Using ‘gist-based’ information to reduce inequalities and improve cancer screening uptake

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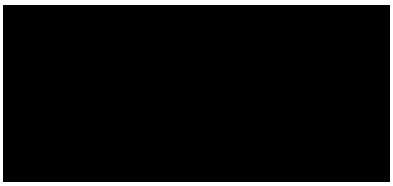
A thesis submitted for the degree of Doctor of Philosophy

UCL

Declaration

I, Samuel Smith, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated.



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Abstract

Colorectal cancer (CRC) is the second most common cause of cancer death in the UK. Screening is key to promoting early diagnosis and thereby improving survival. The English NHS Bowel Cancer Screening Programme (BCSP) invites adults aged 60-69 to complete a home-based Faecal Occult Blood test (FOBt) kit every 2 years. Routinely collected data indicate uptake of only 54% for the first invitation; varying from 35% in the most deprived quintile of residential areas to 61% in the least deprived quintile. Evidently, the full benefits of CRC screening are not being realised and inequalities in CRC outcomes may increase.

Evidence from a number of sources indicates less awareness of CRC, and less recognition of the benefits of screening, in lower SES groups. It is therefore crucial that the screening information booklet mailed with the test enables people of all levels of health literacy to make an informed decision about participating in the BCSP. This thesis describes the development and testing of a health communication intervention that aims to reduce inequalities in uptake.

Study 1 used the 'think-aloud' method to examine responses to the existing information booklet in order to identify barriers to comprehension. The process of designing a supplementary leaflet to facilitate 'gist-based' processing is described. Gist is defined as the qualitative representation of concepts, and gist-based processing is the preference for evaluating information in its simplest form. Performance-based user-testing was used to optimise the content, design and layout of the gist leaflet (study 2). The communicative effectiveness of the leaflet was tested in study 3, which was a community-based randomised controlled trial (registration number: ISRCTN62215021) in which adults approaching the screening age were randomised to be sent standard screening information (control) or standard information plus the gist leaflet (intervention). Findings from 964 respondents showed that the gist leaflet was considered to be readable and useful and did not cause additional worry about CRC. Screening intention and perceived risk were unaffected by the gist leaflet, however knowledge was significantly higher among the intervention group.

Study 4 was a national, cluster randomised trial (registration number: ISRCTN74121020) nested in the existing NHS BCSP (n=163,566). Adults who were

being sent a screening invitation were randomised to receive the standard information or standard information plus the gist leaflet. Randomisation was by day of mailing and stratified by screening hub. The gist leaflet had no effect on the socioeconomic gradient in screening uptake and no effect on screening uptake overall. Among a sub-sample of people being invited for the first time, a small but significant difference in screening uptake was seen in the intervention group. This effect was particularly apparent among men and older people.

Despite the small effects of the gist intervention on screening uptake among specific sub-groups, the provision of supplementary gist-based information in this context is unlikely to reduce the socioeconomic gradient in CRC screening uptake. Implications for the NHS BCSP and future research are discussed.

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1.1 Colorectal Cancer

Colorectal cancer (CRC) is the second most common cause of cancer-specific mortality in the UK, with over 16,000 deaths recorded annually (General Register Office for Scotland, 2012; Northern Ireland Statistics Research Agency, 2012; Office for National Statistics, 2012a). Approximately 40,000 cases of CRC are diagnosed each year in the UK, making it the third most commonly diagnosed cancer (Information Services Division, 2013a; Northern Ireland Cancer Registry, 2012; Office for National Statistics, 2013; Welsh Cancer Intelligence & Surveillance Unit, 2011).

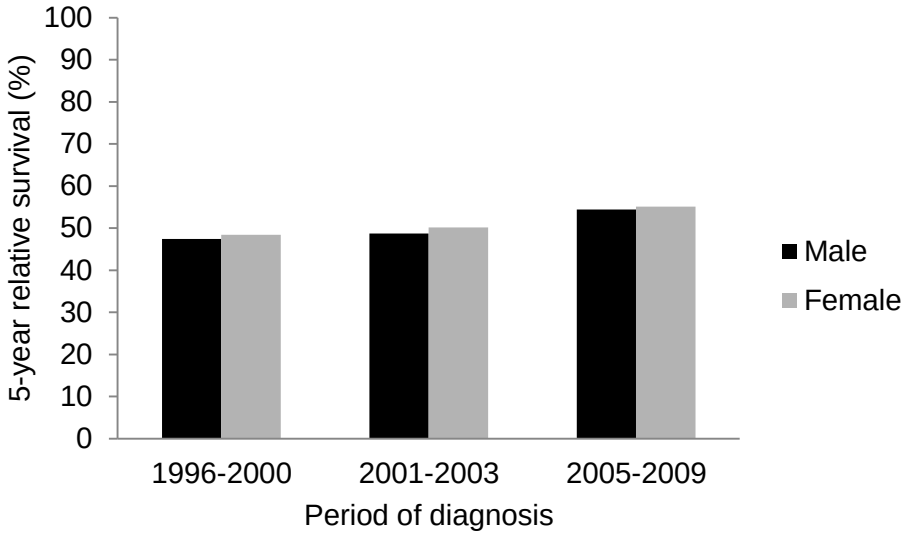
Survival from the disease is dependent to a large degree on the stage at which it is diagnosed. As shown in Table 1-1, cancers classified as Dukes A and B constitute 32.9% of all CRC, and have the highest 5-year relative survival. Less than half of all CRCs diagnosed after lymph node involvement (Dukes C) or when it has metastasised (Dukes D) survive for 5 years after diagnosis. Increasing the number of cancers detected at Dukes A and Dukes B is important to increasing survival.

Table 1-1 5-year relative survival of CRC patients in England (1996-2002) by Dukes stage (Dukes, 1932; National Cancer Intelligence Network, 2008)

Stage at diagnosis	Staging criteria	% of diagnoses	5-year relative survival
Dukes A (Early)	Cancer is limited to inner lining of the colon or rectal (submucosa), but has not spread fully into the muscle	8.7	93.2
Dukes B	Cancer has infiltrated the submucosa to the surrounding muscle, but no lymph nodes are implicated	24.2	77.0
Dukes C	At least one Lymph node has been affected in the area close to the bowel	23.6	47.7
Dukes D (Late)	The cancer has metastasised to other organs	9.2	6.6
Unknown	N/A	34.3	35.4

