never') to 4 (very often') was used for each of these eight questions. The third section consisted of nine questions and asked GP opinions about the NHSBCSP. Questions included GP opinions about whether GPs should be more involved in the programme, the amount of information that GPs receive about the programme, the type of screening test that should be used and GP

remuneration for their involvement. The final section (four items) asked about the organisation of the GP practice.

8.11 Statistical Methods

All data analyses were performed using STATA Version 10. Baseline comparability of the groups was investigated using descriptive statistics. The primary analyses comparing the intervention groups (participation within 12 weeks and participation at 20 weeks for the return of FOBT kits) were conducted on an intention-to-treat basis. As participants could opt-out of screening after randomisation was performed, a per-protocol analysis was performed for people who were actually sent a FOBT pack and hence subject to the intervention.

Given the factorial design, the primary estimate of effectiveness of an intervention should be on a comparison of all individuals allocated to receive it versus those not allocated to receive it (within each of these two groups, half will be allocated to receive the other intervention) [4]. Therefore, the two intervention effects were obtained from a multiple, random effects logistic regression model, adjusting each other and for the covariates (age group, gender, GP Practice, GP signature, previous invitation). The adjusted odds ratios (ORs) are presented, and although the study was not powered to detect for interactions between the two interventions, the interaction effects were also investigated.

8.11.1 Questionnaire statistical analyses

Questionnaire data was double-entered by a private company (Document Technologies Inc) and analysed using STATA Version 10. Demographic, CRC screening-specific characteristics, perceived risk and worry, and participant perceptions for the 'The Facts' booklet were analysed using the Pearson Chi-square test or Fisher's exact test if cell frequencies were below 5. The Wicoxon Mann-Whitney test was used for comparing differences between males and females for the importance of information items. Item analysis and exploratory factor analysis was performed for the views of FOBT screening scale and the TSRQ. The McNemar test was used to compare the change for categorical outcomes between responses to the baseline and follow-up questionnaire (negative views of the screening kit, knowledge items, and the decision-making, perceived risk and worry variables). Paired t-tests were used to compare differences between the baseline and follow-up questionnaire for the knowledge scale and TSRQ subscales.

8.12 Trial Procedure

All participants registered with a GP practice recruited to the trial, and who would be receiving their invitation to the NHSBCSP in October 2009, were sent a baseline questionnaire pack. Participants were informed they would be receiving an invitation to the NHSBCSP in the near future, provided with brief overview of the trial and CRC screening, and also informed that their GP practice was involved in the trial. The baseline questionnaire pack included an invitation letter (see Appendix 8.6), participant information sheet (see Appendix 8.7), consent form (see Appendix 8.8), reply slip (for people not wanting to

participate in the questionnaire component of the trial; see Appendix 8.9), a request for information form (to request a summary of the results of the trial; see Appendix 8.10) and the baseline questionnaire (see Appendix 8.11). The baseline questionnaire pack was sent out six weeks prior to the participants receiving their invitation to screening from the NHSBCSP.

People invited to the NHSBCSP receive an invitation letter (explaining why they have been invited and the rationale for CRC screening; see Appendix 8.12) and an evidence-based information booklet ('Bowel Cancer Screening: The Facts' [53]) one week before they receive their FOBT pack. The FOBT pack includes a FOBT card, spatulas for smearing samples on the card, basic instructions for completing FOBT and a return-post envelope. Potential participants have the opportunity to request not to be sent an FOBT kit for any reason, in the week before receiving the FOBT kit. After excluding patients who had requested not to receive the FOBT kits, SPH staff sorted the participants into their randomised groups and included the relevant intervention materials with the FOBT kit. The FOBT kits were then mailed to the participants. The date and time for people who return their completed FOBT kits is electronically recorded at the SPH, and then uploaded to the main NHSBCSP database. People not returning their FOBT kits within four weeks receive a reminder letter from the SPH. Results letters are normally sent to participants within two weeks of returning their completed kits. Participation or non-participation in screening was verified by NHSBCSP staff in late-April 2010.

Consenting participants who returned their baseline questionnaire were sent a follow-up questionnaire pack two weeks after the FOBT kits were dispatched. The follow-up questionnaire pack included a follow-up invitation letter (see Appendix 8.13) and a follow-up questionnaire (see Appendix 8.14). Participants who had not returned their follow-up questionnaire within three weeks were sent reminder letter (see Appendix 8.15) and a second follow-up questionnaire. No further reminders were sent to the participants. The GP practice questionnaire was sent to all practices eight weeks after participants were sent their FOBT packs.

8.13 Reference List

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Chapter 9: Results of the Factorial RCT

9.0 Objectives of this Chapter

This chapter presents the intention-to-treat and per protocol analyses for participation (primary outcome) in the factorial randomised trial. The analyses include screening participation based on the return of FOBT kits for 12 and 20 weeks, and the intention-to-treat (ITT) and per protocol (people receiving the FOBT pack) results.

9.1 GP Practice and Participant Characteristics

Twenty GP practices from seven PCT regions in the south of England were recruited to the trial (see Table 9.1). The number of participants in each GP practice ranged from 48 to 115 (mean = 64.4, SD = 18.1; median 59). Eight of the 20 GP practices provided an electronic signature from a senior partner for the GP endorsement letter (one letter included a separate signature for all 7 GPs working at the practice). Seven other practices included the name of a senior partner with the phrase “On behalf of the practice”, but did not include an electronic signature (one letter including the names of all six GPs working at the practice). Five GP practices requested that only “On behalf of the practice” be used instead of a name or signature.

Table 9.1: Region, GP signature on endorsement letter and number of participants for all GP practices enrolled in the trial.

GP practice	Region	GP Signature	RCT Participants
H81013	SE/Surrey	No (OBP)	108
H81021	SE/Surrey	No (Name/OBP)	49
H81062	SE/Surrey	Yes	73
H82017	SE/West Sussex	No (Name/OBP)	74
H82043	SE/West Sussex	No (Name/OBP)	62
J82046	SW/Hampshire	Yes (Multiple)	57
J82056	SW/Hampshire	No (OBP)	50
J82057	SW/Hampshire	No (OBP)	58
J82110	SW/Hampshire	Yes	57
J82129	SW/Hampshire	Yes	50
J82144	SW/Hampshire	No (Name/OBP)	64
J82145	SW/Hampshire	No (Name multiple/OBP)	53
J82186	SW/Hampshire	Yes	48
K81030	SE/East Berkshire	No (Name/OBP)	62
L83005	SW/Devon	Yes	71
L83013	SW/Devon	Yes	71
L85008	SW/Somerset	No (Name/OBP)	115
L85009	SW/Somerset	Yes	50
L85035	SW/Somerset	No (OBP)	56
L85004	SW/Somerset	No (OBP)	60
			Total = 1288

Note: SE = South-East, SW = South West, OBP = “On behalf of the Practice”

9.2 Randomisation procedure

644 people were randomised to the two factorial groups (322 people allocated to each of the four intervention groups). As the standard invitation letter for the NHSBCSP allows people to opt out of screening prior to receiving their FOBT kits, not all of those who were randomised received the intervention (per protocol analysis; see Figure 1). Figure 1 shows that 72 people who were randomised to the trial, exercised the option of not receiving the FOBT kit, and therefore, did not receive the intervention.

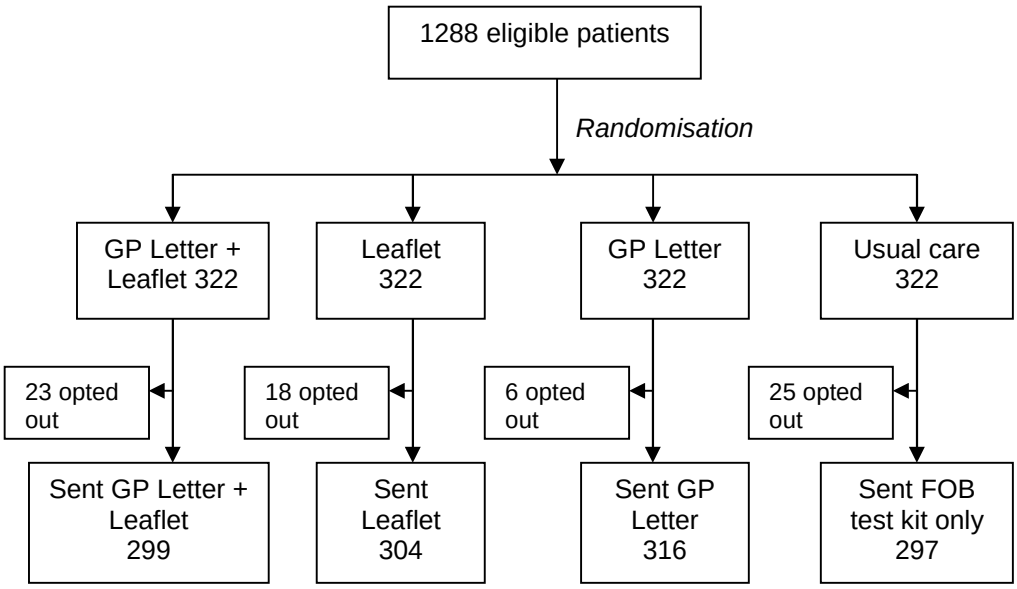

Figure 1: Participant flow chart for the factorial randomised trial.

9.3 Characteristics of Participants

The characteristics of those participating in the trial, including whether or not they received the intervention and a comparison of the factorial groups, are shown in Table 9.2. After individual randomisation within practices, there were 322 people in each of the four intervention groups. There were no statistically significant differences in gender or age group between the four intervention groups. A significantly higher number of people in the 'Letter and Leaflet' group were sent a FOBT kit (p = 0.005) in comparison to the other intervention groups.

There were no significant differences between baseline characteristics for the 'Letter' group or 'Leaflet' group with the exception of FOBT kits sent in the 'Letter' group. More people in the 'Letter' group were sent an FOBT kit in comparison to the 'No Letter' group.

Table 9.2: Participant characteristics for the four intervention groups and two factorial trial groups.

Intervention Groups		Letter and Leaflet	GP Letter Only	Leaflet Only	Usual Care	Total	*P* value
Gender	*Male*	153	153	154	151	611	0.996
	Female	169	169	168	171	677	
Age Group	*60-64*	187	189	183	189	748	0.864
	65-69	125	119	131	123	498	
	70+	10	14	8	10	42	
Previous Invite	*Yes*	44	38	41	47	180	0.508
	No	278	284	271	275	1108	
Sent FOBT	*Yes*	316	304	299	297	1216	0.005
	No	6	18	23	25	72	
GP Signature	*Yes*	123	116	-	-	239	0.954
	No	199	206	-	-	405	
Total		322	322	322	322	1288	

Factorial Trial Groups		GP Letter	No GP Letter	*P* value	Leaflet	No Leaflet	*P* value
Gender	*Male*	306	305	0.956	307	304	0.867
	Female	338	339		337	340	
Age Group	*60-64*	376	372	0.583	370	378	0.513
	65-69	244	254		256	242	
	70+	24	18		18	24	
Previous Invite	*Yes*	82	98	0.199	95	85	0.422
	No	562	546		549	559	
Sent FOBT	*Yes*	620	596	0.004	615	601	0.089
	No	24	48		29	43	
Total		644	644		644	644	

* letter sent with GP signature rather than signed “on behalf of the practice”

9.4 Participation in CRC Screening at 12 weeks (ITT Analysis)

Overall, 703 (54.6%) of all people recruited to the trial returned their FOBT kit within 12 weeks (see Table 9.4.1). The ‘Letter and Leaflet’ group reported the highest proportion of people returning FOBT kits within 12 weeks (194/322; 60.3%). The ‘Leaflet Only’ group had a slightly higher participation rate (177/322; 55.0%) than the ‘Letter Only’ group (174/322; 54.0%). Less than half (158/322; 49.4%) of people in the ‘Usual Care’ group participated in CRC screening. The return rate for people receiving both interventions demonstrated an absolute difference of 10.9% over ‘Usual Care’, strongly suggesting the

effect of both interventions is additive (i.e. the absolute difference of 4.6% for the 'GP Letter Only' group and 5.6% for the 'Leaflet Only' group is approximately the same as the absolute difference observed for the 'Letter and Leaflet' group).

Table 9.4.1: Number of people returning FOBT kits within 12 weeks according to individual intervention group, factorial group and whether or not the endorsement letter was signed by the participant's GP.

	No.	Total	Percent.	95% CI	Difference (in %)
Individual Groups					
Letter and Leaflet	194	322	60.3	55 - 66	10.9
GP Letter Only	174	322	54.0	49 - 60	4.6
Leaflet Only	177	322	55.0	50 - 61	5.6
Usual Care	158	322	49.4	44 - 55	-
Factorial Groups					
Letter	368	644	57.1	53 - 61	5.1
No Letter	335	644	52.0	48 - 56	-
Leaflet	371	644	57.6	53 - 61	6.0
No Leaflet	322	644	51.6	48 - 55	-
GP Letter					
Letter signed	151	239	63.2	57 - 69	9.8
Letter not signed	217	405	53.6	49 - 59	-

For the factorial groups, both the GP endorsement letter and the procedural leaflet increased participation by over 5% - an absolute difference of 5.1% for the GP endorsement letter and 6.0% for the procedural leaflet in comparison to not receiving the respective intervention. The proportion of people participating in screening was higher for those receiving a signed GP's endorsement letter (63.2%) in comparison to people who received the non-signed (on behalf of the practice) endorsement letter (53.6%); an absolute difference of almost 10%. Bivariate analyses for the intervention groups, factorial groups and for people receiving a signed GP endorsement letter are shown in Appendix 9.1).

There were no overall differences between the age groups or gender for the return of FOBT kits at 12 weeks. The relative proportion of kits returned by gender is shown in Table 9.4.2. A higher relative proportion of males receiving the procedural leaflet returned their kits, whereas a slightly higher relative proportion of females returned the FOBT kit after receiving the GP endorsement letter.

Table 9.4.2: Relative proportion of FOBT kits returned at 12 weeks by gender.

		Intervention Groups			
		Letter and Leaflet	*Letter Only*	*Leaflet Only*	*Usual Care*
CRC Screening Participation	*Male*	58.2%	49.7%	55.2%	47.0%
	Female	62.1%	58.0%	54.8%	50.9%

9.4.1 Logistical Regression for participation at 12 weeks (ITT)

The results of the intention-to-treat random effects logistic regression model confirmed that there was no significant interaction between the two interventions (p = 0.976; see Table 9.4.3). There were no significant associations between participation and the included covariates of GP practice (p = 0.746), age (p = 0.952), gender (p = 0.164), or previous invitation to screening (p = 0.118).

Table 9.4.3: Likelihood of people returning FOBT kit within 12 weeks: results of the logistic regression analysis.

	Odds ratio	**95% CI**	***p* Value**
Intervention main effects:*†			
Letter	1.23	0.99 to 1.53	0.064
Leaflet	1.28	1.03 to 1.59	0.029
GP Signature	1.20	0.96 to 1.51	0.111
Interaction:*			
Letter and Leaflet	1.01	0.65 to 1.57	0.976

* The reference category for each main effect was those not receiving the intervention.
† Obtained for model without interaction; each intervention adjusted for the other.

There was no significant association for the GP endorsement letter (OR 1.23; *p* = 0.064) or the inclusion of a GP signature (OR 1.20; *p* = 0.111), however, there was a significant association for the procedural leaflet (OR 1.28; *p* = 0.029).

9.5 Participation in CRC Screening at 12 weeks (Per Protocol Analysis)

703 (57.8%) of people who received the FOBT kit (i.e. did not opt-out of screening after randomisation) returned their FOBT kit within 12 weeks (see Table 9.5.1). The 'Letter and Leaflet' group reported the highest proportion of people returning FOBT kits within 12 weeks (194/316; 61.4%). The 'Leaflet Only' group had a slightly higher participation rate (177/299; 59.2%) than the 'Letter Only' group (174/304; 57.2%). Just over half (158/297; 53.2%) of people in the 'Usual Care' group participated in CRC screening.

In comparison to the ITT analysis for participation at 12 weeks, the absolute differences between the four intervention groups in the per protocol analysis are slightly smaller. The return rate for people receiving both interventions showed an absolute difference of 8.2% over 'Usual Care', in comparison to 10.9% in the ITT analysis. Further, the absolute difference for the 'GP Letter Only' group is also less than the ITT analysis (4.0% versus 4.6%). However, participation for the 'Leaflet Only' group increased from 5.6% to 6.0% in the per protocol analysis. There is still the suggestion of an addictive effect for the two interventions, however, not as convincing as observed in the ITT analysis.

Table 9.5.1: Number of people opting-in to screening who returned FOBT kits within 12 weeks according to individual intervention group, factorial group and whether or not the endorsement letter was signed by the participant's GP.

	No.	Total	Percent.	95% CI	Difference (in %)
Individual Groups					
Letter and Leaflet	194	316	61.4	56 - 67	8.2
GP Letter Only	174	304	57.2	52 - 63	4.0
Leaflet Only	177	299	59.2	54 - 65	6.0
Usual Care	158	297	53.2	47 - 59	-
Factorial Groups					
Letter	368	620	59.4	56 - 63	3.3
No Letter	335	596	56.1	52 - 60	-
Leaflet	371	615	60.3	57 - 64	5.1
No Leaflet	322	601	55.2	51 - 59	-
GP Letter					
Letter signed	151	229	65.9	59 - 72	10.4
Letter not signed	217	391	55.5	50 - 61	-

The per protocol analysis also demonstrated a decrease in the participation rate for the GP endorsement letter factorial group in comparison to the ITT analysis. The participation rate fell from 5.1% in the ITT analysis to 3.3% in the per protocol analysis, whilst the procedural leaflet factorial group did not decrease so dramatically (6.0% versus 5.1%). This is most likely due to the imbalance in the denominator between people receiving the FOBT kit who did/did not receive a GP endorsement letter. The absolute difference for the proportion of people participating in screening remained relatively stable for those receiving a signed GP's endorsement letter in comparison to people who received the non-signed endorsement letter between the two analyses; absolute difference of 10.4% for the per protocol analysis in comparison to 9.8% for the ITT analysis.

There were no overall differences between the age groups or gender for the return of FOBT kits at 12 weeks for people receiving a FOBT kit. The relative

proportion of kits returned by gender is shown in Table 9.5.2. A higher relative proportion of males receiving the procedural leaflet returned their FOBT kits.

Table 9.5.2: Relative proportion of FOBT kits returned by people receiving a kit at 12 weeks by gender.

		Intervention Groups			
		Letter and Leaflet	*Letter Only*	*Leaflet Only*	*Usual Care*
CRC Screening Participation	*Male*	59.3%	51.7%	60.3%	50.7%
	Female	63.3%	62.4%	58.2%	55.4%

9.5.1 Logistical Regression for participation at 12 weeks (Per Protocol Analysis)

The results of the per protocol random effects logistic regression model confirmed that neither there was no significant interaction between the two interventions (p = 0.703; see Table 9.5.3). There were no significant associations between participation and the included covariates of GP practice (p = 0.568), age (p = 0.683), gender (p = 0.119), or previous invitation to screening (p = 0.290).

Table 9.5.3: Likelihood of people returning FOBT kit within 12 weeks for people receiving FOBT kit: results of the logistic regression analysis.

	Odds ratio	**95% CI**	***p* Value**
Intervention main effects:*†			
Letter	1.10	0.90 to 1.43	0.273
Leaflet	1.23	0.98 to 1.55	0.072
GP Signature	1.25	0.98 to 1.57	0.070
Interaction:*			
Letter and Leaflet	0.92	0.58 to 1.45	0.703

* The reference category for each main effect was those not receiving the intervention.
† Obtained for model without interaction; each intervention adjusted for the other.

There was no significant association for the GP endorsement letter (OR 1.10; *p* = 0.273), procedural leaflet (OR 1.23; *p* = 0.072) or the inclusion of a GP signature (OR 1.25; *p* = 0.070).

9.6 Participation in CRC Screening at 20 weeks (ITT Analysis)

Sensitivity analyses were conducted for participation beyond the usual time restriction for the return of FOBT kits. Although the NHSBCSP considers the screening episode closed 12 weeks after sending the FOBT pack, kits returned to the Screening Hub after the close of episode will still be processed, especially if the screening episode occurs during a particular difficult period (e.g. Christmas holidays, postal strikes – both of which occurred during the trial period).

Overall, 711 (57.8%) of all people who were randomised to the trial returned their FOBT kit within 20 weeks (see Table 9.6.1). The 'Letter and Leaflet' group reported the highest proportion of people returning FOBT kits within 12 weeks (197/322; 61.2%). The 'Leaflet Only' group had approximately the same participation rate (178/322; 55.3%) as the 'Letter Only' group (177/322; 55.0%). Just under half (159/322; 49.4%) of people in the 'Usual Care' group participated in CRC screening.

Table 9.6.1: Number of people participating in screening within 20 weeks according to individual intervention group, factorial group and whether or not the endorsement letter was signed by the participant's GP.

	No.	Total	Percent.	95% CI	Difference (in %)
Individual Groups					
Letter and Leaflet	197	322	61.2	56 - 67	11.8
GP Letter Only	177	322	55.0	49 - 61	5.6
Leaflet Only	178	322	55.3	50 - 61	5.9
Usual Care	159	322	49.4	44 - 55	-
Factorial Groups					
Letter	374	644	58.1	54 - 62	5.8
No Letter	337	644	52.3	48 - 56	-
Leaflet	375	644	58.2	54 - 62	6.0
No Leaflet	336	644	52.2	48 - 56	-
GP Letter					
Letter signed	155	239	64.9	58 - 71	10.8
Letter not signed	219	405	54.1	49 - 59	-

For the factorial groups, both the GP endorsement letter and the procedural leaflet increased participation by around 6% - an absolute difference of 5.8% for the GP endorsement letter and 6.0% for the procedural leaflet in comparison to not receiving the respective intervention. The proportion of people participating in screening was higher for those receiving a signed GP endorsement letter (64.9%) in comparison to people who received the non-signed (on behalf of the practice) endorsement letter (54.1%); an absolute difference of almost 11%.

There were no overall differences between the age groups or gender for the return of FOBT kits at 20 weeks. The relative proportion of kits returned by gender is shown in Table 9.6.2. A higher relative proportion of males receiving the procedural leaflet returned their kits, whereas a slightly higher relative proportion of females receiving the GP endorsement letter returned their kits.

Table 9.6.2: Relative proportion of FOBT kits returned at 12 weeks by gender.

		Intervention Groups			
		Letter and Leaflet	*Letter Only*	*Leaflet Only*	*Usual Care*
CRC Screening Participation	*Male*	59.5%	50.3%	55.8%	47.7%
	Female	62.7%	59.2%	54.8%	50.9%

9.6.1 Logistical Regression for participation at 20 weeks (ITT)

The results of the intention-to-treat random effects logistic regression model confirmed that both the 'GP Letter' (OR 1.26; p = 0.038) and the 'Leaflet' (OR 1.28; p = 0.029) interventions significantly increased participation at 20 weeks with no evidence of an interaction effect (p = 0.979; see Table 9.6.3). There were no significant associations between participation and the included covariates of GP practice (p = 0.658), age (p = 0.772), gender (p = 0.200), previous invitation to screening (p = 0.058) or for the inclusion of a GP signature (p = 0.156).

Table 9.6.3: Likelihood of people returning FOBT kit within 20 weeks: results of the logistic regression analysis.

	Odds ratio	**95% CI**	***p* Value**
Intervention main effects:*†			
Letter	1.26	1.01 to 1.58	0.038
Leaflet	1.28	1.03 to 1.59	0.029
GP Signature	1.19	0.94 to 1.50	0.156
Interaction:*			
Letter and Leaflet	1.02	0.66 to 1.58	0.979

* The reference category for each main effect was those not receiving the intervention.
† Obtained for model without interaction; each intervention adjusted for the other.

9.7 Participation in CRC Screening at 20 weeks (Per Protocol Analysis)

Sensitivity analyses were also conducted for participation at 20 weeks for people who received the FOBT kit (i.e. did not opt-out of screening after randomisation). 711 (57.8%) of all people who were randomised to the trial returned their FOBT kit within 20 weeks (see Table 9.7.1). The 'Letter and

Leaflet' group reported the highest proportion of people returning FOBT kits within 20 weeks (197/316; 62.3%). The 'Leaflet Only' group had approximately the same participation rate (178/299; 59.5%) as the 'Letter Only' group (177/304; 58.2%). Just over half (159/297; 53.5%) of people in the 'Usual Care' group participated in CRC screening.

Table 9.7.1: Number of people opting-in to screening who returned FOBT kits within 20 weeks according to individual intervention group, factorial group and whether or not the endorsement letter was signed by the participant's GP.

	No.	Total	Percent.	95% CI	Difference (in %)
Individual Groups					
Letter and Leaflet	197	316	62.3	57 - 68	8.8
GP Letter Only	177	304	58.2	53 - 64	4.7
Leaflet Only	178	299	59.5	54 - 65	6.0
Usual Care	159	297	53.5	48 - 59	-
Factorial Groups					
Letter	374	620	60.3	54 - 62	3.8
No Letter	337	596	56.5	48 - 56	-
Leaflet	375	615	61.0	54 - 62	5.1
No Leaflet	336	601	55.9	48 - 56	-
GP Letter					
Letter signed	155	229	67.7	61 - 74	11.7
Letter not signed	219	391	56.0	51 - 61	-

Similar to the per protocol analysis for participation at 12 weeks, the current 20 week analysis demonstrated a decrease in the absolute difference for the GP letter factorial group. Again, this is most likely due to the imbalance in the denominator between people receiving the FOBT kit who did/did not receive a GP endorsement letter. However, this may also reflect the confounding effect evidenced by the inclusion or exclusion of a GP signature on the endorsement letter. The present sensitivity analysis showed an absolute difference of 11.7% for people receiving a singed GP endorsement letter suggesting an important role this may have encouraging participation in screening.

There were no differences between the age groups or gender for the return of FOBT kits at 20 weeks for people who received a FOBT kit. The relative proportion of kits returned by gender is shown in Table 9.7.2. A higher relative proportion of males receiving the procedural leaflet returned their kits, whereas a slightly higher relative proportion of females receiving the GP endorsement letter returned their kits.

Table 9.7.2: Relative proportion of FOBT kits returned at 20 weeks by gender for people opting-in to screening.

		Intervention Groups			
		Letter and Leaflet	*Letter Only*	*Leaflet Only*	*Usual Care*
CRC Screening Participation	*Male*	60.7%	52.4%	61.0%	51.4%
	Female	63.9%	63.7%	58.2%	55.4%

9.7.1 Logistical Regression for Participation at 20 weeks (Per Protocol Analysis)

As with the ITT analysis, there was no significant interaction between the two interventions (p = 0.697; see Table 9.7.3) nor between participation and the included covariates of GP practice (p = 0.483), age (p = 0.817), gender (p = 0.153), or previous invitation to screening (p = 0.325).

Table 9.7.3: Likelihood of people returning FOBT kit within 20 weeks for people receiving FOBT kit: results of the logistic regression analysis.

	Odds ratio	95% CI	*p* Value
Intervention main effects:*†			
Letter	1.17	0.93 to 1.47	0.186
Leaflet	1.23	0.98 to 1.56	0.073
GP Signature	1.29	1.01 to 1.63	0.039
Interaction:*			
Letter and Leaflet	0.91	0.58 to 1.44	0.697

* The reference category for each main effect was those not receiving the intervention.
† Obtained for model without interaction; each intervention adjusted for the other.

However, a significant association was demonstrated for the inclusion of a GP signature on the endorsement letter (OR 1.29; $p = 0.039$).

9.8 Conclusions

The results of the intention-to-treat (ITT) analyses demonstrate the effectiveness of both the detailed procedural leaflet and the GP endorsement letter can have for increasing participation in the NHSBCSP. However, these results must be viewed in relation to the per protocol analyses which did not indicate a significant association for either intervention, but a significant association for the inclusion of a GP signature. A summary of the results for all four logistic regression analyses is presented in Table 9.8.

Table 9.8: Summary of the results of the logistic regression analysis.

	12 weeks (ITT)		12 weeks (per protocol)		20 weeks (ITT)		20 weeks (per protocol)	
	OR	*Signif*	*OR*	*Signif*	*OR*	*Signif*	*OR*	*Signif*
Procedural Leaflet	1.28	0.029†	1.23	0.072	1.28	0.029†	1.23	0.073
GP Endorsement Letter	1.23	0.064	1.10	0.273	1.26	0.038†	1.17	0.186
Inclusion of GP Signature	1.20	0.111	1.25	0.070	1.19	0.156	1.29	0.039†

† denotes significant association

The effectiveness of the procedural leaflet for improving participation in the NHSBCSP was shown in the ITT analyses, and although falling below the 0.05 significance level, estimates of effect in the per protocol analyses was of similar

magnitude. The results for the GP endorsement letter are somewhat more complex. The endorsement letter demonstrated a uniform improvement for screening participation in the ITT analyses, however, was less influential for either of the per protocol analyses. This was due to the confounding effect caused by the inclusion of an electronic GP signature for a proportion of participants receiving the endorsement letter. The bivariate analyses clearly show the inclusion of an electronic GP signature had a positive effect on peoples' participation in CRC screening in comparison to receiving an endorsement letter signed 'On behalf of the Practice'. The per protocol analyses demonstrate that the failure to include an electronic GP signature for all participants, essentially diluted the effectiveness of the endorsement letter for improving participation in screening.

The confounding effect of the electronic GP signature affecting participation was influenced by two important factors. Firstly, although the results of the ITT analyses generally indicate an improvement for participation in people randomised to the GP letter overall, the per protocol analysis indicates people actually receiving the GP letter had a differential participation rate depending on whether or not they received an electronic signature on their letter. Therefore, the confounding effect of the GP signature was influenced by the randomisation procedure. Secondly, the increased proportion of participants returning their kits indicates the inclusion of an electronic GP signature had a greater affect on people's decision-making than the more impersonal 'On behalf of the Practice'. This is similar to the results of previous CRC screening studies [1, 2] and systematic reviews [3, 4] which have shown more personalised messages from

GP's result in a higher compliance rate for an intervention and are viewed positively by participants. The personalised element of the inclusion of an electronic signature from the GP clearly had an important influence on people's decisions to participate in screening. Conversely, the failure to include a GP signature potentially caused a negative effect on participation in the group most likely to benefit from the intervention (i.e. a person would be influenced by their GP's opinion but may feel aggrieved their GP did not feel bowel cancer screening was sufficiently important to warrant their signature).

Additive Effect of the Interventions and Gender Differences

There was a distinctive additive effect observed when the two interventions were sent together to participants. The 'GP Letter and Leaflet' group consistently demonstrated an improvement in participation of over 10% in the ITT analyses and around 9% for the per protocol analyses in comparison to the 'Usual care' group. Indeed, this additive effect almost exactly replicated the increase in participation observed for the respective factorial groups in each of the four analyses. Coupled with the absence of an interaction effect for the two interventions in the logistic analyses, this would suggest the GP letter and the procedural leaflet are acting independently to produce the additive effect.

The relative proportion of males and females returning their test kits was partly based on which intervention they received. Although there was no indication of a significant effect of gender on participation, a higher relative proportion of men returned their kits when receiving the procedural leaflet. For females, the GP endorsement letter seemed to have a greater effect on the return of test kits

than the procedural leaflet. This may partly be explained by the familiarity females of this age group have with receiving letters of invitation to participate in cervical screening from trusted providers and perceived views of the importance of screening [5-7]. However, given the lack of a significant effect for gender based on the logistic regression analyses, further targeted research would be required to establish the differential effect of the two interventions on participation rates.

Limitations

There are several important limitations of the present trial. The main design weakness was the potential for people to opt-out of CRC screening after randomisation, and therefore, not receive the interventions. Unfortunately, this was due to factors beyond the control of the researcher, rather than a deviation from the trial protocol. Randomisation was expected to occur on the day of the mail-out of the interventions. However, this data was not made available at the time due to circumstances beyond the control of the Screening Hub or the researchers. This led to a slight imbalance in the intervention groups, but there is no suggestion that this had an important effect on the results.

A potentially more problematic limitation was the power of the sample to detect meaningful differences between the interventions. The original sample size calculations were based on detecting an absolute difference of 10% in participation (at the margins) between the two factorial groups. Instead, the two factorial interventions achieved an increase in participation of around 6% in the ITT analyses and 4% for the per protocol analyses. In order to achieve the

power to detect an absolute difference of 5% in participation, approximately three times the number of current participants (over 3500 people) would need to be recruited to reliably assess the effectiveness of the interventions. This would have necessitated a quite significant increase in funding, the number of GP practices recruited and extended the timescales for the trial.

Finally, the relatively low GP participation rate and inability of most practices to provide an electronic signature is concerning for the widespread adoption of the endorsement letter for NHSBCSP in England. The reasons participating practices failed to provide an electronic signature included not having one available, preference for 'On behalf of the Practice' rather than a signature, and uncertainty about which GP should be named on the endorsement letter. Five practices refused to include a named GP on the endorsement letter as these practices felt it was inappropriate given GPs do not have a formal arrangement with the NHSBCSP. Further research is required to determine the interest and ability of GP's to provide an electronic signature for the NHSBCSP if the full potential of the endorsement letter intervention is to be realised.

Relation to Previous Findings

The findings are consistent with previous research from other countries, which have demonstrated that providing personalised invitations from GP's can improve FOBT screening test-return rates [1, 2, 8-11]. Furthermore, the per protocol analysis revealed this effect is mediated by the inclusion of a GP's signature on the endorsement letter which has infrequently been shown in the literature [1, 2].

The additive effect observed in the trial may reflect the influence that each separate intervention had on two distinct groups of potential non-participants. For example, Senore and colleagues [12] found those with a higher education attainment, generally based their decision to participate in screening after reading the information materials, whereas people with a lower education tended not to read the information materials and rely on their GP's advice instead. Alternatively, people with limited health literacy (and associated lower education status) report more barriers to complete FOBT testing [13, 14]. The brief enhanced procedural leaflet may have been sufficient for people with limited health literacy to address these barriers and engage in bowel cancer screening. It is, therefore, plausible that the GP's endorsement letter was influential in those who preferred receiving health advice from their GP, whereas the procedural leaflet helped people overcome perceived barriers to complete the FOBT kits. Further research directly evaluating process variables such as health literacy, the effects of gain-framing versus loss-framing, and the importance of GP's recommendations for bowel cancer screening are required.

Implications for MRC guidance

A primary objective of the present three-year research programme was to develop and evaluate the two interventions in accordance with the MRC framework for complex interventions [15-17]. The factorial trial represented the culmination of this process, which was to conduct a Phase II 'Exploratory Trial'. The present research was able to satisfy the requirements of the Phase II trial by describing the components of a replicable intervention based on a feasible

protocol and comparing an intervention to an appropriate alternative. A Phase III trial requires a fully-defined intervention compared to an appropriate alternative using a theoretically defensible protocol which is reproducible, adequately controlled and with appropriate statistical power [15-17]. The results of the present (Phase II) factorial trial have generated important recommendations for the design and recruitment procedures for potential future UK-based RCT's in this area, and also identified critical considerations for collaboration between the various bodies required to conduct the Phase III trial. Therefore, the present research achieved the primary aims of developing the interventions and the associated methodology to a sufficient level to allow further high-quality research to be conducted for improving CRC screening in the NHSBCSP. The results for the effectiveness of the two interventions for improving participation in the NHSBCSP have been published in the British Journal of Cancer (see Appendix 9.2).

9.9 References

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Chapter 10: Trial Questionnaire Results

10.0 Objectives of the Chapter

This chapter presents the results for the questionnaire outcomes of the trial. The results of respondents who completed both questionnaires are presented in the first section and the results of the GP questionnaire completed by the participating practices in the final section. The main objectives of the chapter are to provide a descriptive analysis of responses for both the participant questionnaire and GP questionnaire components of the trial.

10.1 Participant Questionnaire Response Rate

The response rate was low; 501 (38.9%) of 1288 baseline questionnaires were returned. A further 145 (11.3%) respondents requested not to receive further information about the trial. 33 returned questionnaires were excluded as these did not include consent forms (13), were incomplete (8) or were returned after the cut-off date (12). The overall response rate for valid baseline questionnaires was 36.3% (468/1288).

The response rate for the follow-up questionnaire was much higher; 412 (88.3%) of 468 questionnaires were returned. 296 questionnaires were returned within three weeks of the follow-up mail-out. 172 reminder questionnaires packs were sent to non-respondents. 116 questionnaires were returned (67.4%) after reminder letters were sent. Eight follow-up questionnaires were incomplete and excluded from the analysis. The overall response rate for the return of both questionnaires was 31.4% (404/1288).

10.2 Respondent Demographic Characteristics

The demographic characteristics of respondents returning both questionnaires are shown in Table 10.1.

Table 10.1: Demographic characteristics of respondents returning both questionnaires.

		Letter and Leaflet		GP Letter		Leaflet		Usual Care		Total	
		N	***%***	***N***	***%***	***N***	***%***	***N***	***%***	***N***	***%***
Kit Return	*Yes*	105	*96.3*	89	*94.7*	104	*96.3*	84	*90.3*	382	*94.6*
	No	4	*3.7*	5	*5.3*	4	*3.7*	9	*9.7*	22	*5.4*
Gender	*Male*	47	*43.1*	40	*42.6*	49	*45.4*	44	*47.3*	180	*44.6*
	Female	62	*56.9*	54	*57.4*	59	*54.6*	49	*52.7*	224	*55.4*
Age Group	*60-64*	60	*55.1*	56	*59.6*	65	*60.2*	58	*62.4*	239	*59.2*
	65-69	47	*43.1*	32	*34.0*	40	*37.0*	34	*36.6*	153	*37.9*
	70+	2	*1.8*	6	*6.4*	3	*2.8*	1	*1.0*	12	*2.9*
Marital Status	*Married*	91	*85.1*	77	*83.7*	90	*83.3*	80	*87.0*	338	*84.7*
	Single	4	*3.7*	4	*4.4*	2	*1.9*	4	*4.4*	14	*3.5*
	Widowed	5	*4.7*	3	*3.3*	7	*3.3*	5	*5.4*	20	*5.0*
	Divorced	7	*6.5*	8	*8.7*	9	*8.7*	3	*3.3*	27	*6.8*
Employment Status	*Full-time*	19	*17.8*	13	*14.0*	22	*20.6*	15	*16.3*	69	*17.3*
	Part-time	24	*22.4*	10	*10.8*	16	*16.3*	15	*16.3*	65	*16.3*
	Retired	63	*58.9*	69	*74.2*	69	*64.5*	59	*64.1*	260	*65.2*
	Unemployed	1	*0.9*	1	*1.1*	0	-	3	*3.3*	5	*1.3*
Educational Attainment	*'O' level*	20	*19.1*	18	*19.8*	19	*17.8*	12	*13.6*	69	*17.5*
	'A' level	17	*16.2*	7	*7.7*	5	*4.7*	4	*4.6*	33	*8.4*
	Vocational	21	*20.0*	20	*22.0*	20	*18.7*	27	*30.7*	88	*22.5*
	University	26	*24.8*	26	*28.6*	36	*33.6*	24	*27.3*	112	*28.7*
	None	21	*20.0*	20	*22.0*	27	*25.2*	21	*23.9*	89	*22.8*
Ethnic Group	*White*	106	*98.2*	92	*98.9*	106	*98.2*	91	*98.9*	395	*98.5*
	White/other	1	*0.9*	0	-	0	-	1	*1.1*	2	*0.5*
	Asian	0	-	1	*1.1*	2	*1.8*	0	-	3	*0.8*
	Other	1	*0.9*	0	-	0	-	0	-	1	*0.2*
General Health	*V. Good*	29	*26.9*	18	*19.4*	24	*22.4*	27	*29.3*	98	*24.5*
	Good	63	*58.3*	53	*57.0*	56	*52.3*	47	*51.1*	219	*54.8*
	Fair	13	*12.0*	19	*204*	25	*23.4*	17	*18.5*	74	*18.5*
	Poor	3	*2.8*	3	*3.2*	2	*1.9*	1	*1.1*	9	*2.2*

Almost all respondents completing both questionnaires returned their FOBT kits (382/404; 94.6%). The majority of respondents were married, retired, aged 60-64 years old, and described their ethnicity as White. There were no significant differences between the four intervention groups or the demographic characteristics and return of FOBT kits. Analyses of gender differences

revealed that significantly more women were widowed than men (p = 0.000) and more women reported having an 'O level' or School Certificate in comparison to men (p = 0.000).

10.3 Previous Experience with Screening and CRC

There were no significant differences between the intervention or factorial groups concerning respondent's previous experience with screening or personal experience with CRC (see Table 10.2).

Table 10.2: Previous experience with screening and CRC of respondents.

		Letter and Leaflet		GP Letter		Leaflet		Usual Care		Total	
		N	***%***	***N***	***%***	***N***	***%***	***N***	***%***	***N***	***%***
Aware of NHSBCSP	*Yes*	59	*55.1*	60	*63.8*	57	*52.8*	55	*59.8*	231	*57.6*
	No	48	*44.9*	34	*36.2*	51	*47.2*	37	*40.2*	170	*42.4*
Previous FOBT	*Yes*	31	*28.4*	23	*24.5*	32	*30.2*	21	*22.6*	107	*26.6*
	No	73	*67.0*	67	*71.2*	67	*63.2*	70	*75.3*	277	*68.9*
	Don't Know	5	*4.6*	4	*4.3*	7	*6.6*	2	*2.1*	18	*4.5*
Previous colonoscopy	*Yes*	23	*21.1*	21	*22.3*	21	*19.6*	15	*16.1*	80	*19.9*
	No	85	*78.0*	72	*76.6*	86	*80.4*	77	*82.8*	320	*79.4*
	Don't Know	1	*0.9*	1	*1.1*	0	-	1	*1.1*	3	*0.7*
Previous CRC	*Yes*	0	-	0	-	1	*0.9*	0	-	1	*99.8*
	No	109	*100*	94	*100*	107	*99.1*	93	*100*	403	*0.2*
Family CRC History	*Yes*	12	*11.2*	13	*14.3*	9	*8.6*	14	*15.7*	48	*12.2*
	No	95	*88.8*	78	*85.7*	96	*91.4*	75	*84.3*	344	*87.8*
Friend CRC History	*Yes*	39	*36.8*	32	*34.4*	31	*28.7*	26	*28.0*	128	*32.0*
	No	62	*58.5*	50	*53.8*	63	*58.3*	59	*63.4*	234	*58.5*
	Don't Know	5	*4.7*	11	*11.8*	14	*13.0*	8	*8.6*	38	*9.5*
Current Bowel Cond	*Yes*	19	*17.6*	16	*17.2*	20	*19.0*	9	*8.9*	64	*16.1*
	No	89	*82.4*	77	*82.8*	85	*81.0*	82	*90.1*	333	*83.9*

Over half of respondents (58%) reported being aware of the NHSBCSP prior to receiving the study invitation. Only one person reported a previous diagnosis of CRC. Females were significantly more aware of the NHSBCSP than males (p = 0.000). Significantly more people who reported knowing a close friend diagnosed with CRC returned their FOBT kit (p = 0.008). Significantly less

people who reported a significant bowel condition returned their FOBT kit (p = 0.015).

10.4 Intention, self-efficacy and GP-related outcomes

There were no significant differences between intention to participate in screening or self-efficacy in regards to the four intervention groups, factorial groups or gender (see Table 10.3).

Table 10.3: Intention, self-efficacy and GP-related outcomes.

		Letter and Leaflet		GP Letter		Leaflet		Usual Care		Total	
		N	***%***	***N***	***%***	***N***	***%***	***N***	***%***	***N***	***%***
Intention to participate	*Yes*	105	*98.1*	89	*95.7*	102	*94.4*	85	*93.4*	381	*95.5*
	Don't know	2	*1.9*	4	*4.3*	6	*5.6*	6	*6.6*	18	*4.5*
Self-efficacy	*Very confident*	72	*67.3*	73	*77.7*	74	*69.2*	65	*71.4*	284	*71.2*
	Less confident	35	*32.7*	21	*22.3*	33	*30.8*	26	*28.6*	115	*28.8*
Confidence in GP	*Very confident*	61	*57.6*	59	*62.8*	71	*65.7*	53	*57.6*	244	*61.0*
	Less confident	45	*42.4*	35	*37.2*	37	*34.3*	39	*42.4*	156	*39.0*
Importance of GP opinion	*Very important*	27	*25.2*	32	*34.0*	34	*31.8*	28	*30.1*	121	*30.2*
	Less important	80	*74.8*	62	*66.0*	73	*68.2*	65	*68.9*	280	*69.8*
Receiving GP letter	*Very important*	29	*27.4*	28	*29.8*	26	*24.1*	24	*25.8*	107	*26.7*
	Less important	77	*72.6*	66	*70.2*	82	*75.9*	69	*74.2*	73.3	*73.3*
Embarrassed talking to GP	*Very to slightly*	59	*55.7*	39	*41.5*	44	*40.7*	35	*37.6*	177	*44.1*
	Not at all	47	*44.3*	55	*58.5*	64	*59.3*	58	*62.4*	224	*55.9*
Ask GP about screening	*Yes*	4	*3.8*	9	*9.6*	6	*5.6*	6	*6.5*	25	*6.2*
	No	102	*96.2*	82	*87.2*	101	*93.5*	87	*93.5*	372	*92.8*
	Don't know	0	-	3	*3.2*	1	*0.9*	0	-	4	*1.0*
No. GP visits past year	*None*	13	*12.4*	12	*12.8*	9	*8.4*	10	*10.8*	44	*11.0*
	One to two	49	*46.6*	36	*38.3*	50	*46.7*	51	*54.8*	186	*46.6*
	Three to four	32	*30.5*	26	*27.7*	35	*32.7*	27	*29.0*	120	*30.1*
	Five or more	11	*10.5*	20	*21.2*	13	*12.2*	5	*5.4*	49	*12.3*

People indicating they intended to complete screening were more likely to return their FOBT kits (p = 0.008) as were people who were 'very confident' they could complete the FOBT (p = 0.017). The majority of people reported having a high level of confidence and trust in their GP (61%), although less than a third reported their GPs opinion about CRC screening was 'very important' to them (30%) or that receiving a letter from their GP would influence their

decision to participate in the programme (27%). Very few respondents had previously asked their GP about CRC screening (6%).