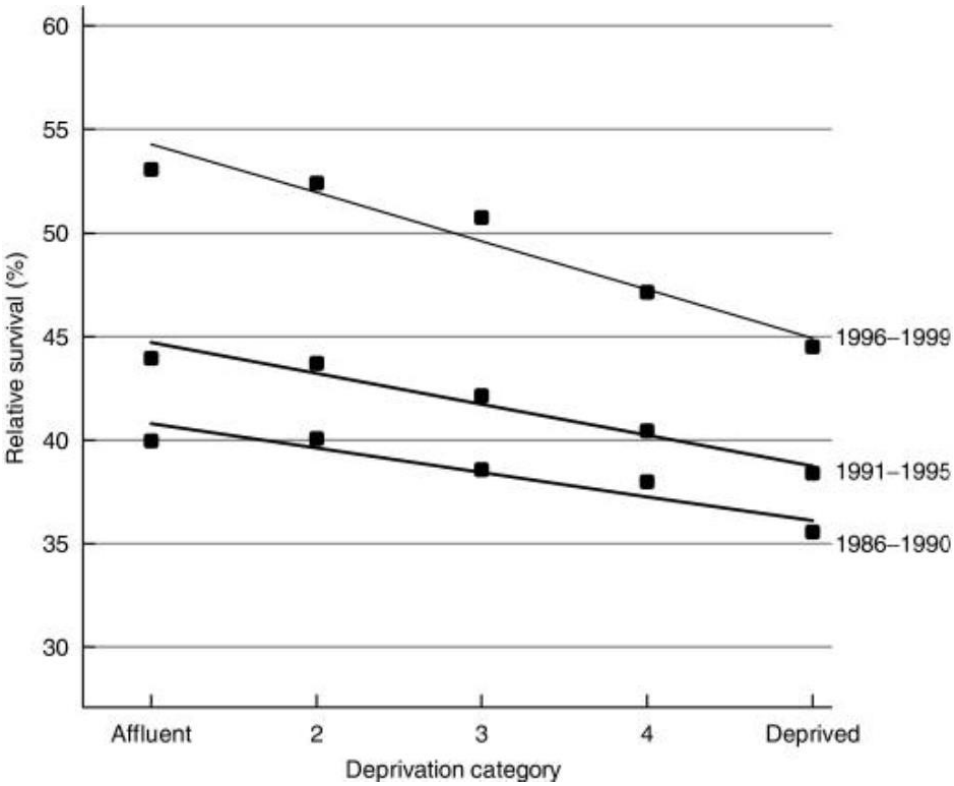
As shown in Figure 1-1, 5-year relative survival has been steadily increasing in recent years (Coleman et al., 2004; Mitry, Rachet, Quinn, Cooper, & Coleman, 2008; Shack, Rachet, Brewster, & Coleman, 2007). The latest figures suggest 54.2% of men and 55.6% of women will survive for at least 5 years after a CRC diagnosis (Office for National Statistics, 2011a).

Figure 1-1 5-year relative survival of colon cancer in England (1996-2009)



Socioeconomic status (SES) is linked to survival from CRC. For example, data from 2.2 million patients diagnosed between 1986 and 1999 in England and Wales were linked with the National Cancer Registry and the NHS Central Register (Coleman et al., 2004). A 'deprivation gap' in 5-year relative survival between the least and most deprived quintiles of neighbourhood deprivation was calculated. This showed that there was a 5.7% deprivation gap in male colon cancer 5-year survival, and a 7.3% gap in women. The deprivation gap was wider for rectal cancer, where a 9.4% difference was noted in men and an 8.3% difference in women. Importantly, colon and rectal cancer were one of the few cancers where the deprivation gap was widening. This is shown in Figure 1-2 where a relatively shallow SES gradient was demonstrated in rectal cancer diagnosis during the periods of 1986-1990 and 1991-1995. But this gradient increased for the diagnosis period of 1996-1999.

Figure 1-2 Relative survival of rectal cancer in relation to deprivation quintile (2000-2004) (Coleman et al., 2004)



Increases in survival are largely due to earlier diagnosis and improvements in treatment that have been observed over the same period (Aarts, Lemmens, Louwman, Kunst, & Coebergh, 2010; Coleman et al., 2004; McArdle & Hole, 2002; Mitry et al., 2008; Raine et al., 2010). As a result, it is plausible to assume that these advances are not being experienced equally across the socioeconomic spectrum and inequalities in CRC outcomes are occurring.

People of low SES may also be more likely to die from CRC. Data from the period of 1993-2003 show that male CRC death was 20% higher among the most deprived wards of neighbourhood deprivation in England and Wales (Romeri, Baker, & Griffiths, 2006). However, this effect was inconsistent over the deprivation categories and there was no effect of deprivation in women. Data separating the sexes are not available in Scotland, but the latest figures indicate a social gradient in mortality overall (Information Services Division, 2011). No statistically significant trends in colon or rectal cancer were observed in Northern Ireland between 1993-

2001, although this data may be out of date and current estimates are yet to be reported (Northern Ireland Cancer Registry, 2004).

1.2 Risk factors for the development of colorectal cancer

It has been estimated that over half (54.4%) of CRC cases in the UK are associated with lifestyle and environmental factors (Parkin, Boyd, & Walker, 2011). Factors such as overweight and obesity (Ning, Wang, & Giovannucci, 2010), fruit and vegetable consumption (van Duijnhoven et al., 2009), eating red and processed meat (Chan et al., 2011; Norat et al., 2005), physical activity (Wolin, Yan, & Colditz, 2011), sedentary behaviour (Boyle, Fritschi, Heyworth, & Bull, 2011) and smoking (Liang, Chen, & Giovannucci, 2009) have all been associated with the development of CRC.

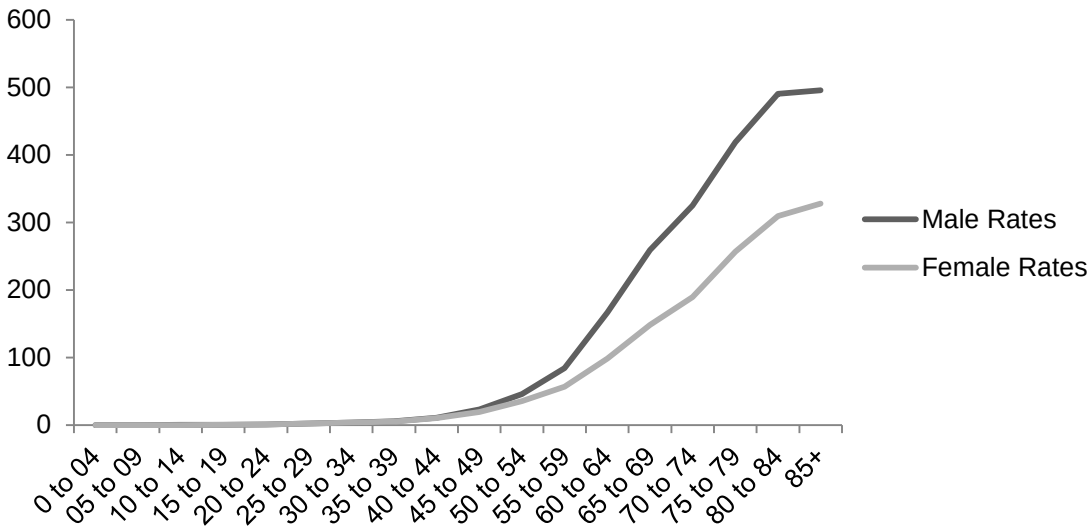
These factors have also been associated with SES. For example, lower SES individuals are more likely to smoke (Kotz & West, 2009), consume harmful amounts of alcohol (Stringhini et al., 2011), be overweight or obese (McLaren, 2007) and have sedentary lifestyles (Hamer, Kivimäki, & Steptoe, 2012). They are also less likely to meet diet (Shohaimi et al., 2004; Stringhini et al., 2011; Watt, Carson, Lawlor, Patel, & Ebrahim, 2009) and physical activity (Hamer et al., 2012; Stringhini et al., 2011) recommendations.

Additional factors unrelated to behaviour increase the risk of CRC development. As shown in Figure 1-3, the likelihood of being diagnosed with CRC increases with age. For example, UK men aged 40-44 have an incident rate of approximately 12 cases per 100,000, while those aged 60-64 have a rate of 162.2 per 100,000. The effect of age is less pronounced in women (Information Services Division, 2013a; Northern Ireland Cancer Registry, 2012; Office for National Statistics, 2013; Welsh Cancer Intelligence & Surveillance Unit, 2011).

People with two or more first- or second-degree relatives who have been diagnosed with CRC are at higher risk for the development of colorectal neoplasia (Church & McGannon, 2000; Lynch & de la Chapelle, 2003). A strong family history is suggestive of an inherited CRC syndrome such as Familial Adenomatous Polyposis (FAP), Hereditary Nonpolyposis CRC (HNPCC; also known as lynch syndrome), MYH-Associated Polyposis (MAP), or Hamartomatous Polyposis (Kastrinos & Syngal, 2012). These largely inherited conditions account for approximately 5% of

all CRC (Chung & Rustgi, 2003; Grady, 2003; Lynch & de la Chapelle, 2003), and therefore the provision of population-based genetic screening for CRC is unlikely to provide sufficient health benefits. People with inflammatory conditions such as ulcerative colitis and Crohn's disease are also at increased risk of developing CRC (Eaden, Abrams, & Mayberry, 2001; Jess, Gamborg, Matzen, Munkholm, & Sørensen, 2005).

Figure 1-3 Age-specific incidence rates per 100,000 of the UK population (2008-2010). Source: Cancer Research UK, 2013



1.3 Screening for Colorectal Cancer

Identifying CRC early is important to improving outcomes from the disease. Despite several recognised symptoms of CRC[1], the majority of early stage bowel cancers, as well as the precursor polyps, are largely asymptomatic (Risio, 2010). The strong association of CRC development with age, and the small proportion of individuals who would be affected by inherited syndromes mean that CRC screening programmes are most effective when they are provided to the whole population of older people. Their aim is to i) detect cancer early when no symptoms are present; or ii) identify and remove pre-cancerous lesions that may turn into cancer over time.

[1] These include: a persistent change in bowel habit; unexplained bleeding from the back passage; blood in stools; an abdominal pain or lump; unexplained weight loss; pain in back passage; tiredness; and a feeling that the bowel does not empty. There is a low awareness of bowel cancer symptoms in the Great Britain (Power, Simon, Judzczyk, Hiom, & Wardle, 2011).

1.3.1 Screening modalities

Several screening modalities are available and used in programmes around the world. Following an international meeting in 2002, the International Colorectal Cancer Screening Network (ICRCSN) was established and tasked with reporting on the international activity of CRC screening initiatives. A subsequent report in 2008 outlined 35 initiatives in 17 countries (Benson et al., 2008). This included 10 routine population-based screening programmes, 9 pilots and 16 research projects. The modalities used can largely be categorised into two groups: early detection and preventative. The following is a brief overview of commonly used screening modalities and their evidence base as first line screening tests for CRC.

1.3.1.1 Early detection screening tests

Early detection tests operate by finding CRCs when they are in the early stage (i.e. Dukes A and B) where 5-year survival is higher.

Guaiac - Faecal Occult Blood Test. The Guaiac Faecal Occult Blood (gFOB) test was developed by Dr. Eric Mueller in 1958. Although the test has developed since this, the principle is similar. A strip of purified card is pre-saturated with dried Guaiac. A small sample of faeces is placed onto the test card with the aid of a spatula. A drop of hydrogen peroxide soloution is placed onto the card. After development, the presence of haem (a component of blood) is indicated by a change of colour within the sample. If blood is present, follow-up testing (usually colonoscopy) is recommended.

Awareness of FOB testing increased following a report in the Journal of the American Medical Association (Greegor, 1967). Since then, clinical trials have shown that it is effective at reducing CRC-related death (Hardcastle et al., 1986, 1996; Hardcastle, Balfour, & Amar, 1980; Mandel et al., 1993; Scholefield, Moss, Mangham, Whynes, & Hardcastle, 2012). A meta-analysis has shown that FOBt screening can reduce cancer-specific mortality by 16% at a population level (Hewitson, Glasziou, Irwig, Towler, & Watson, 2007). This figure rises to 25% for individuals completing the test at least once. Long-term follow-up data from a large US trial suggest that these effects are persistent for at least 30 years (Shaukat et al., 2013). Routinely collected data from the English programme shows that 61.5% of malignancies detected in the first round were found early (either Dukes A or B

cancers) (Logan et al., 2012). There is less support for the role of FOBt screening in preventing CRC, with 20-year follow-up of a large trial demonstrating no change to CRC incidence (Scholefield et al., 2012).

Dietary restrictions are sometimes recommended, as the test depends on the peridoxase properties of haem (a component of haemoglobin), which can be found in some foods (Halloran, 2009). This offers a cheap and reliable method of screening that is suitable for a large population-based programme. The FOB test is used by the NHS Bowel Cancer Screening Programme (BCSP), where three samples are required over a two week period (see Chapter 2 for a full overview of the NHS BCSP).

Immunochemical - Faecal Occult Blood Test. Similar to the gFOBt, the iFOBt uses faecal samples, however it relies on a different chemical reaction. This reaction enables the iFOBt to detect globin within blood (as opposed to haem). This process is based on antibodies specific to human haemoglobin, meaning that the test is more accurate at detecting CRC (Faivre et al., 2012; Launoy et al., 2005). It also requires fewer samples and no dietary restriction is required (Halloran, 2009). Uptake with iFOBt has been shown to be consistently higher than gFOBt screening (Vart, Banzi, & Minozzi, 2012), particularly among lower SES groups (Digby et al., 2013). The iFOBt is more sensitive to small concentrations of blood than the gFOBt, allowing cut-offs to be used that control the levels of false-positive and false-negative results and in turn accommodate the resources (e.g. colonoscopy capacity) of the programme. The disadvantage of iFOBt is that it is sensitive to ambient temperature, meaning seasonal variation in temperature could affect positivity levels (Grazzini et al., 2010).

1.3.1.2 Preventative screening tests

Screening tests that help to prevent CRC operate by identifying colorectal polyps before they develop into CRC. Some modalities offer potential for therapeutic intervention, although others may simply identify polyps and help to guide clinicians in subsequent investigations. All of the following modalities also offer the potential to identify CRC early, but this is not the primary mechanism through which they work.

Flexible Sigmoidoscopy. Flexible sigmoidoscopy (FS) screening uses a thin flexible tube to investigate the distal colon, where the majority of polyps are found. An enema is required prior to participation in order to cleanse the lower bowel. It has the potential for therapeutic intervention. In 2010, the results of a large multicentre randomised controlled trial testing a once-only FS were reported. Among the 55-64 year olds that were invited, CRC incidence was reduced by 23%. In per-protocol analysis, incidence was reduced by 33% and cancer-specific mortality by 43% (Atkin et al., 2010). FS has fewer risks than colonoscopy, with a pooled analysis suggesting 0.34 complications per 1000 procedures (Whitlock, Lin, Liles, Beil, & Fu, 2008). However, the proximal colon is not inspected and the identification of large polyps often precipitates further testing of the whole colon.

Colonoscopy. Colonoscopy is an endoscopic procedure in which a long flexible tube (colonoscope) is used to observe the whole of the large bowel. The test is best performed after the bowel has been cleansed by a laxative. Although a mild sedative is often given, the individual is usually semi-conscious during the procedure.

Colonoscopy is the most widely used modality in the United States (Joseph, King, Miller, & Richardson, 2012) and is considered to be the gold standard test for diagnosis. In addition to detecting polyps and CRC across the entire bowel, it affords the opportunity for therapeutic intervention during the procedure. As a result, colonoscopy is considered to have the most potential for the prevention of CRC. There are however no randomised controlled trials demonstrating its efficacy in preventing CRC or reducing cancer-specific mortality and little community-based sensitivity data available (R. Smith et al., 2011; Whitlock et al., 2008). The procedure is also not without risks; approximately 2.8 serious complications (e.g. post-polypectomy bleeding) occur per 1000 procedures (Stoop et al., 2012; Whitlock et al., 2008).

Computed Tomography colonography. Computed Tomography (CT) colonography is a promising, but relatively untested modality to screen for CRC. The person is placed inside the CT scanner, where 3-D images of the bowel are produced. These are then inspected by a radiologist who is able to observe polyps and CRC. As with colonoscopy, the consumption of a laxative is often recommended.