In the GP endorsement letter factorial group, around a third of people reported that receiving the letter definitely influenced their decision to participate (12%) or influenced their decision to some extent (20%). This was similar to the leaflet group where 13% reported receiving a letter would have definitely influenced their decision or influenced their decision to some extent (21%).

10.5 Decision-Making, Perceived Risk and Worry

Respondents' main reason for participating in CRC screening is shown in Table 10.4. The majority of respondents indicated 'peace of mind' was the main reason for considering participating in screening, although the proportion decreased between the two questionnaires. Few respondents reported a GPs recommendation was the main reason to consider participating in screening.

Table 10.4: Main reason for participating in CRC screening for baseline and follow-up questionnaires.

		Baseline Questionnaire		Follow-Up Questionnaire	
		N	***%***	***N***	***%***
Main reason for screening	*Symptoms*	14	*3.5*	15	*3.8*
	Family history	38	*9.6*	42	*10.5*
	GP recommend	13	*3.3*	13	*3.3*
	Because invited	110	*27.6*	135	*33.8*
	Peace of mind	220	*55.3*	191	*47.8*
	Advice family/friend	3	*0.8*	4	*1.0*

Responses by participants completing both questionnaires in regards to the decision-making, perceived risk and worry variables are shown in Table 10.5. The table also indicates the association between these variables and the return of FOBT kits.

Table 10.5: Decision-making, perceived risk and worry about developing CRC for baseline and follow-up questionnaires.

		Baseline Questionnaire		Follow-Up Questionnaire		Difference between two questionnaires	
		N	***%***	***N***	***%***	***% Diff.***	***p-value***
Importance of decision	*Very important*	245	*60.6*	270	*66.8*	+6.2%	0.015
	Less important	159	*39.4*	134	*33.2*		
Benefit/risk important	*Very important*	207	*51.2*	186	*46.4*	-4.8%	0.107
	Less important	197	*48.8*	215	*53.6*		
Convinced of benefits	*Very convinced*	267	*66.8*	294	*72.6*	+5.8%	0.015
	Less convinced	133	*31.2*	109	*37.4*		
Concerned about risks	*Not concerned*	235	*59.2*	286	*71.0*	+11.8%	0.001
	More concerned	162	*40.8*	117	*29.0*		
Worry	*Very/Somewhat*	111	*27.8*	94	*23.3*	-4.5%	0.049
	Slightly/Not worried	288	*72.2*	310	*76.7*		
Comparative Risk	*Much/slightly more*	66	*16.5*	58	*14.4*	-2.1%	0.280
	Average risk or less	333	*83.5*	345	*85.6*		
Subjective Risk	*Likely/Likely as not*	237	*59.7*	252	*62.7*	+3.0%	0.198
	Not likely/Will not	160	*40.3*	150	*37.3*		

Females were more likely to view the decision to participate as 'very important' than men in both the baseline (p = 0.022) and follow-up (p = 0.016) questionnaires. There were significant increases between baseline and follow-up questionnaire responses for the importance of the decision (p = 0.015), the proportion of people being 'very convinced' of the benefits of screening (p = 0.015) and for not being concerned about the risks of screening (p = 0.001). Worry about being diagnosed with CRC decreased significantly (p = 0.049) between the baseline and follow-up questionnaires. Neither comparative risk nor subjective risk differed between genders or in regards to the return of FOBT kits.

10.6 Knowledge Scale

Respondents total knowledge score increased significantly from the baseline to the follow-up questionnaire (see Table 10.6). At baseline, the mean knowledge score was 4.8 (SD = 2.14, range 0-10) for all respondents. At follow-up, the

mean knowledge score increased to 6.2 (SD = 2.04, range 0-10). Both females and males demonstrated significant increases in knowledge between the baseline and follow-up questionnaires.

Table 10.6: Mean knowledge scores for the baseline and follow-up questionnaires.

	Questionnaire	*N.*	Mean Score	95% CI	Mean Difference	95% CI
All respondents	*Baseline*	397	4.76	4.54-4.97		
	Follow-up	397	6.19	5.98-6.39	1.43†	1.21-1.65
Male	*Baseline*	178	4.48	4.15-4.81		
	Follow-up	178	6.12	5.81-6.44	1.65†	1.29-2.00
Female	*Baseline*	219	4.98	4.71-5.25		
	Follow-up	219	6.24	5.98-6.50	1.26†	0.98-1.53

† = $p = 0.001$

In the baseline questionnaire, women's mean knowledge was significantly higher than men (4.98 versus 4.48; $p = 0.02$), however, this difference was not observed in the follow-up questionnaire. The KR20 coefficient for the knowledge scale was 0.61 for both questionnaires, indicating adequate internal consistency.

The proportion of correct answers increased significantly for all knowledge items between the baseline and follow-up questionnaires (see Figure 1 and Appendix 10.1). Bivariate analyses did not show a significant association between individual knowledge items and FOBT kit return, or between the intervention or factorial groups.

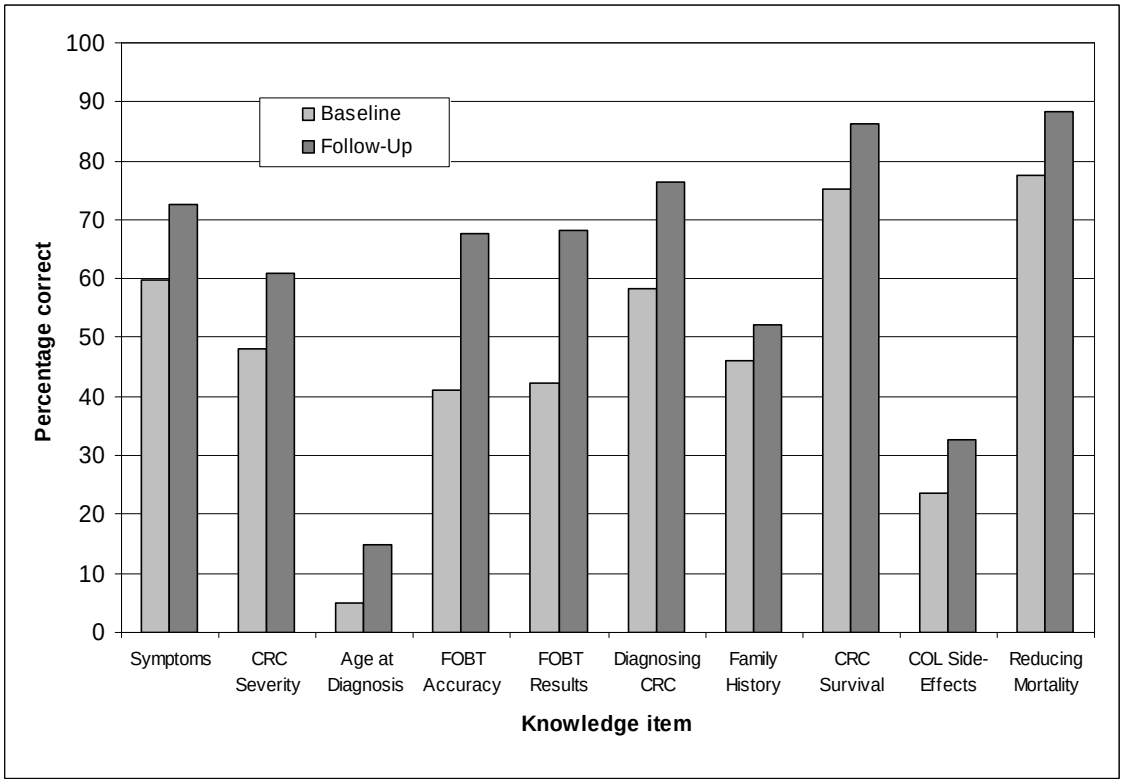

Figure 1: Bar-chart showing proportion of correctly answered individual knowledge items for the baseline and follow-up questionnaires.

Respondents correctly answered two knowledge items (CRC survival and reducing mortality) consistently, whereas two other items (number of people over the age of 60 diagnosed with CRC and possible side-effects associated with colonoscopy) were most frequently answered incorrectly.

10.7 Views about the screening kit

Respondent's views about the FOBT kit are shown in Table 10.7. Bivariate analysis showed no significant differences between the individual items and participation in screening; nor between the individual items or the intervention and factorial groups. Women more frequently reported they had received enough information to make a choice about participating in the baseline (p = 0.013) and follow-up questionnaires (p = 0.044). More men reported being

concerned about doing the test correctly in the follow-up questionnaire (p = 0.026). As shown in Table 10.7, a high proportion of respondents consistently agreed that it was important to receive enough information to make a choice about participating in screening, disagreed storing samples was embarrassing, and agreed they understood why they were asked to do the test.

Table 10.7: Baseline questionnaire respondent views about the FOBT kit.

		Baseline Questionnaire		Follow-Up Questionnaire			
		N	***%***	***N***	***%***	**% Diff.**	***p value***
Important to be given enough information	*Agree*	385	*95.3*	392	*98.5*	+3.2	0.011
	Disagree	19	*4.7*	6	*1.5*		
Difficult to collect samples (*negative attitude*)	*Agree*	118	*29.2*	51	*12.8*	-16.4	0.001
	Disagree	286	*70.8*	347	*87.2*		
Embarrassing to store samples (*negative attitude*)	*Agree*	21	*5.2*	26	*6.5*	+1.3	0.171
	Disagree	383	*94.8*	372	*93.5*		
Concerned about doing test correctly (*negative attitude*)	*Agree*	216	*53.5*	216	*54.3*	+0.8	0.729
	Disagree	188	*46.5*	182	*45.7*		
Taking samples inconvenient (*negative attitude*)	*Agree*	149	*36.9*	95	*23.9*	-13.0	0.001
	Disagree	255	*63.1*	303	*76.1*		
Collecting samples disgusting (*negative attitude*)	*Agree*	124	*30.7*	89	*22.4*	-8.3	0.001
	Disagree	280	*69.3*	309	*77.6*		
Confidence in test results	*Agree*	324	*80.4*	338	*84.9*	+4.5	0.042
	Disagree	79	*19.6*	60	*15.1*		
Understand why asked to do test	*Agree*	380	*94.0*	386	*96.9*	+2.9	0.051
	Disagree	24	*6.0*	12	*3.1*		
Baseline or Follow-Up Questionnaire Only		***N***	***%***	***N***	***%***		
Collecting samples unhygienic	*Agree*	3	*0.7*	-	-		
	Disagree	401	*99.3*	-	-		
Collecting samples messy	*Agree*	189	*46.8*	-	-		
	Disagree	215	*53.2*	-	-		
Kit instructions easy to use	*Agree*	-	-	392	*98.5*		
	Disagree	-	-	6	*1.5*		
Spatulas easy to use	*Agree*	-	-	374	*94.0*		
	Disagree	-	-	24	*6.0*		
Overall experience is positive	*Agree*	-	-	378	*95.0*		
	Disagree	-	-	20	*5.0*		

Note: 'Agree' composite of 'strongly agree' and 'agree'; 'Disagree' composite of 'strongly disagree', 'disagree' and 'uncertain'

There was a significant reduction in the proportion of respondents agreeing it was difficult to collect samples, taking samples was inconvenient, and collecting samples was disgusting. Respondents' confidence in the test results received from the NHSBCSP increased slightly between the two questionnaires.

Concern about doing the test correctly did not significantly increase between the baseline and follow-up questionnaires; with around half of respondents (54%) concerned they could not perform the test correctly.

Almost all respondents disagreed that collecting samples was unhygienic (99%); although almost half believed the procedure would be messy (47%). Almost all respondents agreed that the kit instructions (99%) and spatulas (94%) included with the kit were easy to use and that their overall experience of screening was positive (95%).

Item-analysis of the selected scale items (items included in both the baseline and follow-up questionnaires) is shown in Appendix 10.2. Based on this analysis, a composite score reflecting 'negative' attitudes towards the procedural aspects of completing the FOBT kit was used to provide an overall score (ranging from 0 to 20, where a lower score indicates more negative attitudes towards the test kit).

Table 10.8: Negative attitude scores for the baseline and follow-up questionnaires.

	Questionnaire	*N.*	Mean Score	95% CI	Mean Difference	95% CI
All respondents	*Baseline*	398	13.93	13.56-14.30		
	Follow-up	398	14.88	14.53-15.23	0.95†	0.58-1.31
Male	*Baseline*	176	14.16	13.62-14.67		
	Follow-up	176	14.82	14.29-15.35	0.66‡	0.15-1.18
Female	*Baseline*	222	13.75	13.24-14.26		
	Follow-up	222	14.92	14.46-15.39	1.18†	0.66-1.69

† denotes $p = 0.001$; ‡ denotes $p = 0.01$

Mean negative attitudes towards screening significantly decreased between the baseline and follow-up questionnaires for both genders and overall (see Table 10.8). The mean negative attitude score for the baseline questionnaire was 13.93 (SD = 3.73, median = 14, range = 3 to 20). The mean negative attitude

score for the follow-up questionnaire was 14.88 (SD = 3.54, median = 15, range = 3 to 20); demonstrating a decrease in negative attitudes towards the FOBT procedure. Mean differences were not significantly different between genders for either the baseline or follow-up questionnaire.

10.8 Perceived Health Competence (PHC)

There were no significant differences between the individual PHC scale items and FOBT kit return or between the intervention or factorial groups. The mean PHC score was 3.18 (SD = 0.27) for all respondents. The mean PHC score for males was 3.17 (SD = 0.27) and 3.18 (SD = 0.27) for females. The mean is significantly lower (Cohen's *d* = 0.001) than previously reported research in the UK [1]. However, the mean does not significantly differ (Cohen's *d* = 0.59) for the relatively small sample of people (23) aged over 55 years from this previous research [1]. The median-split method was used to categorise respondents as having 'high' or 'low' PHC (see Table 10.9).

Table 10.9: 'High' and 'Low' categories for PHC scale scores.

	Total		Male		Female	
PHC Scale	***N.***	**%**	***N.***	**%**	***N.***	**%**
High	210	52.0	100	55.6	110	49.1
Low	194	48.0	80	44.4	114	50.9
Total	404	-	180	-	224	-

There were no differences in participation between the two PHC categories or between genders. People categorised as having a high PHC were significantly more like to have a high level of confidence in their GP (*p* = 0.028), not be concerned by the risks of screening (*p* = 0.002), not regard receiving an endorsement letter from their GP as important to the decision to participate (*p* =

0.014) and not be worried about being diagnosed with CRC (p = 0.001 for both the baseline and follow-up questionnaires).

10.9 Health Literacy

There were no significant differences between intervention group, factorial group, gender or FOBT kit return and the individual health literacy scale items. The total literacy score was calculated by summing the three individual items (see Appendix 10.3). The total literacy score for respondents ranged from 0 to 12. The frequency of total scores for respondents is shown in Table 10.10.

Table 10.10: Frequency of total scores for respondents.

Total Score	Number of respondents	Percentage	Cumulative Percentage
0	1	0.2	0.2
4	3	0.6	0.8
5	3	0.6	1.5
6	4	0.9	2.4
7	13	2.8	5.2
8	28	6.0	11.2
9	47	10.1	21.3
10	51	10.9	32.2
11	99	21.2	53.4
12	217	46.6	100

The scale demonstrated adequate internal consistency (α = 0.60). The mean total literacy score was 10.7 (SD = 1.71) and the median was 11. The median-split method was used to categorise respondents as having either 'adequate' literacy (total score ≥11) or 'inadequate' literacy (total score ≤10). Therefore, approximately two-thirds (68%) of respondents were categorised as having 'adequate' literacy.

10.10 Self-Determination Theory (TSRQ)

The mean autonomous regulation score for the baseline questionnaire was 35.55 (SD = 6.31, median = 36, range 8 to 42), increasing to 35.87 (SD = 6.17,

median = 38, range 13 to 42) for the follow-up questionnaire. The mean controlled regulation score for the baseline questionnaire was 14.69 (SD = 7.90, median = 13, range 6 to 42), decreasing to 14.31 (SD = 7.36, median = 13, range 6 to 39) for the follow-up questionnaire. The mean amotivation score for the baseline questionnaire was 6.15 (SD = 2.97, median = 6, range 3 to 18), decreasing to 5.84 (SD = 2.87, median = 6, range 3 to 17) for the follow-up questionnaire. The autonomous regulation subscale demonstrated a very good internal consistency in the baseline (α = 0.85) and follow-up questionnaires (α = 0.85). The controlled regulation subscale also demonstrated a good internal consistency in the baseline (α = 0.80) and follow-up questionnaires (α = 0.77). The amotivation subscale showed a very poor internal consistency for the baseline (α = 0.39) and follow-up questionnaires (α = 0.41).

Paired samples t-tests were used to determine mean differences between the baseline and follow-up questionnaires for all respondents and for both genders (see Table 10.11). The results indicate that, consistent with self-determination theory, respondents felt they had made an autonomous decision to either participate or not in screening (as evidenced by the increase for the autonomous regulation subscale) and the decision was not based on external factors and was intentional (evidenced by the decrease for both the controlled regulation and amotivation subscales).

Table 10.11: Mean TSRQ subscale scores and mean difference for the baseline and follow-up questionnaires.

	TSRQ Subscales	*N.*	Mean Score	95% CI	Mean Diff.	95% CI
All	*Autonomous (Q1)*	386	35.51	34.88 to 36.15		
	Autonomous (Q2)	386	35.96	35.36 to 36.57	0.45	-0.03 to 0.93
	Controlled (Q1)	383	14.77	13.98 to 15.57		
	Controlled (Q2)	383	14.40	13.66 to 15.15	-0.37	-1.00 to 0.27
	Amotivation (Q1)	375	6.19	5.89 to 6.49		
	Amotivation (Q2)	375	5.79	5.50 to 6.08	-0.40†	-0.70 to -1.01
Male	*Autonomous (Q1)*	171	35.12	34.14 to 36.10		
	Autonomous (Q2)	171	35.48	34.50 to 36.46	0.37	-0.35 to 1.07
	Controlled (Q1)	170	14.86	13.60 to 16.02		
	Controlled (Q2)	170	14.21	13.18 to 15.31	-0.65	-1.56 to 0.27
	Amotivation (Q1)	170	6.27	5.80 to 6.73		
	Amotivation (Q2)	170	6.09	5.66 to 6.52	-0.18	-0.62 to 0.27
Female	*Autonomous (Q1)*	219	35.81	34.98 to 36.64		
	Autonomous (Q2)	219	36.39	35.63 to 37.14	0.58	-0.08 to 1.24
	Controlled (Q1)	217	14.62	13.54 to 15.71		
	Controlled (Q2)	217	14.49	13.49 to 15.50	-0.13	-0.99 to 0.73
	Amotivation (Q1)	213	6.09	5.69 to 6.47		
	Amotivation (Q2)	213	5.56	5.18 to 5.93	-0.53†	-0.13 to -0.91

† = $p = 0.01$

The mean difference between baseline and follow-up questionnaires for the subscales of the TSRQ indicated a significant decrease for the amotivation subscale for all respondents ($p = 0.009$) and for females ($p = 0.009$). There were no other significant differences between the subscales.

Bivariate analysis showed that respondents with a high PHC score were significantly more likely to have a higher score for the controlled regulation subscale ($p = 0.026$) and a lower score for the amotivation subscale ($p = 0.033$) in the follow-up questionnaire. Respondents who reported being 'very confident' in their ability to complete the test were also more likely to have a higher score for the controlled regulation subscale in the baseline ($p = 0.001$) and follow-up ($p = 0.001$) questionnaires. Again, this supports the autonomous regulation component of self-determination theory in that people with higher

perceived self-efficacy to perform a task should feel their decision is self-determined.

10.11 Respondent views of procedural leaflet

Respondents views of the detailed procedural leaflet and shown in Table 10.12. Overall, respondents receiving the procedural leaflet reported it was easy to read and included the right amount of information. Respondents also indicated the leaflet was 'very' or 'somewhat' helpful (90%) for making a decision and the suggestions for completing FOBT were 'very' or 'somewhat' useful (99%).

Table 10.12: Respondents' views of the procedural leaflet.

		Total		Male		Female	
		N	***%***	***N***	***%***	***N***	***%***
Useful suggestions	*Very useful*	155	(72.8%)	64	(66.7%)	91	(77.8%)
	Somewhat useful	55	(25.8%)	30	(31.2%)	25	(21.4%)
	Not really useful	3	(1.4%)	2	(2.1%)	1	(0.8%)
Readability	*Easy to read*	205	(96.7%)	91	(95.8%)	114	(97.4%)
	Slightly difficult	6	(2.8%)	3	(3.2%)	3	(2.6%)
	Very difficult	1	(0.5%)	1	(1.0%)	-	-
Amount of information	*Too much info.*	1	(0.5%)	1	(1.0%)	-	-
	About right	211	(99.5%)	94	(99.0%)	117	(100%)
Helpful for decision	*Very helpful*	114	(54.0%)	41	(43.2%)	73	(62.9%)
	Somewhat helpful	75	(35.5%)	40	(42.1%)	35	(30.2%)
	Not very helpful	11	(5.2%)	7	(7.4%)	4	(3.5%)
	Not at all helpful	11	(5.2%)	7	(7.4%)	4	(3.5%)
Influence views	*More positive*	87	(41.2%)	37	(39.0%)	50	(43.1%)
	Not changed	124	(58.8%)	58	(61.0%)	66	(56.9%)
Further information	*Yes*	13	(6.2%)	8	(8.5%)	5	(4.4%)
	No	172	(82.3%)	78	(83.0%)	94	(81.7%)
	Not sure	24	(11.5%)	8	(8.5%)	16	(13.9%)

Most people (59%) reported that their views about CRC screening had not changed after reading the leaflet. There were no significant differences between males and females in regards to their views on the detailed procedural leaflet. Thirteen people provided suggestions for further information that should be included in the leaflet. Three people requested a more accurate definition of a 'smear' and three others asked if information about preventing CRC could be

included. Other suggestions included more advice on securing the tab of the kit, further information about family history and CRC treatments and conditions that could cause a false-positive result.

There were no significant differences between respondents' views about the screening kit in comparison to those who did receive the procedural leaflet and those who did not. There were also no differences between the leaflet and no leaflet factorial groups in regards to self-efficacy, perceived benefits or risks of screening, or overall knowledge scores.

10.12 Respondent views of NHSBCSP 'The Facts' booklet

Respondent views of the NHSBCSP 'The Facts' booklet are shown in Table 10.13. All participants received the NHSBCSP information materials ('The Facts' booklet) with their invitation to screening. In the baseline questionnaire, 56.5% of people reported it was 'very important' to receive information about CRC screening with their invitation. People who reported not reading the booklet were excluded from the analysis. There were no significant differences between the intervention groups, gender or FOBT kit return.

Table 10.13: Respondents' views of the 'The Facts' booklet.

		Total		Male		Female	
Amount read	*All*	254	(63.2%)	112	(62.6%)	142	(63.7%)
	Most	102	(25.4%)	44	(24.6%)	58	(26.0%)
	A little	30	(7.5%)	15	(8.4%)	15	(6.7%)
	Didn't read	16	(4.0%)	8	(4.5%)	8	(3.6%)
Readability	*Easy to read*	374	(96.9%)	165	(96.5%)	209	(97.2%)
	Slightly difficult	12	(3.1%)	6	(3.5%)	6	(2.8%)
Amount of information	*Too much*	7	(1.8%)	4	(2.3%)	3	(1.4%)
	About right	378	(97.9%)	166	(97.1%)	212	(97.1%)
	Not enough	1	(0.3%)	1	(0.6%)	-	-
Helpful for decision	*Very helpful*	219	(56.9%)	84	(49.4%)	135	(62.8%)
	Somewhat helpful	117	(30.4%)	61	(35.9%)	56	(26.1%)
	Not very helpful	35	(9.1%)	18	(10.6%)	17	(7.9%)
	Not at al helpful	14	(3.6%)	7	(4.1%)	7	(3.2%)
Presentation	*Too positive*	11	(2.9%)	6	(3.5%)	5	(2.3%)
	Balanced	374	(97.1%)	164	(96.5%)	210	(97.7%)
Benefits of screening	*Too much*	5	(1.3%)	4	(2.3%)	1	(0.5%)
	Right amount	377	(97.7%)	166	(97.1%)	211	(98.1%)
	Too little	4	(1.0%)	1	(0.6%)	3	(1.4%)
Downsides of screening	*Too much*	1	(0.3%)	1	(0.6%)	-	-
	Right amount	369	(95.8%)	160	(94.1%)	209	(97.2%)
	Too little	15	(3.9%)	9	(5.3%)	6	(2.3%)
Further information	*Yes*	21	(5.4%)	10	(5.8%)	11	(5.1%)
	No	306	(79.1%)	134	(77.9%)	172	(80.0%)
	Not sure	60	(15.5%)	28	(16.3%)	32	(14.9%)

Approximately two-thirds (63%) of people reported reading the entire booklet. Almost all people indicated the booklet was easy to read (97%) and contained the right amount of information (98%). Similarly, almost all people felt the book was balanced (97%), and included the right amount of information about the benefits (98%) and downsides (96%) of screening. Respondents reported the booklet was 'very' (57%) or 'somewhat' (30%) helpful for making the decision to participate or not in screening.

There were no significant differences between males and females concerning their views on 'The Facts' booklet. Twenty-one people provided suggestions for further information that should be included in the leaflet. Most people (10) requested further information about preventing CRC, especially in relation to

diet. The eleven remaining respondents offered a single suggestion not related to prevention. These ranged from including more information on family history, current research, how samples analysed, treatments offered, including less obvious symptoms, and narratives of people's experiences with screening.

10.13 Questionnaire logistic regression analyses

Multivariate logistic regression analyses were performed to establish if there were any significant associations between the respondents' who returned both questionnaires and participation in screening.

10.13.1 Replication analysis

The first analysis replicated the logistic regression model used for participation in screening (per protocol based on return of kits at 20 weeks; see Chapter 9). There were no significant associations for any of the included covariates (previous invitation to screening $p = 0.688$; gender $p = 0.547$, age group $p = 0.157$; GP practice $p = 0.359$; GP signature $p = 0.220$) or evidence of an interaction ($p = 0.313$). Neither the procedural letter (OR = 2.18, CI = 0.72 to 6.62) nor the GP endorsement letter (OR = 1.38, CI = 0.47 to 4.06) was significantly associated with screening participation for respondents receiving the interventions and returning both questionnaires.

10.13.2 Predictors of participation for baseline questionnaire

An exploratory multivariate logistic regression analysis was undertaken to determine associations between the baseline questionnaire responses and participation in screening (if sent an FOBT kit). In the initial model, a

comprehensive list of pertinent variables was evaluated. This included demographic characteristics (age, gender, educational attainment, marital and employment status and self-reported general health), previous CRC screening (previous FOBT, previous colonoscopy, family or friend CRC history and current bowel condition), decision-making factors (self-efficacy, importance of decision, perceived benefits/risks of screening, importance of receiving information, intention to participate), GP-related factors (confidence in GP, importance GPs opinion, influence of receiving a GP letter, embarrassed to speak with GP), psychosocial characteristics (worry, subjective or comparative risk perception, importance of decision, perceived benefits/risks of screening), health literacy, perceived health competence (PHC scale), negative attitudes towards screening scale, TSRQ subscales and baseline CRC knowledge. Respondents' indicating they had a high level of confidence (self-efficacy) for completing the kit was the only significant association determined by the analysis (see Table 10.14).

Table 10.14: Likelihood of people returning FOBT kit within 20 weeks for people receiving FOBT kit: results for the baseline questionnaire logistic regression analysis.

	Odds ratio	**95% CI**	***p* Value**
Main effects:			
Self-efficacy	5.93	1.79 to 19.67	0.004

Sensitivity analyses were performed for each of the grouped variables (e.g. demographic characteristics alone, psychosocial characteristics alone, etc) failed to show any significant associations for participation, with the exception of decision-making factors where self-efficacy again was the only significant association.

10.13.3 Predictors of participation for follow-up questionnaire

A multivariate logistic regression analysis was undertaken to determine associations between the follow-up questionnaire responses and participation in screening (if sent an FOBT kit). As with the baseline questionnaire regression analysis, a comprehensive list of pertinent variables was evaluated; including demographic characteristics, decision-making factors (excluding self-efficacy), GP-related factors, psychosocial characteristics and negative attitudes towards screening scale, TSRQ subscales and follow-up CRC knowledge. The results of the logistic regression analysis are shown in Table 10.15. A higher score on the autonomous regulation subscale of the TSRQ was shown to be significantly associated with screening participation. A negative association was shown for people who did not think it was important to know the benefits and risks of CRC screening before deciding to participate.

Table 10.15: Likelihood of people returning FOBT kit within 20 weeks for people receiving FOBT kit: results for the follow-up questionnaire logistic regression analysis.

	Odds ratio	95% CI	*p* Value
Main effects:			
Autonomous regulation subscale	3.95	1.26 to 12.31	0.018
Importance of benefits and risks	0.26	0.07 to 0.87	0.029

10.14 GP Practice Questionnaire Results

All practices participating in the trial returned the GP questionnaire. 16 (80%) questionnaires were completed by GPs at the practice, 3 (15%) by practice managers and one (5%) was completed by a practice nurse.

10.15 GP Practice characteristics

The number of GPs employed, number of practice nurses and the total list size for each practice is shown in Table 10.17. The majority of practices employed more than seven GPs. Just over half the practices (60%) reported a practice list size of below 15,000 patients.

Table 10.17: Characteristics of participating GP practices.

GP Characteristics		Number	Percent.
Number of GPs at practice	Five to Six	3	15%
	Seven or more	17	85%
Number of practice nurses	Three to Four	7	35%
	Five to Six	8	40%
	Seven or more	5	25%
Practice list size	5001 to 10,000	4	20%
	10,001 to 15,000	8	40%
	15,001 to 20,000	4	20%
	Over 20,001	4	20%

10.16 Workload and resources implications for practices

The workload and resource implications for the practices participating in the trial are shown in Table 10.18. Half of the practices received no enquiries from trial participants about CRC screening. Eight reported receiving between one to five enquiries, one practice reported six to ten enquiries and one practice reported receiving more than eleven. The majority (60%) of practices reported enquiries were resolved over the phone, although four (40%) reported a personal consultation with a GP was required. None of the practices reported that enquiries about CRC screening impacted significantly on GP practice staff time or resources.

Table 10.18: Workload and resource implications for participating GP practices.

Resource Implication Questions		*No. of Practices*	*Percentage*
Trial participants contacting practice	0	10	50%
	1 to 5	8	40%
	6 to 10	1	5%
	11 or more	1	5%
	Total	*20*	
Enquires about screening resolved:	Over telephone	6	60%
	GP consultation	4	40%
	Total	*10*	
Significant workload impact due to enquires	Yes	-	
	No	10	100%
	Total	*10*	

The reason for participant enquires is shown in Table 10.19. Enquires about how to complete the test, bowel symptoms, concerns about increased risk due to family history of CRC or ways to prevent CRC were infrequently received by practices. Questions about the benefits or risks of screening and queries about further diagnostic testing were more frequently asked, although neither category was reported as 'often' by the practices. The reason for why the participant received the FOBT pack and requesting advice on participating or not in screening were most often received enquires by the practice.

Table 10.19: Type and frequency of enquires by participants to their GP practice.

Items	*Never*	*Sometimes*	*Often*	*Very Often*
Why sent screening test	6	1	3	-
Advice on participating	3	3	3	1
How to complete FOBT	9	1	-	-
Bowel symptoms	7	2	1	-
Benefits/risks of screening	3	7	-	-
Family history of CRC	8	1	1	-
Preventing CRC	8	2	-	-
Colonoscopy	4	6	-	-
Total	48	23	8	1

10.17 GP Practice Opinions about the NHSBCSP

Respondent opinions about the NHSBCSP are shown in Table 10.20. Almost all (90%) respondents indicated they received enough information about the

programme, agreed CRC screening should be offered to 60 to 69 year olds, and further, screening should be extended to people aged 50 to 74 years old. The majority (65%) did not believe GPs should be more involved with the NHSBCSP, although views on whether GP involvement would improve participation were evenly reported. Most respondents (55%) indicated greater involvement in the NHSBCSP would have a substantial impact on practice workload, and most agreed (60%) that GPs should be remunerated if practices were involved in the programme.

Table 10.20: GP practice options concerning the NHSBCSP.

GP responses to views about the NHSBCSP	***Yes***	***No***	***Not sure***
NHS should offer CRC screening to 60-69 year olds	18 (90%)	1 (5%)	1 (5%)
NHS should offer CRC screening to 50-74 year olds	18 (90%)	1 (5%)	1 (5%)
Received enough information about NHSBCSP	18 (90%)	-	2 (10%)
Should GPs be more involved in NHSBCSP	4 (20%)	13 (65%)	3 (15%)
Would GP involvement improve participation	7 (35%)	7 (35%)	6 (30%)
Involvement have a substantial impact on workload	11 (55%)	2 (10%)	7 (35%)
Should GPs be remunerated for their involvement	12 (60%)	3 (15%)	5 (25%)
Type of CRC screening test that should be used	**%**		
Current guaiac FOBT	15 (75%)		
Immunochemical FOBT	2 (10%)		
Flexible sigmoidoscopy	1 (5%)		
FOBT and FS	2 (10%)		

Three-quarters of respondents endorsed the current guaiac FOBT for use in the NHSBCSP, with two respondents (10%) each suggesting either an immunochemical FOBT or FOBT in addition to FS should be used, or one respondent indicating FS should be the procedure of choice.

Respondents were asked what extra duties GPs could perform for the NHSBCSP (see Table 10.21). The number of duties reported by respondents ranged from one to five (mean = 2.7; SD = 1.63; median = 2.5).

Table 10.21: Potential extra duties GP practices could perform for the NHSBCSP.

Extra duties that GPs could perform for the programme		
Checking PNLs	14	70%
Providing information on test	8	40%
Informing people of results	5	25%
Counselling for colonoscopy	10	50%
Counselling if needing treatment	14	70%
No extra duties required	3	15%
Median number of extra duties indicated	2.5 (range 1-5)	

Three respondents indicated no extra duties should be performed by GPs. Most respondents (70%) reported that GPs could check prior notification lists (PNLs) or offer counselling for people needing treatment for CRC if practices undertook extra duties. Half of respondents indicated that counselling for colonoscopy could be offered by practices. Less frequently endorsed extra duties included providing further information on screening tests (40%) or informing people of their screening results (25%).

10.18 Discussion

The questionnaire components of the trial aimed to provide a descriptive analysis of participant views of CRC screening, workload implications for practices involved in the trial, and to evaluate selected outcomes for inclusion in further research. The participant component indicated several important outcomes could feasibly be included in further research projects, although there are concerns about recruiting non-screening participants for the questionnaire. The GP questionnaire component showed strong support for the NHSBCSP programme and the trial had minimal impact on practices, however, also indicated some pertinent difficulties for the widespread introduction of the two trial interventions.

Participant Questionnaire

The main findings of the participant questionnaire component were high perceived self-efficacy is a predictor of participation in screening, the detailed procedural leaflet was well-received by participants, and participants reported they made an autonomous decision to return their FOBT kits. This component of the trial also demonstrated that knowledge is increased after receiving high-quality information and negative attitudes about the procedural aspects of CRC screening significantly changed between the baseline and follow-up questionnaires.

The logistic regression analysis for the baseline questionnaire identified a single predictor associated with participation in CRC screening. People reporting they were very confident they could complete the FOBT kit were positively associated with participation in CRC screening. This confirms previous research which indicates perceived self-efficacy is an important factor for participation in CRC screening [2-5]. For the follow-up questionnaire, the logistic regression analysis revealed a positive association for the autonomous regulation subscale of the TSRQ and a negative association for the perceived importance of knowing the benefits and risks of screening for the decision to participate in screening. These results suggest people who participated in screening felt they made an independent decision to return their FOBT kits; however, after returning their kits, it was not important to know the benefits and risks of CRC screening to actually participate. This raises an important concern for the concept of informed decision-making as conceptualised for cancer screening [6, 7]. Whereas participants in the present trial believed they made

an autonomous decision to participate, their rationale for participating does not seem to be based on current conceptions of informed decision-making (i.e. weighing up the benefits against the risks). This result is similar to the pilot qualitative results which identified a 'cognitive dissonance' when people were confronted with the idea of making an informed choice about participating in screening. This suggests a greater understanding of how informed decision-making interacts with the decision to participate in screening is required, and in particular, a more realistic framework which can accommodate notions promoting the importance of factual information for enhancing informed decision-making.

Overall, the results for the TSRQ indicated people made an autonomous decision, were not overtly affected by external factors pressuring them to do the test and were motivated to participate in the programme. The scale generally demonstrated very similar psychometric properties in comparison to previously reported research [8-10] and was related to high perceived health competency and self-efficacy for completing the test. However, the only significant change between the baseline and follow-up questionnaires was found for the amotivation subscale; a scale which is has been excluded from the new TSRQ questionnaire [11]. Furthermore, the changes between the baseline and follow-up questionnaires for both the autonomous and controlled motivation subscales were minimal, suggesting fairly stable attitudes towards self-determination constructs both before and after receiving the FOBT kit. Although the TSRQ does offer some insight into participant perceptions of decision-making for CRC screening, the lack of substantial differences between the two time points,

coupled with the recent omission of the amotivation subscale poses particular difficulties for recommending the TSRQ for further research in this field.

The detailed procedural leaflet was well-received by questionnaire participants. Almost three-quarters (73%) reported the leaflet included very useful suggestions and over half (54%) indicated it was very helpful for their decision to participate or not in CRC screening. Importantly, a large proportion of participants (41%) also reported they were held more positive views of CRC screening after receiving the leaflet. Coupled with the increase in participation observed for people receiving this intervention in the factorial trial, there is strong evidence the detailed procedural leaflet would be an important addition to the NHSBCSP invitation procedure.

Overall, participants reported general attitudes towards CRC screening were positive. The majority of people indicated the screening decision was important, they were convinced of the benefits, not concerned about the risks and were very satisfied with the information they received. Furthermore, participants initial negative views of the FOBT procedure decreased between the baseline and follow-up questionnaires. Previous research has shown peoples' initial negative views of the FOBT kit and the procedure for collecting samples can impact on participation rates [12, 13]. In the present research, the study-specific scale (see Appendix 10.2) showed an overall significant decrease in negative attitudes between the baseline and follow-up questionnaires. Individual scale items also significantly decreased with less people indicating difficulty, inconvenience or disgust associated with collecting their samples.

Interventions which target negative perceptions of the procedural aspects of CRC screening, such as the detailed procedural leaflet, should be promoted to achieve the results evidenced in the present study.

One potential barrier to participation in the NHSBCSP is peoples' concerns about their ability to complete the test [2, 3]. Participant concerns about performing the test correctly were very high prior to receiving the test (54%) and did not substantially change after completing the FOBT kit (54%). As there were no significant differences between the people who received the procedural leaflet and those that didn't, this suggests further work is required to minimise this concern for people invited to CRC screening, especially as this potential barrier was evident in a population who overwhelmingly participated in screening. Identifying whether or not concerns about doing the test correctly are a primary barrier for non-participation in the NHSBCSP, and how the provision of specific information could challenge this perception, is a key area for future research for the programme.

An important finding for the present research was the significant, albeit modest improvement, in overall knowledge between the baseline and follow-up questionnaires. Prior to receiving the NHSBCSP booklet, questionnaire participants answered under half of the knowledge items correctly (mean = 4.8). After receiving the booklet, the overall knowledge score increased to 6.2, with both males and females showing significant increases for all knowledge items. This result is similar to previous studies employing patient information materials [14-17], and demonstrates the effectiveness of providing high-quality

information with the screening invitation. However, there is some concern two items were consistently answered incorrectly (age at diagnosis and side-effects associated with colonoscopy) and that knowledge was not associated with screening participation. Participant views of the NHSBCSP 'The Facts' booklet were very positive. Almost all participants reported the booklet was easy to read, the information was balanced and contained sufficient information. Coupled with the increase in knowledge, the provision of information can be seen as having a positive effect on decision-making for CRC screening.

The two previously validated scales used in the questionnaire component performed reasonably well, although with some reservations for their ability to discriminate between people participating in screening. The perceived health competency scale (PHC) showed similar results to previously reported research [1], but was not associated with CRC participation. It is suggested that the PHC may prove useful for future research in CRC screening given the identified relationships with self-efficacy and decision-making. The brief health literacy scale included in the baseline questionnaire was not particularly useful for differentiating between participants with adequate or low literacy levels. Both the original authors [18, 19] and a subsequent analysis of the scale [20] have suggested only one item is necessary to evaluate health literacy, although differ in their opinion of which item should be included. The present research confirmed the equivocal results previously reported in the literature concerning this scale. It is highly likely the health literacy scale did not perform particularly well given the high literacy level of respondents and further, more targeted research would be required prior to recommending implementing this scale.

GP Questionnaire

The findings from the GP questionnaire component indicate the workload and resources requirements were minimal for practices involved in the trial and participating GPs were very positive about the NHSBCSP. Similar to previous research [21, 22], GPs were very supportive of the current invitation system for the NHSBCSP, and also strongly supported extending CRC screening to include 50-74 year olds. The majority of GPs (75%) agreed with gFOBT as the CRC screening modality of choice for the programme, although they were less enthusiastic about performing further duties for the NHSBCSP. Extra duties which were endorsed by GPs mainly included tasks which could be performed by the practice (e.g. checking prior notification lists for suitable screening candidates) or direct involvement to alleviate patient concerns or anxiety (e.g. counselling if needing colonoscopy or treatment). A potential concern for the use of the GP endorsement letter intervention is that only around a third (35%) of GP's thought this would improve participation in the programme.

Overall, very few practices (10%) received more than five inquiries from trial participants related to CRC screening. The majority (60%) of these inquiries were resolved over the phone. Most inquiries were about either the test itself (e.g. why sent a test, how to complete FOBT, advice on participating) or concerns about CRC occurring (e.g. family history of CRC, advice preventing CRC developing). Although none of the enquiries resulted in GP's reporting a significant impact on their workload, more than half (65%) of respondents thought GP's should not be more involved in the NHSBCSP. This was based

on the belief that their involvement would have a significant impact on workload (55%) and they should be remunerated for any work performed for the programme (60%). This finding is consistent with previous UK-based research [Jepson] which found that although practice staff spent 2% or less of their time on UK CRC screening pilot related activities during the trial, almost half of surveyed GP's reported the NHSBCSP would substantially impact on workloads. These results suggest further engagement with GP's in England would be required to alleviate concerns if they were to become more involved with the NHSBCSP.

The GP questionnaire component of the trial demonstrated that supplying a GP endorsement letter for the NHSBCSP did not have a significant effect on practice resources and enquiries generated by their patient's involvement in the trial were relatively easy to resolve. However, GPs negative views on the potential resource and workload implications for their greater involvement in invitation process and their uncertainty surrounding the effectiveness of integrating a GP endorsement letter to improve patient participation in the programme, suggests further research is required to identify ways to overcome the procedural barriers for further GP involvement in the NHSBCSP.

Limitations

A significant limitation for the participant questionnaire component of the trial concerns two aspects of the response rate. Firstly, the overall response rate was fairly low (31%), which is below an acceptable rate for questionnaire studies and would introduce non-response error [23-25]. Secondly, and

potentially a more problematic limitation for the generalisability of the results, the over-representation (95%) of questionnaire respondents also returned their FOBT kits. However, previous research has demonstrated that survey questionnaire response rates are a function of participation in screening. For example, the response rate for a RCT evaluating informed participation in computed tomography screening for lung cancer found that 80% of screening participants returning questionnaires in comparison to a 7% response rate for non-participants [26]. Similar response rates have been reported in other screening studies [27-29] and also in the pilot phase of this research programme. The present research confirms there is an inherent methodological difficulty for cancer screening research and one which needs to be addressed to improve the evidence-base for this field of research. Another potential limitation is the very low response rate from ethic minorities to the questionnaires and the inability to identify social deprivation status for participants. These two factors have consistently been associated with poor participation rates [30, 31]. Failing to attract people from ethic minorities and the difficulties with receiving approval to access data which would provide an estimation of social deprivation also affects the generalisability of this research.

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Chapter 11: Conclusions

11.0 Summary of Research Findings

The main findings of the research programme are that:

- a GP endorsement letter and a detailed procedural leaflet sent with the FOBT pack can improve participation in the NHSBCSP
- the inclusion of an electronic GP signature on the GP endorsement letter is an essential component for improving participation
- it is feasible to implement a primary care-based intervention and include an additional information leaflet as part of the NHSBCSP invitation process
- GP practices hold favourable views of the NHSBCSP, however, greater engagement is required to alleviate concerns about their involvement in the screening programme

11.1 Interventions Improved Participation

The hypothesised improvement in participation attributable to the two interventions was supported by the results of the research programme. The factorial trial demonstrated the effectiveness a GP endorsement letter and a detailed procedural leaflet can have for improving participation in the NHSBCSP. The effects of the two interventions appear to act independently of each other, as they were shown to improve participation separately, and have an additive effect when both were sent together. Separately, the interventions each improved participation by 5% to 6% for the intention-to-treat analyses in comparison to the current invitation process. When sent together, the interventions increased participation by around 11% suggesting, in the absence

of an observable interaction effect, that the interventions have an additive effect. If introduced in the NHSBCSP, either intervention could modestly improve participation in the programme. If both interventions were used in combination, the resulting relative increase in participation would be approximately 20% greater than currently observed.