A recent meta-analysis of 49 studies showed that the sensitivity of CT colonography for detecting CRC was comparable to colonoscopy (Pickhardt, Hassan, Halligan, & Marmo, 2011). However, only 6 studies in the analysis were performed on asymptomatic groups and so these findings may not generalise to a screening population. A meta-analysis including five prospective cohort studies testing asymptomatic individuals did not contain sufficient numbers of CRC cases to report sensitivity and specificity data for this outcome. However, it did show that CT colonography has a comparable sensitivity to colonoscopy for all adenomas ≥10mm, but not for those ≥ 6mm (de Haan, van Gelder, Graser, Bipat, & Stoker, 2011).

Randomised trials evaluating the effectiveness of CT colonography as a screening test are rare. One recently completed trial and another that is underway were not powered to detect mortality outcomes, and only the former reported detection of advanced neoplasia (advanced adenomas or CRC) as a primary outcome (Sali et al., 2013; Stoop et al., 2012). This showed that although participation in CT colonography was higher than colonoscopy, the detection of advanced neoplasia was higher for colonoscopy. Because of these discrepancies, the diagnostic yield from each test was similar, providing support for both to be used in population-based screening.

There is a very low level of morbidity and burden associated with participating in CT colonography screening (Stoop et al., 2012; Wijkerslooth et al., 2011). Recent data from a Dutch clinical screening trial showed that CTC allowed people to return to their daily activities more quickly than colonoscopy and was associated with comparable levels of anxiety, pain and quality of life (van Dam et al., 2013).

1.4 Summary

CRC is one of the most common causes of cancer death. Survival rates have increased in recent years due to advances in treatment and earlier diagnosis. However, this increase has been faster among higher SES groups, suggesting that deprived groups are not benefiting from these developments.

Several screening modalities are available for CRC, each of which has advantages and disadvantages. The following chapter will outline the screening programme in

England, and will also describe the demographic and socio-cognitive correlates of screening uptake.

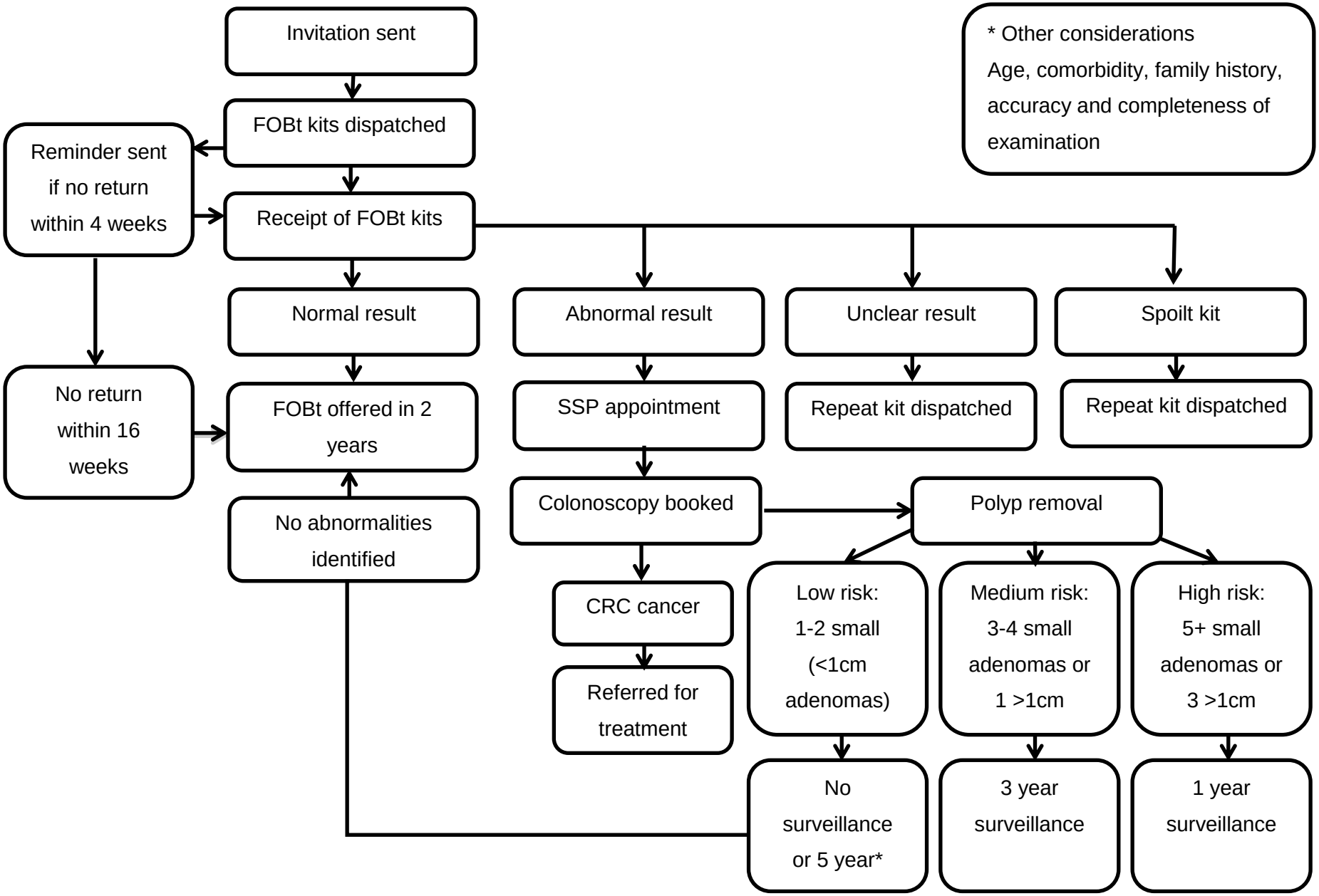
Chapter 2. The NHS Bowel Cancer Screening Programme and individual correlates of screening uptake

2.1 The National Health Service Bowel Cancer Screening Programme

The English National Health Service (NHS) Bowel Cancer Screening Programme (BCSP) is the largest screening programme worldwide (Swan, Siddiqui & Myers, 2012). It provides free biennial guaiac-based Faecal Occult Blood (FOB) testing to people aged 60-69 living in England, a population of approximately 6 million people (Office for National Statistics, 2012b). Follow-up testing is offered to those receiving an abnormal FOB test result (www.cancerscreening.nhs.uk/bowel). The programme began in 2006, and was fully rolled out across the country in 2010. An age extension to include people aged 70-74 will be completed by 2014 (Logan et al., 2011). Similar programmes using FOBt screening are available in Scotland, Wales and Northern Ireland, although Scotland offers screening for people aged 50-69 year and there are no age extensions planned for any of these programmes (www.bowelscreening.scot.nhs.uk/; www.wales.nhs.uk/sites3/home.cfm?orgid=747; www.cancerscreening.hscni.net/).

As can be seen in the summary of the screening pathway shown in Figure 2-1 (adapted from Atkin & Saunders, 2002), there is no healthcare provider involvement until follow-up testing is required (www.cancerscreening.nhs.uk/bowel). An invitation letter and information booklet is sent to the home of everyone registered with a General Practitioner (GP). Together, they provide details on the aim of the programme, as well as informing the individual that they will be sent an FOBt kit in two weeks' time. Invitees are sent an FOBt kit along with an instructional leaflet explaining how to complete the kit and a free-post return envelope. The programme issues a reminder letter and a repeat test kit to people who do not respond within one month. A final letter is sent to those that do not respond to the one month kit, which informs them that they will be sent another invitation in two years' time (Dr. Gemma Vart, personal communication). The invitation highlights that advice should be sought prior to completing a test kit if the person: i) has a current referral to hospital for a bowel investigation by their GP; ii) has had previous bowel surgery, or iii) has had a colonoscopy in the past two years. The outcome of testing is available to participants within 7 days.