GP Endorsement Letter

Overall, the improvement in participation for people receiving a GP endorsement letter is consistent with previous research from other countries, which has demonstrated that personalised invitations improve screening test-return rates [1-5]. However, the differential effect on participation when including an electronic GP signature is an important consideration for both the effectiveness and implementation of this intervention. GP endorsement letters which included an electronic signature performed far better in terms of participation than the same letters which were sent 'On behalf of the Practice'. Indeed, on average, the electronic signature improved participation by above 10% in comparison to letters which did not include a signature. This is commensurate with the increase in CRC screening uptake reported in previous publications using a similar intervention [1, 2]. However, the overall effectiveness of a GP endorsement letter and the differential effect an electronic GP signature can have for participation have not previously been shown in a UK population, and emphasises the important role a personalised approach from a respected clinician can have for people invited to the NHSBCSP.

Detailed Procedural Leaflet

The detailed procedural leaflet demonstrated a uniform improvement in CRC screening participation for analyses conducted for the return of FOBT kits at 12 and 20 weeks. The results of the present research are unique as no trial has demonstrated a detailed procedural leaflet can improve participation in a CRC screening programme. Two previous trials have reported a verbal intervention aimed at explaining how to complete the FOBT kit can increase participation [6, 7]; however, the same effect has not been shown for written information materials. Based on the participant responses about the leaflet in the questionnaire component of the trial, the intervention is postulated to have improved participants' perceived self-efficacy and positive attitudes towards the completing the FOBT kit. Favourable attitudes concerning the effectiveness of CRC screening, positive views of the procedure and a strong sense that the individual is capable of performing the procedure (self-efficacy) has been consistently associated with higher rates of participation [8-12]. The modest improvement in participation for the detailed procedural leaflet is expected to translate into substantial gains in uptake and subsequent identification of CRC within the NHSBCSP.

Additive Effect

The most likely reason for the additive effect demonstrated in the trial was that each separate intervention influenced two distinct groups of potential non-responders. It is suggested that the GPs endorsement letter was influential in those who preferred receiving health advice from their GP, whereas the

procedural leaflet altered negative perceptions of the FOBT kit and enhanced peoples' perceived ability to complete the kit.

Although rarely investigated, the notion that distinct interventions can affect different groups of people invited to screening has previously been demonstrated. For example, a large-scale Italian RCT which evaluating different strategies for inviting people to CRC screening found that those with a higher educational attainment based their decision to participate on the information materials they received, whereas people with lower educational attainment tended to rely on the advice from the GP [13]. The results of a large-scale US-based survey found that trust in the doctor or healthcare provider was pivotal to the decision to participate in CRC screening for lower socio-economic groups and the desire for personalised cancer screening communications for those with higher socio-economic groups [14]. Coupled with the results of the present research programme, these findings would suggest that providing several interventions with the screening invitation process will have a greater effect on improving participation than concentrating on a single intervention, and may indeed prove useful for reducing the disparity in uptake between lower and higher socio-economic groups in England [15].

Previous research has also shown that are differences in participation rates between males and females. There is some evidence that the discrepancy in CRC screening uptake between males and females is related to the frequency of primary care visits, previous screening behaviour, preferences for screening modality and recommendations from a GP [16-18]. Although not associated

with participation in the logistic regression analyses performed for the factorial trial, the bivariate analyses did show a higher proportion of females participating in CRC screening after receiving the GP endorsement letter. These analyses also revealed an improvement in participation for men receiving the detailed procedural leaflet. Further research is required to understand the reasons underlying the differential gender effect on participation for both interventions, and potential ways of using gender-specific information to further enhance the utility of each intervention.

11.2 Participant Perceptions of the Interventions and CRC Screening

The questionnaire component of the trial provided important additional information despite the low response rate, as very few studies have investigated the reasons for observed changes in participation or endeavour to comprehensively investigate participants' views of the intervention materials.

Evaluation of the Materials

Participant perceptions of the detailed procedural leaflet were very positive. Both trial participants and those in the pilot study reported the leaflet included useful suggestions for completing the FOBT kit and around half of the trial participants (54%) indicated it was 'very helpful' for making the decision to participate in screening. Furthermore, around half of both groups of respondents indicated they held more positive attitudes towards CRC screening after reading the leaflet. Coupled with the consistent improvement in participation demonstrated for the leaflet in the factorial trial, this intervention would clearly be an important addition to the NHSBCSP invitation process.

Participant responses to the questionnaire provide evidence to explain the overall improvement in participation for the GP endorsement letter observed in the factorial trial. In the GP endorsement letter factorial group, around a third of people reported that receiving the letter definitely influenced their decision to participate (12%) or influenced their decision to some extent (20%). This was similar to the leaflet group where 13% reported receiving a letter would have definitely influenced their decision or influenced their decision to some extent (21%). Participants were obviously responsive to receiving the GP endorsement letter, and this translated into improved participation in the programme. This result is similar to previous research which has consistently reported the involvement primary care practitioners can have a positive influence on CRC participation rates [19-23]. However, as only 3.3% of people reported this to be the main reason for participating in screening, other individual-level factors clearly have a role in the decision to complete the FOBT kit.

Individual-level Factors and Health Behaviour Models

Potentially the most important individual-level determinants of participation in screening are related to a person's perceived ability to perform the test and their attitudes towards screening and the test procedure. Self-efficacy was shown to be the single most important predictor of participation in the baseline logistic regression analyses performed for the questionnaire participants. A strong sense that the individual can either perform or undergo a screening procedure has consistently been associated with higher rates of participation [24-26].

Furthermore, the follow-up logistic regression analyses indicated that a low perceived concern for the benefits or risks associated with screening was predictive of participation, suggesting participants expected a positive outcome from completing the FOBT kits. This is consistent with the tenants of Social Cognitive Theory (SCT) and the Theory of Planned Behaviour [27-29], in that self-efficacy coupled expectations of a positive outcome from performing screening, would predict participation in the screening programme. It is also important to note that negative perceptions of the FOBT kit dramatically changed between the baseline and follow-up questionnaires. The negative attitudes scale, specifically developed as part of the trial questionnaire component of the research, showed less negative attitudes towards screening, especially in regards to the difficulty, disgust and inconvenience of collecting samples. This is postulated to have occurred due to both an increase in self-efficacy and a change in people's initial perceptions of completing the FOBT kit. Further research is required to determine how the two interventions affected self-efficacy and improved perceptions of completing the FOBT kits.

The theory of self-determination (SDT) was chosen as a component for this research as it evaluates the degree to which behaviours are self-determined, and can demonstrate whether or not decision-making for the target behaviour is due to personal factors (autonomous motivation) or performed as a consequence of social pressures (controlled motivation) [30-32]. Although similar in content to the Theory of Planned Behaviour (TPB) [33, 34] and SCT, it was anticipated that SDT would provide a useful insight into factors affecting decision-making for CRC screening in a UK population. Overall, the results for

the TSRQ (based on the logistic regression model for the questionnaire component of the factorial trial) indicated people made an autonomous decision, were not overtly affected by external factors pressuring them to do the test and were motivated to participate in the programme. However, the self-efficacy scale performed poorly in the pilot study and the TSRQ was modified to exclude the amotivation subscale in 2009 [35]. This was the one subscale that showed a significant difference between the baseline and follow-up questionnaires. The inability of the autonomous and controlled motivation subscales to demonstrate a difference prior to, and after screening, suggests the TSRQ is unlikely to be useful in future research studies.

Both the health literacy scale [36, 37] and the perceived health competency (PHC) scale [38, 39] were of limited utility for differentiating between questionnaire respondents or for illuminating the reasons for individual participation in screening. Although health literacy has become an important component of understanding CRC screening participation [40, 41], only a small proportion of participants returning the trial questionnaires could be regarded as having limited health literacy, and overall, this was not shown to impact on participation or indeed any other individual-level variables. While responses to the PHC were similar to previous research [39], and the median-split method used for the scale suggested people with a high-PHC were less likely to be influenced by the GP endorsement letter, the scale was not predictive of participation. The scale did correlate well with self-efficacy, although without also attracting non-participants within a questionnaire-based study, the utility of the scale is potentially limited for CRC screening research.

Screening Information and Decision-Making

A potential difficulty for the NHSBCSP was that only just over half of people (58%) were aware of the programme before they were invited. This is concerning for two main reasons. Firstly, awareness of screening has been shown to be a predictor of participation [9, 19, 25, 42-44] and not knowing the national screening programme is operating may adversely affect participation rates. Secondly, this lack of public awareness means the NHSBCSP materials will be the initial source of information for a large proportion of people, and uncertainties about completing the test or not appreciating health professionals' perceptions of the importance of screening may reduce interest in completing the FOBT kit. However, participant knowledge was shown to significantly improve after receiving NHSBCSP information materials, and coupled with the efficacy of two interventions for improving participation, the importance of the provision of information materials cannot be understated.

Overall, participants reported highly favourable perceptions the NHSBCSP information materials. Around 6 in 10 people indicated the booklet was 'very helpful' for making the decision to participate in screening. Very positive views were also reported for the content and presentation of the booklet, including information about both the benefits and risks associated with screening. Furthermore, the pilot study demonstrated that people regarded both positive and negative information to be 'extremely important' to include in screening materials. This disputes the notion that people do not want negative information included screening materials [45, 46], although these results are based on

people participating in screening, whereas the views of non-participants may be different.

Generalisability of Questionnaire Responses

A significant limitation for the questionnaire component of the trial, and indeed the pilot questionnaire study, was the inability to recruit non-participants. Around 95% of people returning questionnaires in the research programme participated in CRC screening. This inhibited any opportunity to make comparisons of the individual-level factors affecting participation between those who returned the FOBT kits and those who did not. Although this is an established difficulty with screening research [47-50], the failure to attract non-participants to the research reduces the overall generalisability of the questionnaire component of the research programme. This is a particular concern for ensuring that the interventions are thoroughly evaluated, especially in relation to how the interventions affect individual-level factors necessary for ensuring behavioural change.

GP Involvement and Attitudes towards the NHSBCSP

The most crucial component for the successful implementation of the GP endorsement letter is the support of primary care practitioners. Although discussed in more detail in a following section (see 11.4.1), GPs were generally supportive of the current screening programme, believed the age of invitation to the NHSBCSP should be extended to 50 to 74 year olds, and received sufficient information about the programme. However, this must be tempered by the fact that only around a fifth of practices agreed to participate in the present research

and GPs expressed some reservations regarding becoming involved in the NHSBCSP.

Previously, several UK-based studies have reported GPs are supportive of the screening programme, but are concerned about the additional workload and practice resource requirements for becoming more involved with the NHSBCSP [51-53]. These concerns are echoed in the present research, with over half of the participating practices reporting that their involvement would have a significant impact on workload, and only 20% indicating GPs should be more involved in the NHSBCSP. However, unease about increased workload due to patient inquiries or requests for appointments attributable to participating in the research was unfounded. Indeed, half of all practices involved in the research did not report any contact with their patients concerning CRC screening during the trial period. These findings contrast with previous research [52] which found that GPs who previously participated in the UK Colorectal Cancer Screening Pilot were less likely to express concerns about additional workload. Feeding back the results of the minimal workload requirements to primary care may alleviate these concerns and encourage GPs to become more involved in the programme.

11.3 Complex Interventions and the Current Research Programme

The research programme followed the MRC recommendations for evaluating complex interventions [54-58]. Adhering to this guidance substantially improved both the development of the interventions and the overall conduct of the various phases of the research programme. The current research programme was

formulated as an ‘exploratory trial’ (Phase II), which would lead to a ‘definitive randomised controlled trial’ (Phase III) if the present research demonstrated a significant impact on participation in the NHSBCSP. The interventions were developed after systematically reviewing the available literature, developing the interventions in light of the reviews and theoretical frameworks informing behavioural change, piloting the interventions and outcomes which would be used in the factorial trial, exploring key issues with previous screening participants, and finally, conducting the factorial trial within the NHSBCSP. Throughout this iterative process, the stakeholder representative group provided advice and comments to ensure health professional and patient advocacy input could be used to enhance the interventions. As recommended by the guidance [56], the ‘exploratory trial’ addressed many of the issues required for conducting a ‘definitive trial’, and further, also explored the feasibility of delivering the interventions for both providers and the population in question.

The factorial trial also offers important information for the sample size calculations of future research. Based on the results of the factorial trial, approximately 3,200 participants would be required to detect an absolute difference of 5% in participation in a future definitive trial; this increases to almost 5,000 participants if attempting to detect an absolute difference of 4% in participation. If attempting to include practices with less than 46 people per month invited to CRC screening, as occurred in the present research, the number of GP practices required for the study could well exceed 200 (the mean number of people invited to screening in October 2009 was 23.27). This would

require significant co-ordination with Primary Care Research Networks, the NHS Cancer Screening Programmes and Connecting for Health (CfH) to ensure that a 'definitive trial' could be conducted.

11.4 Recommendations for Implementation

The present research programme identified a number of factors which must be addressed prior to implementing either of the interventions. These factors include:

- significant engagement with primary care to co-ordinate the organisation and mailing of the GP endorsement letters
- commitment from the NHS Cancer Screening Programmes and the Screening Hubs to include the detailed procedural leaflet with the FOBT kit

11.4.1 Engagement with Primary Care

For the GP endorsement letter to be an effective additional resource for the NHSBCSP, it is essential that all GP practices in England are involved. Attempting to comprehensively involve primary care practices in the screening programme would require overcoming several significant barriers. Firstly, all GP practices must be favourably disposed to providing an electronic practice letterhead and an electronic signature to the NHSBCSP. Secondly, the practices would also need to view this additional requirement as non-intrusive to their current workloads, and be assured that involvement in the NHSBCSP would be beneficial to both their patients and their practice. Finally, an agreed mechanism to facilitate the implementation and monitoring of the GP endorsement letter would be required.

The most immediate concern for the implementation of the GP endorsement letter is the ability and interest of practices to provide the necessary components for the intervention. A minor difficulty for the factorial trial was that two PCRN representatives reported several practices contacted had declined to participate as they did not possess an electronic letterhead. The proportion of practices in England which do not have an electronic letterhead is uncertain, although it is expected to be small and could be easily generated for the practices if needed.

A greater obstacle for the implementation of the intervention concerns the electronic GP signature. The factorial trial demonstrated that a signed GP endorsement letter had a greater effect on participation than did a letter signed with 'On behalf of the Practice.' This is a crucial point for the implementation of this intervention and failing to include a signature is likely to diminish the ability of the intervention to affect behavioural change. Providing an electronic signature was a particularly sensitive issue for the majority of practices involved in the trial. For example, five practices refused to provide a GP signature as they felt it was inappropriate given there is no formal agreement with the NHSBCSP to involve GPs in the programme. Alternatively, one practice would only agree to participate if the signatures of all seven GPs at the practice were included on the letter. These difficulties most likely reflect a wider concern GPs hold in regards to their involvement in a screening programme regarding potential workload requirements [51-53] and engaging with the NHSBCSP when there are no formal arrangements with practices.

Few GPs in the present research (20%) believed they should be more involved with the NHSBCSP and around a third (35%) reported GP involvement would not improve participation in the programme. These are significant barriers for the implementation of the intervention. Whilst GP attitudes towards their role in improving participation may be overcome through dissemination of the present research, the need for a mechanism which encourages GP participation in the programme also should be addressed. Over half of participating practices (60%) felt that GPs should be remunerated for their involvement in the NHSBCSP; a finding similar to previous UK studies [52, 53]. A potential way of introducing an incentive for practice participation would be to include patient CRC screening participation as a part of the 'Quality and Outcomes Framework' which may remedy this lack of engagement.

11.4.2 Enhancing Information Provision

In regards to the detailed procedural leaflet, incorporating this intervention into the current NHSBCSP invitation procedure would be fairly straightforward. The leaflet was well-received by participants who overwhelmingly reported the intervention was helpful for making the decision to participate in screening and included useful suggestions for completing the FOBT kit. Stakeholder representatives were also supportive of the intervention and several expressed surprise that the leaflet performed as well, indeed slightly better, than the GP endorsement letter.

There is an obvious cost consideration involved with producing the leaflet (i.e. printing of the double-sided A4 sheet). However, the production costs would be remarkably small given the leaflet is printed in black and white, does not contain images or requires copyright payments to the author, and would not affect the current NHSBCSP postal charges. Based on discussions with DH Publications, who print the information leaflets for the NHS Cancer Screening Programmes, the cost was estimated to be approximately 12 pence per one million copies; or around £300,000 per year (five million people invited to screening every two years). Although requiring further research to determine the actual cost-effectiveness of incorporating the leaflet within the programme, the ability of the leaflet to improve participation in CRC screening by over 5% would be expected to translate into projected savings both in terms of reduced mortality from CRC and reduced costs to the NHS in regards to treatment for CRC.

Alternatively, the NHSBCSP leaflet for completing the FOBT kit could be enhanced by including much of the information presented in the procedural leaflet. Currently, the NHSBCSP 'directions for use' leaflet are extremely brief and do not provide any information for collecting samples other than a suggestion for wrapping toilet paper around a person's hand. As the majority of questionnaire participants indicated the detailed procedural leaflet included useful suggestions and that over 40% of people were more positive about completing the FOBT kit after receiving the leaflet, the intervention is clearly an important advancement on the current information provided by the NHSBCSP.

A further potential area for investigation would be the effectiveness of graphical representations to convey how to complete the FOBT kit. Illustrations and graphical representations have previously been shown to enhance understanding of the screening process [59-61]. For example, the Scottish Bowel Cancer Screening Programme includes a number of photographs specifically demonstrating the correct way to smear a sample of faeces onto the window of the FOBT kit. This may be particularly useful information to include in the English version, given that almost 50% of participants who returned their trial questionnaire were unsure if they had completed the test correctly.

11.5 Recommendations for Future Research

Originally, it was envisaged that the current research programme would lead to a larger trial, which would definitely establish the efficacy and cost-effectiveness of the two interventions across a range socio-economic groups and regional areas in England. The first phase of the research would ascertain the feasibility and requirements for involving GP practices in the NHSBCSP. The second phase would replicate the factorial trial in a larger population of people and locations, and would also endeavour to evaluate individual-level factors affecting participation and non-participation in the screening programme.

Practice Involvement

Attracting GP practices to the research would be difficult; however, the results of the present trial should allay misconceptions about the workload involved and may improve interest for involvement in the trial. Ideally, fostering greater involvement with key stakeholder groups, such as the Royal College of

Physicians, the Society for Academic Primary Care and regional bodies may significantly enhance interest and recruitment for the trial.

An important component for overcoming difficulties with GP interest in providing a singed endorsement letter may be to identify one GP at each practice who would act as lead advocate for the NHSBCSP. This would negate some difficulties associated with which GP signature should be included on the endorsement letter and potentially help structure how the QOF indicators could be accommodated within the current framework.

Practice Workload

A more accurate method for recording trial participant inquiries about CRC screening would be required for future research. Although the system employed in the current research was suitable for the purposes of the trial, and similar to previously published research [51], more detailed information about the nature of the inquiries and the people contacting the practice would be beneficial. This would incur additional requirements for the research; however, it is likely to provide more detailed information for the cost-effectiveness of implementing the interventions and valuable information for the implications for practice involvement.

Cost-Effectiveness

The research would need to be underpinned by detailed health economic modelling of the costs associated with both interventions and the costs incurred for GP practice involvement. Primarily, the cost-effectiveness analysis should

focus on the delivery of the interventions, with future modelling concentrating on whether the increase in participation would result in savings for the NHS in terms of reduced morality and morbidity from CRC.

Questionnaire Research

It is extremely important to note that people who participate in CRC screening are almost exclusively the only people who return questionnaires [47-50]. This was especially evident in the current research programme. Studies which incorporate questionnaires to examine patient views of the interventions should focus recruitment strategies on participant views rather than attempting to determine differences between screening participants and non-participants. An important recommendation for future research is that any study or trial which is reliant on questionnaire outcomes to determine differences between screening participants and non-participants, should avoid using the same recruitment strategy for both groups. This may be achieved either through the use of incorporating a cross-sectional design specifically targeting non-participants (although, comparisons between participants and non-participants would be limited) or concentrating on qualitative designs for comparing differences in beliefs, attitudes and experiences between the two groups.

11.6 Conclusion

Overall, this research has conclusively demonstrated that it is both feasible and effective to include a GP endorsement letter and a detailed procedural leaflet as part of the invitation process of the NHSBCSP. The research further demonstrated the importance of including a GP signature on the endorsement

letter to improve participation in the programme. It is essential for the findings of this research to be implemented by the NHSBCSP as part of a series of initiatives to decrease CRC mortality and morbidity in England. Clearly, more extensive work is required to ensure that the involvement of primary care is both inclusive and sustainable. However, it is imperative that a variety of complimentary initiatives are required to support screening for CRC and improve the health of the aging population.

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Appendix 1.1: RDA Protocol (NIHR Application)

1.0 Title: The impact of a primary-care based information intervention for improving patient participation in the NHS Bowel Cancer Screening Programme.

2.0 Summary: The newly established NHS Bowel Cancer Screening Programme (NHS BCSP) offers all eligible men and women aged 60 to 69 a faecal occult blood test (FOBT) every two years in a home-mailed invitation pack. The proposed research study will investigate the utility of including a primary care-based information intervention (General Practitioner letter and a detailed leaflet to help people understand how to correctly complete a FOBT) in the invitation pack for increasing patient acceptance and adherence to the NHS BCSP. The results of the project are anticipated to inform the enhancement of targeted information materials for the NHS BCSP, evaluate the role of primary care for patient choice in CRC screening and directing future research aimed towards improving patient participation in the programme.

3.0 Objectives: The primary aim of the proposed research is to develop a primary care intervention for improving participation in bowel cancer screening and examine the feasibility of using the intervention in a larger, randomised controlled trial. The main objectives of the project are to:

1) develop and evaluate a primary care-based information intervention (that includes procedural, disease and risk information) to improve patient acceptance and participation in the NHS BCSP
2) evaluate patient perceptions of the role that information materials have for making an informed choice to participate or not in the programme
3) identify factors that contribute to the short and long-term participation in the NHS BCSP and the impact of the intervention for GP resources

It is hypothesised that the educational intervention will increase participation in the NHS BSCP by improving patient acceptance of the programme (enhance understanding, offer of information support from GP, etc) and increasing patient self-efficacy for completing the FOBT. Furthermore, the results of the project will provide valuable data which will inform the design, recruitment and conduct of a larger, randomised controlled trial of information interventions.

4.0 Background: Colorectal cancer (CRC) is a leading cause of mortality and morbidity in the western world. It is the second leading cause of cancer death in Europe[1] and the United States[2]. Survival rates for people diagnosed with CRC are somewhat higher in the US than Europe, although this difference is mostly attributed to differences in the stage of diagnosis[3]. For average risk populations, substantial evidence from randomised controlled trials [4-7] has indicated that screening using the faecal occult blood test (FOBT) can significantly reduce CRC mortality. Furthermore, CRC screening offers the opportunity to detect cancer at an early stage, increasing the chances of effective treatment and improved survival.

Following the success of the UK Bowel Cancer Screening Pilot[8], the NHS Bowel Cancer Screening Programme (NHS BCSP) was introduced in Spring 2006[9]. Men and women aged 60-69 years receive a mailed invitation pack that includes an invitation letter, an evidence-based information booklet about CRC and CRC screening, the FOBT with return envelope and brief instruction leaflet for completing the FOBT. However, there are concerns for the uptake of CRC screening in the population. The overall adherence to CRC screening is generally poor, with approximately 55% of people participating in UK studies[4,8], which is slightly higher than other countries[5,10]. The development and evaluation of feasible and cost-effective interventions that can increase patient acceptance and participation are crucial to the success of an effective CRC screening programme.

Patient knowledge of the availability and benefits of CRC screening, underestimating the risks of developing CRC or lack of interest in testing without symptoms, and patient concerns coupled with negative perceptions of the FOBT procedure have been forwarded as contributing to poor compliance[11,12]. Whereas evidence-based information materials may be able to raise awareness and provide people with more realistic estimations of risk, the procedural barriers to completing the FOBT may not be meet by information provision alone. Given the recent attention to the provision of decision-aids to help people make choices that reflect their personal preferences[13], several investigations have evaluated high-quality, evidence-based information materials designed to improve understanding and increase participation[14-16]. However, these studies have failed to demonstrate a significant improvement in initial or long-term compliance with CRC screening, strongly suggesting alternative strategies are needed to enhance patient acceptance and participation.

One potential strategy to improve participation is an intervention delivered by primary care General Practitioners (GPs). Recent UK surveys have found that doctors are the most trusted profession[17] and that 73% of people would seek information from their doctor about common health care issues in comparison to written information or other sources[18]. Previous research has indicated that the involvement of GPs can improve patient compliance with CRC screening[10,19]. Furthermore, other studies have shown that providing patients with more detailed instructions on the collection, storage and return of FOBT also modestly increases patient compliance with FOBT[20,21]. However, no currently published studies have attempted to combine the important influence that GPs have for patient acceptance and decision-making for CRC screening with an information intervention specifically developed to overcome procedural barriers (patient negative perceptions of CRC screening for performing the FOBT). The opportunity to prospective evaluate the effectiveness of including a primary care-based information intervention that directly addresses patient concerns about procedural barriers to FOBT would be both an internationally unique topic of investigation and advantageous for improving the delivery of the NHS BCSP.

5.0 Investigation plan: The proposed project is an extension of work undertaken by the Department for the NHS BCSP (including the development of the evidence-based, information

booklet included in the invitation package sent to the public eligible for the NHS BCSP) and has been informed by two systematic reviews currently nearing completion concerning i) primary-care based interventions for improving adherence in CRC screening and ii) the utility of information provision for patient decision-making in CRC screening. The proposed study is divided into three main phases:

1) Phase 1: Information Intervention Development (organisation and consultation with key stakeholders to develop and implement the information intervention)
2) Phase 2: Piloting Intervention and Questionnaire (qualitative and quantitative evaluation of information intervention and questionnaire items)
3) Phase 3: Intervention Study (prospective, cross-sectional, before-and-after questionnaire survey and modelling of pertinent outcomes)

5.1 Phase 1 - Information Intervention Development: This phase will inform the development of the primary care-based information intervention. Key stakeholders will be invited to participate in a consultation process, providing advice for the content and presentation of the intervention materials used in the study. The collaboration will consist of General Practitioners (GPs), representatives from bowel cancer patient advocacy groups (Bowel Cancer UK, Colon Cancer Concern, Cancerbackup), staff from the NHS BCSP and an expert in consumer information (NCRI consumer representative). The information intervention consists of two parts: i) a letter from the invited participants GP and ii) a leaflet providing detailed instructions for completing the FOBT.

a) *General Practitioner Letter*: a standardised, one-page letter included in the invitation to screening pack. Four to six GPs (who will have patients invited to the NHS BCSP during the recruitment phase of the intervention study) will be approached to be involved in the study. The letter will include a statement from the GP endorsing bowel cancer screening, further information about symptoms and prevention of CRC, and importantly, an offer to contact the GP to discuss any concerns or questions the patient may have about CRC screening.

b) *Detailed FOBT Leaflet*: a double-sided A4 leaflet that directly addresses procedural barriers to completing the FOBT. The leaflet will include detailed information on the correct procedure for collecting, storing and returning the FOBT will be sent in conjunction with the GP letter. The leaflet will also include patient relevant information about overcoming potential barriers to participation (e.g. what to do if person has loose stools or is constipated), address concerns about the collection of stools (e.g. 'tips' from previous participants) and provide advice for seeking further information about CRC screening. This phase will contribute to the completion of Objective 1.

5.2 Phase 2 - Piloting Intervention and Questionnaire: This phase and Phase 3 are structured to meet the framework set out in the MRC guidance on complex health service interventions. The intention is to assess the applicability of the primary care intervention for use in the intervention study (Phase 3) and for future research (randomised controlled trial) at the completion of the RDA. A pilot questionnaire coupled with in-depth interviews will be used to

explore patient perceptions and views of the intervention materials and barriers to completing the FOBT, and further, evaluate the utility of specific outcome measures that will be used in the intervention study questionnaire.

***5.2.1 Design and sample*:** Approximately 150 people who have previously been invited to the NHS BCSP will be recruited through GP practices. Consenting participants will receive a questionnaire in the mail which will be returned to the research team. The pilot questionnaire will include items evaluating patient views of the intervention materials, the perceived importance of information materials for CRC screening (including perceptions of the current NHS BCSP information materials) and preferred sources for acquiring this information. The pilot will also investigate the utility of the questionnaire outcome measures for assessing knowledge, attitudes and anxiety associated with CRC screening in the intervention study. Analysis of the questionnaire data will primarily concentrate on refining the outcome measures used (reliability and validation of measures) and will also involve a descriptive analysis of participant's perceptions of the information materials. The outcome measures will also be further informed by the interview series. Responses to the questionnaire will provide the basis for selecting participants for the interview series (i.e. people perceiving information materials to be important to the decision to participate in CRC screening versus those who do not, positive versus negative perceptions of the information materials).

***5.2.2 Interview series*:** questionnaire respondents will also be asked to participate in an audio-taped, semi-structured interview aimed at identifying patient perceptions of the intervention materials and exploring views of how to enhance patient acceptance of the FOBT procedure. The qualitative series is informed the currently undertaken systematic reviews and will provide valuable patient feedback on the content and presentation of information in the primary care intervention materials. Interview participants will be purposefully selected based on their responses to the questionnaire. 30-40 participants (15-20 per group) are expected to be selected for the face-to-face interviews. Interviews will be transcribed and analysed using qualitative thematic methods that focus on both anticipated and emergent themes[22] and use constant comparison to ensure that all perspectives are included in the explanation of the data. Attention to participant concerns regarding literacy issues, the presentation of risk information and the role of information materials in comparison to advice from a GP or significant others (e.g. family, friends) will be addressed. The phase will contribute to the completion of Objectives 1 and 2.

5.3 Phase 3 - Intervention Study: The first two phases are instrumental for the development of the primary care intervention and contributing to evaluating the role of patient information for improving understanding and compliance with CRC screening. This phase will enable the intervention to be prospectively examined in a representative sample of people invited to the NHS BCSP and to assess important issues (design, recruitment issues, involvement of GPs, utility of outcome measures, etc) for the development of future research in this area. The main aim is to evaluate the effectiveness of the FOBT screening in comparison to people receiving

current information pack. Completion of this phase of the project will meet Objectives 1, 2 and 3.

***5.3.1 Study design*:** A before-and-after questionnaire survey will be employed in the study. Participants will be randomised to receive either the NHS BCSP current information pack (including an invitation letter, evidence-based information booklet, FOBT card with return envelope and brief instruction leaflet for completing the FOBT) or the primary care information pack (including the GP letter and detailed FOBT instruction leaflet). Approximately 800 participants (400 in each group) will be required for the study. Consenting participants will receive the baseline questionnaire (Q1) 7-8 weeks before their invitation to CRC screening. The intervention questionnaire (Q2) will be sent with the NHS BCSP invitation. One reminder questionnaire, at baseline and intervention, will be sent to non-responding participants.

***5.3.2 Questionnaire* outcomes:** The final content of the questionnaire will be informed by the previous stages of research but is expected to include items evaluating:

i. demographic information (age, gender, socio-economic status, education level, ethnicity)
ii. predictors of CRC screening participation: (perceived risk of developing/dying from CRC, family or personal history of CRC, previous participation in CRC screening)
iii. knowledge and attitudes about CRC and CRC screening
iv. information-seeking behaviour (relative importance of GP advice and information materials for decision-making, important information for
v. self-efficacy, anxiety and decisional-conflict (perceived ability to perform the FOBT, anxiety measure.

***5.3.3 Sample*:** People in the general population, aged between 60-69 years, receiving a mailed invitation to participate in the NHS BCSP would be eligible for inclusion in the study. Either participants who accept or decline the invitation to CRC screening are eligible for inclusion. People with a high risk of developing CRC (e.g. HNPCC, FAP, hereditary or previous history of CRC) would be excluded.

***5.3.4 Justification of sample size*:** Based on the UK Bowel Cancer Screening Pilot[8] and a review of reported rates adherence to CRC screening[10], it was estimated that the FOBT participation rate would be approximately 55% in the current information group. 376 participants per group will be required to detect an absolute difference of 10% (assuming a completion rate of 65% in the enhanced information group and 55% in the current information group) at a power of 80% and a two-tailed α of 0.05.

***5.3.5 Analysis*:** Data will be double entered and analysed using SPSS descriptive statistics, t-test (or non-parametric equivalent if unequal sample sizes) and other relevant statistical analysis as required. Multivariate regression modelling will be used to identify predictors of participation and non-participation in the NHS BCSP among study participants.

***5.3.6 Impact for GP resources*:** the impact of the intervention on the workload and resources of GPs will be assessed through an audit of study participant's contact with GPs and primary care staff. Mechanisms and procedures for auditing the frequency of contact and pertinent concerns raised by participants will be developed in consultation with the collaborating GPs. This component of the research has been informed by previous research[23] and is expected to provide valuable information for directing future projects centring on enhancing GP involvement in the NHS BCSP and the potential impact this may have for primary care resources.

***5.3.7 Impact for future research planning*:** The study will provide valuable data to help in the design, conduct and analysis of the larger scale randomised controlled trial of information interventions for CRC screening delivered by the NHS BCSP. The study will provide data on the response rate by specific groups to the study (e.g. ethnic minority groups, people not participating in the NHS BCSP and who are difficult to attract to research studies). Estimates of response rates will be used to structure the recruitment design of the RCT (e.g. stratifying the recruitment process for the randomised study). The study will also provide important data for further investigations of the workload and resource expenditure for GP participation in the NHS BCSP.

6.0 Dissemination of results: The results of the study will be reported to the collaborative group and also presented to the NHS Cancer Screening Programmes, the NHS Bowel Cancer Advisory Group and the NCRI. Three major peer-reviewed publications are expected to be developed from the research and the results will be presented at national and international conferences. Discussions with other academic institutions are also expected to be developed. Recommendations concerning the implementation and further research programme will be addressed with the relevant bodies.

7.0 Time schedule: Below is the time schedule, including importance milestones, for the proposal.

Year	07	2008				2009				2010		
Month	O-D	J-M	A-J	J-S	O-D	J-M	A-J	J-S	O-D	J-M	A-J	J-S
Contract Neg/Start of Award												
Grant Writing/Submissions												
Phase1: Collaboration/Ethics												
Phase 2: Pilot Study/Analysis												
Final Questionnaire/Ethics												
Phase 3: Recruitment												
Phase 3: Analysis												
Report Writing/Final Analysis												
Final Report/Dissemination												
Submission of DPhil												

O-D = October to December, J-M = January to March, A-J = April to June, J-S = July to September

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Appendix 3.1: Primary Care Involvement in Colorectal Cancer Screening: a Systematic Review

1.0 Search Strategy

The search strategy was developed to identify publications relating to the effectiveness of GP's involvement (endorsement letter, written recommendation, face-to-face discussion, etc) in the invitation process for CRC screening. An example (Medline) of the search strategy is shown in Table 1.

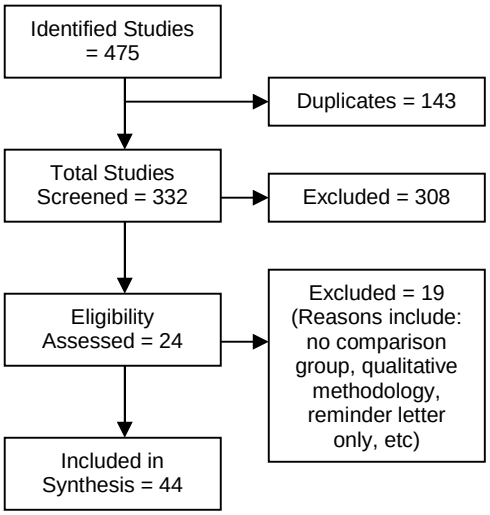
Table 1: Example of the search strategy for the primary care systematic review.

Medline Search Strategy	
1	exp Colorectal Neoplasms/
2	(cancer$ or neoplas$ or tumor$ or tumour$ or adenoma$).ti,ab.
3	(colorectal$ or colon or rectal or rectum or bowel).ti,ab.
4	((cancer$ or neoplas$ or tumor$ or tumour$ or adenoma$) adj3 (colorectal$ or colon or rectal or rectum or bowel)).ti,ab.
5	CRC.ti,ab.
6	1 or 4 or 5
7	exp Mass Screening/
8	exp early diagnosis/
9	(screen$ or prevent$).ti,ab.
10	(earl$ adj3 detect$).ti,ab.
11	7 or 8 or 9 or 10
12	6 and 11
13	(letter$ or invitat$ or invite or support or recommend$ or endorse$ or discuss$ or written$ or counsel$).ti,ab.
14	(practition$ or physician$ or doctor$).ti,ab.
15	(general$ or family or medical).ti,ab.
16	((practition$ or physician$ or doctor$) adj1 (general$ or family or medical)).ti,ab.
17	13 and 16
18	12 and 17

2.0 Results of the Systematic Search

The results of the systematic search are shown in Table 2. There were 475 articles identified from the searches of seven medical databases (Medline, Embase, PsychInfo, British Nursing Index, CINAHL, AMED and the Cochrane Library).

Table 2: Flow diagram for selection of included studies.



Appendix 3.2: Patient Information for Colorectal Cancer Screening: a Systematic Review

1.0 Background

The search strategy was developed to identify publications relating to the provision of CRC screening information materials for patients (booklets, leaflets, audio-visual materials, etc), decision-making for CRC screening and the effects of information for CRC screening (knowledge, awareness, attitudes, etc). An example (Medline) of the search strategy is shown in Table 1.

Table 1: Example of the search strategy for the patient information systematic review.

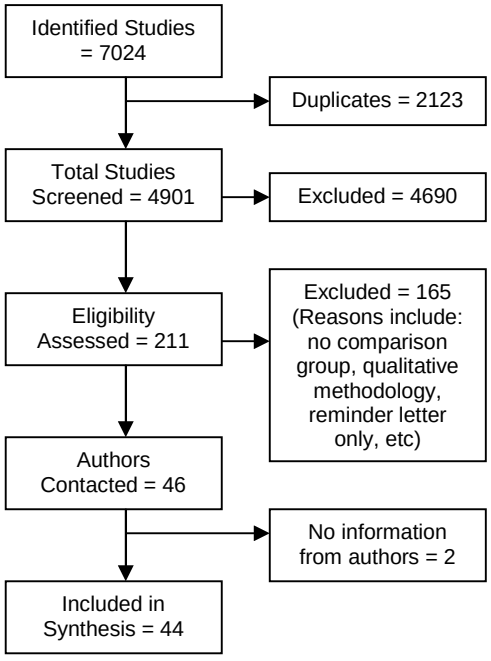
Medline Search Strategy	
1	exp Colorectal Neoplasms/
2	(cancer$ or neoplas$ or tumor$ or tumour$ or adenoma$).ti,ab.
3	(colorectal$ or colon or rectal or rectum or bowel).ti,ab.
4	((cancer$ or neoplas$ or tumor$ or tumour$ or adenoma$) adj3 (colorectal$ or colon or rectal or rectum or bowel)).ti,ab.
5	CRC.ti,ab.
6	1 or 4 or 5
7	exp Mass Screening/
8	exp Early Diagnosis/
9	(screen$ or prevent$).ti,ab.
10	(earl$ adj3 detect$).ti,ab.
11	(earl$ adj1 diagnos$).ti,ab.
12	7 or 8 or 9 or 10 or 11
13	6 and 12
14	exp Decision Theory/ or exp Decision Making, Computer-Assisted/ or exp Decision Making/ or exp Decision Support Techniques/
15	exp Pamphlets/
16	exp Internet/ or exp Health Education/
17	exp Counseling/
18	exp Audiovisual Aids/
19	exp Consumer Health Information/
20	((decision adj3 aid$) or (pamphlet$ or booklet$ or leaflet$ or brochure$ or PIL or handout$ or print$ or written or tape$ or video$ or audio$ or internet or computer$ or visual or multimedia or verbal$ or counsel$)).ti,ab.
21	14 or 15 or 16 or 17 or 18 or 19 or 20
22	exp Knowledge/ or exp Health Knowledge, Attitudes, Practice/
23	exp Attitude to Health/ or Attitude/
24	exp Health Promotion/
25	exp Patient Education Handout/ or exp Patient Education as Topic/
26	exp Informed Consent/
27	exp Consumer Satisfaction/
28	((service$ adj1 user$) or (patient$ or consumer$ or client$ or individual$ or personal$ or

	communit$ or population$ or informed or shared)).ti,ab.
29	(decision$ or informat$ or educat$ or choice$ or prefer$ or priorit$ or value$ or aware$ or understand$ or knowledge or attitude$ or belief$ or consent).ti,ab.
30	(((service$ adj1 user$) or (patient$ or consumer$ or client$ or individual$ or personal$ or communit$ or population$ or informed or shared)) adj3 (decision$ or informat$ or educat$ or choice$ or prefer$ or priorit$ or value$ or aware$ or understand$ or knowledge or attitude$ or belief$ or consent)).ti,ab.
31	22 or 23 or 24 or 25 or 26 or 27 or 30
32	21 or 31
33	13 and 32

2.0 Methods

The results of the systematic search are shown in Table 2. There were 475 articles identified from the searches of seven medical databases (Medline, Embase, PsychInfo, British Nursing Index, CINAHL, AMED and the Cochrane Library).

Table 2: Flow diagram for selection of included studies.



Appendix 4.1: Draft GP Leaflet

GP Letterhead

Supporting Bowel Cancer Screening

Dear [*Participants Name*],

We are writing to you to express our support for the NHS Bowel Cancer Screening Programme. Bowel cancer is one of the most common forms of cancer in the UK. Most people diagnosed with bowel cancer are over 60 years old. Screening aims to detect bowel cancer at an early stage, in people with no symptoms, when treatment is more likely to be effective.

As a Practice, we strongly recommend you complete the screening kit enclosed in this pack. If you have any questions, or would like more information about screening for bowel cancer you can contact the Programme Hub on Freephone 0800 707 60 60. However, if you have any specific concerns, or are worried about bowel symptoms, and would prefer to speak to someone at this Practice in confidence, please feel free to contact us.

It is also very important that you are aware of the symptoms of bowel cancer. The most common symptoms to look out for are:

- a persistent change in bowel habit, especially going to the toilet more often or diarrhoea
- bleeding from the back passage without any obvious reason or blood in your bowel motions
- abdominal pain, especially if it is severe
- a lump in your abdomen

Most of these symptoms will not be cancer. However, if you have experienced one or more of these symptoms for more than four weeks you should contact us as soon as possible.

Yours sincerely,

Appendix 4.2: Stakeholder Detailed Procedural Leaflet (prior to changes)

Before You Begin

Please carefully read the instruction leaflet that came with your kit before you begin. The test can detect tiny amounts of blood that you can not see in your bowel motions. This is why you are asked to take samples of your bowel motions in the privacy of your home. You will need the following

- the kit – open one flap for each bowel motion
- a pen – to write your name and the date on the kit flap
- two cardboard sticks – that are found in the kit
- what you have chosen to use to collect your sample (see 'Tips for Collecting Your Sample' below)

You will need to visit the toilet three (3) times to complete the test. If you keep everything within reach of the toilet it will be easier to do the test.

Tips for Collecting Your Sample

There are a number of easy ways to make sure that collecting your sample is not too messy or unpleasant. Many people have said that it is no worse than changing their children's nappies. Take a moment to think about which way would suit you best from the following suggestions:

- fold several pieces of toilet paper over your hand and catch part of your bowel motion before it goes in the toilet water
- a plastic or latex glove with the folded toilet paper (like the gloves used in home hair dying/colouring products)
- wrap a small plastic bag around your hand (you can also use this to dispose of the cardboard sticks in an outside bin)
- use a small plastic container that you can firmly hold or safely rest in the toilet bowl. A clean plastic take-away container or something similar is fine. Covering the container with several pieces of toilet paper will make it easier to dispose of the bowel motion and clean the container
- cling film loosely draped over the toilet bowl and held in place by the toilet seat

For people with loose bowel motions or diarrhoea:
You can still do the test. Having loose bowel motions will not affect the test result. It may be best to use a container if you have loose bowel motions.

For people who have irregular bowel motions:
Constipation is a common condition, with about 1 in 8 people in the UK experiencing the problem. It may take a little longer to collect your three samples, but you can still do the test. After taking your first sample, you still have 14 days to return the kit.

Storing Your Sample

You will need to keep your kit in a handy place near your toilet. Please remember to keep the kit away from direct sunlight or heat. Although the kit is unlikely to have an overpowering smell, you can:

- put the kit in an envelope
- keep the kit in a container with a lid

Returning Your Kit

You have 14 days after taking your first sample to return the kit to the Screening Centre. If at all possible, try to post the kit earlier in the week as kits will not be tested on weekends. The hygienic envelope is completely safe to send in the post.

Any Questions?

If you have any questions about the kit or bowel cancer screening then you can call:

Freephone - 0800 707 60 60

All calls are taken by Screening Centre staff and are dealt with in the strictest confidence. Please do not feel embarrassed to ask for more information or advice.

Keep an Eye on Symptoms

Although screening can improve your chances of detecting bowel cancer, it is very important to keep an eye out for any of the following symptoms:

- a persistent change in bowel habit, especially going to the toilet more often or diarrhoea for several weeks;
- bleeding from the back passage without any obvious reason
- abdominal pain, especially if it is severe
- a lump in your abdomen

Please see your GP if you develop any of these symptoms.