Figure 2-1 NHS Bowel Cancer Screening Programme pathway



There are four possible outcomes after returning a screening kit. A clear result indicates that no windows on the test kit contained blood and no action is necessary. Another test kit is sent out in two years. An unclear result indicates that 1-4 (but not all) windows tested positive for blood. Up to two more repeat tests are necessary (Dr Gemma Vart, personal communication).

The person will be called for a colonoscopy if there are consistent unclear results. An abnormal result indicates that 5-6 windows have tested positive for blood. People receiving this result are invited to an appointment to discuss further testing. A spoilt test kit means that there is a technical fail and another test kit needs to be completed.

2.1.1 Screening Hubs

The English programme is organised nationally and run by five regional screening hubs (Rugby [North-Western], Guildford [Southern], St Mark's [London], Gateshead [North-Eastern] and Nottingham [Eastern]; see Figure 2-2). Each hub is responsible for assembling test packs (FOB kits, invitation letters and information materials), mailing them, logging returned kits, dispatching results within 7 days of receipt (including follow-up appointments if necessary), facilitating polyp surveillance and providing a freephone helpline.

Figure 2-2 Location of the NHS Bowel Cancer Screening Hubs

A single hub can dispatch as many as 3.5 million written communications to the public every year (Halloran, 2010). This figure includes initial screening invitations, reminders and result letters. These communications necessitate the use of a highly organised and logistically complex system. In three hubs (Southern, London and Eastern), these tasks are outsourced to a specialist mailing company. The contract for this was awarded to Real Digital International and UK Mail in April, 2011. At the remaining two hubs (North-Eastern and North-Western) the mailing is performed 'in house'.

Encrypted data are sent weekly to either Real Digital International or the screening hubs from a central database known as the Bowel Cancer Screening System (BCSS). The appropriate letter is produced using this data, and a unique barcode is printed on each one. This same barcode is printed onto an accompanying screening kit. When the invitation packs are being prepared, the packaging machine matches each letter to the corresponding screening kit. The same barcode is printed on other correspondence to ensure result letters are administered to the correct person. If the barcodes do not match, the packing machine stops immediately and provides a digital report to a member of staff. The appropriate information booklet is included as part of this process. Each stage of the packing process adds additional complexity.

Because of the logistics of the screening programme and the small administrative differences between each screening hub, any changes to the screening process (e.g. a public health intervention) must be accommodated within the scope of the programme. Even small changes can lead to large shifts in how the invitation packs are fulfilled and administered.

2.1.2 Screening Centres

The screening centres organise and run the follow-up colonoscopy clinics that are attended by people who receive an abnormal result from their FOB test. The first contact with a healthcare professional is with a Specialist Screening Practitioner (SSP) to discuss follow-up testing. During the appointment, the SSP provides a brief overview of the bowel and the adenocarcinoma sequence, how an abnormal result is calculated, and the advantages and disadvantages of follow-up testing. They will also answer any further questions about the screening process.

Screening centres also refer people that require additional treatment to a local hospital, collect outcome data, educate primary care specialists and promote bowel cancer screening among the local community.

2.1.3 Future developments

The NHS BCSP is constantly developing following the publication of empirical data and policy initiatives. One of the major shifts that will occur over the next few years is the introduction of a once-only Flexible-Sigmoidoscopy (FS) screening programme for people aged 55 years. This follows successful trial data showing the effectiveness of FS screening to reduce cancer-specific mortality (Atkin et al., 2010). There is evidence to suggest that it would be a cost-effective introduction to the current screening programme (Whyte, Chilcott, & Halloran, 2012). A soft launch of FS screening was started in May, 2013 and is gradually being rolled out across the country.

A further future development is the replacement of gFOBt screening with biennial immunochemical FOBt screening. Although it has yet to be piloted in the existing NHS Bowel Cancer Screening Programme, health economic analysis suggests it may be cost-effective (Whyte et al., 2012). Plans have been made for a pilot in 2014 and its eventual introduction thereafter (Logan et al., 2011).

2.2 Uptake of colorectal cancer screening and its social and individual correlates

Prior to the introduction of the NHS BCSP, it was estimated that over 1800/2400 lives per year could be saved by FOBt screening if uptake of 60/80% was achieved (Parkin, Tappenden, Olsen, Patnick, & Sasieni, 2008). Researchers and policy makers aiming to improve colorectal cancer (CRC) survival should be mindful of inequalities in CRC outcomes, and ensure that they are not exacerbated by the introduction of public health initiatives (Goldman & Lakdawalla, 2005; Marmot et al., 2010). The monitoring of uptake levels in screening programmes is therefore a necessary quality assurance measure to ensure that the programme achieves its goals and does not cause further inequalities (Halloran, Launoy, & Zappa, 2012).

2.2.1 Uptake of colorectal cancer screening

As shown in Table 2-1, uptake of CRC screening in the early trials, where invitations were sent from primary care rather than the screening programme, ranged from 42%-53% (Hardcastle et al., 1996, 1980; Lallemand, Vakil, Pearson, & Box, 1984; Nichols et al., 1986). Both men and women were invited in all trials, pilots and programmes. A variety of different age ranges were used, with younger people (40-60 years) being invited in the earlier trials and narrower age bands used in the pilots and national programmes. Larger and more sophisticated trials were performed as the evidence base developed, with the first multicentre trial (3+ recruitment sites) reported by Nichols and colleagues in 1986.

Findings from the largest trial (n=152,850) which included men and women aged 50-74 provided the necessary clinical data to support population-based screening using gFOBt in the UK (Hardcastle et al., 1996). A UK demonstration pilot was therefore set up in two English health authorities and three Scottish health boards. Uptake in the first round of the demonstration pilot for men and women aged 50-69 was 56.8% (UK Colorectal Cancer Screening Pilot Group, 2004). This suggested there would be a sufficient level of acceptability within the target population to warrant national programmes in England, Scotland, Wales and Northern Ireland.

Uptake of screening is one of several quality assurance measures recorded by each of the national programmes. Using results from England, von Wagner and colleagues reported that uptake following the first 2.6 million invitations was 53.6% (von Wagner et al., 2011a). Similar figures were reported in Scotland (54.5%) and Wales (55.2%) during the first round of screening (Heard & Beer, 2011; ISD Scotland, 2012). At the time of writing, Northern Ireland is yet to release uptake figures.

Uptake of CRC screening in all contexts reported here was consistently below 60%. This figure compares unfavourably with other UK cancer screening programmes (breast and cervical) that report uptake levels of 70-80% (The NHS Information Centre, Screening and Immunisations team, 2011, 2012). However, the low uptake of CRC screening is not due to poor participation among men only, with female participation only marginally higher (see section 2.3.3 for information on gender differences in CRC screening uptake).