Helping You with the Test

Tips and Advice on How to Collect, Store and Return Your Bowel Cancer Screening Kit

Can I Do the Test?

Some people think they may not be able to do the test because:

- they don't think that they are at risk of bowel cancer
- they are not sure how to collect their three (3) samples
- they think that doing the test will be too messy
- they loose bowel motions or persistent diarrhoea
- they are constipated or have irregular bowel motions
- they think that it will take too long
- they are not sure how to store the kit

If you see yourself as one of these people, then this leaflet will give you advice and easy-to-follow suggestions on how you can complete the NHS Bowel Cancer Screening kit.

Important Facts about Bowel Cancer

Bowel cancer is the second leading cause of cancer deaths in the UK (more than breast or prostate cancer). Eight out of 10 people who are diagnosed with bowel cancer are aged over 60. Both men and women are at risk of developing bowel cancer. Returning your completed kit reduces your chances of dying from bowel cancer. It may also lead to bowel polyps being detected before they develop into bowel cancer.

Appendix 4.3: Invitation to Stakeholders

University of Oxford

Cancer Research UK
Primary Care Education Research Group

Department of Primary Health Care

Old Road Campus, Headington, Oxford OX3 7LF, UK	*Tel:* +44 (0)1865 226788 *Fax:* +44 (0)1865 226784
Director: Joan Austoker	*E-mail:* crcpcerg@dphpc.ox.ac.uk

Evaluating Informed Choice in Bowel Cancer Screening: Proposed Research Programme

The **NHS Cancer Screening Programmes** has adopted the position that people who are invited to screening should be offered the choice whether or not to participate and that each person should appreciate the benefits and risks of the screening programme for them as an individual. In an effort to facilitate an **informed choice** for people invited to national **Bowel Cancer Screening Programme**, a high-quality, evidence-based booklet (*Bowel Cancer Screening: The Facts*) has recently been developed by the Cancer Research UK – Primary Care Education Research Group. The proposed research programme aims to explore and evaluate the role of informed choice in bowel cancer screening decisions.

Purpose of Research

The main purpose of this research is to improve the understanding of the role that informed choice has in cancer screening decisions. It is anticipated that this work will further refine the provision of high-quality patient information by the NHS Cancer Screening Programmes and will form the basis for future research in both the Breast and Cervical Screening Programmes.

Rationale for Research

There is a paucity of empirical research that has been undertaken to explore the type information people invited to cancer screening want in order to be 'informed', or indeed, the role that information materials have for patient decision-making in cancer screening. This programme of research forms part of NHS Cancer Screening Programmes continuing objective to improve information services to the public through the evaluation of patient materials such as *Bowel Cancer Screening: The Facts*, and further, will build on the previous work conducted for the UK Colorectal Cancer Screening Pilot and by the CRUK – Primary Care Education Research group concerning informed choice in cancer screening.

Proposed Research Programme

The proposed programme of research was developed in consultation with the NHS Cancer Screening Programmes. Developing a programme of research, specifically evaluating how people are using cancer screening information materials to facilitate an informed choice, requires a consideration of the broader factors associated with people's perceptions of cancer and screening, patient decision-making and current conceptions of what constitutes high-quality patient information. To this end, this programme of research aims to incorporate the views of patients, health professionals and other key stakeholders to determine:

a) the type of information required for a patient to be considered 'informed'
b) the role and importance of patient information in bowel cancer screening decisions/choices
c) the utility of providing 'enhanced' (e.g. computerised decision-aid) patient information for bowel cancer screening decisions/choices

The culmination of the research programme will be the development of a set of consensus based criteria to evaluate the quality of bowel cancer screening information materials. The research programme is divided into two stages:

i. ***Pilot research*****:** the development and validation of outcome measures (e.g. knowledge scale) for inclusion in the randomised controlled trial and for use in other research studies
ii. ***Randomise controlled trial*****:** comparing 'The Facts' booklet to enhanced patient information (e.g. computerised patient decision-aid)

Requirements for Stakeholders

Understandably, the time and investment of stakeholder participants will be kept to a minimum. Stakeholders would be asked to provide their views on the piloted outcome measures (specifically the development of the knowledge scale) and participate in a semi-structured interview regarding their views on the role of patient information for facilitating informed choice in cancer screening. Meetings for the formal consensus group will be held to a minimum (anticipating four meetings), with the structure and format to be resolved with participants.

Funding for Research

The funding for this research programme will be based on a project grant application (3 years) being submitted to Cancer Research UK.

Related Research Projects

A number of related research projects are also planned for evaluating patient and health professional perceptions and experiences of the bowel screening programme and the colonoscopy investigation. These projects will be developed further in the near future.

Further information

For more information concerning the proposed programme of research please see "Further Information – Details of Study Protocol" (attached) or if you have any comments or queries, please contact Paul Hewitson (address and details below). Thank you for your time.

Kind regards,

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Appendix 4.4: Summary of Stakeholder Responses

The following appendix summarises stakeholder group comments on the draft detailed procedural leaflet (conducted as part of the first phase of the research programme). Overall, stakeholder group members were very positive about the leaflet. However, there were a number of comments regarding specific parts of the leaflet that were required modification (see Table A) prior to the pilot evaluation. After making these changes, the representatives viewed the draft procedural leaflet for further advice, although no changes were suggested. One charity group provided only very limited comments of the leaflet, indicating they felt the current directions for use leaflet was sufficient, that people should be strongly encouraged to participate in screening (reduce or remove all negative information) and that including extra information would only lead to confusion for participants.

The majority of stakeholder group representatives did not feel that it was appropriate for them to comment on the content of the GP endorsement letter. Instead, they indicated that the GP representatives on the stakeholder group and the GPs recruited to the trial would be best placed to make any comments.

Table A: Summary of comments from stakeholder groups members concerning modifications to leaflet.

Section of Leaflet	Summary of Comments	Modification after Comments
Title: "Helping You with the Test"	Several suggested changes for title; consistent comment that needs to be shorter	Changed to "Help with the Test"
Subtitle	No comments	No changes
"Who is the leaflet for" section	Consistent comments to change title of section; majority requested less formal statements	Change of title to "Should I do the test?"; Significant change of text (simplify opening sentence; removal third-person pronoun 'they'); removed 'store kit' sentence
Reinforcing severity of CRC section ("Important Facts About Bowel Cancer")	Change title of section; criticisms included 'too wordy' (format too dense for readers, difficult to follow). Several comments that section lacked overall point (attempt to cover too many topics)	Change title to "Returning you screening kit can:"; Significant changes to format (use of bullet points) and removal of two lines of text; emphasised reducing risk from developing CRC through participation
"Before you begin" section	Consistent comments that this section was repeating information included in the 'directions for use' leaflet provided with the kit.	Removal of section; modified to reinforce rationale for person being invited to screening and how FOBT detects CRC
Addressing general barriers section ("Tips for collecting your sample")	Number of comments on the content of information; criticisms include too detailed and too much information Minor comments concerning the use of cling-film as an option for collection	Section significantly changed; split into two sections (addressing 'time' and 'procedural' barriers separately); significant change in wording (underlining options and removal of use of cling-film for collection)
Addressing specific barriers section (for people with diarrhoea or constipation)	No major comments; two members suggested changes to wording for one section	Minor modification to wording for 'constipation' section
Storing sample section	Minor comments regarding wording of section	Minor changes to wording
Returning your kit section	No comments	No changes
Further information section ("Any questions?")	One comment concerning changing wording to improve clarity	Minor change to sentence concerning Screening Hub staff
Awareness of symptoms section ("Keep an eye on symptoms")	Majority suggested this is a very important section to include	No changes

Appendix 4.5: Pilot Detailed Procedural Leaflet

Why are bowel motions tested?

The NHS Bowel Cancer Screening programme sends everyone aged 60-69 a faecal occult blood test (called the kit) every two years. "Occult" means "hidden" and the kit can detect traces of blood that you normally can not see in your bowel motions. Blood in your bowel motions can be caused by many things – it does not always mean that you have bowel cancer.

You will need to take a sample of your bowel motion on three (3) separate visits to the toilet. If you keep everything you need within reach of the toilet, it will be easier to do the test.

"It will take too much time"

Collecting a sample of your bowel motion should only take a minute or two of your time. Make sure you have everything you need to do the kit within easy reach when you are sitting on the toilet, this should make it even quicker. As well as your kit, you will need a pen and whatever you choose to use to collect your sample.

"It will be too messy"

There are a number of easy ways to make sure that collecting your sample is not too messy or unpleasant. Take a moment to think about which way would suit you best from the following ways:

- fold several pieces of toilet paper over your hand and catch part of your bowel motion before it goes in the toilet water
- a plastic or rubber glove with the folded toilet paper (you can get these from a chemist or supermarket)
- wrap a small plastic bag around your hand (you can also use this to dispose of the cardboard sticks in an outside bin)
- use a small plastic container that you can firmly hold or safely rest in the toilet bowl. A clean plastic take-away container or something similar is fine. Covering the container with several pieces of toilet paper will make it easier to dispose of the bowel motion and clean the container

For people with loose bowel motions or diarrhoea:
You can still do the test. Having loose bowel motions will not affect the test result. It may be easier to use a container to collect you samples if you have loose bowel motions.

For people who have irregular bowel movements:
Constipation is common; it affects about 1 in 8 people. It may take a little longer to collect your three samples, but you can still do the test. After taking your first sample, you still have 14 days to take two more samples and return the kit.

Storing Your Sample

It is a good idea to keep your kit in a handy place near your toilet. You will need to keep your kit in a handy place near your toilet. Please remember to keep the kit away from direct sunlight or heat. Although the kit is unlikely to smell, you can:

- put the kit in an envelope
- keep the kit in a container with a lid

Returning Your Kit

You have 14 days after taking your first sample to return the kit to the Screening Centre. If at all possible, try to post the kit earlier in the week as kits are not tested on weekends. The hygienic envelope is completely safe to send in the post.

Any Questions?

If you have any questions about the kit or bowel cancer screening then you can call:

Freephone - 0800 707 60 60

All calls are answered by trained staff and are dealt with in the strictest confidence. Please do not feel embarrassed to ask for more information or advice.

Keep an Eye on Symptoms

Although screening can improve your chances of detecting bowel cancer, it is very important to keep an eye out for any of the following symptoms:

- a persistent change in bowel habit, especially going to the toilet more often or diarrhoea for several weeks;
- bleeding from the back passage without any obvious reason
- abdominal pain, especially if it is severe
- a lump in your abdomen

Please see your GP if you develop any of these symptoms.

Help with the Test

Tips and Advice on How to Collect, Store and Return Your Bowel Cancer Screening Kit

Should I Do the Test?

This leaflet is for people who:

- don't think they are at risk of bowel cancer
- not quite sure how to collect their three (3) samples
- think that it will take too much time
- think that it will be too messy
- suffer from constipation or loose bowel motions
- are a bit embarrassed to ask for help

If you see yourself as one of these people, then this leaflet will give you advice and easy-to-follow suggestions on how you can complete the NHS Bowel Cancer Screening kit.

Returning your screening kit can:

- reduce your risk of dying from bowel cancer
- increase the chance of detecting a bowel polyp before it develops into bowel cancer

Bowel cancer is the second leading cause of cancer deaths in the UK (more than breast or prostate cancer). Eight out of 10 people who are diagnosed with bowel cancer are aged over 60. Both men and women are at risk of developing bowel cancer.

Appendix 5.1: Protocol for the Pilot Study

Public Perceptions of the NHS Bowel Cancer Screening Programme: A Pilot Study (Version 1: 02/04/2008)

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1.0 Purpose of Research

This study aims to:

- evaluate and refine the content and format of a detailed information leaflet designed to help people overcome procedural barriers to completing the faecal occult blood test (FOBT)
- to investigate the utility of specific questionnaire outcome measures for the UK population
- one-year pilot study (postal questionnaire survey and qualitative interview series)

2.0 Background

Bowel cancer is a leading cause of mortality and morbidity in the western world. It is the second leading cause of cancer death in Europe[1] and the United States[2]. Survival rates for people diagnosed with bowel cancer are somewhat higher in the US than Europe, although this difference is mostly attributed to differences in the stage of diagnosis[3]. Screening aims to reduce mortality in the target population by identifying cancer at an early stage when treatments are more likely to be effective. For average risk populations, substantial evidence from a recent systematic review[4] of published randomised controlled trials [5-7] has indicated that screening using the faecal occult blood test (FOBT) can significantly reduce bowel cancer mortality.

Following the success of the UK Bowel Cancer Screening Pilot[8], the NHS Bowel Cancer Screening Programme (NHS BCSP) was introduced in Spring 2006[9]. Men and women aged 60-69 years receive a mailed invitation pack that includes an invitation letter, an evidence-based information booklet about bowel cancer screening, the FOBT kit with return envelope and brief instruction leaflet for completing the test. However, there are concerns for the uptake of bowel cancer screening in the population. The overall adherence to bowel cancer screening is generally poor, with approximately 55% of people participating in UK studies[5,8], which is slightly higher than other countries[4,10]. The development and evaluation of feasible and cost-effective interventions that can increase patient acceptance and participation are crucial to the success of an effective bowel cancer screening programme.

Patient knowledge of the availability and benefits of bowel cancer screening, underestimating the risks of developing bowel cancer, lack of interest in testing without symptoms, and patient concerns about their ability to complete FOBT coupled with negative perceptions of the FOBT procedure have been forwarded as contributing to poor compliance[10-12]. Several studies have demonstrated that providing patients with more detailed instructions on the collection, storage

and return of FOBT can modestly increase patient compliance with FOBT[13,14]. However, these studies did not measure patient-specific outcomes (e.g. knowledge, self-efficacy, decision-making) or attempted to evaluate patient perceptions of the information materials (e.g. how the materials affected decision-making). Indeed, a recent systematic review of forty-four published articles concerning information provision for decision-making in bowel cancer screening[15] found some evidence to support an increase in participation in screening, although there was a great diversity in the type of outcomes measured by the studies and the type of information provided to participants (verbal, brief leaflets, comprehensive written booklets, video, computerised decision-aids). Although the current research suggests that patient information materials may be able to increase participation in bowel cancer screening, there is very little available research investigating how people's perceptions of the materials affect their decision to participate or have evaluated patient-specific outcomes in their research.

Recent research has indicated that there is some degree of variation in the type of information favoured by people when making a decision about whether or not to participate in bowel cancer screening[16,17]. Specifically, concerns have been raised in regards to the type of information included in the current NHS BCSP information booklet and the perceived lack of information about the procedural aspects of performing FOBT (e.g. collecting, storing and returning FOBT) that may affect people's interest or perceived ability to participate in bowel cancer screening. The present study will evaluate and refine the content and format of a detailed information leaflet designed to help people overcome procedural barriers to completing FOBT, assess people's perceptions of the current NHS BCSP information booklet and investigate the utility of specific questionnaire outcome measures (knowledge, self-determination) for the UK population. It is expected that the results of the pilot research will be used to improve the provision of information for the NHS BCSP and to provide patient-based outcome measures that will be used in future planned research.

2.1 Theoretical Framework

The theoretical framework of the study is centred on a synthesis of basic research on how people process health information combined with the development and evaluation of theory-based interventions to promote healthy behaviour. The research project is influenced by recent work by Rothman and colleagues[18,19], which emphasises the role of patient information materials in initiating changes in health behaviour, and self-determination theory[20,21]. Self-determination theory suggests that the more autonomously motivated a behaviour is, the more likely an individual will engage and maintain this behaviour[20,21]. The research also draws heavily on behavioural theory, specifically concerning social cognitive approaches[22] to evaluate people's perceived self-efficacy for participating in bowel cancer screening. Although we have included outcomes in the proposal that are firmly based in behavioural theory (e.g. self-efficacy, intention to participate, perceived risk, knowledge and attitudes towards bowel cancer screening), we are cognisant of difficulties encountered when limiting cancer screening research to one particular theoretical approach, such as the difficulties encountered with the Health Belief Model (HBM) and the Transtheoretical Model (TTM) in this field of research[23,24]. The current research will attempt to incorporate the traditional methods of behavioural research with more recently developed frameworks in an attempt to reconcile the reasons for people's participation and non-participation in bowel cancer screening and the effectiveness that information can have for improving participation in bowel cancer screening.

2.2 MRC Framework

The structure of the design and methodology of the research programme was based on the MRC framework[25,26], with particularly attention to theoretical phase (Pre-Clinical) and the modelling phase (Phase 1). The theoretical basis for the study was developed from an extensive systematic review of the literature concerning patient information for bowel cancer screening[15] and built on previous qualitative research conducted by the Department[16,27]. Together with the pilot research phase of the study (aiming to refine the outcome measures and clarify modelling issues), satisfying the pre-clinical and first phase of the framework[25-26].

3.0 Detailed Information Leaflet

The primary aims of the pilot study are to develop and refine a detailed information leaflet to provide advice for people for completing FOBT and to explore people's perceptions of bowel cancer and information for bowel cancer screening. The detailed information leaflet aims to provide advice and suggestions to people invited to the NHS BCSP for overcoming the procedural barriers to completing FOBT. The leaflet was based on research conducted during the development of the current NHS BCSP patient information materials. This research included a systematic review of current research concerning patient information for bowel cancer screening[15] and a large-scale focus group study that aimed to explore UK public perceptions of information for bowel cancer screening[16].

The detailed information leaflet was developed and refined with advice and support from patient advocacy and health professionals, who will continue to be involved in the 3-year project as key stakeholder representatives. These included Mrs Christine Gratus (NCRI Consumer Liaison Group), Mrs Diane McCloud (Research Nurse, bowel cancer survivor), patient advocacy group representatives (Bowel Cancer UK, Beating Bowel Cancer), cancer screening experts (Dr Joan Austoker, Dr Clare Bankhead), NHS BCSP staff (Director and Senior Administrator for the South of England Screening Hub), NHS National Cancer Screening Programme representatives (Director Mrs Julietta Patnick and Informed Choice Co-ordinator Ms TJ Day), General Practitioners (Prof Paul Glasziou, Prof David Mant) and a representative of the Department of Health Cancer Policy Team (Mr Tim Elliott).

4.0 Research Plan

The main aims of the pilot study are to evaluate and refine the content and format of the detailed information leaflet and to investigate the utility of the questionnaire outcome measures for use in the future planned research. The research design and methodology has been reviewed by the CI's DPhil supervisors, the Department of Primary Health Care internal research advisory panel, the NHS Cancer Screening Programme and during the NIHR Research Training Fellowship application process (involving two rounds of external reviews and a panel interview). The recruitment of participants has been organised with the assistance of the NHS BCSP Southern Programme Hub. The study is funded by the National Institute for Health Research and the NHS Cancer Screening Programmes. There are two main components of the pilot study. These are:

i. Postal questionnaire study
ii. Interview series

4.1 Postal Questionnaire Survey

The postal questionnaire survey will evaluate people's views towards the detailed patient information leaflet and the current NHS BCSP patient information materials. The pilot questionnaire will also develop and assess pertinent outcome measures that form the theoretical basis of the research (knowledge scale, self-efficacy, self-determination scale).

4.1.1 Sample Population and Recruitment

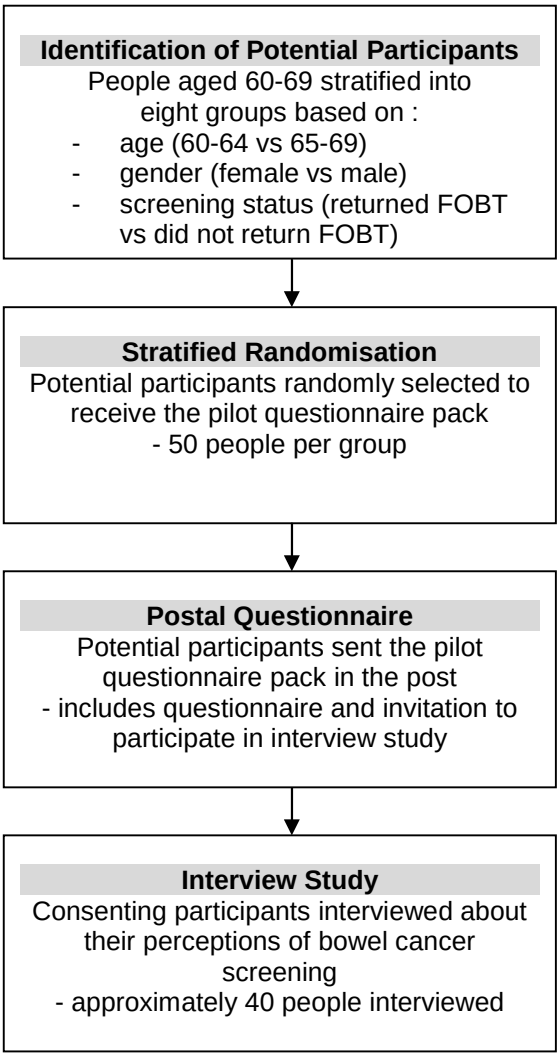
The recruitment method for the pilot study is designed to include a representative sample of people invited to screening and also inform future planned research. The method was devised after extensive consultation with the NHS BCSP staff at the South of England Programme Hub. Potential participants will be stratified into eight groups based on gender (male vs female), age (60-64 vs 65-69) and participation status (returned FOBT vs did not return FOBT). A computer generated method of randomisation will be used in each of the eight stratified groups to select potential participants for the pilot study.

4.1.2 Study Design

Four hundred people who have been selected for inclusion in the study will receive a mailed questionnaire pack which will include an invitation letter, participant study information sheet, consent form, request for information sheet, questionnaire and pre-paid return envelope. The questionnaire pack will also include the NHS BCSP patient information booklet ("Bowel Cancer

Screening: The Facts") and the detailed patient leaflet. A reminder letter, including the above, will be sent to potential participants who have not returned their questionnaire with consent form within two weeks (please see Figure 1).

Figure 1: Flow diagram of the pilot study.



4.1.3 Questionnaire outcomes

The pilot questionnaire will include the following items evaluating:

i. demographic information (age, gender, education level, ethnicity)
ii. predictors of participation: (perceived risk of developing/dying from bowel cancer, family or personal history of bowel cancer, previous participation in bowel cancer screening)
iii. patient satisfaction with information materials ('Bowel Cancer Screening: The Facts' and the detailed information leaflet)
iv. information-seeking behaviour (relative importance of GP advice and information materials for decision-making)
v. knowledge scale (bowel cancer and bowel cancer screening)
vi. self-efficacy (perceived ability to perform the FOBT)
vii. bowel cancer screening attitudes scale
viii. self-determination (Treatment Self-Regulation Questionnaire)

4.1.4 Development of Questionnaire Scales

The development of the knowledge scale was based on a review of previous published research[15, 28, 29] and responses from focus group members during the evaluation of the current information materials used by the NHS BCSP[27]. The development of the knowledge scale is

based on similar procedures used previously by the investigators for a randomised trial of information for PSA testing for prostate cancer[30]. Reader comprehension of the items in the scale was evaluated using a convenience sample of health professionals and representatives of the key stakeholder group. The Treatment Self-Regulation Questionnaire the bowel cancer attitudes scale is a validated scale that has been used in previous research[31-32]. The attitudes scale is also a validated measure that has been used in UK-based research[29].

4.1.5 Sample Size

The number of participants is based on the number of people required to validate the questionnaire scales (knowledge, Treatment Self-Regulation Questionnaire) as a function of the estimated response rate to the questionnaire. The proposed psychometric analyses require a ratio of approximately five times as many respondents as there are items, although a ratio of 10 respondents per item is considered[33-34]. The Treatment Self-Regulation Questionnaire includes 15 items and the finalised version of the knowledge scale is expected to include 8 to 12 items. This means that a minimum of 75 participants would be required for the pilot study. Based on an estimated response rate to the questionnaire of 50%, this would mean that 200 participants would be enrolled in the study (or 50 participants more than required for the analysis).

4.1.6 Analysis

Data will be double entered and analysed using SPSS descriptive statistics, t-test (or non-parametric equivalent if unequal sample sizes) and other relevant statistical analysis as required. Data will be analysed using descriptive statistics, t-test (or non-parametric equivalent if unequal sample sizes) and other relevant comparative analyses as required. Item analysis will be used to evaluate (included evaluating inter-correlations of items, item difficulty, item discriminability). Internal reliability for the scales will calculated using either the alpha co-efficient (for the self-determination scale, attitudes scale) or the KR-20 statistic for the knowledge scale (alpha co-efficient for dichotomous data).

4.2 Interview Study

The interviews will explore participant's perceptions of completing FOBT and their views on the detailed information leaflet (specifically on ways the leaflet may be improved). The interviews will also explore wider issues concerning people's understanding of bowel cancer and bowel cancer screening, the facilitators and barriers for bowel cancer screening, and determine the external validity of the outcome measures used in the questionnaire.

4.2.1 Sample Population and Recruitment

Recruitment for the interview component of the study is based on the participant returning their request for further information sheet. Forty people who have indicated their interest in taking part in the interview study will be sent an interview invitation letter, an interview study information sheet and an interview consent form. Maximum variation sampling will be used in selection of people for the qualitative component of the pilot study, based on the participant's age (60-64 versus 65-69) and responses to the questionnaire (knowledge, self-efficacy and self-determination scales).

4.2.2 Study Design and Analysis

Interviews will be conducted at a convenient place and time for the participants and last between 30 minutes and one hour (participants will also be offered the opportunity to complete the interviews by telephone). Participants will need to sign a second consent form indicating that they have read and understood the interview information sheet, understand that the interviews will be recorded and that no personal identifiers will be used in the reporting of the study. Interviews will be transcribed and analysed using qualitative thematic methods that focus on both anticipated and emergent themes[35-36] and use constant comparison to ensure that all perspectives are included in the explanation of the data. Interviews will continue until no new themes emerge (i.e. data saturation). Data will be managed using the Atlas.ti software.

The interviews will concentrate on people's perceptions of completing FOBT and their views on the detailed information leaflet (specifically on ways this leaflet may be improved). The interviews will also explore wider issues concerning people's understanding of bowel cancer

and bowel cancer screening, what information may be important for them to make a decision to participate or not in screening and what other influences are important to decision-making (e.g. views of family members, advice from GPs, etc). The interviews will also provide face and content validity for the outcome measures (knowledge, self-efficacy, self-determination) included in the pilot questionnaire. Attention to participant concerns regarding literacy issues, the presentation of risk information and the role of information materials in comparison to advice from a GP or significant others (e.g. family, friends) will also be addressed.

5.0 Dissemination of Results

The detailed information leaflet will be further refined after the completion of the pilot study. Results of the pilot study (both questionnaire and qualitative interviews) will be reported to members of the key stakeholder group. A formal meeting will be arranged to enable further discussion of the format and content of the intervention materials based on the results of the pilot study. A peer-reviewed publication is expected to be developed from the research and the results will be presented at national and international conferences.

6.0 Timeline

	Year 1 - 2008						Year 2 - 2009					
Task	**Jan Feb**	**Mar Apr**	**May Jun**	**July Aug**	**Sep Oct**	**Nov Dec**	**Jan Feb**	**Mar Apr**	**May Jun**	**July Aug**	**Sep Oct**	**Nov Dec**
P1: Initial development of materials												
P2: Ethics application/submission												
P2: Pilot recruitment/mail-out												
P2: Pilot data entry and analysis												
P2: Pilot interviews and analysis												
P2: Final report/stakeholder discuss												
P2: Refine materials/questionnaire												
P2: Dissemination/stakeholder mtng												

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Appendix 7.7: Pilot Questionnaire

Questionnaire number

Information for Bowel Cancer Screening

Public Perceptions of Bowel Cancer Screening

– Your views –

Thank you for agreeing to take part in this study. This questionnaire is about people's views concerning information for the NHS Bowel Cancer Screening Programme and what people understand about bowel cancer screening.

Enclosed is a leaflet *"Help with the Test"* information booklet *"Bowel Cancer Screening: The Facts"*, questionnaire and FREEPOST envelope. **Please read the 'Help with the Test' leaflet <u>before</u> completing the questionnaire.** Although you would have received the information booklet *"Bowel Cancer Screening: The Facts"* when you were invited to screening, please look through the booklet before completing the questionnaire. After you have completed the questionnaire, please return it to us in the FREEPOST envelope provided.

Please tick [√] the appropriate responses to questions or write the answers in the space provided.

It would be very helpful to us if you could try to complete all the questions. For many of the questions we are asking for your opinion. There is no right or wrong answer to these questions. For other questions you simply may not know the answer. If so, please tick the 'not sure' or 'don't know' box.

All the information you give will be treated as <u>strictly confidential</u>.

Thank you very much for your help.

If you have any questions please contact Paul Hewitson at:

Department of Primary Health Care
University of Oxford
Old Road Campus
Old Road, Headington, Oxford, OX3 7LF
Tel: 01865 289359

Section A. Background

1. Were you aware that the NHS had introduced a Bowel Cancer Screening Programme before you received your invitation?
- ☐ Yes
- ☐ No

2. Have you ever completed a faecal occult blood (FOB) test before you received your invitation to the NHS Bowel Cancer Screening Programme?
- ☐ Yes
- ☐ No
- ☐ Don't know

3. Did you complete and return the faecal occult blood (FOB) test that you received from the NHS Bowel Cancer Screening Programme?
- ☐ Yes
- ☐ No
- ☐ Not yet

4. Have you ever discussed testing for bowel cancer with your GP?
- ☐ Yes
- ☐ No
- ☐ Don't remember

5. In the last 10 years, have you ever had a colonoscopy examination? **(explain)**
- ☐ Yes
- ☐ No
- ☐ Don't remember

6. Have you ever been diagnosed with bowel cancer?
- ☐ Yes
- ☐ No

7. Has your mother/father/brother/sister ever been diagnosed with bowel cancer?
- ☐ Yes
- ☐ No
- ☐ Don't know

8. Have any of your other close relatives or friends been diagnosed with bowel cancer?
- ☐ Yes
- ☐ No
- ☐ Don't know

9. How likely do you think it is that you will develop bowel cancer at some point in the near future?
- ☐ Definitely will
- ☐ Very likely
- ☐ As likely as not
- ☐ Not very likely
- ☐ Definitely will not

10. Compared to other people like you, do you think that your own chances of getting bowel cancer at some point in your life are…
- ☐ Much less
- ☐ A little less
- ☐ About the same
- ☐ A little more
- ☐ Much more

Section A: *Continued*

11. In your opinion, how convinced are you about the benefits of bowel cancer screening?

- ☐ Completely convinced
- ☐ Very convinced
- ☐ Slightly convinced
- ☐ Not convinced at all

12. Compared to other decisions you make about your health, how important is the decision to participate in bowel cancer screening?

- ☐ Extremely important
- ☐ Very important
- ☐ Slightly important
- ☐ Not important at all

13. How worried are you that you could be diagnosed with bowel cancer?

- ☐ Very worried
- ☐ Moderately worried
- ☐ Slightly worried
- ☐ Not worried at all

14. What would be (or was) the <u>main</u> reason you would consider doing the bowel cancer screening test?

(please tick only one box)

- ☐ Symptoms
- ☐ Family history
- ☐ GP recommendation
- ☐ Peace of mind
- ☐ Family member's advice

15. Is it embarrassing for you to talk to your GP about bowel cancer screening?

- ☐ Extremely embarrassing
- ☐ Very embarrassing
- ☐ Slightly embarrassing
- ☐ Not embarrassing at all

16. Is it embarrassing for you to talk to your family or friends about bowel cancer screening?

- ☐ Extremely embarrassing
- ☐ Very embarrassing
- ☐ Slightly embarrassing
- ☐ Not embarrassing at all

17. How difficult would it be (or was it) for you to collect your sample for bowel cancer screening?

- ☐ Extremely difficult
- ☐ Very difficult
- ☐ Slightly difficult
- ☐ Not difficult at all

18. If asked to do bowel cancer screening in the future, how confident are you that you can complete the faecal occult blood test?

- ☐ Very confident
- ☐ Somewhat confident
- ☐ Slightly confident
- ☐ Not confident at all

Section B: Your views on the Leaflet

19). The following questions are about the enclosed information leaflet **'Help with the Test'**. Please make sure you have read through the information leaflet before answering the following questions.

a. Do you think that the leaflet would be useful for you to complete bowel cancer screening?

- ☐ Yes, very useful
- ☐ Yes, somewhat useful
- ☐ No, not really useful
- ☐ Not useful at all

b. How did you feel about the level of detail in the information booklet?

- ☐ Too much detail
- ☐ About the right amount of detail
- ☐ Not enough detail

c. How did you find the way the information leaflet was written?

- ☐ Easy to read
- ☐ Slightly difficult to understand
- ☐ Very difficult to understand
- ☐ I did not understand the information

d. Did you find the suggestions for collecting your sample useful?

- ☐ Yes, very useful
- ☐ Yes, somewhat useful
- ☐ No, not really useful
- ☐ Not useful at all

e. Did you find the suggestions for storing your sample useful?

- ☐ Yes, very useful
- ☐ Yes, somewhat useful
- ☐ No, not really useful
- ☐ Not useful at all

f. Having read through this leaflet, how has it influenced your views about bowel cancer screening?

- ☐ I am more positive about screening
- ☐ My views have not changed
- ☐ I am more negative about screening
- ☐ Not sure

h. Are there any aspects of the design or the layout of the leaflet that you think could be changed?

- ☐ Yes
- ☐ No
- ☐ Not sure

If yes, what other information would you like? _____

_____

i. Would you like any other information that is not included in the leaflet?

- ☐ Yes
- ☐ No
- ☐ Not sure

If yes, what other information would you like? _____

_____

Section C: Your views about the Booklet

20). The following questions are about the enclosed information NHS booklet **'Bowel Cancer Screening: The Facts'**. Please try to read through the information booklet before answering the following questions.

a. How much of the information booklet did you read?

- ☐ All of the information booklet
- ☐ Most of the information booklet
- ☐ A little of the information booklet
- ☐ I didn't read any of the booklet

b. How did you feel about the level of detail in the information booklet?

- ☐ Too much detail
- ☐ About the right amount of detail
- ☐ Not enough detail

c. How did you find the way the information booklet was written?

- ☐ Easy to read
- ☐ Slightly difficult to understand
- ☐ Very difficult to understand
- ☐ I did not understand the information

d. How do you feel about the way the information is presented?

- ☐ It's too positive
- ☐ The information is balanced
- ☐ It's too negative

e. How did you feel about the amount of information in the booklet?

- ☐ Too much information
- ☐ About the right amount of information
- ☐ Not enough information

f. How much information was there about the downsides of bowel cancer screening?

- ☐ More than I wanted
- ☐ About right
- ☐ Less than I wanted

g. How much information was there about the benefits of bowel cancer screening?

- ☐ More than I wanted
- ☐ About right
- ☐ Less than I wanted

h. If you were making a decision about whether or not to participate in bowel cancer screening, how useful would you find the information booklet?

- ☐ Very useful
- ☐ Somewhat useful
- ☐ Not very useful
- ☐ Not useful at all

i. Would you like any other information that is not included in the leaflet?

- ☐ Yes
- ☐ No
- ☐ Not sure

If yes, what other information would you like? _____

_____

Section D: Understanding of Bowel Cancer Screening

21). We would like to ask you some questions about your understanding of bowel cancer and bowel cancer screening. The questions are not meant to be a test – we are simply interested to find out what information you may understand about bowel cancer and bowel cancer screening. Please read each question carefully and place a tick in the box that best represents your opinion. After you have answered 'true' or 'false' to each question, also tick the box to indicate how sure you are that your answer is correct. Several of the questions sound the same, but please try to complete all of the questions.

	True or False?		*How sure are you that your answer is correct?*			
Bowel Cancer Screening Questions	**True**	**False**	***Totally sure***	***Very sure***	***Not very sure***	***Not sure at all***
a. Bowel cancer is the second leading cause of cancer deaths in the UK.	☐	☐	☐	☐	☐	☐
b. The risk of developing bowel cancer increases with age.	☐	☐	☐	☐	☐	☐
c. Bowel cancer screening will always detect if you have bowel cancer.	☐	☐	☐	☐	☐	☐
d. About 98 in every 100 people will have a normal result after screening.	☐	☐	☐	☐	☐	☐
e. A normal result means that you will not develop bowel cancer in the future.	☐	☐	☐	☐	☐	☐
f. Having one or more family members who have had bowel cancer increases your chances of developing the disease.	☐	☐	☐	☐	☐	☐
g. 6 out of 10 people diagnosed with bowel cancer are over 60 years old.	☐	☐	☐	☐	☐	☐
h. Bowel cancer screening reduces your risk of dying from bowel cancer by 16%.	☐	☐	☐	☐	☐	☐
i. If blood detected in a person's screening test, they definitely have bowel cancer.	☐	☐	☐	☐	☐	☐
j. Bowel cancer can develop from a bowel polyp.	☐	☐	☐	☐	☐	☐
k. About 2 in every 100 people who complete bowel cancer screening will be offered a colonoscopy.	☐	☐	☐	☐	☐	☐

Section D *Continued*

Bowel Cancer Screening Questions	*True or False?* True	False	*How sure are you that your answer is correct?* ***Totally sure***	***Very sure***	***Not very sure***	***Not sure at all***
l. A person can have bowel cancer without having any symptoms.	☐	☐	☐	☐	☐	☐
m. About 1 in 10 people will be diagnosed with bowel cancer after a colonoscopy.	☐	☐	☐	☐	☐	☐
n. An unclear result does not mean that the person has bowel cancer, but hey do have to take the test again.	☐	☐	☐	☐	☐	☐
o. The faecal occult blood test can detect tiny amounts of blood that you can't see in your bowel motions.	☐	☐	☐	☐	☐	☐
p. About 1 in 20 people will develop bowel cancer in their lifetime.	☐	☐	☐	☐	☐	☐
q. If bowel cancer is detected early, there is over a 90% chance of survival.	☐	☐	☐	☐	☐	☐
r. There are no side effects associated with having a colonoscopy.	☐	☐	☐	☐	☐	☐
s. Bowel cancer is the most commonly diagnosed cancer in the UK.	☐	☐	☐	☐	☐	☐
t. If a person has an abnormal result, they will be asked to have a colonoscopy.	☐	☐	☐	☐	☐	☐
u. A bowel polyp is not the same as bowel cancer.	☐	☐	☐	☐	☐	☐
v. Bowel cancer screening is offered to people aged 60-69 ever two years.	☐	☐	☐	☐	☐	☐
w. A colonoscopy is the most effective way to diagnose bowel cancer.	☐	☐	☐	☐	☐	☐
x. A change in bowel habit for more than 6 weeks is a symptom of bowel cancer.	☐	☐	☐	☐	☐	☐

Section E: Importance of Information

22.) The following questions ask you about what information you think should to be included in an information booklet about bowel cancer screening. Please indicate how important you think it is to include this information in a booklet by putting a tick in the box that best represents your opinion.

If I was making a decision about participating in bowel cancer screening, I would want to know about:	*Not important*	*Slightly important*	*Very important*	*Extremely important*
a. The purpose of bowel cancer screening.	☐	☐	☐	☐
b. Who is at risk of developing bowel cancer.	☐	☐	☐	☐
c. The symptoms of bowel cancer.	☐	☐	☐	☐
d. The location and function of the bowel.	☐	☐	☐	☐
e. How bowel cancer can develop.	☐	☐	☐	☐
f. How reliable or accurate is the screening test for bowel cancer.	☐	☐	☐	☐
g. How to do the bowel cancer screening test.	☐	☐	☐	☐
h. The benefits or advantages of bowel cancer screening.	☐	☐	☐	☐
i. The risks or disadvantages of bowel cancer screening.	☐	☐	☐	☐
j. The meaning of a normal and an abnormal test result.	☐	☐	☐	☐
k. When people will receive their test results.	☐	☐	☐	☐
l. What is a colonoscopy and how is it performed.	☐	☐	☐	☐
m. The benefits or advantages of colonoscopy.	☐	☐	☐	☐
n. The risks or disadvantages of colonoscopy.	☐	☐	☐	☐
o. The benefits of treatment for bowel cancer.	☐	☐	☐	☐
p. The side-effects of treatment for bowel cancer.	☐	☐	☐	☐
q. Where to get further information about bowel cancer.	☐	☐	☐	☐

r. Is there any other information you think is important to include in a booklet about bowel cancer screening? _____

_____

Section F: Attitudes towards Bowel Cancer Screening

23). The following questions relate to the reasons why you would either complete bowel cancer screening or continue to do so. Different people have different reasons for doing that, and we want to know how true each of the following reasons is for you. All 15 questions are to the same question – "The reason I would complete bowel cancer screening is…" Please indicate the extent to which each reason is true for you by putting a circle around the number on the seven point scale (where 1 = 'not true at all' and 7 = 'very true').

The reason I would complete bowel cancer screening is:	***Not At All True***		***Somewhat True***				***Very True***
a. Because I feel I want to take responsibility for my own health.	1	2	3	4	5	6	7
b. Because I would feel guilty or ashamed of myself if I did not complete the FOBT card.	1	2	3	4	5	6	7
c. Because I personally believe it is the best thing for my health.	1	2	3	4	5	6	7
d. Because others would be upset if I did not.	1	2	3	4	5	6	7
e. Because I have carefully thought about it and believe it is very important for many aspects of my life.	1	2	3	4	5	6	7
f. I really don't think about it.	1	2	3	4	5	6	7
g. Because I would feel bad about myself if I did not complete the FOBT card.	1	2	3	4	5	6	7
h. Because it is an important choice I really want to make.	1	2	3	4	5	6	7
i. Because I feel pressure from others to do so.	1	2	3	4	5	6	7
j. Because it is easier to do what I am told than think about it.	1	2	3	4	5	6	7
k. Because it is consistent with my goals is life.	1	2	3	4	5	6	7
l. Because I want others to approve of me.	1	2	3	4	5	6	7
m. Because it is very important for being as healthy as possible.	1	2	3	4	5	6	7
n. Because I want others to see I can do it.	1	2	3	4	5	6	7
o. I don't really know why.	1	2	3	4	5	6	7

Section F *Continued*

24). The following questions ask you about your views about bowel cancer screening. There are not right or wrong answers. Please indicate the extent to which each reason is true for you by putting a circle around the number on the four point scale.

	Your views on bowel cancer…	**Strongly Agree**	**Agree**	**Disagree**	**Strongly Disagree**
a.	I am afraid to even think about bowel cancer	1	2	3	4
b.	I would be too embarrassed to have a bowel examination	1	2	3	4
c.	When it comes to bowel cancer, if I had something wrong, I would rather know as soon as possible	1	2	3	4
d.	If I had bowel cancer, I would rather not know about it	1	2	3	4
e.	If I had bowel cancer, I would not want to know until the very end	1	2	3	4
h	The thought of bowel cancer scares me	1	2	3	4

25). The following questions ask you about how confident you are about completing the faecal occult blood (FOB) test. The FOB test is the card you received in your invitation to bowel cancer screening pack. There are not right or wrong answers. Please indicate the extent to which each reason is true for you by putting a circle around the number on the four point scale.

	How confident are you about…	**Strongly Agree**	**Agree**	**Disagree**	**Strongly Disagree**
a.	I am confident that I can collect a sample of my bowel motion	1	2	3	4
b.	I am confident that I can put a small amount of my bowel motion on the FOB test card	1	2	3	4
c.	I am confident that I can store my FOB test card correctly	1	2	3	4
d.	I am confident that I can post my completed FOB card back to the Screening Hub	1	2	3	4

Section G: About You

26) Please complete the background questions below.

a. What is your age group?

- ☐ 60-64 years
- ☐ 65-69 years
- ☐ 70 or over

b. What is the highest level qualification you have?

- ☐ 'O' level *(or equivalent)*
- ☐ 'A' level *(or equivalent)*
- ☐ Clerical or commercial qualification
- ☐ College or university degree
- ☐ None of these

c. What is your current marital status?

- ☐ Married or living as married
- ☐ Widowed
- ☐ Single or never married
- ☐ Divorced or separated

d. In general, would you say that your health is:

- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor
- ☐ Very poor

e. What ethnic group would you use to describe yourself as?

- ☐ White
- ☐ White (other)
- ☐ Black African
- ☐ Black Caribbean
- ☐ Asian
- ☐ Mixed race
- ☐ Other *(please specify)*
- ☐ _____

THANK YOU FOR THAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE

Please return the questionnaire and your consent form in the FREEPOST envelope provided

Appendix 5.3: Ethics and R&D Timeline for Pilot Study

Event	Date	Time	Comments
Ethics Submission	02/04/2008	-	Ethics submitted to Oxfordshire REC
Response from Ethics	06/05/2008	5 weeks	Minor changes requested (Chair's approval sought for changes)
Ethics Approval	28/05/2008	3 weeks	Chair approval finalised for ethics
Transfer of Proposal	06/062008	1 week	Attempt to transfer proposal to Dr Halloran (IRAS form for Dr Halloran to become PI)
Transfer Completed	17/06/2008	1 week	Proposal transferred to Dr Halloran (miscommunication results in proposal not being submitted to RSCH R&D)
R&D Submitted	15/07/2008	4 weeks	Proposal transferred to RSCH R&D
R&D Approval	22/09/2008	10 weeks	Proposal approved by RSCH R&D – sent to Lead R&D Officer for authorisation (2 week delay due to the single R&D Officer at RSCH away due to annual leave; no reason for further 8 week delay)
R&D Approval	15/10/2008	4 weeks	Confirmation that authorisation form has been signed
	Total time	**28 weeks**	
Download participant information for pilot questionnaire (Hub)	17/10/2008	-	Visit Guildford to receive patient contact details for questionnaire – informed unable to download information
Download participant information for pilot questionnaire (NHS CSP)	21/10/2008	1 week	Contact NHS CSP to request information (approved); 22-25 Oct only person who can complete download off sick
Receive participant information	27/10/2008	1 week	Receive information from NHS CSP
Transfer information to Hub	30/10/2008	-	Receive patient contact details from Southern Hub
Pilot Questionnaire Admin	02/11/2008	-	Questionnaires packed
Mail-Out	03/11/2008	1 week	Questionnaire mailed out
	Total time	**31 weeks**	

RSCH = Royal Surrey County Hospital
NHS CSP = NHS Cancer Screening Programme Central Office

Appendix 5.4: Invitation Letter

Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF

Tel: 01865 289359

INVITATION LETTER

Public Perceptions of the NHS Bowel Cancer Screening Programme (NRES Study Number: 08/H0606/39)

Dear ……

This letter is to invite you to complete a short postal questionnaire looking at your perceptions of bowel cancer screening and views on information provided by the NHS Bowel Cancer Screening Programme. Before you decide to take part, it is important for you to understand why the research is being done and what it will involve for you. Please take the time to read the attached study information sheet and feel free to contact us if you have any questions or if something about the study is unclear.

The NHS Bowel Cancer Screening Programme offers screening every two years to all men and women aged 60 to 69. Several months ago you received an invitation to participate in screening. It does not matter if you completed the screening test or not, we are interested to learn more about your thoughts and views of bowel cancer screening and how you think that the programme can be improved. Your opinions and experiences are of great interest to us and would be very helpful in our research.

The study is being run by the Department of Primary Health Care at the University of Oxford in conjunction with the NHS Cancer Screening Programmes. The overall goal of our research is to improve the information provided to people who are invited to the NHS Bowel Cancer Screening Programme.

We have enclosed a study information sheet with further details on the research. We would be grateful if you could complete the attached consent form to say whether or not you would be willing to take part in this study and return it in the freepost envelope provided. A reminder letter will be sent after two weeks if we have not heard from you.

You are under no obligation to take part in the study and can choose to leave it at any time without giving a reason. Whether or not you participate in the study

will have no affect on your normal medical care. If you have any queries about this research or if something about the study is unclear, please contact Paul Hewitson on 01865 289359.

Yours sincerely,

Dr Steven Halloran
Director: Bowel Cancer Screening Hub - South of England

Appendix 5.5: Pilot Study Information Sheet

Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF

Tel: 01865 289359

Study Information Sheet

Public Perceptions of the NHS Bowel Cancer Screening Programme (NRES Study Number: 08/H0606/39)

Introduction

You are invited to take part in a research study looking at people's perceptions of bowel cancer screening and their views on the information provided by the NHS Bowel Cancer Screening Programme. The NHS Bowel Cancer Screening Programme offers screening every two years to all men and women aged 60 to 69. However, only about half of the people invited decide to take part in screening. This could be due to a number of reasons, one of which may be the difficulty people have when trying to complete the faecal occult blood test (FOBT). Those who have completed the test may also have concerns about the information provided by the Programme or have valuable ideas about overcoming difficulties with FOBT. We are seeking your opinions and views on a detailed information leaflet designed to provide suggestions for completing FOBT and your perceptions of bowel cancer screening.

Why are we doing this research?

Our overall aim for the study is to improve the information that is provided to people invited to take part in the NHS Bowel Cancer Screening Programme. We are interested to find out people's perceptions and understanding of bowel cancer screening and their views about the information leaflets (included in this pack) used by the Programme. The study also aims to refine several questionnaire outcomes that will be used in a large-scale research study conducted by the University of Oxford next year.

Why have I been invited to take part?

Your name was randomly selected from a list of people who were sent an invitation to participate in the NHS Bowel Cancer Screening Programme a few months ago. <u>This research study is open to people who either have or have not participated in bowel cancer screening</u>. Our study is interested in the views of

all people who were invited to the NHS Bowel Cancer Screening Programme. This study will involve 400 men and women.

Do I have to take part?

It is up to you to decide whether or not you wish to take part. You would be free to withdraw from the study at any point and without giving a reason. This would not affect the standard of any future medical care you may receive. If you do not wish to be part of this study and do not want to be contacted again, please complete the reply slip included in this pack and send it back in the freepost envelope.

What will I be asked to do?

If you decide to take part, you will be asked to read through the information leaflets included in this pack, fill out a short questionnaire and sending it back to us in a freepost envelope. The questionnaire will take 15-30 minutes to complete. We are also asking if people would like to be involved in an interview study. You can complete the questionnaire without being involved in the interview study. If you would like further information about the interview study, please complete the 'Request for Information' sheet included in this pack.

What are the benefits of taking part?

If you decide to take part, your responses to the questionnaire may be used to improve the information provided by the NHS Bowel Cancer Screening Programme. Your responses will also assist us to refine several questionnaire outcomes that will be used in a large-scale research study conducted by the University of Oxford next year.

Will my taking part in this study be kept confidential?

Your involvement in this study will be kept completely confidential. The questionnaire will be anonymous (i.e. your name will not appear anywhere in print) and all information gathered will be treated in the strictest confidence. If you decide to participate in the interview study, no names or personal identifiers will be used.

The University of Oxford supports the principles of the Research Governance Framework developed by the Department of Health. This framework is designed to ensure that the proper monitoring of studies can occur so that the public can have confidence in, and benefit from, quality research in health and social care. Monitoring or auditing of the conduct of this research may be carried out by representatives of the University, in accordance with the Research Governance Framework.

What would happen to the results of the research study?

We also intend to publish the findings of the study in a medical journal. The overall questionnaire findings would be included in the publication but this would be completely anonymous. We will send you a summary of the research findings at the end of the study.

Who is organising and funding this research?

The research is being conducted by the University of Oxford and is funded by the NHS Cancer Screening Programmes.

Who has reviewed this study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair and that the rights of study participants are assured. This project has been checked by the Oxfordshire C Research Ethics Committee.

Who should I contact for further information?

If you have any queries about this research or if something about the study is unclear, please contact Paul Hewitson on 01865 289359. If you have any complaints about any aspect of this study please contact:

Professor David Mant
Department of Primary Health Care
University of Oxford University
Old Road, Headington
Oxford OX3 1LR

PLEASE COMPLETE AND RETURN THE ATTACHED CONSENT FORM IF YOU WISH TO BE INVOLVED IN THE STUDY

Appendix 5.6: Pilot Study Consent Form

Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF

Tel: 01865 289359

CONSENT FORM

Title of Study: Public Perceptions of the NHS Bowel Cancer Screening Programme

(NRES Study Number: 08/H0606/39)

Study ID Number:

Name of researcher obtaining consent: Paul Hewitson

Please initial each box

1. I can confirm that I have read and understand the information sheet dated 26/03/2008 (Version 1) for the above study. I have had the opportunity to consider the information before deciding to take part. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that, for the purposes of audit and monitoring, relevant data collected during this study may be looked at by individuals from the University of Oxford. I give permission for these individuals to have access to my data. ☐

4. I agree to take part in the above study. ☐

Name: _____

Signature: _____

Date: _____

PLEASE RETURN YOUR CONSENT FORM IN THE FREEPOST ENVELOPE PROVIDED – THANK YOU FOR YOUR TIME

Appendix 5.7: Pilot Request for Information Form

Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF

Tel: 01865 289359

Request for Further Information

(NRES Study Number: 09/H0606/60)

We would like to send you a summary of the results of the study. If you are interested in finding out how what the results of this study were then please tick the box and fill in your details below and we will send you a summary of the results.

Summary of the Results of the Study

Please send me a summary of the results of this study. ☐

Interested in Participating in an Interview

Please send me further information about participating in the interview study. ☐

You can contact me at:

Name: _____

Address: _____

_____

_____

_____

Appendix 5.8: Pilot Questionnaire Non-response Slip

Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF

Tel: 01865 289359

Reply Slip

Please do not send me any further information

Title of Study: Public Perceptions of the NHS Bowel Cancer Screening Programme

(NRES Study Number: 08/H0606/39)

Study ID Number:

Please tick the box

1. Please do not send me any further information concerning this study ☐

PLEASE RETURN YOUR REPLY SLIP IN THE FREEPOST ENVELOPE PROVIDED – THANK YOU FOR YOUR TIME

Appendix 5.9: Pilot Reminder Letter

Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF

Tel: 01865 289359

Reminder Letter

Public Perceptions of the NHS Bowel Cancer Screening Programme (NRES Study Number: 08/H0606/39)

Dear ……..

We recently wrote to you asking if you would like to complete a short postal questionnaire looking at your perceptions of bowel cancer screening and views on information provided by the NHS Bowel Cancer Screening Programme. As we have not heard back from you we are sending this reminder in case you wish to take part. If you have decided you do not wish to take part and do not return the enclosed form we will not contact you again.

Before you decide to take part, it is important for you to understand why the research is being done and what it will involve for you. Please take the time to read the attached study information sheet and feel free to contact us if you have any questions or if something about the study is unclear.

<u>It does not matter if you completed the screening test or not</u>, we are interested to learn more about your thoughts and views of bowel cancer screening and how you think that the programme can be improved. Your opinions and experiences are of great interest to us and would be very helpful in our research.

The study is being run by the Department of Primary Health Care at the University of Oxford in conjunction with the NHS Cancer Screening Programmes. The overall goal of our research is to improve the information provided to people who are invited to the NHS Bowel Cancer Screening Programme.

We have enclosed a study information sheet with further details on the research. We would be grateful if you could complete the attached consent form to say whether or not you would be willing to take part in this study and return it in the freepost envelope provided. A reminder letter will be sent after two weeks if we have not heard from you.

You are under no obligation to take part in the study and can choose to leave it at any time without giving a reason. Whether or not you participate in the study will have no affect on your normal medical care. If you have any queries about this research or if something about the study is unclear, please contact Paul Hewitson on 01865 289359.

Yours sincerely,

Dr Steven Halloran
Director: Bowel Cancer Screening Hub - South of England

Appendix 5.10: Pilot Interview Invitation Letter

Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF
Tel: 01865 289359

INTERVIEW STUDY INVITATION LETTER

Public Perceptions of the NHS Bowel Cancer Screening Programme (NRES Study Number: 08/H0606/39)

Dear ……

Recently you returned a questionnaire about your perceptions of bowel cancer screening and views on information provided by the NHS Bowel Cancer Screening Programme. You indicated that you may be willing to be interviewed about your views on bowel cancer screening and the information leaflets. This letter is to ask if you are still willing to be interviewed for the study.

The study is being run by the Department of Primary Health Care at the University of Oxford in conjunction with the NHS Cancer Screening Programmes. The overall goal of our research is to improve the information provided to people who are invited to the NHS Bowel Cancer Screening Programme. We have enclosed an interview study information sheet with further details about the study and how you can be involved.

Taking part in the study would involve an informal interview with a researcher at a time and place convenient to you (in your own home if you wish). The interview would take between 30 minutes to one hour and would be tape recorded. However, your name will not appear anywhere in print and all information gathered would be treated in strict confidence.

We would be grateful if you could complete the attached consent form if you are willing to take part and return the form in the free post envelope provided. You are under no obligation to take part in the study and can choose to leave it at any time without giving a reason. Participating in the study or leaving the study at any time will have no affect on your normal medical care. If you have any queries about this research or if something about the study is unclear, please contact Paul Hewitson on 01865 289359.

If you have any questions about this research please call Paul Hewitson on 01865 289359. Thank you for your time.

Yours sincerely,

Appendix 5.11: Pilot Interview Study Information Sheet

Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF

Tel: 01865 289359

Interview Study Information Sheet

Public Perceptions of the NHS Bowel Cancer Screening Programme (NRES Study Number: 08/H0606/39)

Introduction

You are invited to take part in a research study looking at people's perceptions of bowel cancer screening and their views on the information provided by the NHS Bowel Cancer Screening Programme. The NHS Bowel Cancer Screening Programme offers screening every two years to all men and women aged 60 to 69. However, only about half of the people invited decide to take part in screening. This could be due to a number of reasons, one of which may be the difficulty people have when trying to complete the faecal occult blood test (FOBT). Those who have completed the test may also have concerns about the information provided by the Programme or have valuable ideas about overcoming difficulties with FOBT. We are seeking your opinions and views on a detailed information leaflet designed to provide suggestions for completing FOBT and your perceptions of bowel cancer screening.

Why are we doing this research?

Our overall aim for the study is to improve the information that is provided to people invited to take part in the NHS Bowel Cancer Screening Programme. We are interested to find out people's perceptions and understanding of bowel cancer screening and their views about the information leaflets (included in this pack) used by the Programme. The study also aims to refine several questionnaire outcomes that will be used in a large-scale research study conducted by the University of Oxford next year.

Why have I been invited to take part?

Your name was randomly selected from a list of people who were sent an invitation to participate in the NHS Bowel Cancer Screening Programme a few months ago. This research study is open to people who either have or have not participated in bowel cancer screening. Our study is interested in the views of

all people who were invited to the NHS Bowel Cancer Screening Programme. This study will involve 400 men and women.

Do I have to take part?

It is up to you to decide whether or not you wish to take part. You would be free to withdraw from the study at any point and without giving a reason. This would not affect the standard of any future medical care you may receive.

What will I be asked to do?

If you decide to take part, a trained researcher would interview you. The interview would be informal, would last approximately 30 minutes to 1 hour and could take place either in your own home or a convenient location (whichever you prefer). You can also be interviewed by telephone if you wish. If the interview were in a location other than your home, the cost of any travelling expense would be reimbursed. If you agree, the interview would be tape-recorded, but the contents of the interview would be anonymised and treated in strict confidence. The audio-tapes will be destroyed at the end of the study or earlier if you choose to withdraw from the study. The interview would not form part of your medical care and therefore no health advice could be offered.

What are the benefits of taking part?

If you decide to take part, your responses to the questionnaire may be used to improve the information provided by the NHS Bowel Cancer Screening Programme. Your responses will also assist us to refine the questionnaire outcomes that will be used in a large-scale research study conducted by the University of Oxford next year.

Will my taking part in this study be kept confidential?

Your involvement in this study will be kept completely confidential. The interview will be anonymous (i.e. your name will not appear anywhere in print) and all information gathered will be treated in the strictest confidence. If you decide to participate in the interview study, no names or personal identifiers will be used.

What would happen to the results of the research study?

We also intend to publish the findings of the study in a medical journal. The overall questionnaire findings would be included in the publication but this would be completely anonymous. We will send you a summary of the research findings at the end of the study.

Who is organising and funding this research?

The research is being conducted by the University of Oxford and is funded by the NHS Cancer Screening Programmes.

Who has reviewed this study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair and that the rights of study participants are assured. This project has been checked by the Oxfordshire C Research Ethics Committee.

Who should I contact for further information?

If you have any queries about this research or if something about the study is unclear, please contact Paul Hewitson on 01865 289359. If you have any complaints about any aspect of this study please contact:

Professor David Mant
Department of Primary Health Care
University of Oxford University
Old Road, Headington
Oxford OX3 1LR

Appendix 5.12: Pilot Interview Initial Contact Consent Form

Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF
Tel: 01865 289359

INTERVIEW CONSENT FORM

Title of Study: Public Perceptions of the NHS Bowel Cancer Screening Programme
(NRES Study Number: 08/H0606/39)

Study ID Number:

Name of researcher obtaining consent: Paul Hewitson

1. I agree to take part in the interview study. ☐

   To arrange an interview you can contact me on:

Name: _____

Address: _____

_____

_____

Tel number: _____

Signature: _____

Date: _____

2. I do not wish to take part in the interview study and do not wish to be contacted further. ☐

Name: _____

Signature: _____

Date: _____

PLEASE RETURN YOUR CONSENT FORM IN THE FREEPOST ENVELOPE PROVIDED – THANK YOU FOR YOUR TIME

Appendix 5.13: Pilot Interview Consent Form

Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF

Tel: 01865 289359

INTERVIEW CONSENT FORM

Title of Study: Public Perceptions of the NHS Bowel Cancer Screening Programme

(NRES Study Number: 08/H0606/39)

Study ID Number:

Name of researcher obtaining consent: Paul Hewitson

Please initial each box

1. I can confirm that I have read and understand the information sheet dated 26/03/2008 (Version 1) for the above study. I have had the opportunity to consider the information, ask questions and have had these satisfactorily answered by Paul Hewitson before deciding to take part. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I agree to the interview being tape-recorded, and agree that any words I may say during the interview can be used anonymously, in the presentation of the research. ☐

4. I agree to take part in the above study. ☐

Name: _____

Signature: _____

Date: _____

PLEASE RETURN YOUR CONSENT FORM IN THE FREEPOST ENVELOPE PROVIDED – THANK YOU FOR YOUR TIME

Appendix 5.14: Analyses for the Pilot Knowledge Scale

The Kuder-Richardson-20 analysis for all pilot knowledge items is shown in Table 1. Due to the method used by STATA to calculate the KR-20 statistic, only respondents who answered all knowledge items (93 respondents) were included. The results indicate that Items E, I, S, T, U, and V are poorly correlated with the other items of the scale, and therefore, would be excluded from the scale.

Table 1: Summary of the Kuder-Richardson-20 STATA analysis of the pilot knowledge items for people previously participating in screening.

```
Kuder-Richarson coefficient of reliability (KR-20)
Number of items in the scale = 23
Number of complete observations =   93
```

Item	Obs	Item difficulty	Item variance	Item-rest correlation
Kn_A	93	0.8280	0.1424	0.2876
Kn_B	93	0.9462	0.0509	0.3515
Kn_C	93	0.8925	0.0960	0.2716
Kn_D	93	0.9032	0.0874	0.2506
Kn_E	93	0.9785	0.0210	0.1771
Kn_F	93	0.9355	0.0604	0.2485
Kn_G	93	0.8495	0.1279	0.2509
Kn_H	93	0.8495	0.1279	0.2011
Kn_I	93	0.9892	0.0106	0.0424
Kn_J	93	0.8172	0.1494	0.4015
Kn_K	93	0.8925	0.0960	0.3150
Kn_L	93	0.8280	0.1424	0.2722
Kn_M	93	0.8710	0.1124	0.3125
Kn_N	93	0.9785	0.0210	0.4137
Kn_P	93	0.9032	0.0874	0.4496
Kn_Q	93	0.9355	0.0604	0.2365
Kn_R	93	0.6452	0.2289	0.4524
Kn_S	93	0.7742	0.1748	0.0166
Kn_T	93	0.8602	0.1202	0.1649
Kn_U	93	0.9570	0.0412	0.1522
Kn_V	93	0.9785	0.0210	0.0611
Kn_W	93	0.8710	0.1124	0.3397
Kn_X	93	0.5591	0.2465	0.3056
Test		0.8714		0.2424

```
KR20 coefficient is 0.6826
Note:  Kn_O not included as 100% correct response rate.
```

The internal consistency analysis (alpha) for the knowledge scale is shown in Table 2. The results indicate that items E, I, S, T, U, and V are poorly correlated with the other items of the scale (item-rest correlation), and therefore, would be excluded from the scale. Furthermore, three items (Items I, S and V) would be excluded based on the subsequent increase in the total alpha score if these items were removed.

Table 2: Summary of the alpha STATA analysis of the pilot knowledge items for people previously participating in screening.

```
test scale = mean(unstandardized items)
```

Item	Obs	Sign	item-test correlation	item-rest correlation	average inter-item covariance	alpha
Kn_A	101	+	0.2947	0.2575	.0098665	0.6950
Kn_B	101	+	0.5239	0.4503	.0092932	0.6724
Kn_C	100	+	0.3699	0.2595	.0096824	0.6856
Kn_D	101	+	0.3917	0.2923	.0095813	0.6822
Kn_E	101	+	0.2432	0.1726	.0101854	0.6915
Kn_F	101	+	0.2287	0.2370	.0101709	0.6938
Kn_G	101	+	0.4520	0.3316	.0091993	0.6777
Kn_H	100	+	0.3539	0.2266	.0096454	0.6884
Kn_I	101	+	0.0867	0.0502	.0105128	0.6962
Kn_J	100	+	0.5426	0.4254	.0087838	0.6680
Kn_K	101	+	0.4651	0.3628	.0092557	0.6755
Kn_L	99	+	0.3847	0.2503	.0103328	0.6845
Kn_M	100	+	0.4647	0.3556	.0091948	0.6755
Kn_N	101	+	0.4375	0.3943	.0099284	0.6837
Kn_P	101	+	0.5469	0.4579	.0089785	0.6674
Kn_Q	100	+	0.4697	0.3860	.0093983	0.6760
Kn_R	101	+	0.5322	0.3868	.0085589	0.6700
Kn_S	101	-	0.1067	-0.0488	.0108063	0.7189
Kn_T	101	+	0.3088	0.1831	.0098402	0.6923
Kn_U	101	+	0.2321	0.1624	.0101971	0.6918
Kn_V	100	+	0.1243	0.0731	.0104414	0.6956
Kn_W	101	+	0.4037	0.2919	.0094521	0.6813
Kn_X	100	+	0.5133	0.3586	.0086435	0.6742
Test scale					.0096499	0.6951

Appendix 5.15: Analyses of the Negative Attitudes Scale

The proportion of responses to the individual items in the negative attitudes towards CRC scale for both participants in the pilot study and for previously published research [1] is shown in Table 1.

Table 1: Percentage of responses to the individual items in the negative attitudes towards CRC screening scale for current pilot and previous research.

	Strongly Agree		**Agree**		**Disagree**		**Strongly Disagree**	
	PR	***Pilot***	***PR***	***Pilot***	***PR***	***Pilot***	***PR***	***Pilot***
Too afraid	6.3%	*4.9%*	26.1%	*23.5%*	52.4%	*52.0%*	15.2%	*19.6%*
Too embarrassed	3.2%	*3.0%*	9.2%	*10.8%*	54.7%	*43.1%*	32.9%	*43.1%*
Know soon as possible	59.8%	*54.9%*	36.2%	*6.9%*	3.0%	*9.8%*	1.1%	*28.4%*
Rather not know	2.6%	*3.9%*	6.0%	*1.0%*	42.7%	*19.6%*	48.7%	*75.5%*
Know only at the end	1.9%	*1.0%*	4.4%	*1.0%*	42.6%	*12.7%*	51.1%	*85.3%*
Thought scares me	15.5%	*26.5%*	55.1%	*57.8%*	26.1%	*9.8%*	3.2%	*5.9%*

Note: 'PR' denotes previous research [1].

As can be seen in Table 1, there are marked differences between the response categories for the participants in the pilot study and the results from previous research. This is especially evident for the items 'know as soon as possible', 'rather not know' and 'know only at the end'. It is possible these differences reflect the greater age range of respondents in the previously published research on the scale in comparison to the age range of participants in the pilot study (e.g., different opinions concerning negative attitudes towards screening would be affected by the age of the person responding).

In an effort to determine if these differences were only evident for all age groups in comparison to the age range pilot respondents, a separate examination was undertaken for the attitude categories. The proportion of people in the three attitude categories for the age range of 55-74 from the previously reported study

compared with those of the participants in the pilot study (aged 60 to 69 years old; see Table 2).

Table 2: Percentage of respondents for each category of the negative attitudes scale for current pilot and previous research (aged 55-74).

	Total		**Males**		**Females**	
	PR	***Pilot***	***PR***	***Pilot***	***PR***	***Pilot***
High (positive)	33.5	*54.9*	39.5	*63.1*	38.2	*48.2*
Medium	39.5	*32.3*	38.2	*30.4*	33.8	*33.9*
Low (negative)	27.0	*12.8*	22.7	*6.5*	28.0	*12.9*

Note: 'PR' denotes previous research [1].

As can be seen in Table 2, there are also large differences between the proportion of people classified into the 'high', 'medium' or 'low' negative attitudes categories between the previously published research and participants in the pilot study. Overall, participants in the pilot study were categorised as more positive towards screening (over half the sample in comparison to around a third for the previously published research) and very few pilot participants were categorised as having 'low' (negative) attitudes towards CRC screening in comparison to the previously published research.

References

1. McCaffery K, Wardle J, Waller J. Knowledge, attitudes, and behavioural intentions in relation to the early detection of colorectal cancer in the United Kingdom. *Prev Med* 2003; 36: 525-535.

Appendix 6.1: Pilot Interview Schedule

Public Perceptions of Bowel Cancer Screening: A Pilot Study

Interview Schedule

Hello, my name is Paul Hewitson and I'm a research fellow at the Department of Primary Health Care based at the University of Oxford. Firstly, I'd just like to thank you for agreeing to take part in this interview study. I really do appreciate you giving up your time to help us today.

Basically, today I'd like to speak to you about your views and perceptions of bowel cancer screening and also your views on the information materials used by the NHS Bowel Cancer Screening Programme. Your thoughts and ideas about the leaflet and booklet will also be helping us to improve the information that is given to people by the NHS BCSP. I'll be asking you some questions about the information materials I sent you – so I just wondering if I could check with you whether you have these to hand?

The interviews normally take between half-an-hour to three-quarters of an hour to complete, although you can stop the interview at any time if you are uncomfortable with any of the questions or wish to end the interview for any other reason. If it is OK with you, I would like to record our conversation so that I have an accurate record of what we talk about today. You name will be kept anonymous and anything that you tell me will not be shared with anyone involved in your medical care. Would you be happy for me to use the tape recorder?

A. Clarification

1) Before we start, do you have any questions about this interview, or would you like to know anything else about this study?

B. Bowel Cancer and Bowel Cancer Screening

2) Just to begin, I'd like to ask you few general questions about when you first received the bowel cancer screening invitation in the post…

Prompts:

- Had you heard anything about the Bowel Cancer Screening Programme before you received your invitation? – where did you hear about the BCSP?
- Did you know *why* you were being asked to complete the bowel cancer screening test? (received your invitation to bowel cancer screening)

3) Are you concerned or worried at all about developing bowel cancer?

Prompts:

- Compared to other health-related aspects of your life, how important is bowel cancer screening for you?
- What were your main reasons for deciding to participate in bowel cancer screening?

4) Did you know or understand much about bowel cancer before you received your invitation to screening?

- Did you understand what the purpose of screening was? (see 1)
- Had you previously heard about any tests used to screen for bowel cancer?
- Were you aware of any of the symptoms of bowel cancer?
- I was wondering if you could explain in your own words, how bowel cancer develops? - did you know anything else about bowel cancer?

C. Bowel Cancer Screening Procedure

5) When you first received the invitation, what were your initial thoughts concerning the test you were being asked to do for bowel cancer screening?

Prompts:

- Did you feel confident that you could complete the bowel cancer screening test correctly (kit that was sent to you)? – why was that?
- Some people have said that a barrier for them participating in screening is because they are embarrassed or find collecting the samples disgusting; what are your thoughts about that?
- Did you have any problems storing the test?
- Did you understand why you needed to take three separate samples?

6) Did you feel that the information about how to collect your samples and complete the test was clear or not?

Prompts:

- Was there anything that you found confusing at all in regards to the instruction leaflet?
- Would you have any ideas or suggestions that other people may find helpful concerning completing bowel cancer screening?

D. Bowel Cancer Screening Information

7) Could I ask if you have had an opportunity to look over the 'Help with the Test' leaflet or the booklet 'Bowel Cancer Screening: The Facts'

- *if no*: did you have any problems reading the leaflet?

8) What are your views on the information leaflet 'Help with the Test' that we sent you?

Prompts:

- Is there anything about the leaflet that you liked?
- Is there anything about the leaflet that you don't like?
- Did you find any of the phrasing to be confusing for you?
- Would you find the leaflet helpful if you were asked to do the test again?
- Do you think that we should include any other information in the leaflet?
- Would you have any suggestions for how to make the leaflet more appealing to people?

9) Just turning to the larger booklet, "Bowel Cancer Screening: The Facts", what were your thoughts on this booklet?

Prompts:

- You would have received this booklet with your invitation to screening; I was just wondering did you read much of the booklet before you decided to do the test?
- Is there anything about the booklet that you liked?
- Is there anything about the booklet that you don't like?
- How did you feel about the amount of information in the booklet?...was it too much or too little?
- Do you think that we should include any other information in the booklet?

10) What information do you think should be included in information leaflets about the NHS Bowel Cancer Screening Programme?

Prompts:

- Is it important for you to be informed about the benefits or advantages of screening in the information materials?
- Is it important for you to be informed about the risks or downsides of screening in the information materials?
- Do you know what happens if a person has a positive or abnormal screening result? (new)
- Do you think that you should have information about what happens if you have a positive or abnormal screening result? – if so, how much detail? (treatment?)
- Is there any other information that you would like included in the information materials?

12) If you felt that you wanted further information about bowel cancer screening or had any questions about the test, where would you go or look for this information?

Prompts:

- If you had any questions about bowel cancer screening do you think that you would speak to your GP?
- Would you feel comfortable talking to your GP about bowel cancer screening?
- Is there anyone else that you might talk to about bowel cancer screening if you had any questions?
- If a letter from your GP which endorsed bowel cancer screening was included in the invitation to screening, would that have any effect on your intention to do the test?

E. Informed Choice

13) The NHS Cancer Screening Programme believes that people should be provided with enough information so that they can make an informed choice to participate or not in the bowel cancer screening programme – I was wondering, do you feel that you made an informed choice about completing screening?

Prompts:

- Do you think that it is important that people should make an informed choice to participate or not in bowel cancer screening?

F. Completion of Interview

14) I only have a couple of further questions for you before the interview is completed, Do you have any suggestions for how the Bowel Cancer Screening Programme could be improved or better delivered to people?

Prompts:

- Were you satisfied with the amount of time between returning your kit and receiving the results letter?
- Were you anxious at all during this time?
- And finally, do you think that you will do the test again if asked in two years time?

15) Did you have any other questions about the study that you would like to ask me?

Prompts:

- Thank the person for spending time talking with us concerning bowel cancer and bowel cancer screening
- Inform the person that they will receive a summary of the results of the study around March 2009
- Offer the person the opportunity to see (be sent) the transcribed interview so that they can decide if they wish to remove any parts they are uncomfortable about
- Make certain that if the person has any need to contact the researchers, that they have full contact details

Appendix 7.1: Factorial Trial Protocol

A Primary Care Based Intervention to Improve Participation in the NHS Bowel Cancer Screening Programme (Protocol Version 2: 20/03/2009)

Short Title Public Perceptions of Bowel Cancer Screening

Investigator: Paul Hewitson
Research Fellow
Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF

Tel: 01865 289359
Fax: 01865 289287
Email: paul.hewitson@dphpc.ox.ac.uk

Supervisors: Dr Joan Austoker – Director, CRUK Primary Care Education Research Group, Department of Public Health, University of Oxford

Prof Paul Glasziou – Director, Centre for Evidence-Based Medicine, Department of Primary Health Care, University of Oxford

Funding: National Institute for Health Research (NIHR) / NHS Cancer Screening Programmes

Support: Part of the NIHR Clinical Research Network Portfolio; Study No.: 6013 (NIHR Primary Care Research Network/NIHR Cancer Research Network)

1.0 Purpose of Research

This factorial randomised trial aims to:

- improve participation in the NHS Bowel Cancer Screening Programme (BCSP) through the provision of a General Practitioner (GP) endorsement letter and/or a detailed leaflet for overcoming procedural barriers to completing the faecal occult blood test (FOBT)
- evaluate patient perceptions of the role that GP endorsement and information materials have on making an informed choice to participate or not in the programme
- identify patient factors that contribute to the short and long-term participation in the NHS BCSP and the impact of the intervention for GP resources
- three-year study (information development, pilot study, factorial randomised controlled trial and dissemination of results)

2.0 Summary

The newly established NHS Bowel Cancer Screening Programme (NHS BCSP) offers all eligible men and women aged 60 to 69 a faecal occult blood test (FOBT) every two years in a home-mailed invitation pack. The research trial will evaluate the effectiveness of including a GP endorsement letter and/or a detailed FOBT procedural leaflet in the home-mailed invitation pack for improving participation in the NHS BCSP. The results of the project are anticipated to inform the enhancement of targeted information materials for the NHS BCSP, evaluate the role of primary care for patient choice in bowel cancer screening and directing future research aimed towards improving patient participation in the programme.

3.0 Research Synopsis

Interventions	GP Endorsement Letter Detailed Procedural Leaflet ('Help with the Test')
Study Design	Factorial randomised trial (2 X 2 design)
Study Settings	NHS Bowel Cancer Screening Hub - South of England Primary Care Practices (South-East and South West England)
Study Participants	People aged 60-69 invited to the NHS Bowel Cancer Screening Programme (NHS BCSP)
No. of Participants	Approximately 1,000
Study Period	Recruitment for 'Baseline Questionnaire' = 21st Sep to 25th Sep Screening Invitation = 26th Oct to 30th Oct FOBT Kits and Interventions = 2nd Nov to 6th Nov 'Follow-Up Questionnaire' = 23rd Nov to 30th Nov Reminder 'Follow-Up Questionnaire' = 14th Dec to 18th Dec Verify participation/non-participation = 1st Feb to 5th Feb
Primary Objective	Evaluate the effectiveness of the interventions for improving participation in the NHS BCSP
Primary Outcome	Verified participation or non-participation in the NHS BCSP
Secondary Objectives	Assess predictors of participation/non-participation in the NHS BCSP and satisfaction with information materials
Secondary Outcomes	Knowledge, self-efficacy, self-determination, perceptions of the information materials, attitudes towards bowel cancer screening

4.0 Background

Bowel cancer is a leading cause of mortality and morbidity in the western world. It is the second leading cause of cancer death in Europe[1] and the United States[2]. Survival rates for people diagnosed with bowel cancer are somewhat higher in the US than Europe, although this difference is mostly attributed to differences in the stage of diagnosis[3]. Screening aims to reduce mortality in the target population by identifying cancer at an early stage when treatments are more likely to be effective. For average risk populations, substantial evidence from a recent systematic review[4] of published randomised controlled trials [5-7] has indicated that screening using the faecal occult blood test (FOBT) can significantly reduce bowel cancer mortality.

Following the success of the UK Bowel Cancer Screening Pilot[8], the NHS Bowel Cancer Screening Programme (NHS BCSP) was introduced in Spring 2006[9]. Men and women aged 60-69 years receive a mailed invitation pack that includes an invitation letter, an evidence-based information booklet about bowel cancer screening, the FOBT kit with return envelope and brief instruction leaflet for completing the test. However, there are concerns for the uptake of bowel cancer screening in the population. The overall adherence to bowel cancer screening is generally poor, with approximately 55% of people participating in UK studies[5,8], which is slightly higher than other countries[4,10]. The development and evaluation of feasible and cost-effective interventions that can increase patient acceptance and participation are crucial to the success of an effective bowel cancer screening programme.

Patient knowledge of the availability and benefits of bowel cancer screening, underestimating the risks of developing bowel cancer or lack of interest in testing without symptoms, and patient concerns coupled with negative perceptions of the FOBT procedure have been forwarded as contributing to poor compliance[10-12]. Whereas evidence-based information materials may be able to raise awareness and provide people with more realistic estimations

of risk, the procedural barriers to completing the FOBT may not be meet by information provision alone. Given the recent attention to the provision of decision-aids to help people make choices that reflect their personal preferences[13], several investigations have evaluated high-quality, evidence-based information materials designed to improve understanding and increase participation[14-16]. However, these studies have failed to demonstrate a significant improvement in initial or long-term compliance with bowel cancer screening, strongly suggesting alternative strategies are needed to enhance patient acceptance and participation.

One potential strategy to improve participation is an intervention delivered by primary care General Practitioners (GPs). Recent UK surveys have found that doctors are the most trusted profession[17] and that 73% of people would seek information from their doctor about common health care issues in comparison to written information or other sources[18]. Previous research has indicated that the involvement of GPs can improve patient compliance with bowel cancer screening[10,19]. Furthermore, other studies have shown that providing patients with more detailed instructions on the collection, storage and return of FOBT also modestly increases patient compliance with FOBT[20,21]. However, no currently published studies have attempted to combine the important influence that GPs have for patient acceptance and decision-making for bowel cancer screening with an information intervention specifically developed to overcome procedural barriers (patient negative perceptions of bowel cancer screening for performing the FOBT). The opportunity to prospective evaluate the effectiveness of including a primary care-based information intervention that directly addresses patient concerns about procedural barriers to FOBT would be both an internationally unique topic of investigation and advantageous for improving the delivery of the NHS BCSP.

4.1 Theoretical Framework

The theoretical framework of the study is centred on a synthesis of basic research on how people process health information combined with the development and evaluation of theory-based interventions to promote healthy behaviour. The research project is influenced by recent work by Rothman and colleagues[22,23], which emphasises the role of patient information materials in initiating changes in health behaviour, and self-determination theory[24,25]. Self-determination theory suggests that the more autonomously motivated a behaviour is, the more likely an individual will engage and maintain this behaviour[24,25]. The research also draws heavily on behavioural theory, specifically concerning social cognitive approaches[26] to evaluate people's perceived self-efficacy for participating in bowel cancer screening. Although we have included outcomes in the proposal that are firmly based in behavioural theory (e.g. self-efficacy, intention to participate, perceived risk, knowledge and attitudes towards bowel cancer screening), we are cognisant of difficulties encountered when limiting cancer screening research to one particular theoretical approach, such as the difficulties encountered with the Health Belief Model (HBM) and the Transtheoretical Model (TTM) in this field of research[27,28]. The current research will attempt to incorporate the traditional methods of behavioural research with more recently developed frameworks in an attempt to reconcile the reasons for people's participation and non-participation in bowel cancer screening and the effectiveness that information can have for improving participation in bowel cancer screening.

4.2 MRC Framework

The structure of the design and methodology of the research programme was based on the MRC framework[29,30], with particular attention to the Pre-Clinical (theoretical), Phase 1 (modelling) and Phase 2 (exploratory trial) of the guidance. The theoretical basis for the study was developed from an extensive systematic review of the literature concerning patient information for bowel cancer screening[31] and built on previous qualitative research conducted by the Department[32,33]. Together with the pilot research phase of the study (aiming to refine the outcome measures and clarify modelling issues), this satisfies the pre-clinical and Phase 1 of the framework[29,30]. The framework also formed the basis for employing a factorial design for the RCT which will allow the opportunity to discriminate the relative impact that the two interventions may have on participating in bowel cancer screening, without the considerable expense and complexity of a much larger RCT. Effectively, this enables us to ascertain the most effective intervention for improving participation in screening (satisfying Phase 2), before embarking on a future definitive RCT and considering implementation based on these findings (Phases 3 and 4 of the framework)[29].

5.0 Three-Year Research Programme

The proposed research programme is an extension of work undertaken by the University of Oxford Department of Primary Health Care for the NHS BCSP, including the development of the evidence-based, information booklet (Bowel Cancer Screening: The Facts) currently included in the NHS BCSP invitation materials. The research has also been informed by discussions with lay, patient advocacy and health professional representatives.

There are three main phases for the three-year research plan. These are:

- Stakeholder consultation(*ongoing*): development of a detailed procedural leaflet to provide advice and 'tips' for collecting, storing and returning their FOBT kit ('Help with the Test' leaflet)
- Intervention pilot study (*Oct 2008 – April 2009*): questionnaire and interview series that aimed to evaluate the detailed procedural leaflet, current NHS BCSP information ('*Bowel Cancer Screening: The Facts*') and evaluate outcome measures main trial
- Factorial randomised controlled trial (*May 2009 – Sept 2010*): two interventions will simultaneously be evaluated in this trial. A before-and-after questionnaire design will be employed to ascertain if either a letter from a GP which endorses the NHS BCSP and/or a detailed procedural leaflet ('Help with the Test') will improve screening participation

The study has been extensively discussed and refined with the help of the NHS BCSP management. The recruitment of participants has been organised with the assistance of the NHS BCSP South of England Programme Hub. The study is funded by the National Institute for Health Research and the NHS Cancer Screening Programmes.

5.1 Stakeholder Consultation and Intervention Pilot Study

The development of the detailed FOBT procedural leaflet was based on a systematic review of published literature concerning information provision for bowel cancer screening[31] and focus groups conducted during the development of the current NHS BCSP information materials[33]. Advice and comments on the detailed FOBT procedural leaflet were sought from key stakeholders including representatives from patient advocacy groups (Beating Bowel Cancer, Bowel Cancer UK), lay representatives (NCRI Consumer Liaison Group representative, bowel cancer survivor representative), NHS BCSP staff, cancer screening researchers and General Practitioners. The detailed FOBT procedural leaflet, the current NHS information booklet ('*Bowel Cancer Screening: The Facts*') and outcome measures that would be used in the factorial trial (e.g. knowledge scale, attitude scale, etc) were evaluated in the intervention pilot study conducted in late-2008 (analysis of the pilot study will continue until April 2009).

Three hundred people (200 who had completed screening and 100 who did not participate) were recruited for the intervention pilot study. The response rate for pilot questionnaires returned by participants was far greater in the screened group than in the non-screened group. The overall response rate was 36.9% (109/295); 51% (102/200) for the screened group and 7.4% (7/95) for the non-screened group. The outcome measures evaluated in the pilot study have been refined for inclusion in the main trial. The results of the pilot study do suggest that the leaflet was well received by participants and may be useful to people who have concerns about the most effective ways of completing the FOBT kit. For example:

- almost all people reported the leaflet would be useful for completing screening
- the leaflet was easy to read and contained the right amount of detail
- the suggestions for collecting and storing the samples were well received

In-depth interviews were conducted with twenty-one people who completed the pilot questionnaire. Participants were drawn from eight regions covering the south-east, central and midlands of England. Questions asked of participants during the interview ranged from their views about FOBT and bowel cancer screening in general, to more specific questions concerning their perceptions of the information materials ('Help with the Test' leaflet and 'The Facts' booklet), their understanding of bowel cancer screening and the role information. The results of the pilot study suggested that, although the information materials were useful and the role of GPs important to making a decision about screening, other factors (i.e. beliefs

about prevention, knowing someone who had bowel cancer, etc) were instrumental in choosing to participate in the screening programme. The results of the questionnaire and qualitative components of the pilot study were reported to the key stakeholders to inform the second round of discussions concerning improving the 'Help with the Test' leaflet. The comments and suggestions by the stakeholders have been incorporated into the current leaflet.

6.0 Factorial Randomised Trial

The factorial randomised trial represents the final phase of the research programme. This phase will enable the intervention to be prospectively examined in a representative sample of people invited to the NHS BCSP and to assess important issues (design, recruitment issues, involvement of GPs, utility of outcome measures, etc) for the development of future research in this area. The main aim is to evaluate the effectiveness of either the GP endorsement letter or the detailed FOBT procedural leaflet on participation rates in comparison to the standard information currently sent by the NHS BCSP.

6.1 Study Interventions (Detailed FOBT Procedural Leaflet/GP Endorsement Letter)

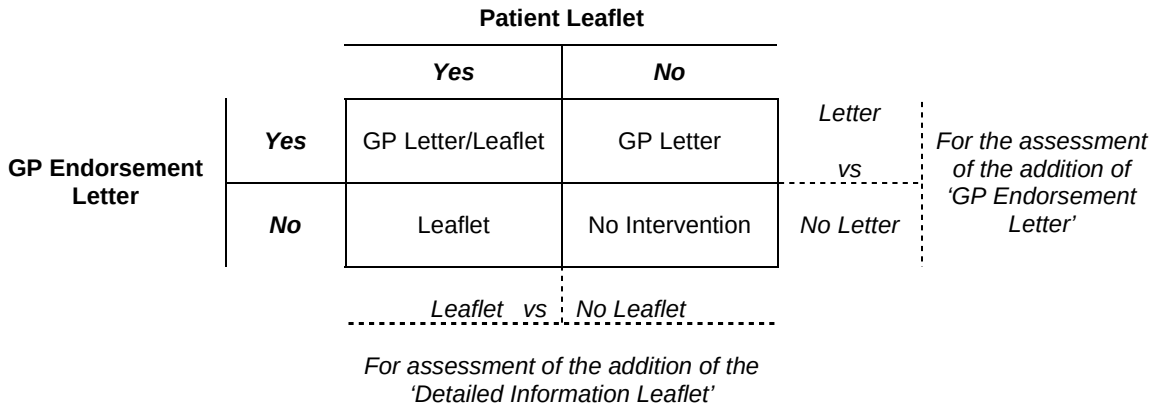
Two interventions will be evaluated in the research programme. These are:

- Detailed FOBT procedural leaflet ('Help with the Test') – a double-sided A4 leaflet that directly addresses the procedural barriers to completing the FOBT kit. The detailed procedural leaflet aims to provide people with suggestions and 'tips' for the collection, storage and return of their FOBT kit. The leaflet includes detailed information about overcoming potential barriers to participation, address concerns about the collection of stools and provide advice on the storage and return of the FOBT kit
- GP endorsement letter – a letter endorsing the NHS BCSP from the person's GP Practice which will be sent with their invitation to participate in the NHS BCSP

6.2 Study Design

Currently, people invited to the NHS BCSP receive an invitation letter and an evidence-based patient booklet ('Bowel Cancer Screening: The Facts') one week before they receive their FOBT kit. The FOBT kit includes a FOBT card, spatulas for smearing samples on the card, basic instructions for completing FOBT and a return-post envelope. The trial will evaluate the effectiveness of the intervention materials for improving participation in FOBT screening in comparison to people receiving current NHS BCSP information. The design of the trial is presented in Figure 1.