Table 2-1 Overview of studies that report first round UK uptake figures in General Practice trials, demonstration pilots and national programmes

Context	Study	Setting	Population	Uptake definition	1st round uptake	Socio-demographic differences in uptake
General Practice colorectal cancer screening trials	Hardcastle et al., (1980) Lancet	Single centre General Practice based trial, Midlands	Men and women 45+ (n=1638)	Return of a completed test	45%	Age, not statistically tested No clear direction
	Lallemand et al., (1984) BMJ	Two-centre General Practice based trial, did not specify area	Men and women 45+ (n=4284)	Return of a completed test	42%	Age and gender, not statistically tested Suggestion of age x gender interaction, not statistically tested
	Nichols et al., (1986) BMJ	Multicentre General Practice trial, Basingstoke and North Hampshire	Men and women aged 40-70 years. Excluded if 'unsuitable', mental/emotional problems, other medical problems and if symptomatic (n=23,345).	Return of a completed test	42% (note: various strategies were used to improve uptake)	Age, gender and other member of household invited all had statistically significant effect Older people had higher uptake Women had higher uptake If 2 or more people in the household were invited, the household had higher uptake
	Harcastle et	Multicentre General Practice trial,	Men and women	Return of a	53.4%	Age and sex differences, not

Context	Study	Setting	Population	Uptake definition	1st round uptake	Socio-demographic differences in uptake
	al., (1996) Lancet	Nottingham	50-74 (45-74 in pilot). Excluded serious illness (n=152,850)	completed test		statistically tested Women higher uptake. No clear relationship for age
UK colorectal cancer screening demonstration pilot	UK Colorectal Cancer Screening Pilot Group (2004) BMJ[a]	Two English health authorities and three Scottish health boards	Men and women 50-69 All individuals within area invited (n=478,250)	Return of a completed test	56.8%	Age and sex differences, not statistically tested Women higher uptake No clear relationship for age
National Programmes	von Wagner et al., (2011a) Int J Epidem[a]	Nationwide screening programme, England	Men and women 60-69 All individuals invited (n=2,658,859)	Return of a completed test	53.6%	Age, sex, ethnicity, screening hub and social deprivation all had a statistically significant effect Women had higher uptake Older people had higher uptake Less ethnically diverse areas had higher uptake Non-London hubs had higher uptake

Context	Study	Setting	Population	Uptake definition	1st round uptake	Socio-demographic differences in uptake
						Lower neighbourhood deprivation areas had higher uptake
	ISD Scotland (2012) Online report	Nationwide screening programme, Scotland	Men and women 50-69. All individuals invited (n=not reported)	Return of a completed test for which a result was obtained	54.5%	Sex and deprivation differences, not statistically tested Women has higher uptake than men Lower neighbourhood deprivation areas had higher uptake
	Heard & Beer., (2011) online report	Nationwide screening programme, Wales	Men and women 60-69 All individuals invited (n=412,025)	Returned a used test kit within the same screening episode	55.2%	Sex and unitary authority differences, not statistically tested. Women higher uptake

Notes: [a] Several studies have reported uptake using this data. Where this has occurred, the largest study has been reported. Where sample sizes are equal, the study reporting uptake in the most detail is presented.

Uptake of CRC screening in England also compares favourably with other European programmes such as Italy (iFOBt/Flexible sigmoidoscopy; 48%), Czech Republic (gFOBt, 20%), Croatia (gFOBt; 19.9%) and France (gFOBt; 42%) (Goulard, Boussac-Zarebska, Ancelle-Park, & Bloch, 2008; Katičić et al., 2012; Seifert, Zavoral, Fric, & Bencko, 2008; Zorzi et al., 2012). However, a large pilot of gFOBt screening in Finland (n=52,994) demonstrated that it is possible to achieve higher uptake (70.8%) (Malila, Oivanen, Malminiemi, & Hakama, 2008).

Differences between levels of uptake among those with and without a previous screening history have been reported (Steele et al., 2010a). The data reported above are from the first round of invitations. Data from the English and Scottish arms of the UK demonstration pilot suggests incidence screening [1] uptake is substantially higher (Steele et al., 2010a). For example, data from the English arm showed that uptake was 82.6% among people who had participated in round 1, compared with 13.5% among previous non-responders. Scotland is the only national programme to release uptake figures that include people who have been invited more than once (Information Services Division, 2013b). However, they do not distinguish between prevalence and incidence screening in their reported uptake figure of 54.9%.

2.3 Inequalities in first round screening uptake

Overall uptake figures can disguise inequalities that can occur between population sub-groups. Furthermore, monitoring uptake in these sub-groups helps to evaluate whether the introduction of a new health technology has the potential to increase existing inequalities in health (Marmot et al., 2010). The identification of groups who have particularly poor uptake rates forms an important part of quality assurance for screening programmes.

2.3.1 Socioeconomic status

Datasets linking individual-level measures of deprivation (e.g. education and income) and screening uptake are not currently available. An area-based deprivation score is therefore calculated using the Index of Multiple Deprivation (IMD) 2004. The IMD provides a score for small area concentrations of deprivation

[1] The term prevalence screening is used to indicate people being screened for the first time, and the term incidence screening is used to refer to subsequent screens (Steele et al., 2010a).

based on income, employment, health, education & training, access to services, living environment/housing, physical environment and crime. England, Northern Ireland, Scotland and Wales each have their own version of the score which weights each factor slightly differently (Payne & Abel, 2012).

Data from the first round of the UK CRC screening demonstration pilot suggests neighbourhood deprivation affects uptake (Moss et al., 2012)[1]. Moss and colleagues demonstrated that uptake ranged between 45.8% in the most deprived quintile to 70.2% in the least deprived category. Furthermore, uptake was strikingly graded across all levels of deprivation and not simply low in the least affluent areas.

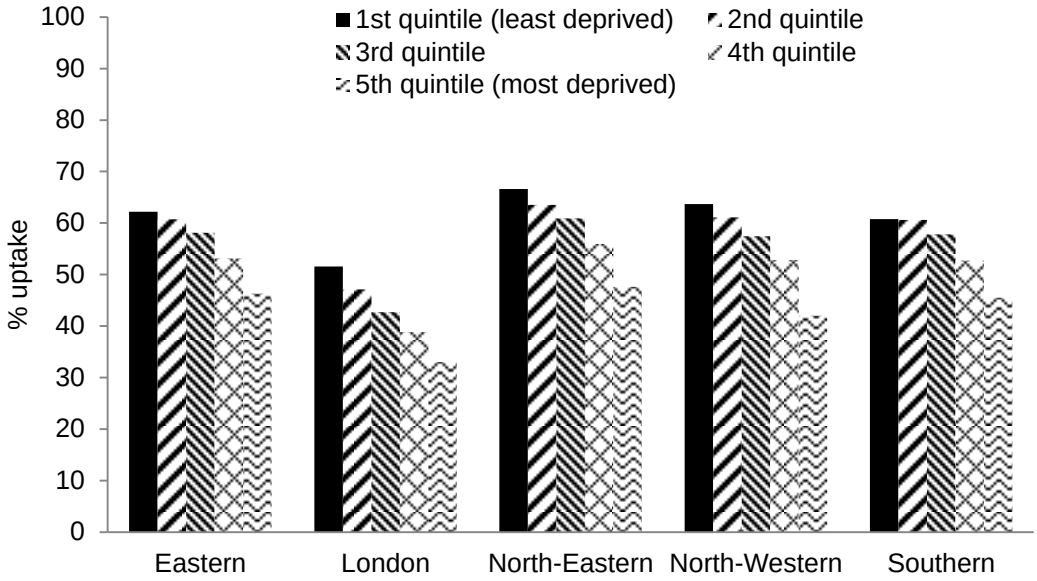
In the Scottish arm of the trial, there was also a significant association between uptake and neighbourhood deprivation, as measured by the Scottish Index of Multiple Deprivation (SIMD) (Steele et al., 2010b). Female rates dropped from 66.5% to 44.5% in the least to most deprived areas, while male rates dropped from 57.3% to 37.7%. In both sexes, there was a steady decline with each quintile of deprivation.

Using IMD quintiles, von Wagner and colleagues showed that uptake in the first round of invitations to the NHS BCSP was highest in least deprived quintile (61.1%) (von Wagner et al., 2011a). In comparison, those in the most deprived quintile had an overall uptake of 35%, with consistent declines in each quintile. SES remained a significant correlate of screening uptake, even after controlling for all routinely collected socio-demographic variables. As shown in Figure 2-3, overall uptake varied in each of the screening hubs and there was a consistent socioeconomic status (SES) gradient in uptake (Logan et al., 2012).

The latest report from the Scottish national programme single showed a similarly strong SES gradient in uptake (Information Services Division, 2013b). Using 60% uptake as the programme target, they showed that only men in the most affluent quintile and women in the two most affluent quintiles achieved this goal. Uptake among men living in the most deprived quintile was as low as 39.6%.