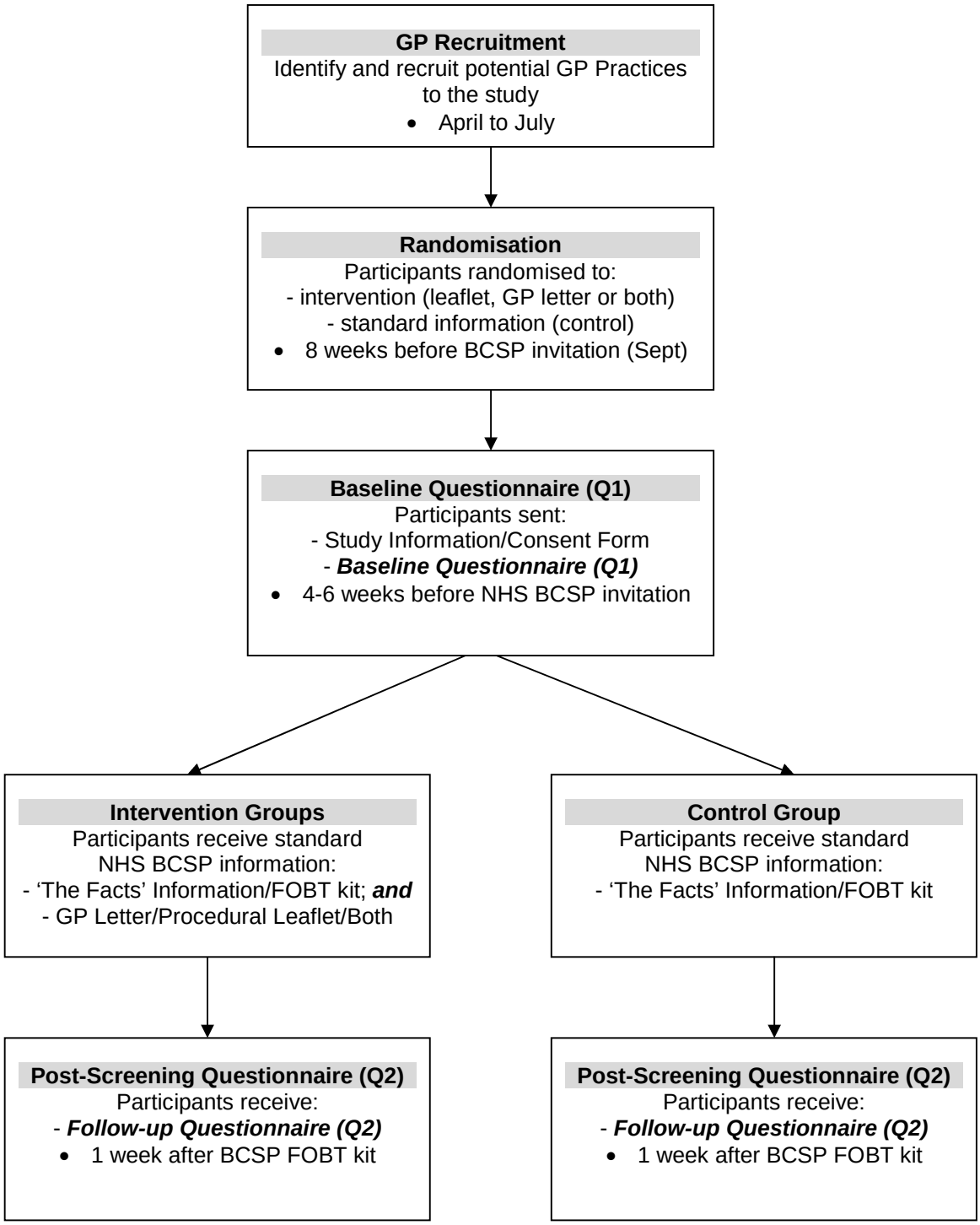
Figure 1: Design of the factorial randomised controlled trial



Note: all participants will receive the standard NHS BCSP information and screening kit.

Approximately 1,000 people invited to the NHS BCSP will be asked to participate in the study. After collaborating GP Practices are recruited, participants will be centrally randomised using a random number generator. Study participants will receive the baseline questionnaire four to six weeks before their invitation to screening (please see Figure 2).

Figure 2: Flow diagram of the factorial randomised trial.



The follow-up questionnaire (Q2) will be sent one to two weeks after participants receive their NHS BCSP FOBT kit. The post-screening questionnaire will include the same outcome measures as used in the baseline questionnaire, allowing for statistical comparisons of possible changes in knowledge, self-efficacy, perceived risk, self-determination and attitudes towards bowel cancer screening. The post-screening questionnaire will also assess participant's views of the intervention materials and the potential influences on their decision

to either complete, or not complete, the FOBT kit. One reminder questionnaire will be sent to non-responding participants four weeks after they are sent the follow-up questionnaire (Q2).

6.3 Study Settings

The study will be conducted in collaboration with the NHS Bowel Cancer Screening Programme Hub - South of England, based at the University of Surrey. The Programme Hub operates the call and recall system to send out FOBT kits, analyse samples and despatch results for the south of England.

6.3.1 Recruitment of GP Practices

General Practitioner (GP) Practices will be recruited in the south-east and south-west of England with the help of the NIHR Primary Care Research Network (PCRN). GP practices will be selected on the basis of overall socio-economic status of patients (based on deprivation index[34,35], number of patients aged 60-69 and geographical location (city versus rural). Discussions with PCRN groups for facilitating recruitment of GP Practices were started in late-March and it is expected that all GP Practices will be recruited by July 2009.

6.4 Study Participants

People in the general population, aged between 60-69 years, receiving their mailed invitation to participate in the NHS BCSP would be eligible for inclusion in the study. People who accept or decline the invitation to the NHS BCSP bowel cancer screening are eligible for inclusion. People who have been excluded from the NHS BCSP (e.g. current bowel cancer patients, people currently involved in bowel cancer surveillance programmes, etc) or who have directly requested to be excluded from the NHS BCSP would not be included in the study.

6.4.1 Justification of Sample Size

Based on the UK Bowel Cancer Screening Pilot[8] and a review of reported rates adherence to bowel cancer screening[10], it was estimated that the FOBT participation rate would be approximately 45% in the current information group (the 45% FOBT participation rate is based on the assumption that approximately 5% of people who are invited to screening are not eligible for the programme due to existing medical conditions or having recently moved from the invited area). 376 participants per group will be required to detect an absolute difference of 10% (assuming a completion rate of 65% in the enhanced information group and 55% in the current information group) at a power of 80% and a two-tailed α of 0.05 (please see Appendix A in this document).

6.5 Primary Outcome (Participation in the NHS BCSP)

The primary outcome for the trial is verified participation in the NHS BCSP. As part of the quality assurance process employed by the NHS BCSP, verification of participation of all people who have been invited to the programme is assessed 12 weeks after the FOBT kits have been posted. Verification of participation will be conducted by NHS BCSP staff to ensure patient confidentiality.

6.6 Secondary Outcomes (Questionnaire)

The baseline and follow-up questionnaire includes:

vi. demographic information (age, gender, socio-economic status, education level, ethnicity)
vii. predictors of bowel cancer screening participation: (perceived risk of developing/dying from bowel cancer, family or personal history of bowel cancer, previous participation in bowel cancer screening)
viii. knowledge and attitudes about bowel cancer and bowel cancer screening
ix. evaluation of materials (perceptions of the 'Help with the Test' leaflet and current NHS BCSP information materials)
x. information-seeking behaviour (relative importance of GP advice and information materials for decision-making, important information for decision-making)
xi. self-efficacy (perceived ability to perform the FOBT)
xii. self-determination (Treatment Self-Regulation Questionnaire)

6.7 Analysis

Data will be double entered and analysed using STATA descriptive statistics, t-test (or non-

parametric equivalent if unequal sample sizes) and other relevant statistical analysis as required. Data will be analysed using descriptive statistics, t-test (or non-parametric equivalent if unequal sample sizes) and other relevant comparative analyses as required. Multivariate regression modelling will be used to identify factors associated with predictors of participation and non-participation in the NHS BCSP. The primary outcome, completing and returning the FOBT kit, will be verified with the NHS BCSP at 12 weeks.

6.8 Impact for GP Resources

The impact of the intervention on the workload and resources of GPs will be assessed through an audit of study participant's contact with GPs and primary care staff. Mechanisms and procedures for auditing the frequency of contact and pertinent concerns raised by participants will be based on a brief questionnaire completed by the collaborating GPs. This component of the research has been informed by previous research[36] and is expected to provide valuable information for directing future projects centring on enhancing GP involvement in the NHS BCSP and the potential impact this may have for primary care resources. The cost-effectiveness will be based on the direct costs of providing the information intervention and on GP resources.

6.9 Impact for future research planning

The study will provide valuable data to help in the design, conduct and analysis of the larger scale randomised controlled trial of information interventions for bowel cancer screening delivered by the NHS BCSP. The study will provide data on the response rate by specific groups to the study (e.g. ethnic minority groups, people not participating in the NHS BCSP and who are difficult to attract to research studies). Estimates of response rates will be used to structure the recruitment design of the RCT (e.g. stratifying the recruitment process for the randomised study). The study will also provide important data for further investigations of the workload and resource expenditure for GP participation in the NHS BCSP.

7.0 Dissemination of Results

The results of the study will be reported to the collaborative group and also presented to the NHS Cancer Screening Programmes, the NHS Bowel Cancer Advisory Group and the NCRI. Three major peer-reviewed publications are expected to be developed from the research and the results will be presented at national and international conferences. Discussions with other academic institutions are also expected to be developed. Recommendations concerning the implementation and further research programme will be addressed with the relevant bodies.

8.0 Timeline for Research Project

	2009										2010
Task	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**
Consultation with stakeholders											
Ethics Submit/Approval (11 May)											
R&D Submitted/Approval											
Randomisation/Hub Organisation											
Q1 Mail-out											
Invite / FOBT kit / Letter/Leaflet											
Q2 Mail-Out											
Q2 Reminder Mail-out											
Confirmation of Participation											
Data Entry/Analysis											

	2010										
Task	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**
Confirmation of Participation (*cont*)											
Data Entry/Analysis (*cont*)											
Final analysis											
Dissemination/stakeholder mtng											
Final report/Peer review pubs.											

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Appendix A: Detailed sample size calculation for the factorial trial

The present research project is based on a factorial randomised controlled design. The trial is powered to detect the main effects of each intervention (the trial is not powered to detect an interaction between the two interventions, which is considered to be low).

Justification of Sample Size
Based on the UK Bowel Cancer Screening Pilot[8] and current reported rates of participation in the NHS BCSP (personal communication), it was estimated that the FOBT participation rate would be approximately 45% in the standard information group (please see Figure 3). The 45% FOBT participation rate is based on the assumption that approximately 5% of people who are invited to screening are not eligible for the programme due to existing medical conditions or having recently moved from the invited area).

80% Power
Assuming a completion rate of 65% in either the patient leaflet and/or GP endorsement group (marginal total 65%) and 45% in the standard information group (marginal total 55%), 376 participants per group (total 752) will be required to detect an absolute difference of 10% at a power of 80% and a two-tailed α of 0.05.

Figure 3: Design of the factorial randomised controlled trial including expected response rates for interventions and marginal totals.

		GP Endorsement Letter		
		Yes	**No**	***Marginal Total***
Detailed Procedural Leaflet	**Yes**	Group 1 (Both): 65%	Group 3 (Letter): 65%	65%
	No	Group 2 (Leaflet): 65%	Group 4 (Control): 45%	55%
	Marginal Total	65%	55%	

- 'GP Endorsement Letter' verses 'No Letter' - Grps 1/2 (65%) versus Grps 3/4 (55%) = 10%; 376 per group (Total participants required = 752)
- 'Detailed Procedural Leaflet' versus 'No Leaflet' - Grps 1/3 (65%) versus Grps 2/4 (55%) = 10%; 376 per group (Total participants required = 752)

Sample size for interaction
The sample size for the study would need to be expanded significantly to detect an interaction between the two interventions. Based on previous research, the current sample size would need to be increased four-fold (3,008 required participants) to detect an interaction of the same magnitude as the main effects (i.e. a 20% increase in uptake for the letter/leaflet group).

Appendix 7.2: Stakeholder Summary

Stakeholder Summary for 'Primary Care Based Interventions for Improving Participation in the NHS Bowel Cancer Screening Programme'

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Funding: National Institute for Health Research (NIHR) / NHS Cancer Screening Programmes

Support: NIHR National Cancer Research Network

1.0 Aim of Document

The aim of this document is to provide key stakeholders with a summary of the results of the pilot study concerning the detailed procedural leaflet and further information about the proposed factorial randomised controlled trial.

2.0 Role of Stakeholders

The primary role of stakeholders is to provide advice, criticisms and suggestions for improving the detailed procedural leaflet ('Help with the Test') that will be evaluated in the factorial randomised trial. Previously, stakeholder's comments were integral to the development of the pilot version of the leaflet. It is hoped that the results of the pilot study included in this document will be useful for key stakeholders to further formulate their thoughts and provide suggestions for improving the detailed procedural leaflet. Stakeholders will also receive further information on the progress and results of the randomised trial at the conclusion of the study.

3.0 Background

The NHS Bowel Cancer Screening Programme (BCSP) was introduced in England in July 2006. Currently, the participation rate for the programme is approximately 52% (December 2008). Although the participation rate for England is similar to other FOBT programmes, interventions that can improve peoples' acceptance of the screening test or enhance peoples' understanding of the importance of cancer screening, may result in increased participation in the programme. The present three-year research programme will evaluate whether or not targeted interventions have an effect on participation and satisfaction with the NHS BCSP.

4.0 Research Programme

The current three-year research programme is funded by the National Institute for Health Research and the NHS Cancer Screening Programmes. There are three phases to the research programme:

1) Stakeholder involvement (*ongoing*): development of a detailed procedural leaflet to provide advice and 'tips' for collecting, storing and returning the FOBT kit ('Help with the Test' leaflet)
2) Pilot study (*Oct 2008 – April 2009*): questionnaire and interview series that aimed to evaluate the procedural leaflet, current NHS BCSP information ('The Facts') and evaluate outcome measures for the main randomised controlled trial
3) Factorial randomised controlled trial (*May 2009 – Mar 2010*): two interventions will simultaneously be evaluated in this trial. A before-and-after questionnaire design will be employed to ascertain if either a letter from a GP which endorses the NHS BCSP and/or a detailed procedural leaflet ('Help with the Test') will improve screening participation (please see Figure 1)

Figure 1: Design of the factorial randomised controlled trial

		'Help with the Test' Leaflet	
		Yes	***No***
GP Endorsement Letter	***Yes***	Letter/Leaflet (200 people)	GP Letter (200 people)
	No	Leaflet (200 people)	No Intervention (200 people)

Note: all participants will receive the standard FOBT Kit information.

Randomised participants in the trial will receive a baseline questionnaire (Q1) six weeks before their invitation to the NHS BCSP. They will then receive the 'Help with the Test' leaflet, the GP endorsement letter or both interventions at the time they receive their FOBT Kit. The intervention questionnaire (Q2) will also be sent with the FOBT Kit. A reminder intervention questionnaire will be sent to people who have not returned Q2 approximately four weeks after the FOBT Kit was received.

5.0 Trial Interventions

Two interventions will be evaluated in the research programme. These are:

- Detailed procedural leaflet ('Help with the Test') – a double-sided A4 leaflet that directly addresses the procedural barriers to completing the FOBT kit. The detailed procedural leaflet aims to provide people with suggestions and 'tips' for the collection, storage and return of their FOBT kit. The leaflet includes detailed information about overcoming potential barriers to participation, address concerns about the collection of stools and provide advice on the storage and return of the FOBT kit
- GP endorsement letter – a letter endorsing the NHS BCSP from the person's General Practitioner which will be sent with their invitation to participate in the NHS BCSP

The detailed procedural leaflet will be further developed and refined with advice and support from key stakeholders. This leaflet was recently been evaluated in the pilot phase of this research programme (see 6.0 Results of the Pilot Study). The GP endorsement letter will be developed when the recruitment of GP Practices begins (April 2009).

6.0 Results of the Pilot Study

The pilot study aimed to evaluate the 'Help with the Test' leaflet, perceptions of the NHS BCSP booklet ('Bowel Cancer Screening: The Facts') and to develop outcome measures for the main trial (e.g. knowledge scale, attitude scale) was completed in late 2008. Two hundred people who had completed FOBT and one-hundred people who had not participated in screening were sent the pilot questionnaire that included the pilot 'Help with the Test' leaflet.

6.1 Questionnaire Results

The response rate for pilot questionnaires returned by potential participants was far greater in the screened group than in the non-screened group. Only people who returned their consent form with their pilot questionnaire were included in the analysis. Ten people (8 no consent; 2 incomplete questionnaires) in the screened group and three people (2 no consent; 1 incomplete questionnaire) in the non-screened group were excluded from the analysis. Therefore, the overall response rate for valid questionnaires was 36.9% (109/295); 51% (102/200) for the screened group and 7.4% (7/95) for the non-screened group.

Demographic characteristics of the pilot participants are shown in Table 1. There were no significant differences in regards to participant characteristics between males and females in the screened group (the low sample size for the non-screened group does not allow for statistical comparisons).

Table 1: Participant characteristics for people returning the pilot questionnaire.

	Screened Group			**Non-Screened Group**		
	Total	***Male***	***Female***	***Total***	***Male***	***Female***
Age	**102**			**7**		
60-64	53 (52%)	23	30	2 (29%)	1	1
65-69	49 (48%)	23	26	5 (71%)	4	1
Martial Status						
Married	76 (75%)	38	38	7 (100%)	5	2
Widowed	11(11%)	1	10			
Single	3 (3%)	0	3			
Divorced	12 (12%)	7	5			
Education						
'O' Level	21 (21%)	6	15	4 (57%)	3	1
'A' Level	6 (6%)	4	2	1 (14%)	1	0
Clerical/Commercial	17 (17%)	9	8	2 (29%)	1	1
University/College	21 (21%)	11	10			
None of above	37 (36%)	16	21			
General Health						
Excellent	17 (17%)	9	8	4 (57%)	2	2
Good	66 (65%)	28	38	1 (14%)	1	0
Fair	16 (16%)	8	8	2 (29%)	2	0
Poor	3 (3%)	1	2			
Ethnicity						
White	101 (99%)	46	55	7 (100%)	5	2
White (Other)	1 (1%)	0	1			
Aware of BCSP						
Yes	57 (56%)	20	37	5 (71%)	4	1
No	45 (44%)	26	19	2 (29%)	1	1
Previous FOBT						
Yes	26 (25%)	10	16	4 (57%)	3	1
No	75 (74%)	35	40	3 (43%)	2	1
Don't know	1 (1%)	1	0			

Participants' responses to the 'Help with the Test' leaflet are shown in Table 2. There were no significant differences between males and females in the screened group regarding their perceptions of the booklet. People in the non-screened group were generally less enthusiastic about the leaflet, although the small sample size makes comparisons difficult. Almost all screened group participants reported that the leaflet contained the right amount of detail (98%) and was easy to read (95%). Approximately three-quarters of screened group respondents indicated that the suggestions for collecting (74%) and storing (72%) the FOBT sample were 'very useful'. Only one person (1%) reported that the information for collecting the FOBT sample was 'not really useful', with four people reporting that the information for storing the FOBT sample was 'not really useful' (3%) or 'not useful at all' (1%). A high proportion of people reported that the leaflet would be 'very useful' (79%) or 'somewhat useful' (20%) for helping people complete screening. Approximately half of people (51%) indicated that they were more positive about CRC screening after reading the leaflet, in contrast to 48% who reported that it had not changed their minds. 91 (83%) people did not think that the layout or design needed to be changed.

Table 2: Participants' responses to 'Help with the Test' leaflet for all participants, the non-screened and screened groups.

	All (109)	**Non-Screened Group (7)**	**Screened Group**	
			Male (46)	***Female (56)***
Useful for decision				
Very	86 (79%)	3 (43%)	35 (76%)	48 (86%)
Somewhat useful	22 (20%)	4 (57%)	10 (22%)	8 (14%)
Not very useful	1 (1%)	0	1 (2%)	0
Level of detail				
About right	107 (98%)	7 (100%)	44 (96%)	56 (100%)
Not enough	2 (2%)	0	2 (4%)	0
Readability				
Easy to read	103 (95%)	6 (86%)	43 (93%)	54 (96%)
Slightly difficult	6 (5%)	1 (14%)	3 (7%)	2 (4%)
Suggestions (collecting)				
Very useful	81 (74%)	4 (57%)	33 (72%)	44 (79%)
Somewhat useful	26 (24%)	2 (29%)	12 (26%)	12 (21%)
Not really useful	2 (2%)	1 (14%)	1 (2%)	0 (0%)
Suggestions (storing)				
Very useful	79 (72%)	3 (43%)	32 (70%)	44 (78%)
Somewhat useful	25 (23%)	3 (43%)	12 (26%)	10 (18%)
Not really useful	4 (4%)	1 (14%)	2 (4%)	1 (2%)
Not useful at all	1 (1%)	0	0	1 (2%)
Influenced views of FOBT				
More positive	56 (51%)	3 (43%)	27 (59%)	26 (46%)
Not changed	52 (48%)	4 (57%)	19 (41%)	29 (52%)
Not sure	1 (1%)	0	0	1 (2%)
Change design				
Yes	5 (5%)	0	3 (7%)	2 (4%)
No	91 (83%)	7 (100%)	36 (78%)	48 (86%)
Not sure	13 (12%)	0	7 (15%)	6 (10%)
Include further information				
Yes	5 (5%)	0	3 (7%)	2 (4%)
No	89 (82%)	7 (100%)	37 (80%)	45 (81%)
Not sure	14 (13%)	0	6 (13%)	8 (15%)

Two people suggested changing the design to stress that piles are a cause of bleeding or emphasise that the FOBT is disposable. The other three responses concerned correcting a typographical error in the leaflet (now corrected). Five people each

provided a single suggestion for improving the leaflet by including further information about piles, diet to prevent CRC, diverticulitis, a persons' next screening date, and what to do if you have large stools.

6.2 Summary Points for Questionnaire Responses

It is important to note that research in this field can suffer from social desirability bias (essentially, participants respond more favourably to the questions than they 'honestly' feel). It is also important to indicate that the vast majority of responses are from people who participated in the programme, and therefore, have generally positive attitudes towards bowel cancer screening. However, the results of the pilot study do suggest that the leaflet was well received by participants and may be useful to people who have concerns about the most effective ways of completing the FOBT kit. For example:

- almost all people reported the leaflet would be useful for completing bowel cancer screening
- the leaflet was easy to read and contained the right amount of detail
- the suggestions for collecting and storing the samples were well received (although it is hoped that this could be increased in the non-screened group)

Unfortunately, there were very few suggestions from questionnaire participants regarding any specific changes that could be incorporated into the leaflet. In-depth interviews were conducted with a selection of questionnaire respondents to further investigate views concerning the information materials and bowel cancer screening in general.

6.3 Interview Series Results

In-depth interviews were conducted by telephone with 21 people (20 who completed screening and one who did not) between late-November to mid-December (please see Table 3). Participants were drawn from eight regions covering the south-east, central and midlands of England. Questions asked of participants during the interview ranged from their views about FOBT and bowel cancer screening in general, to more specific questions concerning their perceptions of the information materials ('Help with the Test' leaflet and 'The Facts' booklet), their understanding of bowel cancer screening and the role information. Participants were sent the detailed procedural leaflet and 'The Facts' booklet before the interviews.

Table 3: Gender and age groups for participants in the interview series.

	Aged 60-64	**Aged 65-69**	***Total***
Male	3	7	10
Female	7	4	11
Total	10	11	***21***

The analysis of the interview series is still on-going (analysis began on the qualitative data in late-February), however, a preliminary analysis of responses concerning participants' perceptions of the leaflet has been undertaken and is briefly described below.

Nearly all of the respondents were very positive about the 'Help with the Test' leaflet, offering few suggestions in regards to either including any further information or changing the current layout. A selection of the comments made by respondents is presented below:

Q05: "Yes. I found that very clear…I think there's enough information there for people."

Q10: "I think it was very informative and to me, I mean it was easy to do it – will it take too much time, will it be messy – everything was there…No. I mean it tells you to keep your eye on your symptoms, which I thought was good. Yeah, no I think you've done quite a good job here."

Q12: "…but I can imagine that in doing it some people would find it unpleasant, and that in itself might be a bit of a deterrent. I wouldn't know what one could do about it other than really emphasise the seriousness of bowel cancer, which the documentation does tell you. It explains clearly all about it. Whether there's a bit of information overload is another matter."

Q14: "I thought it was well written. I think, I couldn't think of anything. I thought you reassured people the whole time, you know and it won't take too much time, and storing the samples. No I thought it was well written."

Q21: "Yes it was pretty good, it was clear, there's no technical language you know. No I thought all in all it was pretty satisfactory really."

The only suggestions for improving the leaflet tended to reflect respondents lack of understanding for why some people decide not to participate in bowel cancer screening. Several other comments were related to reinforcing preventative behaviours after screening or changing wording to avoid highlighting the barriers of participating (e.g. Q03 "Will it take too much time?"). A selection of the comments made by respondents is presented below:

Q01: "The suggestions about lifestyle are useful. I think I know them, but you know having had an all clear it would be quite nice for people perhaps who don't know to say the sort of things to avoid, like you know avoiding constipation and keeping fit you know, exercising, that sort of thing."

Q03: "Yes, yes. And this is to try and sort of prod the non-believers into saying come on do something about it I would presume…Do you not think that that wouldn't be a bad idea though overall? Well perhaps not overtly but just a little bit more subtly?...Little bit more, little stronger than at present shall we say." [encouraging people to do the test]

Int: "Okay, so trying to frame our message somewhat more positively?"

Q03: "Yeah, yeah, yeah, yeah, be a bit more positive about it. Good idea. Because after all if you catch it, ooh dear, you know, that sort of thing, and well this might just spot it in time."

Q04: "And have some…Because some people could really, be really scared, which I probably would have been had anything been found, but knowing that you're going to have someone there with you, you know, that you know to talk to you, understand you…I think really it's making people understand that if something is found that they will have really really good support."

Q03: Will it take too much time? I see I've got a question mark down against that. Yes, I see. Oh you're asking…Yes I see. Well I don't suppose it's going to take too much time is it? But are you putting the idea in people's heads that it might take too much time?

Q18: "No, but I suppose, well once you've done this study, my guess is that you would get perhaps a number of criticisms or views sort of forming as you've just said that a number of people find the whole idea of taking samples of their stools to be disgusting."

Int: "Yes."

Q18: "Now whether you can sort of say something about that, and say really you know you do get used to it…I think to reassure people that if you know they find it difficult at first, just persevere a bit and they'll work it out."

6.4 Interview Series Summary Points

Based on the preliminary coding of the data, several main points have emerged. These included:

- the majority of people interviewed had already decided that they would participate in screening before they received their invitation, although all did indicate that they read the information materials (most usually more than once) to understand what they needed to do to participate
- information materials were regarded as integral to the invitation to participate in screening, but were not the primary reason for their participation
- the majority of people had little difficulty in completing the FOBT kit
- several people indicated that the convenience of completing the FOBT in the privacy of the home was important for them, although several people also suggested that it was necessary to ensure that sample collection occurred when family/friends were not expected to be visiting
- many respondents could not understand why people would not participate in bowel cancer screening; although they acknowledged the testing process was 'unpleasant', as it wasn't a problem for them, they could not understand why it would be an insurmountable obstacle for others
- respondents were generally unwilling to include overtly strongly worded messages that would cause fear or could be seen as demanding that people participated in screening for their own good

7.0 Suggestions for Improving the 'Help with the Test' leaflet

It is hoped that the results of the pilot study provide some basis for stakeholders to suggest improvements to the 'Help with the Test' leaflet. From the pilot results, it would seem that the majority of respondents were satisfied with the content of the leaflet. However, any suggestions for improving the leaflet or any criticisms of the leaflet in its current form would be greatly received. Certain aspects of the design/content of the leaflet are required to ensure that the leaflet can be included as part of a NHS programme. These include:

- the leaflet will be printed on either silk/gloss superior paper (170gsm+ paper)
- possible use of coloured paper or coloured text (e.g. headings) that conform to guidelines produced by the Royal National Institute of Blind People, Plain English Campaign and others
- conforming the NHS Cancer Screening Programmes policy of informed choice (i.e. avoidance of fear-provoking or coercive language)

Please fell free to either call or email me with any comments or questions that you may have regarding the research. Thank you for your time and your help with this research programme.

Kind regards, Paul

Appendix 8.1: GP Endorsement Letter

GP Letterhead

Supporting Bowel Cancer Screening

Dear [*Participants Name*],

We are writing to you to express our support for the NHS Bowel Cancer Screening Programme. Bowel cancer is one of the most common forms of cancer in the UK. Most people diagnosed with bowel cancer are over 60 years old. Screening aims to detect bowel cancer at an early stage, in people with no symptoms, when treatment is more likely to be effective.

As a Practice, we strongly recommend you complete the screening kit enclosed in this pack. If you have any questions, or would like more information about screening for bowel cancer you can contact the Programme Hub on Freephone 0800 707 60 60. However, if you have any specific concerns, or are worried about bowel symptoms, and would prefer to speak to someone at this Practice in confidence, please feel free to contact us.

It is also very important that you are aware of the symptoms of bowel cancer. The most common symptoms to look out for are:

- a persistent change in bowel habit, especially going to the toilet more often or diarrhoea
- bleeding from the back passage without any obvious reason or blood in your bowel motions
- abdominal pain, especially if it is severe
- a lump in your abdomen

Most of these symptoms will not be cancer. However, if you have experienced one or more of these symptoms for more than four weeks you should contact us as soon as possible.

Yours sincerely,

Appendix 8.2: Detailed Procedural Leaflet

Why are bowel motions tested?

An early symptom of bowel cancer is blood in your bowel motions. Because bowel cancer is more likely to be diagnosed in men and women over 60, the NHS sends everyone aged 60-69 a bowel cancer screening test every two years. The test can detect traces of blood that you normally can not see in your bowel motions. Blood in your bowel motions can be caused by many things – it does not always mean that you have bowel cancer. But it is important to complete the kit to make sure.

"It will take too much time"

Collecting a sample of your bowel motion should only take a minute or two of your time. Make sure you have everything you need to do the test within easy reach when you are sitting on the toilet, this should make it even quicker. As well as your test, you will need a pen and whatever you choose to use to collect your sample. You will need to take a sample of your bowel motion on three (3) separate visits to the toilet. If you keep everything you need within reach of the toilet, it will be easier to do the test.

"It will be too messy"

There are a number of easy ways to make sure that collecting your sample is clean and simple. Take a moment to think about which way would suit you best from the following suggestions:

- fold several pieces of toilet paper over your hand and catch part of your bowel motion before it goes in the toilet water
- a plastic or rubber glove with the folded toilet paper (you can get these from a chemist or supermarket)
- wrap a small plastic bag around your hand (you can also use this to dispose of the cardboard sticks in an outside bin)
- use a small plastic container that you can firmly hold or safely rest in the toilet bowl. A plastic take-away container that you have thoroughly cleaned or something similar is fine. Covering the container with several pieces of toilet paper will make it easier to dispose of the bowel motion into the toilet and clean the container

For people with loose bowel motions or diarrhoea:
You can still do the test. Having loose bowel motions will not affect the test result. It may be easier to use a container to collect you samples if you have loose bowel motions.

For people who have irregular bowel movements:
Constipation is common; it affects about 1 in 8 people. It may take a little longer to collect your three samples, but you can still do the test. After taking your first sample, you still have 14 days to take two more samples and return the test.

Storing your sample

It is a good idea to keep your test in a handy place near your toilet. Please remember to keep the test away from direct sunlight or heat. Although the test is unlikely to smell, you can:

- put the test in a large envelope
- keep the test in a container with a lid

Returning your screening test

You have 14 days after taking your first sample to return the test to the laboratory, using the envelope provided. If at all possible, try to post the test earlier in the week as tests are not tested on weekends. The envelope is completely safe to send in the post.

Any Questions?

If you have any questions about the test or bowel cancer screening then you can call:

Freephone - 0800 707 60 60

All calls are answered by trained staff and are dealt with in the strictest confidence. Please do not feel embarrassed to ask for more information or advice.

Keep an eye on symptoms

Although screening can improve your chances of detecting bowel cancer, it is very important to keep an eye out for any of the following symptoms:

- a persistent change in bowel habit, such as going to the toilet more often, constipation or diarrhoea for several weeks;
- bleeding from the back passage without any obvious reason
- abdominal pain, especially if it is severe
- a lump in your abdomen

Please see your GP if you develop any of these symptoms.

Help with the Test

Tips and advice on how to collect, store and return your NHS Bowel Cancer Screening test

Are you one of these people?

This leaflet is for people who:

- don't think they are at risk of bowel cancer
- think that it will take too much time
- think that it will be too messy
- suffer from constipation or loose bowel motions
- are not quite sure how to collect their three (3) samples

If you are one of these people, then this leaflet will give you advice and easy-to-follow suggestions on how you can complete the NHS Bowel Cancer Screening test.

Returning your screening test can:

Every year, more people die of bowel cancer than breast or prostate cancer. The earlier bowel cancer is found, the better the chances of successful treatment. So by doing the test you will:

- reduce your risk of dying from bowel cancer
- increase the chance of detecting a bowel polyp before it develops into bowel cancer

Appendix 8.3: PCRN GP Study Information Sheet

Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF

Tel: 01865 289359

General Practitioner Study Information Sheet

Primary Care Based Intervention to Improve Participation in the NHS Bowel Cancer Screening Programme

1.0 Introduction

The NHS Bowel Cancer Screening Programme (NHS BCSP) was introduced in spring 2006. Men and women aged 60-69 years receive a mailed the faecal occult blood test (FOBT) to complete in the privacy of their own home. Currently, General Practitioners (GPs) are not directly involved in the delivery of the NHS BCSP but are notified when invitations for bowel cancer screening are being sent out in their area. GPs also receive a copy of the results letters sent to their patients.

There are concerns that the current uptake of bowel cancer screening by the public is poor (approximately 50% as of Dec 2008) and that the endorsement or inclusion of GPs in the programme may improve participation rates. The present three-year research programme will evaluate whether or not a GP endorsement letter and/or a detailed FOBT procedural leaflet have an effect on participation and satisfaction with the NHS BCSP.

2.0 Factorial Randomised Controlled Trial

The factorial randomised controlled trial is the final phase of a three-year research programme. Approximately 1,000 people aged 60-69 who will be invited to the NHS BCSP will receive either a standardised letter from their GP Practice which endorses bowel cancer screening, a detailed FOBT procedural leaflet or both interventions. The aim of the trial is to evaluate if either the GP endorsement letter or a detailed FOBT procedural leaflet improves participation in the NHS BCSP. Participants will be recruited to the trial based on:

a) receiving their invitation to the NHS BCSP in October 2009, and
b) collaboration of their GP Practice in the trial

The present study is supported by the National Institute for Health Research and the NHS Cancer Screening Programmes.

3.0 Recruitment of GP Practices

The trial is part of the National Institute for Health Research Clinical Research Network portfolio.
In collaboration with the NIHR Primary Care Research Network, the research team at the Department of Primary Health Care are attempting to recruit GP Practices to be involved in a

factorial randomised trial that aims to improve participation in the NHS BCSP. Approximately 12-16 GP Practices across the south-west and south-east of England will be involved in the study.

4.0 What is Required?

As the research team is based at the Department of Primary Health Care, we recognise the time constraints of GP Practices. A previous study conducted during the UK Colorectal Cancer Screening Pilot[1] reported that there was a fairly minimal workload impact on GP Practices. Participating GP Practices will be asked to:

a) review and agree the wording of a draft letter (on the respective GP Practice letterhead) that will be sent to participants with their FOBT kits (sent by the NHS BCSP Hun rather than from the GP Practice)
b) complete a brief questionnaire concerning the workload impact of the trial (telephone enquiries from people invited to bowel cancer screening, requested consultations, etc) and the views of the GP Practice concerning the NHS BCSP

The GP Practice letter is expected to be a one-page document that endorses participation in bowel cancer screening and an offer to discuss any pertinent concerns a patient may have about bowel cancer screening with a representative from the GP Practice. The brief questionnaire will ask several questions concerning the impact of the trial on the workload and resources of the GP Practice and doctors/staff perceptions of the NHS BCSP.

5.0 Results of the Trial

The results of the study will be reported to the collaborative group and also presented to the NHS Cancer Screening Programmes, the NHS Bowel Cancer Advisory Group and the NCRI. Three major peer-reviewed publications are expected to be developed from the research and the results will be presented at national and international conferences. Discussions with other academic institutions are also expected to be developed. Recommendations concerning the implementation and further research programme will be addressed with the relevant bodies.

6.0 References

1. Jepson R, Weller D, Alexander, Walker J. Impact of UK Colorectal Cancer Screening Pilot on Primary Care. British Journal of General Practice 2005, *55*: 20-25.

7.0 Contact Information

For further information about the study or if you have any comments or questions about the research, please feel free to contact Paul Hewitson at the Department of Primary Health Care, University of Oxford.

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Appendix 8.4: GP Protocol for the Factorial Trial

A Primary Care Based Intervention to Improve Participation in the NHS Bowel Cancer Screening Programme (GP Protocol Version 1: 21/03/2009)

Short Title Public Perceptions of Bowel Cancer Screening

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Funding: National Institute for Health Research (NIHR) / NHS Cancer Screening Programmes

Support: Part of the NIHR Clinical Research Network Portfolio; Study No.: 6013 (NIHR Primary Care Research Network/NIHR Cancer Research Network)

1.0 Purpose of Research

This study aims to:

- improve participation in the NHS Bowel Cancer Screening Programme (NHS BCSP) through the provision of a General Practitioner (GP) endorsement letter and/or a detailed leaflet for overcoming procedural barriers to completing the faecal occult blood test (FOBT)
- evaluate patient perceptions of the role that GP endorsement and information materials have on making an informed choice to participate or not in the programme
- identify patient factors that contribute to the short and long-term participation in the NHS BCSP and the impact of the intervention for GP resources
- three-year study (information development, pilot study, factorial randomised controlled trial and dissemination of results)

2.0 Summary

The NHS BCSP offers all eligible men and women aged 60 to 69 a faecal occult blood test (FOBT) every two years in a home-mailed invitation pack. The proposed research study will investigate the utility of including a primary care-based information intervention (General Practitioner letter and a detailed procedural leaflet to help people overcome procedural barriers to completing the screening test) in the FOBT kit for increasing patient participation in the NHS BCSP. The results of the project are anticipated to inform the enhancement of targeted information materials for the NHS BCSP, evaluate the role of primary care for patient choice in bowel cancer screening and directing future research aimed towards improving patient participation in the programme.

3.0 Background

The NHS BCSP was introduced in England in July 2006. Currently, the participation rate for the programme is approximately 50% (December 2008). Although the participation rate for England is similar to other FOBT programmes, interventions that can improve peoples' acceptance of the screening test or enhance peoples' understanding of the importance of cancer screening, may result in increased participation in the programme. The present three-year research programme will evaluate whether or not targeted interventions have an effect on participation and satisfaction with the NHS BCSP.

4.0 Research Synopsis

Interventions	GP Endorsement Letter Detailed Procedural Leaflet ('Help with the Test')
Study Design	Factorial randomised trial (2 X 2 design)
Study Settings	NHS Bowel Cancer Screening Hub - South of England Primary Care Practices (South-East and South West England)
Study Participants	People aged 60-69 invited to the NHS BCSP
No. of Participants	Approximately 1,000
Study Period	Recruitment for 'Baseline Questionnaire' = 21st Sep to 25th Sep Screening Invitation = 26th Oct to 30th Oct FOBT Kits and Interventions = 2nd Nov to 6th Nov 'Follow-Up Questionnaire' = 9th Nov to 13th Nov Verify participation/non-participation = 1st Feb to 5th Feb
Primary Objective	Evaluate the effectiveness of the interventions for improving participation in the NHS BCSP
Primary Outcome	Verified participation or non-participation in the NHS BCSP
Secondary Objectives	Assess predictors of participation/non-participation in the NHS BCSP and satisfaction with information materials
Secondary Outcomes	Knowledge, self-efficacy, self-determination, perceptions of the information materials, attitudes towards bowel cancer screening

5.0 Research Programme

The current three-year research programme is funded by the National Institute for Health Research and the NHS Cancer Screening Programmes. There are three phases to the research programme:

4) Stakeholder involvement (*ongoing*): development of a detailed procedural leaflet to provide advice and 'tips' for collecting, storing and returning the FOBT kit ('Help with the Test' leaflet)
5) Pilot study (*Oct 2008 – April 2009*): questionnaire and interview series that aimed to evaluate the detailed procedural leaflet, current NHS BCSP information ('The Facts') and evaluate outcome measures for the main trial
6) Factorial randomised controlled trial (*May 2009 – Mar 2010*): two interventions will simultaneously be evaluated in this trial. A before-and-after questionnaire design will be employed to ascertain if either a letter from a GP which endorses the NHS BCSP and/or a detailed procedural leaflet ('Help with the Test') will improve screening participation (please see Figure 1)

Figure 1: Design of the factorial randomised controlled trial

		'Help with the Test' Leaflet	
		Yes	***No***
GP Endorsement Letter	***Yes***	GP Letter/Leaflet (250+ people)	GP Letter (250+ people)
	No	Leaflet (250+ people)	No Intervention (250+ people)

Note: all participants will receive the standard FOBT Kit information.

Randomised participants in the trial will receive a baseline questionnaire (Q1) four to six weeks before their invitation to the NHS BCSP. They will then receive the 'Help with the Test' leaflet, the GP endorsement letter or both interventions at the time they receive their FOBT Kit. The follow-up questionnaire (Q2) will be sent one week after people receive their FOBT kit. A reminder follow-up questionnaire will be sent to people who have not returned Q2 approximately 4 weeks after the FOBT kit was received.

6.0 Trial Interventions

Two interventions will be evaluated in the factorial randomised trial. These are:

- GP endorsement letter – a letter endorsing the NHS BCSP from the person's General Practitioner which will be sent with their invitation to participate in the NHS BCSP
- Detailed FOBT procedural leaflet ('Help with the Test') – a double-sided A4 leaflet that directly addresses the procedural barriers to completing the FOBT kit. The detailed procedural leaflet aims to provide people with suggestions and 'tips' for the collection, storage and return of their FOBT kit. The leaflet includes detailed information about overcoming potential barriers to participation, address concerns about the collection of stools and provide advice on the storage and return of the FOBT kit

The GP endorsement letter will be developed after the recruitment of GP Practices begins (April 2009). The letter will need to be standardised, in an effort to ensure that all trial participants receive the same type of information. The letter will be refined after discussions with participating GP Practices, but is expected to include:

a) the aim of cancer screening
b) importance of recognising the symptoms of bowel cancer
c) an endorsement by the GP Practice that participation in the bowel cancer screening programme by the patient may be beneficial (especially if cancer is detected at an early stage)
d) an offer to contact the GP practice if the patient has any concerns about participating in the NHS BCSP

The GP Practice letter is expected to be a one-page document that endorses participation in bowel cancer screening and an offer to discuss any pertinent concerns a patient may have about bowel cancer screening with a representative from the GP Practice. The detailed procedural leaflet was recently been evaluated in the pilot phase of this research programme and has been refined with advice and support from key stakeholders involved in this study (two patient representatives, Beating Bowel Cancer, Bowel Cancer UK, NHS BCSP staff, NHS cancer Screening staff and patient information health professionals).

7.0 Involvement of GP Practices

In collaboration with the NIHR Primary Care Research Network, the research team will recruit representative GP Practices from across the south-east and south-west of England (the area covered by the NHS Southern Bowel Cancer Screening Hub). Approximately 12-16 GP Practices across the south-west and south-east of England will be involved in the trial.

The impact of the trial in regards to the workload and resources of participating GP Practices will be undertaken as part of the trial. The brief questionnaire will ask several questions concerning the impact of the trial on the workload and resources of the GP Practice (number of enquires/consultations, nature of enquires, etc) and doctors/staff perceptions of the NHS BCSP (views concerning bowel cancer screening and the NHS BCSP).

8.0 Dissemination of Results

The results of the study will be reported to the collaborative group and also presented to the NHS Cancer Screening Programmes, the NHS Bowel Cancer Advisory Group and the NCRI. Three major peer-reviewed publications are expected to be developed from the research and the results will be presented at national and international conferences. Discussions with other academic institutions are also expected to be developed. Recommendations concerning the implementation and further research programme will be addressed with the relevant bodies.

9.0 Timeline for Trial

	2009										2010
Task	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**
Consultation with stakeholders											
Ethics Submit/Approval (11 May)											
R&D Submitted/Approval											
Randomisation/Hub Organisation											
Q1 Mail-out											
Invite / FOBT kit / Letter/Leaflet											
Q2 Mail-Out											
Q2 Reminder Mail-out											
Confirmation of Participation											
Data Entry/Analysis											

	2010										
Task	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**
Confirmation of Participation (*cont*)											
Data Entry/Analysis (*cont*)											
Final analysis											
Dissemination/stakeholder mtng											
Final report/Peer review pubs.											

Appendix 8.5: GP Practice Questionnaire

Cancer Screening Programmes

Study ID Number

Public Perceptions of Bowel Cancer Screening

– Views of General Practice –

Thank you for agreeing to take part in this research – we appreciate your involvement in our trial and for taking the time to complete this questionnaire. Your feedback concerning the involvement of your GP Practice will help us to understand the impact of the trial on staff resources. We will also be asking you about your views and perceptions of the NHS Bowel Cancer Screening Programme. After you have completed the questionnaire, please return it to us in the FREEPOST envelope provided.

Please place a tick [√] in the box that best represents your opinion or write the answer in the space provided.

All the information you give will be treated as strictly confidential.

Thank you very much for your help with this research

If you have any questions please contact Paul Hewitson at:

Department of Primary Health Care
University of Oxford
Old Road Campus
Old Road, Headington, Oxford, OX3 7LF
Tel: 01865 289359

Section A: Enquires to the Practice

The following section is concerned with the number and management of enquires about bowel cancer screening by participants during the study period. Please place a tick in the box for each question.

01. How many trial participants contacted your GP Practice after they had received their screening kit?	☐ 1 0 ☐ 2 1 to 5 ☐ 3 6 to 10 ☐ 4 11 or more
02. How did the majority of trial participants want to resolve their enquiry about bowel cancer screening?	☐ 1 Over the telephone ☐ 2 Personal consultation with nurse ☐ 3 Personal consultation with GP ☐ 4 Other ☐ 9 Not applicable
03. Did enquires about bowel cancer screening significantly impact on GP Practice staff time and/or resources?	☐ 1 Yes ☐ 0 No ☐ 9 Not applicable

Section B: Reason for Enquires to the Practice

04) The following section asks you about the reasons for why your patients contacted you about bowel cancer screening during the study period. Please place a tick in the box for each question.

Patient's contacted the Practice asking:	**Never**	**Sometimes**	**Often**	**Very Often**
a. Questions about why they were sent a screening test?	☐ 1	☐ 2	☐ 3	☐ 4
b. Advice on whether or not to participate in the screening programme?	☐ 1	☐ 2	☐ 3	☐ 4
c. Instructions or clarification on how to perform the faecal occult blood test?	☐ 1	☐ 2	☐ 3	☐ 4
d. Questions about bowel symptoms?	☐ 1	☐ 2	☐ 3	☐ 4
e. Specific questions or concerns about the benefits or risks of screening?	☐ 1	☐ 2	☐ 3	☐ 4
f. Questions about having a family history of bowel cancer or other cancers?	☐ 1	☐ 2	☐ 3	☐ 4
g. Questions about how to prevent bowel cancer developing?	☐ 1	☐ 2	☐ 3	☐ 4
h. Questions about the next stage of screening or having a colonoscopy?	☐ 1	☐ 2	☐ 3	☐ 4

Section C: Primary Care and Bowel Cancer Screening

The following section asks about your opinion about the NHS Bowel Cancer Screening Programme and the faecal occult blood test (FOBT). Please place a tick in the box that best represents your opinion.

05. Do you agree that the NHS should offer routine bowel cancer screening to people aged 60-69 every two years?	☐ 1 Yes ☐ 0 No ☐ 9 Not sure
06. Do you agree that the NHS should offer routine bowel cancer screening to people aged 50-74 every two years?	☐ 1 Yes ☐ 0 No ☐ 9 Not sure
07. Did you receive enough information about the NHS Bowel Cancer Screening Programme before it started in your area?	☐ 1 Yes ☐ 0 No ☐ 9 Not sure
08. Do you think that GPs should be more involved in the NHS Bowel Cancer Screening Programme?	☐ 1 Yes ☐ 0 No ☐ 9 Not sure
09. Do you think that greater involvement by GPs in the Programme would improve patient participation in screening?	☐ 1 Yes ☐ 0 No ☐ 9 Not sure
10. Would greater GP involvement in the Programme have a substantial impact on the workload of your Practice?	☐ 1 Yes ☐ 0 No ☐ 9 Not sure
11. Do you think that GP Practices should be remunerated for their involvement in the NHS Bowel Cancer Screening Programme?	☐ 1 Yes ☐ 0 No ☐ 9 Not sure
12. What extra duties do you think that GPs could perform for the Programme? *(please tick each box that applies)*	☐ 1 Checking prior notification lists ☐ 2 Providing information on the test ☐ 3 Informing people of their results ☐ 4 Counselling for colonoscopy ☐ 5 Counselling if needing treatment ☐ 6 No extra duties required
13. Which type of bowel cancer screening test should the NHS use? *(please tick only one box)*	☐ 1 Current guciac FOBT ☐ 2 An immunochemical FOBT ☐ 3 Flexible Sigmoidoscopy (FS) ☐ 4 FOBT and FS ☐ 5 Colonoscopy ☐ 6 No screening test

Please turn over the page and complete the final section

Section D: About You and Your Practice…	
14. What is your role at your Practice?	☐ 1 General Practitioner ☐ 2 Practice Manager ☐ 3 Practice Nurse ☐ 4 Administration/Reception ☐ 5 Other health professional
15. How many General Medical Practitioners (partners, salaried, registrar, etc) work at your Practice?	☐ 1 One to Two ☐ 2 Three to Four ☐ 3 Five to Six ☐ 4 Seven or more
16. How many Practice Nurses work at your General Practice?	☐ 1 One to Two ☐ 2 Three to Four ☐ 3 Five to Six ☐ 4 Seven or more
17. What is the total list size of your Practice?	☐ 1 Less than 5000 ☐ 2 5,001 to 10,000 ☐ 3 10,001 to 15,000 ☐ 4 15,001 to 20,000 ☐ 5 Over 20,001

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE

Please return this questionnaire with your consent form in the FREEPOST envelope provided

Appendix 8.6: Study Invitation Letter

Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF

Tel: 01865 289359

STUDY INVITATION LETTER

Public Perceptions of the NHS Bowel Cancer Screening Programme
(NRES Study Number: 09/H0606/60)

Dear ……

This letter is to invite you to participate in a questionnaire study that aims to improve the delivery of the NHS Bowel Cancer Screening Programme. Before you decide to take part, it is important for you to understand why the research is being done and what it will involve for you. Please take the time to read the attached study information sheet and feel free to contact us if you have any questions or if something about the study is unclear.

The NHS Bowel Cancer Screening Programme offers screening every two years to all men and women aged 60 to 69. In the next month, you will receive an invitation from the NHS to participate in bowel cancer screening. You were selected to receive this invitation to participate in the research because your GP Practice is involved with this study. It does not matter if you intend to complete the screening test or not, we are interested to learn more about your thoughts and views of bowel cancer screening and how you think that the programme can be improved. Your opinions and experiences are of great interest to us and would be very helpful in our research.

The study is being run by the Department of Primary Health Care at the University of Oxford in conjunction with the NHS Cancer Screening Programmes. The overall goal of our research is to improve the information provided to people who are invited to the NHS Bowel Cancer Screening Programme. We have enclosed a study information sheet with further details on the research. We would be grateful if you could complete the questionnaire and consent form if you are willing to take part in this study and return it in the freepost envelope provided.

You are under no obligation to take part in the study and can choose to leave it at any time without giving a reason. You can still take part in screening if you do not participate in the study. Whether or not you decide participate in the study will have no effect on your normal medical care. If you have any queries about this research or if something about the study is unclear, please contact Paul Hewitson on 01865 289359.

Yours sincerely,

Dr Stephen Halloran, FRCPath; Director: Bowel Cancer Screening Hub - South of England

Appendix 8.7: Participant Study Information Sheet

Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF

Tel: 01865 289359

Study Information Sheet

Public Perceptions of the NHS Bowel Cancer Screening Programme
(NRES Study Number: 09/H0606/60)

Introduction

You are invited to take part in a research study looking at people's views on the information provided by the NHS Bowel Cancer Screening Programme and their perceptions of bowel cancer screening. Currently, just over half the people invited to the programme decide to take part in screening. There are a number of reasons why people decide to participate or not participate in the programme. Some people take part because they think that screening is a good idea or they are concerned about developing bowel cancer. Some people decide they do not want to participate because of their perceptions of the screening test or due to difficulties experienced when trying to complete the test

What is the NHS Bowel Cancer Screening Programme?

The NHS Bowel Cancer Screening Programme offers screening every two years to all men and women aged 60 to 69. People are sent a simple test kit, called the faecal occult blood test (FOBT), to complete in the privacy of their own home. The test involves collecting a small sample from three separate bowel motions and, using a specially designed prepaid envelope, returning the test for further analysis. The test can detect small amounts of blood, which you cannot normally see, in a bowel motion sample.

The screening test does not diagnose bowel cancer, but gives an indication as to whether further investigations are required. Small amounts of blood can occur in a bowel motion due to other conditions, such as piles (haemorrhoids) or stomach ulcers; it does not mean that a person has bowel cancer. You will receive more detailed information about the NHS Bowel Cancer Screening Programme when your invitation is sent in a few weeks time.

Why are we doing this research?

Our overall aim for the study is to improve the information provided to people invited to take part in the NHS Bowel Cancer Screening Programme. We are interested to find out the role General Practitioners may have on people's decisions to participate or not in the programme, people's views on the information materials they receive with their invitation and also their perceptions about bowel cancer screening.

Why have I been invited to take part?

A number GP Practices across the south-east and south-west of England were selected to take part in this research. You have been asked to take part because you will be invited to routine bowel cancer screening during the month of October 2009 and because your GP Practice has agreed to participate in this research. Our study is interested in the views of all people who are invited to the NHS Bowel Cancer Screening Programme – both people who decide they wish to take part and those who decide they do not want to participate in screening. This study will involve over 1,000 men and women.

What will happen if I take part?

You will receive your postal invitation to participate in the NHS Bowel Cancer Screening Programme during the month of October 2009. This will include a screening invitation letter and an information booklet about bowel cancer screening. If you are not eligible to participate or do not wish to receive a bowel cancer screening test, you will receive information on how to contact the screening programme to request that you are not sent any further materials with your screening invitation letter. About a week after receiving your invitation, the screening kit (FOBT) will be sent along with step-by-step instructions for completing the test at home and sending the test back in the post. The test will then be processed and the results sent to you within two weeks.

People involved in this study will be randomly allocated to one of four groups:

a) the standard information group (receiving information currently sent by the programme)
b) GP letter group (standard information plus a letter from their GP Practice)
c) leaflet group (standard information plus a detailed procedural leaflet to help with completing the test)
d) combined group (standard information plus both the GP letter and procedural leaflet)

People who do not return their consent form to the study will not receive a second questionnaire after they are sent their screening kit (although they will still receive either the standard information, a letter from their GP, the detailed procedural leaflet or both with their kit). At the end of the study, participation or non-participation in bowel cancer screening will be verified for all people who were invited to take part in the research. No personal identifiable information will be available to the research team for people who do not consent to the study.

What will I be asked to do?

If you decide to take part, you will be asked to complete the questionnaire and consent forms included in this pack and send it back to us in the freepost envelope provided. The questionnaire will take 15-20 minutes to complete. To be included in the study, you will need to send your questionnaire back before you receive your invitation to the NHS Bowel Cancer Screening Programme. You will receive a second questionnaire soon after you are invited to take part in the NHS Bowel Cancer Screening Programme in the next few weeks.

Do I have to take part?

It is up to you to decide whether or not you wish to take part. You would be free to withdraw from the study at any point and without giving a reason. This would not affect the standard of any future medical care you may receive. If you do not wish to be part of this study and do not want to be contacted again concerning this research, please complete the reply slip included in this pack and send it back in the freepost envelope.

What are the benefits of taking part?

If you decide to take part, your responses to the questionnaire may be used to improve the delivery and information provided by the NHS Bowel Cancer Screening Programme to people invited to screening.

Will my taking part in this study be kept confidential?

Your involvement in this study will be kept completely confidential. The questionnaire will be anonymous (i.e. your name will not appear anywhere in print) and all information gathered will be treated in the strictest confidence.

The University of Oxford supports the principles of the Research Governance Framework developed by the Department of Health. This framework is designed to ensure that the proper monitoring of studies can occur so that the public can have confidence in, and benefit from, quality research in health and social care. Monitoring or auditing of the conduct of this research may be carried out by representatives of the University, in accordance with the Research Governance Framework.

What would happen to the results of the research study?

We will be writing a report of the research for the NHS Cancer Screening Programmes and also intend to publish the findings of the study in a medical journal. The overall questionnaire findings would be included in the publication but this would be completely anonymous. We will send you a summary of the research findings at the end of the study.

Who is organising and funding this research?

The research is being conducted by the University of Oxford and is funded by the NHS Cancer Screening Programmes and the NHS National Institute for Health Research.

Who has reviewed this study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair and that the rights of study participants are assured. This project has been checked by the Oxfordshire C Research Ethics Committee.

Who should I contact for further information?

If you have any queries about this research or if something about the study is unclear, please contact Paul Hewitson on 01865 289359. If you have any complaints about any aspect of this study please contact:

Professor David Mant
Head of Department
Department of Primary Health Care
University of Oxford University
Old Road, Headington
Oxford OX3 1LR

Tel: 01865 289288
Fax: 01865 289287

PLEASE COMPLETE AND RETURN THE CONSENT FORM AND QUESTIONNAIRE

IF YOU WISH TO BE INVOLVED IN THE STUDY

Appendix 8.8: Factorial Trial Consent Form

	NHS Cancer Screening Programmes	_____ Study ID Number

CONSENT FORM

Title of Study: Public Perceptions of the NHS Bowel Cancer Screening Programme
(NRES Study Number: 09/H0606/60)

Study ID Number:

Name of researcher obtaining consent: Paul Hewitson

Please initial each box

1. I can confirm that I have read and understand the information sheet dated 23/03/2009 (Version 1) for the above study. I have had the opportunity to consider the information before deciding to take part. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I agree to take part in the above study. ☐

Name: _____

Signature: _____

Address: _____

_____

_____

_____

Date: _____

PLEASE RETURN YOUR CONSENT FORM AND YOUR QUESTIONNAIRE IN THE FREEPOST ENVELOPE PROVIDED – THANK YOU FOR YOUR TIME

Appendix 8.9: Factorial Trial Reply Slip

Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF

Tel: 01865 289359

Reply Slip

Please do not send me any further information

Title of Study: Public Perceptions of the NHS Bowel Cancer Screening Programme
(NRES Study Number: 09/H0606/60)

Study ID Number:

Please tick the box

1. Please do not send me any further information concerning this study ☐

PLEASE RETURN YOUR REPLY SLIP IN THE FREEPOST ENVELOPE PROVIDED – THANK YOU FOR YOUR TIME

Appendix 8.10: Factorial Trial Request for Summary of the Results

Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF

Tel: 01865 289359

Request for Further Information

(NRES Study Number: 09/H0606/60)

We would like to send you a summary of the results of the study. If you are interested in finding out how what the results of this study were then please tick the box and fill in your details below and we will send you a summary of the results.

Summary of the Results of the Study

Please send me a summary of the results of this study. ☐

Please see the consent form for my mailing address. ☐

Or

You can contact me at:

Name: _____

Address: _____

_____

_____

_____

Appendix 8.11: Factorial Trial Baseline Questionnaire

Cancer Screening Programmes

Study ID Number

Public Perceptions of Bowel Cancer Screening

– Your views –

Thank you for agreeing to take part in this study – we really appreciate you taking the time to complete this questionnaire which will help us to improve the information provided to people invited to bowel cancer screening. We will be asking you about your views and understanding of bowel cancer and bowel cancer screening. It should take around 15 to 20 minutes to complete. After you have completed the questionnaire, please return it with your consent form to us in the FREEPOST envelope provided.

Please place a tick [√] in the box that best represents your opinion or write the answer in the space provided.

It would be very helpful to us if you could try to complete all the questions. For many of the questions we are asking for your opinion. There is no right or wrong answer to these questions. For other questions you simply may not know the answer. If so, please tick the 'not sure' or 'don't know' box.

All the information you give will be treated as strictly confidential.

Thank you very much for your help with this research

If you have any questions please contact Paul Hewitson at:

Department of Primary Health Care
University of Oxford
Old Road Campus
Old Road, Headington, Oxford, OX3 7LF
Tel: 01865 289359

Section A: Background Information

01.	Did you know that the NHS had introduced a national Bowel Cancer Screening Programme before you received your invitation to this study?	☐ 1 Yes ☐ 0 No
02.	Have you ever completed a faecal occult blood test (FOBT) before? (*either as part of the NHS Bowel Cancer Screening Programme or any other reason*)	☐ 1 Yes ☐ 0 No ☐ 9 Don't know
03.	In the last 10 years, have you had a colonoscopy examination? (*a colonoscopy is a flexible tube with a camera that is passed into your rectum to examine the lining of the bowel wall*)	☐ 1 Yes ☐ 0 No ☐ 9 Don't remember
04.	Have you ever been diagnosed with bowel cancer?	☐ 1 Yes ☐ 0 No
05.	Has your mother/father/brother/sister ever been diagnosed with bowel cancer?	☐ 1 Yes ☐ 0 No
06.	Have any of your close friends or other relatives ever been diagnosed with bowel cancer?	☐ 1 Yes ☐ 0 No ☐ 9 Don't know
07.	Have you ever been diagnosed with another significant bowel condition (*e.g. Ulcerative Colitis, Crohn's Disease, Celiac Disease, Inflammatory Bowel Disease, Irritable Bowel Syndrome, etc*?)	☐ 1 Yes ☐ 0 No
08.	Compared to other decisions you make about your health, how important is the decision to participate or not in bowel cancer screening?	☐ 1 Very important ☐ 2 Somewhat important ☐ 3 Slightly important ☐ 4 Not important at all
09.	What would be the <u>main</u> reason that you would consider doing the bowel cancer screening test? *(please tick only one box)*	☐ 1 Current symptoms ☐ 2 Family history ☐ 3 GP recommendation ☐ 4 Because I was invited ☐ 5 Peace of mind ☐ 6 Advice from family/friend
10.	Is it important for you to know the benefits and the risks of bowel cancer screening before you decide to participate?	☐ 1 Very important ☐ 2 Somewhat important ☐ 3 Slightly important ☐ 4 Not important at all

Section A: *Continued…*	
11. In your opinion, how convinced are you about the benefits of participating in bowel cancer screening?	☐ 1 Very convinced ☐ 2 Somewhat convinced ☐ 3 Slightly convinced ☐ 4 Not convinced at all
12. How concerned are you about the risks of participating in bowel cancer screening?	☐ 1 Very concerned ☐ 2 Somewhat concerned ☐ 3 Slightly concerned ☐ 4 Not concerned at all
13. How worried are you that you could be diagnosed with bowel cancer if you participate in bowel cancer screening?	☐ 1 Very worried ☐ 2 Somewhat worried ☐ 3 Slightly worried ☐ 4 Not worried at all
14. How confident are you that you could complete the bowel cancer screening test?	☐ 1 Very confident ☐ 2 Somewhat confident ☐ 3 Slightly confident ☐ 4 Not confident at all
15. Compared to other people like you, do you think that your own chances of developing bowel cancer at some point in your life are…	☐ 1 Much more ☐ 2 A little more ☐ 3 About the same ☐ 4 A little less ☐ 5 Much less
16. How likely do you think that it is that you will develop bowel cancer at some point in the near future?	☐ 1 Definitely will ☐ 2 Very likely ☐ 3 As likely as not ☐ 4 Not very likely ☐ 5 Definitely will not
17. For you, how important is it that you receive an information booklet that explains bowel cancer and bowel cancer screening with your invitation to the programme?	☐ 1 Very important ☐ 2 Somewhat important ☐ 3 Slightly important ☐ 4 Not important at all
18. Do you think that you will do the bowel cancer screening test when you receive your invitation in a few weeks?	☐ 1 Yes ☐ 0 No ☐ 9 Don't know

Section B: Your General Practitioner and Medical Information

19.	Have you ever asked your GP about testing for bowel cancer?	☐ 1 Yes ☐ 0 No ☐ 9 Don't remember
20.	In the last 12 months, about how many times did you visit your GP for any reason?	☐ 0 None ☐ 1 One to two times ☐ 3 Three to four times ☐ 4 Five or more times
21.	Do you have confidence and trust in your GP?	☐ 1 Yes, definitely ☐ 2 Yes, to some extent ☐ 3 No, not really ☐ 4 Don't know, can't say
22.	Is it embarrassing for you to talk to your GP about bowel problems?	☐ 1 Very embarrassing ☐ 2 Somewhat embarrassing ☐ 3 Slightly embarrassing ☐ 4 Not embarrassing at all
23.	For you, how important is your GPs opinion about whether or not you participate in bowel cancer screening?	☐ 1 Very important ☐ 2 Somewhat important ☐ 3 Slightly important ☐ 4 Not important at all
24.	Would receiving a letter from your GP that supported bowel cancer screening influence your decision to participate or not in the programme?	☐ 1 Yes, definitely ☐ 2 Yes, to some extent ☐ 3 No, not really ☐ 4 Don't know, can't say
25.	How often do you have someone help you to read hospital or patient education materials (*e.g. booklets or leaflets*)?	☐ 1 Never ☐ 2 Occasionally ☐ 3 Sometimes ☐ 4 Often ☐ 5 Always
26.	How confident are you filling out medical forms by yourself?	☐ 1 Not at all ☐ 2 A little bit ☐ 3 Somewhat ☐ 4 Quite a bit ☐ 5 Extremely
27.	How often do you have problems learning about health matters because of difficulty understanding written information?	☐ 1 Never ☐ 2 Occasionally ☐ 3 Sometimes ☐ 4 Often ☐ 5 Always

Section C: Your Views about the Screening Kit

28) The following questions are about your views on the screening kit that will be sent to you by the NHS Bowel Cancer Screening Programme. There are no right or wrong answers, we are just interested in what you think about the screening kit, whether you intend to do the test or not. Please place a tick in the box that best represents your opinion.

		Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
a.	It is important to be given enough information to make a choice about participating or not in screening.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b.	It will be very difficult for me to collect my samples for the screening kit.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c.	It will be embarrassing to store the screening kit between collecting the samples.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d.	I am concerned about doing the test correctly.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e.	Taking samples from several separate bowel motions will be inconvenient.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f.	Collecting my samples for the screening kit will be disgusting.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g.	I have confidence that the results I would receive from the screening programme will be correct.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h.	Collecting my samples for the screening kit will be very messy.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i.	I understand the reason why I am being asked to do the test.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
j.	Collecting my samples for the screening test is unhygienic.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Section D: Your Understanding of Bowel Cancer Screening

29) We would like to ask you some questions about your understanding of bowel cancer and bowel cancer screening. The questions are not meant to be a test – we are simply interested in finding out what information you may understand about bowel cancer and bowel cancer screening. Please read each question carefully and place a tick in the box (true, false, or don't know) that best represents your opinion.

	True	False	Don't Know
a. You can have bowel cancer without having any symptoms.	☐ 1	☐ 0	☐ 9
b. Bowel cancer is the second leading cause of cancer deaths in the UK.	☐ 1	☐ 0	☐ 9
c. About 4 in 10 people diagnosed with bowel cancer are over 60 years old.	☐ 1	☐ 0	☐ 9
d. The bowel cancer screening test will always detect if you have bowel cancer.	☐ 1	☐ 0	☐ 9
e. About 98 in every 100 people will have a normal result after participating in screening.	☐ 1	☐ 0	☐ 9
f. A colonoscopy is the most effective way to diagnose bowel cancer.	☐ 1	☐ 0	☐ 9
g. If a family member has had bowel cancer, it does not increase your chances of developing the disease.	☐ 1	☐ 0	☐ 9
h. If bowel cancer is detected at the earliest stage, there is over a 90% chance of survival.	☐ 1	☐ 0	☐ 9
i. There are no possible side-effects or risks associated with having a colonoscopy.	☐ 1	☐ 0	☐ 9
j. Participating in screening reduces the chances of dying from bowel cancer.	☐ 1	☐ 0	☐ 9

Section E: Managing Your Health

30) The following questions ask you about the way you are able to manage your own health. Please place a tick in the box that best represents your opinion.

	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
a. I handle myself well with respect to my health.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. No matter how hard I try, my health just doesn't turn out the way I would like it.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. It is difficult for me to find effective solutions to the health problems that come my way.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. I succeed in the projects I undertake to improve my health.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e. I'm generally able to accomplish my goals with respect to my health.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f. I find my efforts to change things I don't like about my health are ineffective.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g. Typically, my plans for my health don't work out well.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h. I am able to do things for my health as well as most other people.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Section F: Completing the Test

31) The following questions are about whether you think that you can complete the test bowel cancer screening or not. Please indicate the extent to which each reason is true for you by placing a tick in the box on the seven point scale (where 1 = 'Not at all True' and 7 = 'Very true').

	Not At All True			*Somewhat True*			*Very True*
a. I am confident that I can complete and return the bowel cancer screening test.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
b. I feel able to collect my samples from three separate bowel movements.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

Section G: Attitudes towards Bowel Cancer Screening

32) The following questions are about the reasons why you would either decide to complete bowel cancer screening or not. Different people have different reasons for deciding to complete bowel cancer screening or not, and we would like to know how true each of the following reasons is for you. All 15 statements are concerned with the same question: **"The reason I would complete bowel cancer screening is…?"** Please indicate the extent to which each reason is true for you by placing a tick in the box on the seven point scale (where 1 = 'Not true at all' and 7 = 'Very true').

The reason I would complete bowel cancer screening is…?

a. Because I feel I want to take responsibility for my own health.

☐ 1 Not At All True ☐ 2 ☐ 3 ☐ 4 Somewhat True ☐ 5 ☐ 6 ☐ 7 Very True

b. Because I would feel guilty or ashamed of myself if I did not complete the FOBT card.

☐ 1 Not At All True ☐ 2 ☐ 3 ☐ 4 Somewhat True ☐ 5 ☐ 6 ☐ 7 Very True

c. Because I personally believe it is the best thing for my health.

☐ 1 Not At All True ☐ 2 ☐ 3 ☐ 4 Somewhat True ☐ 5 ☐ 6 ☐ 7 Very True

d. Because others would be upset if I did not.

☐ 1 Not At All True ☐ 2 ☐ 3 ☐ 4 Somewhat True ☐ 5 ☐ 6 ☐ 7 Very True

e. Because I have carefully thought about it and believe it is very important for many aspects of my life.

☐ 1 Not At All True ☐ 2 ☐ 3 ☐ 4 Somewhat True ☐ 5 ☐ 6 ☐ 7 Very True

f. I really don't think about it.

☐ 1 Not At All True ☐ 2 ☐ 3 ☐ 4 Somewhat True ☐ 5 ☐ 6 ☐ 7 Very True

g. Because I would feel bad about myself if I did not complete the FOBT card.

☐ 1 Not At All True ☐ 2 ☐ 3 ☐ 4 Somewhat True ☐ 5 ☐ 6 ☐ 7 Very True

Section G: *Continued…*

The reason I would complete bowel cancer screening is…?

h. Because it is an important choice that I really want to make.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
Not At All True			Somewhat True			Very True

i. Because I feel pressure from others to do so.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
Not At All True			Somewhat True			Very True

j. Because it is easier to do what I am told than to think about it.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
Not At All True			Somewhat True			Very True

k. Because it is consistent with my goals in life.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
Not At All True			Somewhat True			Very True

l. Because I want others to approve of me.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
Not At All True			Somewhat True			Very True

m. Because it is very important for being as healthy as possible.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
Not At All True			Somewhat True			Very True

n. Because I want others to see that I can do it.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
Not At All True			Somewhat True			Very True

o. I don't know why.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
Not At All True			Somewhat True			Very True

Section H: About You…		
33.	Are you?	☐ 1 Male ☐ 2 Female
34.	What is your age group?	☐ 1 60-64 years ☐ 2 65-69 years ☐ 3 70 or over
35.	What is your current marital status?	☐ 1 Married or living as married ☐ 2 Single or never married ☐ 3 Widowed ☐ 4 Divorced or separated
36.	What is your current employment status?	☐ 1 Full-time employment ☐ 2 Part-time employment ☐ 3 Retired ☐ 4 Unemployed
37.	In general, would you say that your health is:	☐ 1 Very Good ☐ 2 Good ☐ 3 Fair ☐ 4 Poor ☐ 5 Very Poor
38.	What is the highest educational qualification you have?	☐ 1 'O' level or School Certificate ☐ 2 'A' level or Higher School Certificate ☐ 3 Vocational qualification/Apprenticeship ☐ 4 College/University degree ☐ 5 None of these
39.	What ethnic group would you describe yourself as?	☐ 1 White ☐ 2 White (other) ☐ 3 Black African ☐ 4 Black Caribbean ☐ 5 Asian ☐ 6 Mixed race ☐ 7 Other (*please specify*) _____

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE

Please return this questionnaire with your consent form in the FREEPOST envelope provided

Appendix 8.12: NHS BCSP Invitation Letter Example

[Date/Month] 2009

Mrs A Example-Subject
Hembury House
Cheriton
Shobrooke
Crediton
Devon
YY1 5TT
S1 278/7/26

NHS No:333 333 4444

Dear Mrs Example-Subject

This is an invitation to take part in the NHS Bowel Cancer Screening Programme. This opportunity is available to all men and women aged 60-69 who are registered with a GP in England. If you have received this invitation and are aged 70 or over, this is because the screening age range is being extended to 60-75 in your area. This is happening gradually across England over the next few years. Your GP knows that the NHS Bowel Cancer Screening Programme is being offered in his or her area. The aim of the screening programme is to detect bowel cancers at an early stage, when there are better chances of successful treatment and cure.

You will automatically be sent a test kit, including full instructions, in about a week's time. The kit is simple to use in the privacy of your own home. If you wish to take advantage of the screening programme, all you have to do is complete the kit and return it to us in the **Freepost** envelope that will be provided. You will receive a result letter within two weeks.

We do not have knowledge of your medical history, and screening may not be appropriate for everybody. For example if you:
- have had a colonoscopy or a barium enema plus a sigmoidoscopy within the last 2 years;
- are on a bowel polyp surveillance programme;
- are currently being treated for bowel cancer;
- have had your large bowel removed;
- are currently being treated for ulcerative colitis or Crohn's Disease;
- are currently awaiting bowel investigations arranged by your GP.

If you fall into any of the above categories, or you do not wish to participate in the screening programme, please contact us to let us know. The **Freephone** number is at the top of this letter. If you need help from family or a carer to use the kit, please call (or ask them to call) the **Freephone** number for further important information. Please take the time to read the enclosed leaflet *'Bowel Cancer Screening - The Facts'*, which may help to answer any questions you have. You can also call the **Freephone** number if you have any queries about whether to take part.

Yours sincerely

Appendix 8.13: Follow-Up Invitation Letter

Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF

Tel: 01865 289359

FOLLOW-UP STUDY INVITATION LETTER

Public Perceptions of the NHS Bowel Cancer Screening Programme
(NRES Study Number: 09/H0606/60)

Dear ……

Previously, you kindly completed and returned your baseline questionnaire as part of the above study. We are writing to you now to ask if you would be able to complete to follow-up questionnaire enclosed in this pack. It does not matter if you completed the screening test or not, we are interested to learn more about your thoughts and views of bowel cancer screening and how you think that the programme can be improved. Your opinions and experiences are of great interest to us and would be very helpful in our research.

The study is being run by the Department of Primary Health Care at the University of Oxford in conjunction with the NHS Cancer Screening Programmes. The overall goal of our research is to improve the information provided to people who are invited to the NHS Bowel Cancer Screening Programme. We would be grateful if you could complete the questionnaire if you are willing to continue to take part in this study and return it in the freepost envelope provided.

You are under no obligation to take part in the study and can choose to leave it at any time without giving a reason. Whether or not you participate in the study will have no affect on your normal medical care. If you have any queries about this research or if something about the study is unclear, please contact Paul Hewitson on 01865 289359.

Yours sincerely,

Dr Steven Halloran
Director: Bowel Cancer Screening Hub - South of England

Appendix 8.14: Follow-Up Factorial Trial Questionnaire

Cancer Screening Programmes

Study ID Number _____

Public Perceptions of Bowel Cancer Screening

– Follow-up Questionnaire –

Thank you for again agreeing to take part in this study – we really appreciate you taking the time to complete this questionnaire which will help us to improve the information provided to people invited to bowel cancer screening. We will be asking you about your views and understanding of bowel cancer and bowel cancer screening. It should take around 15 to 20 minutes to complete. After you have completed the questionnaire, please return it to us in the FREEPOST envelope provided.

Please place a tick [√] in the box that best represents your opinion or write the answer in the space provided.

It would be very helpful to us if you could try to complete all the questions. For many of the questions we are asking for your opinion. There is no right or wrong answer to these questions. For other questions you simply may not know the answer. If so, please tick the 'not sure' or 'don't know' box.

All the information you give will be treated as strictly confidential.

Thank you very much for your help with this research

If you have any questions please contact Paul Hewitson at:

Department of Primary Health Care
University of Oxford
Old Road Campus
Old Road, Headington, Oxford, OX3 7LF
Tel: 01865 289359

Section A: Background Information

1. Have you already completed and returned your screening kit (the faecal occult blood test) to the NHS Bowel Cancer Screening Programme?	☐ 1 Yes (*please go to Question 3*) ☐ 0 No (*please go to Question 2*)
2. If no, do you think that you will complete and return your screening kit to the NHS Bowel Cancer Screening Programme?	☐ 1 Yes ☐ 0 No ☐ 9 Not sure
3. Did you receive a letter from your GP Practice with your bowel cancer screening kit?	☐ 1 Yes ☐ 0 No ☐ 9 Not sure
4. Did you receive a leaflet ('Help with the Test') that gave advice on how to complete your bowel cancer screening kit?	☐ 1 Yes ☐ 0 No ☐ 9 Not sure
5. Compared to other decisions you make about your health, how important is (or was) the decision to participate or not in bowel cancer screening?	☐ 1 Very important ☐ 2 Somewhat important ☐ 3 Slightly important ☐ 4 Not important at all
6. What would be (or was) the main reason that you would do the bowel cancer screening test? *(please tick only one box)*	☐ 1 Current symptoms ☐ 2 Family history ☐ 3 GP recommendation ☐ 4 Because I was invited ☐ 5 Peace of mind ☐ 6 Advice from family/friend
7. Is there (or was there) anything that made it difficult for you to complete the bowel cancer screening test? *(please tick only one box)*	☐ 1 No significant difficulties ☐ 2 Irregular bowel movements ☐ 3 Physical condition or disability ☐ 4 Visual impairment ☐ 5 Persistent diarrhoea ☐ 6 Constipation ☐ 7 Other (*please write below*) _____
8. How worried are you that you could be diagnosed with bowel cancer?	☐ 1 Very worried ☐ 2 Somewhat worried ☐ 3 Slightly worried ☐ 4 Not worried at all

Section A: *Continued…*	
9. For you, how important is your GPs opinion about whether or not you participate in bowel cancer screening?	☐ 1 Very important ☐ 2 Somewhat important ☐ 3 Slightly important ☐ 4 Not important at all
10. Is it important for you to know the benefits and the risks of bowel cancer screening before you decide to participate?	☐ 1 Very important ☐ 2 Somewhat important ☐ 3 Slightly important ☐ 4 Not important at all
11. In your opinion, how convinced are you about the benefits of participating in bowel cancer screening?	☐ 1 Very convinced ☐ 2 Somewhat convinced ☐ 3 Slightly convinced ☐ 4 Not convinced at all
12. How concerned are you about the risks of participating in bowel cancer screening?	☐ 1 Very concerned ☐ 2 Somewhat concerned ☐ 3 Slightly concerned ☐ 4 Not concerned at all
13. Compared to other people like you, do you think that your own chances of developing bowel cancer at some point in your life are…	☐ 1 Much more ☐ 2 A little more ☐ 3 About the same ☐ 4 A little less ☐ 5 Much less
14. How likely do you think that it is that you will develop bowel cancer at some point in the near future?	☐ 1 Definitely will ☐ 2 Very likely ☐ 3 As likely as not ☐ 4 Not very likely ☐ 5 Definitely will not
15. Do you think that you will do the bowel cancer screening test if invited in two years time?	☐ 1 Yes ☐ 2 No ☐ 9 Not sure

Section B: Further Information about Screening

16. Did you contact your GP or GP Practice about bowel cancer screening after you received your invitation?	☐ 1 Yes *(please go to Question 10)* ☐ 0 No *(please go to Question 11)*
17. *If yes*, what was the <u>main</u> reason you contacted your GP or GP Practice? *(please tick only one box)*	☐ 1 Why you were sent a screening kit ☐ 2 Advice on whether to participate ☐ 3 Questions about bowel symptoms ☐ 4 Advice on how to complete the test ☐ 5 When you'll receive your results ☐ 6 Other (*please write below*) _____
18. Did you contact the Screening Hub about bowel cancer screening after you received your invitation?	☐ 1 Yes *(please go to Question 12)* ☐ 0 No *(please go to Question 13)*
19. *If yes*, what was the <u>main</u> reason you contacted the Screening Hub? *(please tick only one box)*	☐ 1 Why you were sent a screening kit ☐ 2 Advice on whether to participate ☐ 3 Questions about bowel symptoms ☐ 4 Advice on how to complete the test ☐ 5 When you'll receive your results ☐ 6 Other (*please write below*) _____
20. Would (or did) receiving a letter from your GP Practice influence your decision to participate or not in the screening programme?	☐ 1 Yes, definitely ☐ 2 Yes, to some extent ☐ 3 No, not really ☐ 9 Don't know, can't say
21. Is it embarrassing for you to talk to your GP about bowel cancer screening?	☐ 1 Very embarrassing ☐ 2 Somewhat embarrassing ☐ 3 Slightly embarrassing ☐ 4 Not embarrassing at all
22. Is it embarrassing for you to talk to your family or close friends about bowel cancer screening?	☐ 1 Very embarrassing ☐ 2 Somewhat embarrassing ☐ 3 Slightly embarrassing ☐ 4 Not embarrassing at all

Section C: Your Views about the Screening Kit

23) The following questions are about your views on the screening kit sent to you by the NHS Bowel Cancer Screening Programme. There are no right or wrong answers, we are just interested in what you think about the screening kit you were sent. Please place a tick in the box that best represents your opinion.

	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
a. I feel that I was given enough information to make a choice about participating or not in screening.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. The instructions in the bowel cancer screening kit are easy to use.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. The spatulas enclosed with the screening kit make it easy to complete the test.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. It is very difficult for me to collect my samples for the screening kit.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e. It is embarrassing to store the screening kit between collecting the samples.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f. I am concerned about doing the test correctly.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g. Taking samples from several separate bowel motions is inconvenient.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h. Collecting my samples for the screening kit is disgusting.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i. My overall experience with the screening kit for bowel cancer is positive.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
j. I understood the reason why I was being asked to do the test.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
k. I have confidence that the results I will receive from the screening programme are correct.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Section D: Your Views on the Information Booklet

24) The following questions are about the 16-page orange booklet **"Bowel Cancer Screening: The Facts"** that you received with your invitation to bowel cancer screening. Please place a tick in the box that best represents your opinion.

a. How much of the booklet did you read?	☐ 1 All of the booklet ☐ 2 Most of the booklet ☐ 3 A little of the booklet ☐ 4 I didn't read the booklet
b. How did you find the way the leaflet was written?	☐ 1 Easy to read ☐ 2 Slightly difficult to understand ☐ 3 Very difficult to understand ☐ 4 I did not understand the information
c. How did you feel about the amount of information in the leaflet?	☐ 1 Too much information ☐ 2 About the right amount ☐ 3 Not enough information
d. How helpful was the information in making your decision to participate or not in bowel cancer screening?	☐ 1 Very helpful ☐ 2 Somewhat helpful ☐ 3 A little helpful ☐ 4 Not helpful at all
e. How did you feel about the way the information was presented?	☐ 1 It was too positive ☐ 2 The information was balanced ☐ 3 It was too negative
f. How much information was there about the advantages or benefits of bowel cancer screening?	☐ 1 More than I wanted ☐ 2 About the right amount ☐ 3 Less than I wanted
g. How much information was there about the downsides or risks of bowel cancer screening?	☐ 1 More than I wanted ☐ 2 About the right amount ☐ 3 Less than I wanted
h. Would you like any information that is not included in the booklet?	☐ 1 Yes ☐ 0 No ☐ 9 Not sure
If yes, what other information would you like?	_____ _____

Section D: Your Understanding of Bowel Cancer Screening

25) We would like to ask you some questions about your understanding of bowel cancer and bowel cancer screening. The questions are not meant to be a test – we are simply interested in finding out what information you may understand about bowel cancer and bowel cancer screening. Please read each question carefully and place a tick in the box (true, false, or don't know) that best represents your opinion.

	True	False	Don't Know
a. You can have bowel cancer without having any symptoms.	☐ 1	☐ 0	☐ 9
b. Bowel cancer is the second leading cause of cancer deaths in the UK.	☐ 1	☐ 0	☐ 9
c. About 4 in 10 people diagnosed with bowel cancer are over 60 years old.	☐ 1	☐ 0	☐ 9
d. The bowel cancer screening test will always detect if you have bowel cancer.	☐ 1	☐ 0	☐ 9
e. About 98 in every 100 people will have a normal result after participating in screening.	☐ 1	☐ 0	☐ 9
f. A colonoscopy is the most effective way to diagnose bowel cancer.	☐ 1	☐ 0	☐ 9
g. If a family member has had bowel cancer, it does not increase your chances of developing the disease.	☐ 1	☐ 0	☐ 9
h. If bowel cancer is detected at the earliest stage, there is over a 90% chance of survival.	☐ 1	☐ 0	☐ 9
i. There are no side-effects associated with having a colonoscopy.	☐ 1	☐ 0	☐ 9
j. Participating in screening reduces the chances of dying from bowel cancer.	☐ 1	☐ 0	☐ 9

Section F: Attitudes towards Bowel Cancer Screening

26) The following questions are about the reasons why you would either decide to complete bowel cancer screening or not. Different people have different reasons for deciding to complete bowel cancer screening or not, and we would like to know how true each of the following reasons is for you. All 15 statements are concerned with the same question: **"The reason I would complete bowel cancer screening is…?"** Please indicate the extent to which each reason is true for you by placing a tick in the box on the seven point scale (where 1 = 'Not true at all' and 7 = 'Very true').

The reason I would complete bowel cancer screening is…?

a. Because I feel I want to take responsibility for my own health.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
Not At All True			Somewhat True			Very True

b. Because I would feel guilty or ashamed of myself if I did not complete the FOBT card.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
Not At All True			Somewhat True			Very True

c. Because I personally believe it is the best thing for my health.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
Not At All True			Somewhat True			Very True

d. Because others would be upset if I did not.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
Not At All True			Somewhat True			Very True

e. Because I have carefully thought about it and believe it is very important for many aspects of my life.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
Not At All True			Somewhat True			Very True

f. I really don't think about it.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
Not At All True			Somewhat True			Very True

g. Because I would feel bad about myself if I did not complete the FOBT card.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7
Not At All True			Somewhat True			Very True

Section F: *Continued…*

The reason I would complete bowel cancer screening is…?

h. Because it is an important choice that I really want to make.

☐ 1 Not At All True ☐ 2 ☐ 3 ☐ 4 Somewhat True ☐ 5 ☐ 6 ☐ 7 Very True

i. Because I feel pressure from others to do so.

☐ 1 Not At All True ☐ 2 ☐ 3 ☐ 4 Somewhat True ☐ 5 ☐ 6 ☐ 7 Very True

j. Because it is easier to do what I am told than to think about it.

☐ 1 Not At All True ☐ 2 ☐ 3 ☐ 4 Somewhat True ☐ 5 ☐ 6 ☐ 7 Very True

k. Because it is consistent with my goals in life.

☐ 1 Not At All True ☐ 2 ☐ 3 ☐ 4 Somewhat True ☐ 5 ☐ 6 ☐ 7 Very True

l. Because I want others to approve of me.

☐ 1 Not At All True ☐ 2 ☐ 3 ☐ 4 Somewhat True ☐ 5 ☐ 6 ☐ 7 Very True

m. Because it is very important for being as healthy as possible.

☐ 1 Not At All True ☐ 2 ☐ 3 ☐ 4 Somewhat True ☐ 5 ☐ 6 ☐ 7 Very True

n. Because I want others to see that I can do it.

☐ 1 Not At All True ☐ 2 ☐ 3 ☐ 4 Somewhat True ☐ 5 ☐ 6 ☐ 7 Very True

o. I don’t know why.

☐ 1 Not At All True ☐ 2 ☐ 3 ☐ 4 Somewhat True ☐ 5 ☐ 6 ☐ 7 Very True

Section G: Your Views on the 'Help with the Test' Leaflet

27) The following questions are about the leaflet **"Help with the Test"** that you may have received with your screening kit. Please place a tick the box that best represents your opinion. If you did not receive the "Help with the Test" leaflet, you do not have to complete this section.

a. Did you find the suggestions for completing the bowel cancer screening test useful?	☐ 1 Yes, very useful ☐ 2 Yes, somewhat useful ☐ 3 No, not really useful ☐ 4 No, not useful at all
b. How did you find the way the leaflet was written?	☐ 1 Easy to read ☐ 2 Slightly difficult to understand ☐ 3 Very difficult to understand ☐ 4 I did not understand the information
c. How did you feel about the amount of information in the leaflet?	☐ 1 Too much information ☐ 2 About the right amount of information ☐ 3 Not enough information
d. How helpful was the information for making your decision?	☐ 1 Very helpful ☐ 2 Somewhat helpful ☐ 3 Slightly helpful ☐ 4 Not helpful at all
e. Did reading the leaflet influence your views about bowel cancer screening?	☐ 1 I am more positive about screening ☐ 2 My views have not changed ☐ 3 I am more negative about screening
f. Would you like any information that is not included in the leaflet?	☐ 1 Yes ☐ 0 No ☐ 9 Not sure
If yes, what other information would you like?	_____ _____

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE

Please return this questionnaire in the FREEPOST envelope provided

Appendix 8.15: Follow-Up Factorial Trial Questionnaire Reminder Letter

Department of Primary Health Care
University of Oxford
Old Road, Headington
Oxford OX3 7LF

Tel: 01865 289359

FOLLOW-UP STUDY REMINDER LETTER

Public Perceptions of the NHS Bowel Cancer Screening Programme
(NRES Study Number: 09/H0606/60)

Dear ……

Thank you for kindly completing and returning your baseline questionnaire for the 'Public Perceptions of the NHS Bowel Cancer Screening' trial. Recently, we hope you would have received a follow-up questionnaire in the mail. Unfortunately, we have not received your follow-up questionnaire which is why we are sending you this reminder letter and another follow-up questionnaire (we also hope you accept our apologies for the two mistakes in the previous questionnaire which have now been corrected). It does not matter if you completed the screening test or not, we are interested to learn more about your thoughts and views of bowel cancer screening and how you think that the programme can be improved. Your opinions and experiences are of great interest to us and would be very helpful in our research.