[1] Uptake rates reported in in this section that were not reported in the previous section are sub-samples of larger studies that provide greater detail on the socio-demographic correlates of uptake.

Figure 2-3 Percentage uptake at each of the screening hubs



2.3.2 Ethnicity

The association between ethnicity and screening uptake was not reported in the early clinical trials. Using data from the United Kingdom (UK) demonstration pilot, Moss and colleagues linked uptake with neighbourhood ethnic density information from the Census Dissemination Unit to indirectly observe the effect of ethnicity on uptake[1] (Moss et al., 2012). First round uptake data indicated that areas densely populated with people who originated from the Indian subcontinent had significantly lower uptake than less ethnically diverse areas (49.3% vs. 64.5% respectively). There was also a significant interaction, whereby the effect of SES was greater in areas with a high proportion of people from the Indian subcontinent. There were no data on ethnicity available from the Scottish arm of the trial.

Data from the first round of screening in the English NHS BCSP also demonstrate that the most ethnically diverse areas (defined as those that have the highest proportion of non-white residents in each postcode sector) have lower uptake, ranging between 38.1% to 55% for the most and least ethnically diverse areas respectively (von Wagner et al., 2011a). Ethnicity remained a significant correlate of screening uptake after controlling for other socio-demographic variables. However, it should be noted that there was not a gradient in uptake between the extremes, with

[1] This was an indirect observation because the data is based on the density of ethnic minorities in an area as opposed to individual-level data.

only the two most ethnically diverse quintiles showing markedly different uptake. The effect of ethnicity was also more pronounced among men than women. No data from either the Scottish or Welsh programmes are available on differences in uptake by ethnicity.

The use of area-level ethnicity data has the potential to bias interpretations and miss inequalities within ethnic groups. More detailed analyses of ethnicity have been provided comparing uptake of the NHS breast cancer screening programme to CRC screening uptake within two sites of the English colorectal screening pilot (Szczepura, Price, & Gumber, 2008). Using validated name recognition software, people were identified as belonging to one of several religio-linguistic groups. Uptake levels varied significantly between these groups: Hindu-Gujarati (40%); Hindu-Other (34.51%); Muslim (26.1%); Sikh (32.5%); South Asian Other (excluded from analysis); and non-Asian (78%). A similar pattern was observed with breast screening uptake, where Muslim women had the lowest uptake and non-Asian groups the highest. These findings suggest that there may be important differences between ethnic minority groups that are masked by the simplistic categorisation of ethnicity in some studies.

2.3.3 Gender

The General Practice trial based in Basingstoke and North Hampshire reported that women were significantly more likely to participate in FOBt screening than men (Nichols et al., 1986). Data from both arms of the UK CRC screening pilot supported this finding in a larger sample (Moss et al., 2012; Steele et al., 2010b; UK Colorectal Cancer Screening Pilot Group, 2004). In the first round of the current screening programme, uptake was higher in women (56.35%) than men (50.96%) (von Wagner et al., 2011a). This has also been documented in the Scottish and Welsh programme (Heard & Beer, 2011; ISD Scotland, 2012). The effect of SES on uptake in the NHS BCSP was stronger in women (von Wagner et al., 2011a). However, the effect was small, suggesting caution should be taken when interpreting the clinical significance of this finding.

2.3.4 Age

As with gender, the early General Practice trials suggested age may be associated with uptake of CRC screening, however this was not always tested statistically and

there was no clear consensus on the direction of the association (Hardcastle et al., 1996, 1980; Lallemand et al., 1984). The Basingstoke and North Hampshire trial was one of the few early trials that reported statistical differences. Their findings indicated that older people (55-70 years) had a significantly higher uptake than the younger group (40-54 years) (Nichols et al., 1986). However, this trial invited participants from a particularly large age range, and understanding uptake among 40-49 year olds is no longer relevant. It is therefore important to understand if the same phenomenon occurs in the narrower age ranges used in UK programmes.

More relevant data investigating this issue are available from the Scottish and English arms of the demonstration pilot (Moss et al., 2012; Steele et al., 2010b). In the English data, age was restricted to 60-69 years, while the Scottish arm used 50-69 years. In both studies, uptake was shown to increase with age, although there was only a 1.8% difference in uptake between the younger and older groups in the English arm (Moss et al., 2012).

Data from the national programmes generally support these findings. Older people (65-69) within the first round of the English national programme were also more likely than younger people (60-64) to participate in screening (54.5% vs. 52.8%) (von Wagner et al., 2011a). There was also a stronger socioeconomic gradient in uptake among older groups. In the Glasgow site of the Scottish programme where screening is offered from 50, uptake was also higher in older groups (≤55=45.8%; 56-64=54.6%; ≥65=55.3%) (Mansouri, McMillan, Grant, Crighton, & Horgan, 2013). Descriptive analyses reported in the Welsh programme support these findings (Heard & Beer, 2011).

2.3.5 Relationship status

The measurement of individual socio-demographic markers such as marital or relationship status are difficult to record within screening programmes. However, two studies performed in a UK context are noteworthy. Nichols and colleagues reported that individuals living in a household with two or more people (a likely marker of having a long-term partner) that were invited to CRC screening were more likely to return a screening kit (Nichols et al., 1986). The second study was a subset of participants in the FS screening trial (n=4130) that recorded self-reported marital status (van Jaarsveld, Miles, Edwards, & Wardle, 2006). Participants were classified as being part of one of three groups: i) cohabiting and invited with partner; ii) co-

habiting and invited alone and iii) living alone and invited alone. Findings indicated that uptake was associated with both relationship status and co-invitation, with uptake levels of 74.8%, 68.8% and 63.4% in the respective groups. Although this study was performed outside of an FOBt context, it provides a useful insight into the role of marital/relationship status and screening uptake.

2.4 Socio-cognitive correlates of screening participation

Although demographic factors such as SES have been associated with screening uptake, they do not answer the important question of why uptake rates differ. Social scientists attempting to explain why people perform health behaviours have focussed on intrinsic factors (Conner & Norman, 2005). These include psychosocial factors such as life experiences and social resources, as well as individual-level factors that include personality and cognitions. It has been suggested that cognitions (e.g. knowledge, attitudes and beliefs) are the most proximal determinants of health behaviours.

Social Cognition Models (SCMs) propose that cognitions mediate the relationship between more distal factors such as SES and behaviour. Unlike SES, they are considered to be more amenable to change. Identifying the socio-cognitive determinants of behaviour can contribute to the development of interventions that address SES differences in uptake.

Multiple SCMs are available, but no single theory stands out as being superior in the prediction of screening behaviour (Jimbo et al., 2013). Furthermore, their rigid structures often prohibit the inclusion of other known correlates of screening behaviour. As a result, SCM research can be criticised for limiting the extent to which new discoveries can be made. Despite this, some constructs embedded in these models are consistently associated with screening uptake (Kiviniemi, Bennett, Zaiter, & Marshall, 2011). These factors tend to overlap between the models and will be discussed in more detail here.

2.4.1 Perceived risk

Perceived risk (also known as perceived susceptibility) is a common feature of SCMs. In the Health Belief Model (HBM) it forms an important part of the threat perception component of the model shown in Figure 2-4 (Rosenstock, 1966, 1974).