The study is being run by the Department of Primary Health Care at the University of Oxford in conjunction with the NHS Cancer Screening Programmes. The overall goal of our research is to improve the information provided to people who are invited to the NHS Bowel Cancer Screening Programme. We would be grateful if you could complete the questionnaire if you are willing to continue to take part in this study and return it in the freepost envelope provided.

You are under no obligation to take part in the study and can choose to leave it at any time without giving a reason. Whether or not you participate in the study will have no affect on your normal medical care. If you have any queries about this research or if something about the study is unclear, please contact Paul Hewitson on 01865 289359.

Yours sincerely,

Dr Steven Halloran
Director: Bowel Cancer Screening Hub - South of England

Appendix 9.1 Bivariate Analyses for the Factorial RCT

1.0 Introduction

The following appendix reports the bivariate analyses for screening participation in regards to intervention group, factorial group and people receiving a signed GP endorsement letter.

2.0 Bivariate Analyses for participation at 12 weeks (ITT)

The intention-to-treat (ITT) bivariate analysis indicated that more people in 'Letter and Leaflet' group participated in screening at 12 weeks (see Table 1.1).

Table 1.1: CRC screening participation at 12 weeks for all intervention groups.

		Intervention Groups				
		Letter and Leaflet	*Letter Only*	*Leaflet Only*	*Usual Care*	*Total*
CRC Screening Participation	*Yes*	194*	174	177	158	703
	No	128	148	145	164	585
	Total	322	322	322	322	1288

* denotes $p = 0.042$

People receiving a leaflet were more likely to return their FOBT kit in the 'Leaflet' group (see Table 1.2). There were no differences between in two arms of the 'Letter' group in regards to CRC screening participation

Table 1.2: CRC screening participation at 12 weeks for 'Letter' and 'Leaflet' groups.

		Letter Group			**Leaflet Group**		
		Letter	*No Letter*	*p Value*	*Leaflet*	*No Leaflet*	*p Value*
Participation	*Yes*	368	335	0.065	371	332	0.029
	No	276	309		273	312	

In the 'Letter' group, people who received a GP endorsement letter signed by a GP were more likely to participate in screening than those receiving 'On behalf of the Practice' letter (see Table 1.3).

Table 1.3: CRC screening participation at 12 weeks for people receiving a GP letter with and without a GP signature.

		GP Signature		No GP Signature		*p Value*
Participation	*Yes*	151	*63.2%*	217	*53.6%*	0.017
	No	88	*36.8%*	186	*46.4%*	

2.1 Bivariate Analyses for participation at 12 weeks (Per Protocol Analysis)

The per protocol bivariate analysis indicated no significant differences between the four intervention groups at 12 weeks for people receiving the FOBT kit (see Table 1.4).

Table 1.4: CRC screening participation at 12 weeks in all intervention groups for people opting-in to screening.

		Intervention Groups				
		Letter and Leaflet	*Letter Only*	*Leaflet Only*	*Usual Care*	*Total*
CRC Screening Participation	*Yes*	194	174	177	158	703
	No	122	130	122	139	513
	Total	316	304	299	297	1216

No significant differences were observed in screening participation for either the 'Letter' or the 'Leaflet' factorial groups for people receiving the FOBT kit (see Table 1.5).

Table 1.5: CRC screening participation at 12 weeks for 'Letter' and 'Leaflet' groups.

		Letter Group			Leaflet Group		
		Letter	*No Letter*	*p Value*	*Leaflet*	*No Leaflet*	*p Value*
Participation	*Yes*	368	335	0.267	371	332	0.073
	No	252	261		244	269	

In the 'Letter' group, people who received a FOBT kit and a GP endorsement letter signed by a GP were significantly more likely to participate in screening (see Table 1.6).

Table 1.6: CRC screening participation at 12 weeks for people receiving a GP letter with and without a GP signature.

		GP Signature		No GP Signature		*p Value*
Participation	*Yes*	151	*65.9%*	217	*55.5%*	0.011
	No	78	*34.1%*	174	*44.5%*	

2.2 Bivariate Analyses for participation at 20 weeks (ITT)

Bivariate analysis indicated that the 'Letter and Leaflet' group had a significantly higher participate rate (p = 0.028) than the other intervention groups at 20 weeks (see Table 1.7).

Table 1.7: CRC screening participation at 20 weeks for all intervention groups.

		Intervention Groups				
		Letter and Leaflet	*Letter Only*	*Leaflet Only*	*Usual Care*	*Total*
CRC Screening Participation	*Yes*	197*	177	178	159	711
	No	125	145	144	163	577
	Total	322	322	322	322	1288

* denotes p = 0.028

Both factorial groups significantly increased participation in screening based on the bivariate analyses. As shown in Table 9.8, people receiving the procedural leaflet were significantly more likely to participate in screening (p = 0.029), as were people receiving a GP endorsement letter (p = 0.038).

Table 1.8: CRC screening participation at 20 weeks for 'Letter' and 'Leaflet' groups.

		Letter Group			Leaflet Group		
		Letter	*No Letter*	*p Value*	*Leaflet*	*No Leaflet*	*p Value*
Participation	*Yes*	374	337	0.038	375	336	0.029
	No	270	307		269	308	

In the 'Letter' group, people who received a GP endorsement letter signed by a GP were significantly more likely to participate in screening (see Table 1.9).

Table 1.9: CRC screening participation at 20 weeks for people receiving a GP letter with and without a GP signature.

		GP Signature		No GP Signature		*p Value*
Participation	*Yes*	155	*67.7%*	219	*52.1%*	0.005
	No	84	*32.3%*	114	*47.9%*	

2.3 Bivariate Analyses for participation at 20 weeks (Per Protocol Analysis)

Bivariate analysis indicated there were no significant differences between the four intervention groups at 20 weeks for people opting-in to screening (see Table 1.10).

Table 1.10: CRC screening participation at 20 weeks in all intervention groups for people opting-in to screening.

		Intervention Groups				
		Letter and Leaflet	*Letter Only*	*Leaflet Only*	*Usual Care*	*Total*
CRC Screening Participation	*Yes*	197	177	178	159	711
	No	119	127	121	138	505
	Total	316	304	299	297	1216

As shown in Table 1.11, neither factorial group demonstrated a significant increase in participation at 20 weeks for people opting-in to in screening.

Table 1.11: CRC screening participation at 20 weeks for 'Letter' and 'Leaflet' groups for people opting-in to screening.

		Letter Group			Leaflet Group		
		Letter	*No Letter*	*p Value*	*Leaflet*	*No Leaflet*	*p Value*
Participation	*Yes*	374	337	0.181	375	336	0.073
	No	246	259		240	265	

In the 'Letter' group, people who received a GP endorsement letter signed by a GP were significantly more likely to participate in screening (see Table 1.12).

Table 1.12: CRC screening participation at 20 weeks for people receiving a GP letter with and without a GP signature for people opting-in to screening.

		GP Signature		No GP Signature		***p Value***
Participation	*Yes*	155	*67.7%*	219	*56.0%*	0.004
	No	74	*32.3%*	172	*44.0%*	

Appendix 9.2 British Journal of Cancer Publication

Title

Hewitson P, Ward AM, Heneghan C, Halloran SP, Mant D. Primary care endorsement letter and a patient leaflet to improve participation in colorectal cancer screening: results of a factorial randomised trial. *Brit J Cancer* 2011; 105: 475-480.

Abstract

Background: The trial aimed to investigate whether a GP letter encouraging participation and a more explicit leaflet explaining how to complete faecal occult-blood testing included with the England Bowel Cancer Screening Programme invitation materials would improve uptake.

Methods: A randomised controlled 2x2 factorial trial was conducted in the south of England. 1288 patients registered with 20 general practices invited for screening in October 2009 participated in the trial. Participants were randomised to either a GP endorsement letter and/or an enhanced information leaflet with their FOBT kit. The primary outcome was verified return of the test to within 20 weeks.

Results: Both the GP endorsement letter and the enhanced procedural leaflet each increased participation by approximately 6% - the GP letter by 5.8% (95%CI 4.1% to 7.8%), the leaflet by 6.0% (95%CI 4.3% to 8.1%). Based on the intention to treat analysis, the random effects logistic regression model confirmed that there was no important interaction between the two interventions and estimated an adjusted rate ratio of 1.11 (p = 0.038) for the GP letter and 1.12 (p = 0.029) for the leaflet. In the absence of an interaction, an additive effect for receiving both the GP letter and leaflet (11.8%, 95%CI 8.5% to 16%) was confirmed. The per protocol analysis indicated the insertion of an electronic GP signature on the endorsement letter was associated with increased participation (p = 0.039).

Conclusions: Including both an endorsement letter from each patient's GP and a more explicit procedural leaflet could increase participation in the English Bowel Cancer Screening Programme by approximately 10%, a relative improvement of 20% on current performance.

Keywords: Colorectal cancer, Cancer screening, Primary care, Patient information

Trial Registration: Current Controlled Trials ISRCTN84055957

Introduction

Colorectal cancer (CRC) is the second leading cause of cancer deaths in the UK (CRUK Cancerstats) and survival rates are lower than in other European countries (Berrino *et al,* 2007). Only 13% of UK CRC cases are diagnosed at the earliest stage of the disease (NCIN, 2009). As screening using the faecal occult blood test (FOBT) can increase early-stage diagnosis, significantly reducing bowel cancer mortality (Hewitson *et al*, 2007), a national screening programme was introduced in spring 2006 and currently covers all areas of England.

The England Bowel Cancer Screening Programme invites men and women aged 60-69 (increasing to 60-74 years from April 2010) to participate in faecal occult blood screening every two years. Eligible people receive an invitation letter and information booklet by post. A week later (unless they decline participation during that week) they receive the test kit which includes brief instructions and a freepost envelope for return of the kit. Currently, around half (49%-52%) of the eligible population return their test kits (Weller *et al*, 2006; von Wager *et al*, 2010). Although these participation rates are comparable with other European screening programmes (Denis *et al*, 2007), increasing informed participation may result in a larger reduction in mortality (Parkin *et al*, 2008) and previous research has consistently indicated that the involvement of GPs may be beneficial (Subramanian *et al*, 2004; Brawarsky *et al*, 2004; Senore *et al*, 2010). At

present, GPs in the UK are not directly involved in bowel cancer screening - they only receive a copy of the results letters sent to their patients.

The simplest method of involving primary care in the screening process is for the invitation to participate to include a personal letter from the GP (at present the invitation comes from a Screening Hub not previously known to the patient). Although increasing participation can be achieved by repeated invitations to non-responders (Steele *et al*, 2010) evidence from other countries suggests that an endorsement letter from the patient's GP can significantly improve participation (Senore *et al*, 2010; Cole *et al*, 2007; Zajac *et al*, 2007). However, the GP endorsement letter seems to affect only a proportion of the invited population. The potential improvement in participation through inclusion a GP signature on the endorsement letter was demonstrated by Cole and colleagues (2002), although other studies have not shown a significant increase in participation using this method (Ling *et al*, 2009; Segnan *et al*, 2005).

Other patient-specific factors such as poor knowledge of the benefits of bowel cancer screening, concerns about performing the faecal occult blood test, and perceived self-efficacy for completing the bowel cancer screening procedure can also contribute to poor participation (Weller *et* al, 2006; Subramanian *et al*, 2004). Another potential difficulty concerns the effect of limited health literacy for screening participation. People with limited health literacy have lower participation rates and report more barriers to completing FOBT than people with adequate health literacy (Peterson *et al*, 2007). Addressing these difficulties, several primary care-based studies suggest providing patients with detailed instructions on the collection, storage and return of test kits can increase compliance (Miller *et al*, 2005; Stokamer *et al*, 2005). Coupling this strategy of providing potential screening participants with more detailed instructions based on social cognitive approaches to alleviate misconceptions about screening (Bandura, 2004) and the presentation of risk information in a more effective manner (Rothman *et al*, 1999; Rothman *et al*, 2006) may positively effect FOBT participation.

We therefore report here the results of a factorial trial to assess the impact on participation in the English screening programme of including with the test kit: 1) a letter from the patient's GP recommending participation in the programme and 2) an information leaflet explaining more explicitly how to undertake faecal occult-blood testing.

Materials and Methods

A 2x2 factorial randomised controlled trial design was adopted to assess the effectiveness of the two interventions – a GP letter and/or a leaflet giving more explicit information on how to carry out and return the faecal occult blood test. Factorial trials have a number of advantages over the standard parallel group design. Firstly, they enable efficient simultaneous investigation of two interventions by including all participants in both analyses and secondly, the factorial trial can consider both the separate effects of the intervention and the benefits of receiving both interventions together (McAlister *et al* 2003, Montgomery *et al*, 2003). Finally, the design can reduce the total number of participants required to assess multiple interventions aimed at achieving the same outcome (Gurusamy *et al*, 2011, Montgomery *et al*, 2003).

Interventions

The *GP endorsement letter* was a personally addressed letter from each patient's general practice which: i) recommended that the patient complete the test; ii), offered support if the patient had any questions about screening; iii) emphasised the importance of being aware of bowel cancer symptoms. We included several key messages in the letter based on the views of the pilot participants, influential statements reported in previous UK-research (Woodrow *et al*, 2008) and phrased using a 'gain-frame' approach identified as important when targeting detection behaviours (Rothman *et al*, 2006). The key messages included in the endorsement letter indicated the risk of developing bowel cancer was highest in the patients' age group, there are often no symptoms associated with early bowel cancer and screening can detect bowel cancer at an early stage. Eight of the 20 practices involved provided electronic GP signatures; the others were sent "on behalf of the practice".

The *enhanced procedural leaflet* was extensively piloted and revised with 109 people previously invited to bowel cancer screening (see Appendices) and modified with advice from an expert

steering group involved in the trial. Pilot respondents indicated that the leaflet was easy to read (95%), sufficiently detailed (98%), and included 'very useful' information for collecting samples (76%), storing samples (75%) and for the decision to participate or not in screening (81%). The leaflet addressed potential barriers to screening identified from the pilot study and previous research (Weller *et* al, 2006; Woodrow *et al*, 2008; Subramanian *et al*, 2004). Based on social cognitive theory (Bandura, 2004) and effective methods for improving risk communication (Rothman *et al*, 1999) the leaflet included an educational or knowledge building component (reinforcing messages concerning the effectiveness and rationale for screening) and motivational components designed to improve self-efficacy (advice on how to collect samples, concerns about time required, and what people with loose or irregular bowel motions should do).

Recruitment and Participants

Approximately 25,000 people from more than 920 GP practices were invited for bowel cancer screening during October 2009 by the Southern Programme Hub. Following a consultation with the national bowel cancer screening programme, 20 of 88 eligible general practices in southern England whose patients were scheduled to receive a screening invitation in the month of October 2009 agreed to participate. We sent patients from these practices a preliminary letter in August 2009 (6 weeks before their scheduled invitation date in October). This letter informed them that they would be receiving an invitation to participate in the near future and that their own general practice was involved; it also provided brief information about the trial and bowel cancer screening in general. They then received a standard invitation letter from the NHS national screening service in October 2009. This letter explained the rationale for bowel screening and why they have been invited; an evidence-based information booklet was also included with the letter.

We included men or women registered with a GP practice in the south of England and who would be sent an invitation to bowel cancer screening in October 2009. We excluded those who specifically requested to be withdrawn from the programme or who were currently ineligible for invitation (i.e. current bowel cancer patients, people currently in bowel cancer surveillance programmes, etc). The age range for inclusion in the trial was 60 to 75 years old. The programme normally invites people aged 60-69 to screening. However, two regions were involved in piloting the age extension to the programme, which meant participants from two GP practices aged 70-75 were also included.

Of the people invited for screening, only one from each household was included in the trial. The number eligible in each GP Practice ranged from 48 to 115 (median = 59) and the total number of people randomised for the trial was 1288. These were randomised to four groups: i) GP endorsement letter, ii) enhanced procedural instruction leaflet; iii) GP letter plus leaflet; iv) no additional intervention ("usual care"). The GP letter and leaflet were sent out with the occult-blood testing kits one week after the invitation letter.

Randomisation Procedure

We randomised using a block randomisation using the 'ralloc' command in STATA Version 10; allocation was concealed to the researchers, practices and Screening Hub staff responsible for recording test-kit returns. There were 644 people randomised to the two factorial groups (322 people allocated to each of the four intervention groups, see Figure 1). As the standard invitation letter allows people to opt not to be sent the test kit, not all those randomised received the intervention.

Sample Size

The sample size was based on detecting a difference in main effects between the two factorial groups (e.g. GP letter versus no GP letter or leaflet versus no leaflet), not a difference between the four intervention groups (Montgomery *et al*, 2003; McAlister *et al*, 2003). The planned sample size of 387 participants per factorial group provided 80% power (α=0.05) to detect an absolute difference between the two factorial interventions of 10%; the interventions were thought to act independently and the study was not powered to detect interaction. It was not thought feasible to conduct a larger study with the resources available although a difference of approximately 10% was recognised to be of potential public health importance, particularly given the low cost (and hence potential for cost-effectiveness) of the interventions.

Main outcome and statistical method
The primary outcome of the trial was verified return of the test kit to the Screening Hub within 20 weeks of being invited to screening. We performed data analyses using STATA version 10. The primary analysis was conducted on an intention-to-treat basis; a per-protocol analysis was also performed for people who were actually sent a test kit and hence were subject to the intervention. The statistical significance of the main intervention effects was assessed using a multiple, random effects logistic regression model, adjusting for the other intervention and five covariates (age, gender, GP Practice, previous invitation, inclusion or not of a GP signature) (Montgomery *et al*, 2003; Green *et al*, 2003; McAlister *et al*, 2003). As the outcome rate was >10%, the adjusted odds ratios from the regression model were used to estimate rate ratios by Zhang's method (Zhang *et al*, 1998).

Ethical approval
Ethical approval was granted by the NHS National Research Ethics Service (Oxfordshire REC C – 09/H0606/60).

Results
The characteristics of those participating in the trial, including whether or not they received the intervention and a comparison of the factorial groups, are shown in Table 1. There were no statistically significant differences for gender, age group or previous invitation to screening between the four intervention groups. People randomised to the 'GP Letter and Leaflet' group (p = 0.005) and the 'GP Letter' factorial group (p = 0.004) were more likely to receive the FOBT kit than other participants.

[Insert Table 1]

Figure 1 shows that 322 people were allocated to each of the four intervention groups but 72 people receiving the screening invitation exercised the option not to receive the kit (and therefore did not receive the intervention).

[Insert Figure 1]

Table 2 shows the response rate in each of the three intervention groups individually and the comparison between the factorial groups. Both the GP endorsement letter and the enhanced procedural information leaflet each increased participation above usual care by about 6% - the GP endorsement letter from 52.3% to 58.1% (absolute difference 5.8%, 95%CI: 4.1 to 7.8%); the leaflet from 52.2% to 58.2% (absolute difference 6.0%, 95%CI: 4.3 to 8.1%). The return rate in people receiving both interventions was 61.2% (absolute difference from usual care 11.8%), suggesting the effect of both interventions is additive (i.e., the absolute difference of GP letter 5.6% and leaflet 5.9% together is 11.5%). The absolute difference of approximately 10% in the return rate for people receiving both interventions suggests a relative improvement of around 20% on current rates of participation in the English bowel cancer screening programme. The proportion of people participating in screening was higher for those receiving a signed GP endorsement letter (64.9%) in comparison to people who received the non-signed ('on behalf of the practice') endorsement letter (54.1%); an absolute difference in screening participation of almost 11%.

[Insert Table 2]

This additive effect was confirmed by the random effects logistic regression model (see Table 3) which shows there is no suggestion of a significant interaction between the two interventions (odds ratio 1.02, p = 0.979).

[Insert Table 3]

In the intention to treat analysis, the logistic regression model indicated there was no significant effect on the kit return-rates by age (p = 0.77), GP practice (p = 0.66), gender (p = 0.20), GP signature (p = 0.16) or previous invitation to screening (p = 0.56). Both the 'Leaflet' (p = 0.029)

and ‘GP Letter’ (p = 0.038) was significantly associated with an increase in participation. In the per-protocol analysis, the insertion of an electronic GP signature on the endorsement letter was associated with increased participation (p = 0.039), and again there was no significant association with other covariates.

The adjusted odds ratios associated with each intervention are also reported in Table 3. The adjusted rate-ratios calculated from these odds ratios were 1.11 for the GP letter (p = 0.038) and 1.12 for the enhanced leaflet (p = 0.029), on the basis of intention to treat, and slightly lower (1.06 and 1.08 respectively) when the analysis was restricted to those who received the intervention (per protocol analysis); reflecting the fact that the return rate in the no-treatment groups (61% and 62% respectively) is higher when patients opting out of screening are excluded from the denominator (number of people receiving the FOBT kit, rather than total number invited).

Discussion

Main findings

A letter of endorsement from the GP and a how-to-do-it procedural leaflet sent with the faecal-occult blood kit each appears able to achieve a small but important increase in participation in the national bowel cancer screening programme. The effects appear to act independently of each other and would be additive in practice. The non-randomised comparison of the effect of a GP signature also suggests that it is better if the endorsement letter is signed by the patient’s own GP rather than by the more impersonal ‘on behalf of the practice’.

Relation to previous findings

The findings are consistent with previous research from other countries which have demonstrated personalised invitations improve screening test-return rates (Brawarsky *et al*, 2004; Senore *et al*, 2010; Segnan *et al*, 2005; Cole *et al*, 2007; Zajac *et al*, 2007) and emphasise the important role that invitation materials can have on participation in screening (Steele *et al*, 2010). Furthermore, the per-protocol analysis revealed this effect is mediated by the inclusion of a GP signature on the endorsement letter. Similar to previous research (Miller *et al*, 2005; Stokamer *et al*, 2005), the intervention would seem to enhance participants’ perceived self-efficacy to complete the FOBT kit.

The additive effect observed in the trial may reflect the influence that each separate intervention had on two distinct groups of potential non-participants. For example, Senore and colleagues (Senore *et al*, 2010) found those with a higher education generally based their decision to participate in screening after reading the information materials, whereas people with a lower education tended not to read the information materials and rely on their GPs advice instead. Alternatively, people with limited health literacy (and associated lower education status) report more barriers to completing FOBT testing (Peterson *et al*, 2007). The brief enhanced procedural leaflet may have been sufficient for people with limited health literacy to address these barriers and engage in bowel cancer screening. It is therefore plausible that the GP endorsement letter was influential in those who preferred receiving health advice from their GP, whereas the procedural leaflet helped people overcome perceived barriers to completing the FOBT kits. Further research directly evaluating process variables such as health literacy, the effects of gain- versus loss-framing and the importance of GP recommendations for bowel cancer screening are required.

Limitations

The main design weakness was the potential for patients to opt-out of the trial after randomisation but before the intervention was delivered. This led to a slight imbalance in the intervention groups but there is no suggestion that this had an important effect on the results. Similarly, although the power of the study to demonstrate interaction was limited, there was no suggestion of important interaction between the two interventions. The lack of an individual general practice effect on test-return in the regression analyses suggests the findings are likely to be generalizable across practices. The relatively low GP participation rate and the inability for a number of GP practices to provide an electronic signature, may have implications for the widespread adoption of the endorsement letter for bowel cancer screening.

A further concern was the possibility of a 'priming effect' as participants were told about the trial and informed they would receive an invitation to screening six weeks in advance. In one previous study, participation in screening was increased when people received an advanced notification letter prior to their invitation (Cole *et al*, 2007). However, as the usual care group in our trial did not participate in screening at a rate much above the national average for participation in the national programme, priming did not appear to have an important effect.

Implications and conclusion

The results emphasise that minor amendment to the way screening is conducted can have important effects on uptake rates. Adding a GP letter and a more explicit instruction leaflet appears able to increase participation by at approximately 10% (potentially providing a 20% relative improvement in the current participation rate). However, as less than half the GP practices recruited to this trial provided an electronic signature to the Screening Hub on request, this suggests there is a lack of general practice engagement with the programme. Including bowel cancer screening uptake as a QOF indicator may provide the necessary incentive to remedy this lack of engagement.

Given the low-cost of including a GP endorsement letter and more explicit how-to-do-it leaflet, it is very likely that the two interventions would be cost-effective. Sending the initial invitation from general practices might also reduce the level of initial opt-out but the potential gain in participation would have to be weighed against the increased cost and administrative complexity.

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Figure 1 Trial flow chart

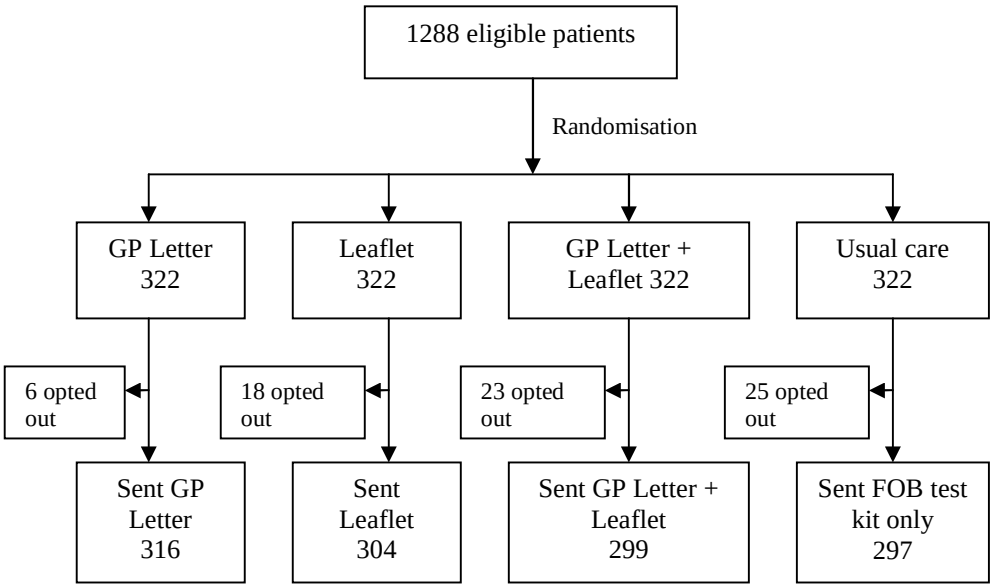

Table 1: Participant characteristics for the four intervention groups and two factorial trial groups.

Intervention Groups		**GP Letter and Leaflet**	**GP Letter Only**	**Leaflet Only**	**Usual Care**	**Total**	***p* Value**
Gender	*Male*	153	153	154	151	611	0.996
	Female	169	169	168	171	677	
Age Group	*60-64*	187	189	183	189	748	0.864
	65-69	125	119	131	123	498	
	70+	10	14	8	10	42	
Previous Invite	*Yes*	44	38	41	47	180	0.508
	No	278	284	271	275	1108	
Sent FOBT	*Yes*	316	304	299	297	1216	0.005
	No	6	18	23	25	72	
GP Signature	*Yes*	123	116	-	-	239	0.954
	No	199	206	-	-	405	
Total		322	322	322	322	1288	

Factorial Trial Groups		**GP Letter**	**No GP Letter**	***p* Value**	**Leaflet**	**No Leaflet**	***p* Value**
Gender	*Male*	306	305	0.956	307	304	0.867
	Female	338	339		337	340	
Age Group	*60-64*	376	372	0.583	370	378	0.513
	65-69	244	254		256	242	
	70+	24	18		18	24	
Previous Invite	*Yes*	82	98	0.199	95	85	0.422
	No	562	546		549	559	
Sent FOBT	*Yes*	620	596	0.004	615	601	0.089
	No	24	48		29	43	
Total		644	644		644	644	

* letter sent with GP signature rather than signed “on behalf of the practice”

Table 2: Number of people returning faecal occult blood test-kits within 20 weeks according to individual intervention group, factorial group, and whether or not the endorsement letter was signed by the patient's general practitioner.

	No.	*Total*	*Percentage*	*95% CI*	*Difference*	*95% CI*
Individual groups						
GP Letter+Leaflet	197	322	61.2%	56% to 67%	11.8%	8.5% to 16%
GP Letter Only	177	322	55.0%	49% to 61%	5.6%	3.3% to 8.7%
Leaflet Only	178	322	55.3%	50% to 61%	5.9%	3.6% to 9.1%
Usual Care	159	322	49.4%	44% to 55%	-	-
Factorial groups						
GP Letter	374	644	58.1%	54% to 62%	5.8%	4.1% to 7.8%
No GP Letter	337	-	52.3%	48% to 56%	-	-
Leaflet	375	644	58.2%	54% to 62%	6.0%	4.3% to 8.1%
No Leaflet	336	-	52.2%	48% to 56%	-	-
GP Letter						
GP Letter Signed*	155	239	64.9%	58% to 71%	10.8%	8.6% to 14%
GP Letter Not Signed	219	405	54.1%	49% to 59%	-	-

* letter sent with GP signature rather than signed "on behalf of the practice"

Table 3: Likelihood of patients returning a faecal occult blood test kit within 20 weeks: results of the logistic regression analysis

Participation (ITT analysis)	*Odds ratio*	*95% CI*	*Rate ratio ++*	*p Value*
Intervention main effects:*†				
GP Letter	1.26	1.01 to 1.58	1.11	0.038
Leaflet	1.28	1.03 to 1.59	1.12	0.029
Interaction:*				
GP Letter and Leaflet	1.02	0.66 to 1.58	-	0.979
Participation (sent FOBT kit)	*Odds ratio*	*95% CI*	*Rate ratio ++*	*p Value*
Intervention main effects:*†				
GP Letter	1.17	0.93 to 1.47	1.06	0.186
Leaflet	1.23	0.98 to 1.56	1.08	0.073
GP Signature	1.29	1.01 to 1.63	1.11	0.039
Interaction:*				
GP Letter and Leaflet	0.91	0.58 to 1.44	-	0.697

* The reference category for each main effect was those not receiving the intervention.
† Obtained for model without interaction; each intervention adjusted for the other.
++ estimated as OR / (1-p) + (OR x p) where OR is the odds ratio and p is the proportion of kits returned in those not receiving the intervention

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Appendix 10.1: Analyses of the Knowledge Scale

1.0 Background

The knowledge scale consisted on 10 items which attempted to cover a range of areas important to understanding CRC and CRC screening. Respondents completed the same knowledge scale in both the baseline and follow-up questionnaires.

2.0 Internal Consistency Analysis

The KR-20 coefficient for the baseline knowledge scale was 0.61 (see Table 1). The item-rest correlation (correlation between the item with the total of all other items) was adequate (≥ 0.20) for all items with the exception of Item C. This is likely to be due to the very low number of correct responses to this item (4.75% of respondents correctly answered the item).

Table 1: Internal consistency (KR-20) results for the baseline knowledge scale.

	Number	Item Difficulty	Item Variance	Item-rest correlation
Item A	400	0.6025	0.2395	0.3105
Item B	400	0.4775	0.2495	0.2574
Item C	400	0.0475	0.0452	0.1771
Item D	400	0.4125	0.2423	0.2763
Item E	400	0.4200	0.2436	0.3327
Item F	400	0.5825	0.2432	0.2931
Item G	400	0.4575	0.2482	0.3321
Item H	400	0.7500	0.1875	0.4104
Item I	400	0.2350	0.1798	0.2295
Item J	400	0.7725	0.1757	0.2002

The KR-20 coefficient for the follow-up knowledge scale was 0.61 (see Table 2). The item-rest correlation (correlation between the item with the total of all other items) was adequate (≥ 0.20) for all items.

Table 2: Internal consistency (KR-20) results for the follow-up knowledge scale.

	Number	Item Difficulty	Item Variance	Item-rest correlation
Item A	401	0.7257	0.1991	0.2269
Item B	401	0.6085	0.2382	0.2537
Item C	401	0.1496	0.1272	0.2976
Item D	401	0.6758	0.2191	0.3645
Item E	401	0.6808	0.2173	0.2636
Item F	401	0.7631	0.1808	0.3148
Item G	401	0.5212	0.2496	0.3735
Item H	401	0.8628	0.1183	0.2183
Item I	401	0.3267	0.2200	0.3870
Item J	401	0.8828	0.1035	0.2346

The internal consistency for the knowledge scale was the same for both the baseline and follow-up questionnaires.

3.0 Individual Item Analysis

The McNemar test was used to determine the difference between respondents' answers to the baseline and follow-up knowledge scale. Only those respondents' answering individual items in both the baseline and the follow-up questionnaires were included in the analysis.

The proportion of correct answers significantly increased between the baseline and follow-up questionnaires for all knowledge items (see Table 3). The greatest increase in correct answers between the baseline and follow-up questionnaires occurred for Item E (number of people who will receive a normal result after participating in screening). The smallest increase was for Item G (family history) which increased only 6.1% between the baseline and follow-up questionnaires.

Table 3: Number of correct responses to the individual items for the baseline and follow-up questionnaires and percentage change between questionnaires.

		Baseline Questionnaire		Follow-Up Questionnaire			
Item		***N***	***%***	***N***	***%***	**% Diff.**	
A. You can have CRC without having any symptoms	*Correct*	242	*59.9*	291	*72.6*	+12.7%	0.001
	Incorrect	162	*40.1*	110	*27.4*		
B. CRC is the second leading cause of cancer deaths in the UK	*Correct*	193	*48.0*	244	*60.9*	+12.9%	0.001
	Incorrect	209	*52.0*	157	*29.1*		
C. About 4 in 10 people diagnosed with CRC are over 60 years old	*Correct*	20	*5.0*	60	*15.0*	+10.0%	0.001
	Incorrect	384	*95.0*	341	*85.0*		
D. The CRC test will always detect if you have bowel cancer	*Correct*	166	*49.2*	271	*67.6*	+18.4%	0.001
	Incorrect	237	*50.8*	130	*32.4*		
E. About 98 in every 100 people will receive a normal test result	*Correct*	171	*42.3*	273	*68.1*	+25.8%	0.001
	Incorrect	233	*57.7*	128	*31.9*		
F. A colonoscopy is the most effective way to diagnose CRC	*Correct*	235	*58.3*	306	*76.3*	+18%	0.001
	Incorrect	168	*41.7*	95	*23.7*		
G. Family history does not increase your chances of developing CRC	*Correct*	186	*46.0*	209	*52.1*	+6.1%	0.039
	Incorrect	218	*54.0*	192	*47.9*		
H. If CRC is detected early, there is over a 90% chance of survival	*Correct*	304	*72.3*	346	*86.3*	+14.0%	0.001
	Incorrect	100	*27.7*	55	*13.7*		
I. No side-effects associated with having a colonoscopy	*Correct*	96	*23.8*	131	*32.7*	+8.9%	0.001
	Incorrect	308	*76.2*	270	*67.3*		
J. Participating in screening reduces your chances of dying from CRC	*Correct*	313	*77.5*	355	*88.3*	+10.8%	0.001
	Incorrect	91	*22.5*	47	*11.7*		

There is some concern that the item relating to the number of people diagnosed with CRC over the age of 60 years old (Item C) was consistently answered incorrectly by the respondents. Although there was an increase in the proportion of people answering the item correctly between the baseline and the follow-up questionnaires, only 15% of respondents correctly answered this item in the follow-up questionnaire. All respondents would have received the NHS BCSP publication 'The Facts', which specifically states that "*Eight out of 10 people who are diagnosed with bowel cancer are over 60*." Half of the respondents would have also received the procedural leaflet which also includes this information. However, clearly this important facet of information was not transferred to the respondents. This did not have a dramatic effect for the questionnaire respondents, given the overwhelming majority (95%) participated in screening, however, suggest either the item was misunderstood

by participants (potentially as it included numerical information) or that people are not aware CRC is an age-related cancer.

Appendix 10.2: Views of the Screening Kit Item Analysis

1.0 Background

The following section details the item analysis for selected items in the 'Views of the Screening Kit' scale. Ten attitudinal items were included in the baseline questionnaire scale and 11 items in the follow-up questionnaire. The eight items included in both questionnaires form the basis of the item analysis.

In the baseline questionnaire, seven items (Items B, C, D, E, F, H and J) addressed possible barriers or negatives aspects of the FOBT screening procedure. Two of these items (Items H and J) were not included in the follow-up questionnaire. The three remaining items in the baseline questionnaire (Items A, G and I) addressed the positive aspects of FOBT screening and were included in the follow-up questionnaire. In the follow-up questionnaire, five items (Items D, E, F, G and H) addressed possible barriers or negatives aspects of the FOBT screening procedure. Three items (Items A, I, J and K) addressed the positive aspects of FOBT screening and two items (Items B and C) concerned views of the test kit (kit instructions and spatulas included with the kit).

Item analysis was performed on respondents completing only the baseline questionnaire (*N* = 404) and the follow-up questionnaires (*N* = 398). The results for the baseline questionnaire only are shown in Section 2, and for both questionnaires in Section 3.

2.0 Baseline 'Views about the screening kit' results

The correlation matrix for the eight baseline questionnaire items is shown in Table 1. Items A, G and I were weakly correlated with the other items in the scale, suggesting these should be removed from the composite scale.

Table 1: Correlation matrix for the scale items in the baseline questionnaire for all respondents (*N* = 404).

	Item A	Item B	Item C	Item D	Item E	Item F	Item G	Item I
Item A	1.0000							
Item B	0.0410	1.0000						
Item C	0.3240	0.6076	1.0000					
Item D	-0.0138	0.5333	0.4204	1.0000				
Item E	0.0634	0.6320	0.5838	0.4920	1.0000			
Item F	0.0610	0.4882	0.5361	0.4064	0.6238	1.0000		
Item G	0.0469	0.0936	0.0788	0.1559	0.1722	0.1514	1.0000	
Item I	0.0521	0.1611	0.1401	0.0992	0.1161	0.1216	0.1812	1.0000

2.1 Internal Consistency for the baseline scale Items

The internal consistency (alpha coefficient) for the scale items is shown in Table 2. The item-test correlation (the correlation of each item with the total score) was strong for the majority of items, with the exception of Items A, G and I.

Table 2: Analysis of internal consistency for each of the baseline 'views about the screening kit' scale items.

	Obs	Sign	Item-test correlation	Item-rest correlation	Item alpha
Item A	404	+	0.2085	0.0546	0.7870
Item B	404	+	0.7839	0.6860	0.6910
Item C	404	+	0.7312	0.6142	0.7042
Item D	404	+	0.7188	0.5447	0.7164
Item E	404	+	0.8171	0.7162	0.6786
Item F	404	+	0.7499	0.6141	0.7001
Item G	403	+	0.3320	0.1793	0.7723
Item I	404	+	0.3477	0.1831	0.7738
				Test scale	0.7585

Based on the above analysis, removal of Items A, G and I would increase the internal consistency of the scale. Given each of these items is related to positive aspects of FOBT screening, it is possible the internal consistency of the

scale is not unidimensional, therefore, affecting the magnitude of the alpha coefficient. The internal consistency analysis was performed after iterative removal of each of the positive items (see Table 3).

Table 3: Analysis of internal consistency for each of the baseline 'views about the screening kit' scale items after removal of items.

	Obs	Sign	Item-test correlation	Item-rest correlation	Item alpha
Item B	404	+	0.8165	0.7175	0.8073
Item C	404	+	0.7705	0.6512	0.8225
Item D	404	+	0.7644	0.5865	0.8458
Item E	404	+	0.8490	0.7488	0.7948
Item F	404	+	0.7813	0.6391	0.8247
				Test scale	0.8497

The removal of the three positive items resulted in a higher internal consistency for the baseline questionnaire scale ($\alpha = 0.85$).

2.3 Follow-up 'Views about the screening kit' results

The correlation matrix for the eight follow-up questionnaire items is shown in Table 4. Items A, K and J were weakly correlated with the other items in the scale, suggesting these should be removed from the composite scale.

Table 4: Correlation matrix for the scale items in the baseline questionnaire for all respondents (*N* = 398).

	Item A	Item D	Item E	Item F	Item G	Item H	Item K	Item J
Item A	1.0000							
Item D	0.3199	1.0000						
Item E	0.1770	0.4594	1.0000					
Item F	0.0534	0.3201	0.2618	1.0000				
Item G	0.3000	0.5841	0.5399	0.3822	1.0000			
Item H	0.2466	0.4291	0.5076	0.3808	0.6259	1.0000		
Item K	0.3670	0.1844	0.1527	0.1521	0.2655	0.2188	1.0000	
Item J	0.5964	0.2336	0.1888	0.1229	0.2802	0.2663	0.4565	1.0000

2.4 Internal Consistency for the follow-up scale Items

The internal consistency (alpha coefficient) for the follow-up scale items is shown in Table 5. The item-test correlation (the correlation of each item with the total score) was strong for the majority of items, with the exception of Items A, K and J.

Table 5: Analysis of internal consistency for each of the baseline 'views about the screening kit' scale items.

	Obs	Sign	Item-test correlation	Item-rest correlation	Item alpha
Item A	398	+	0.4957	0.3929	0.7741
Item D	398	+	0.6981	0.5774	0.7435
Item E	398	+	0.6765	0.5334	0.7500
Item F	398	+	0.6098	0.4832	0.7816
Item G	398	+	0.8101	0.7067	0.7159
Item H	398	+	0.7563	0.6341	0.7309
Item K	398	+	0.4775	0.3467	0.7779
Item J	398	+	0.5186	0.4101	0.7715
				Test scale	0.7821

The removal of the three positive items (see Table 6) resulted in a slightly higher internal consistency for the follow-up questionnaire scale ($\alpha = 0.79$).

Table 6: Analysis of internal consistency for each of the baseline 'views about the screening kit' scale items after removal of items.

	Obs	Sign	Item-test correlation	Item-rest correlation	Item alpha
Item D	398	+	0.7152	0.5709	0.7506
Item E	398	+	0.7235	0.5630	0.7502
Item F	398	+	0.6730	0.4150	0.8156
Item G	398	+	0.8296	0.7103	0.7009
Item H	398	+	0.7841	0.6433	0.7240
				Test scale	0.7884

Appendix 10.3: Health Literacy Item Analysis

1.0 Individual Scale Items

The following section details the item analysis for the three health literacy items used in the baseline questionnaire (Lit A = Q25; Lit B = Q26; Lit C = Q27). As shown in Table 1, there was some variation between the three items in regards to the level of endorsement for each item, especially in relation to item 'Lit A'.

Table 1: Number of responses for each of the scale items.

	Lit A		Lit B		Lit C	
Response format	***N***	***%***	***N***	***%***	***N***	***%***
Never‡/Not at all†	2	*0.4*	14	*3.0*	2	*0.4*
Occasionally‡/A little bit†	3	*0.6*	15	*3.2*	4	*0.9*
Sometimes‡/Somewhat†	8	*1.7*	43	*9.2*	43	*9.2*
Often‡/Quite a bit†	31	*6.7*	130	*27.9*	113	*24.3*
Never‡/Extremely†	422	*90.6*	264	*56.7*	304	*65.2*
Total	*466*	-	*466*	-	*466*	-

‡ Response format for Lit A "How often do you have someone help you to read hospital or patient education materials?" and Lit C "How often do you have problems learning about health matters because of difficulty understanding written information?"
† Response format for Lit B "How confident are you filling out medical forms by yourself?"

2.0 Correlation of the Health Literacy Items

The correlation matrix for the three health literacy items is shown in Table 2. The three literacy items were all significantly correlated.

Table 2: Correlation matrix for the scale items.

	Lit A	Lit B	Lit C
Lit A	1.0000		
Lit B	0.3154†	1.0000	
Lit C	0.3308†	0.4513†	1.0000

† denotes $p = 0.001$

3.0 Internal Consistency for the Health Literacy Items

The internal consistency (alpha coefficient) for the health literacy items is shown in Table 3. The item-test correlation (the correlation of each item with the total score) was strong for both the 'Lit B' and 'Lit C' items. The item-test correlation for 'Lit C' was lower, however, not sufficiently weak to warrant removal from the overall scale.

Table 3: Analysis of internal consistency for each of the scale items.

	Obs	Sign	Item-test correlation	Item-rest correlation	Item alpha
Lit A	466	+	0.5763	0.3315	0.6303
Lit B	466	+	0.8615	0.4932	0.4244
Lit C	466	+	0.7890	0.5047	0.3703
				Test scale	0.6038

Two previous studies have suggested that a single item, either 'Lit B' [1] or 'Lit C' [2], can be used instead of all three items for evaluating health literacy in populations. Therefore, the 'Lit A' item was removed to determine if this had any effect on the internal consistency of the scale. Removal of 'Lit A' from the scale did not dramatically improve the internal consistency of the scale (0.63 with removal of 'Lit A'). Therefore, all three items were retained for the calculation of the overall health literacy score.

4.0 Total Literacy Score

The total literacy score was calculated by adding the three individual items together. Although some authors have argued that only one item ('Lit B') is required to calculate 'adequate' literacy [1], we chose to use the sum of the three health literacy items given the satisfactory item analysis results, alternate

views on the use of the scale [2, 3] and the strong correlation between the total literacy scale and the single 'Lit B' item (item-test correlation = 0.86). The frequency of scores for respondents is shown in Table 4. The total literacy score for respondents ranged from 0 to 12.

Table 4: Frequency of total scores for respondents.

Total Score	Number	Percent.	Cumulative Percent.
0	1	0.2	0.2
4	3	0.6	0.8
5	3	0.6	1.5
6	4	0.9	2.4
7	13	2.8	5.2
8	28	6.0	11.2
9	47	10.1	21.3
10	51	10.9	32.2
11	99	21.2	53.4
12	217	46.6	100

The mean total literacy score was 10.7 (sd = 1.71) and the median was 11. The median-split method was used to categorise respondents as having either 'adequate' literacy (total score ≥11) or 'inadequate' literacy (total score ≤10). Therefore, approximately two-thirds (68%) of respondents were categorised as having 'adequate' literacy.

5.0 References

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