Figure 2-4 Health Belief Model - adapted from Sheeran and Abraham (2005)

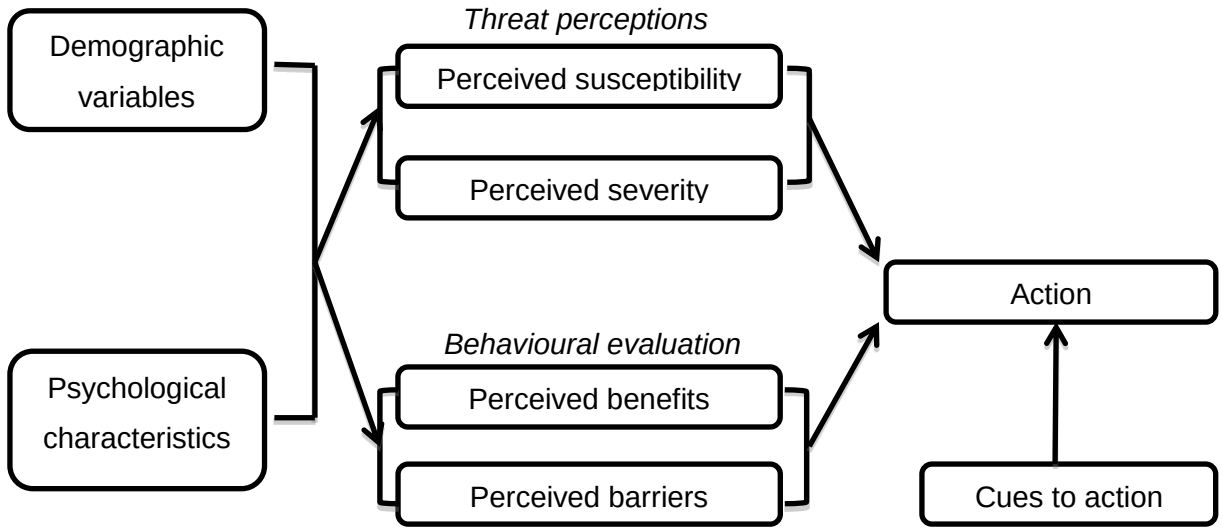
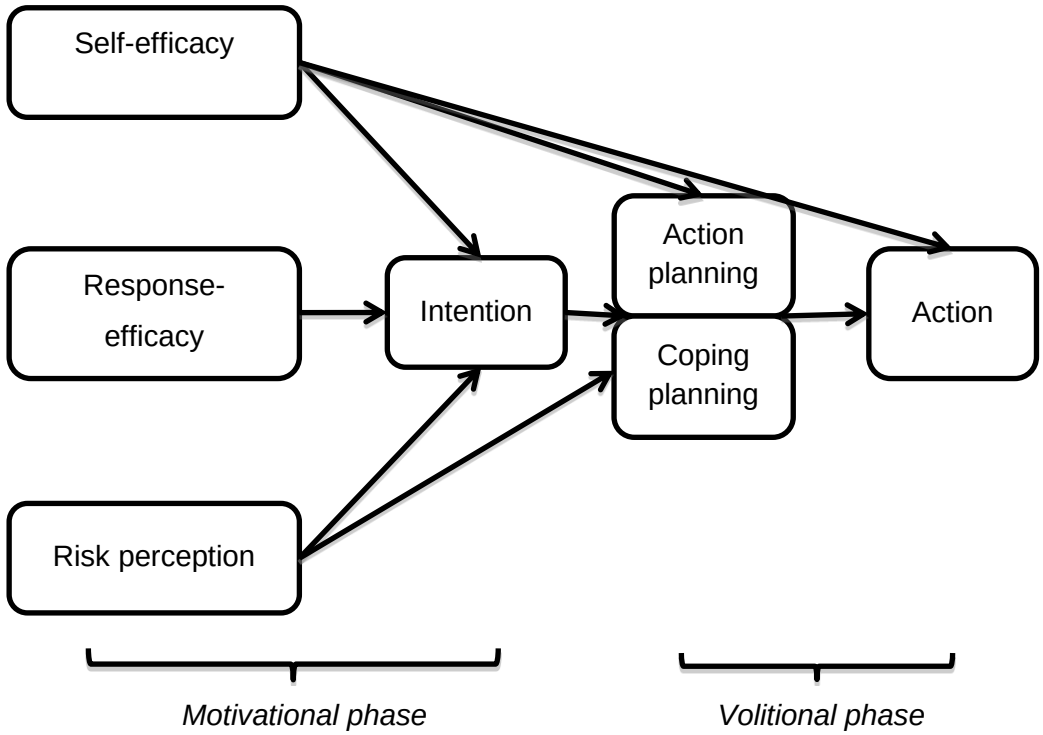


Figure 2-5 The Health Action Process Approach - adapted from http://userpage.fu-berlin.de/health/hapa.htm



The model argues that threat perceptions are formed after perceiving a risk and considering how severe the threat could be (Becker, Maiman, Kirscht, Haefner, & Drachman, 1977). As shown in Figure 2-5, the Health Action Process Approach (HAPA) suggests that higher levels of perceived risk increase the likelihood of forming a behavioural intention and also enhance coping strategies used during behavioural enactment (Schwarzer, 1992, 2001, 2008).

A number of different risk perception measures have been tested within the literature, each of which is said to assess a different aspect of the construct. For example, absolute risk measures (i.e. 'I think my chance of X would be…') are more traditionally used, but research has shown people have difficulty understanding risk in these terms (Lipkus, Samsa, & Rimer, 2001). As a result, comparative risk measures which provide a more personal context (i.e. 'compared to someone of your age and gender, my risk of X is…') are also used. The two measures are strongly correlated with each other (Janssen, van Osch, de Vries, & Lechner, 2013; Lipkus et al., 2000; Weinstein et al., 2007), but comparative risk may be tapping into the emotional component of risk as evidenced by its closer association with cancer-specific worry (Klein, 2002; Lipkus, Klein, Skinner, & Rimer, 2005; Zajac, Klein, & McCaul, 2006).

There is little research investigating the antecedents of perceived risk, aside for obvious factors such as family history (DiLorenzo et al., 2006). However, a large survey of screening age UK men and women (n=18,447) contributes to answering this question (Robb, Miles, & Wardle, 2004a). This study investigated the demographic, health and emotional factors linked with perceived risk of CRC. The survey was cross-sectional which limits assertions of causality. However, it was shown that men had lower perceived risk while those with a family history, poorer subjective health, and who reported more CRC symptoms and anxiety, had higher perceived risk. SES as measured by neighbourhood deprivation was associated with perceived risk, although the direction of the effect was inconsistent.

Cross-sectional evidence is generally supportive of the relationship between perceived risk and CRC screening uptake. For example a comprehensive review found that 58% of studies found significant relationships between perceived risk and FOBt uptake, with the remaining studies finding no association (Kiviniemi et al., 2011). No studies identified a negative relationship. Higher estimates were observed

in both reviews for CRC preventative tests such as colonoscopy and flexible sigmoidoscopy. However, the studies that were included were largely dominated by US research where these tests are more common. Improving the evidence base in a UK context is required to progress the field of risk communication.

A limitation with perceived risk research is the use of weak study designs that make it difficult to determine cause and effect (Vernon, 1999). For example, a study with prospective data from white middle-class women suggested that mammography attendance may lead to increased perceived risk, while the inverse may not be true (Aiken, Fenaughty, West, Johnson, & Luckett, 1995). Although useful in demonstrating the importance of investigating perceived risk, studies are needed that make use of more rigorous study designs if the field is to progress.

In this regard, a study performed with American male car manufacturer employees is particularly important to observe as it collected baseline and then 2-year follow-up data after a screening colonoscopy was offered (Vernon, Myers, Tilley, & Li, 2001). Men with no personal history of polyps were more likely to report high perceived risk (i.e. ≥ 3 on a 5-point scale) if they had a family history, were a current smoker and if they had been screened in the last 2 years. At follow-up, these findings remained, but the outcome of the examination had consequences. For example, 9.3% of individuals who did not have a colonoscopy had high perceived risk, while this figure rose to 15.2% for those with a normal outcome and 43.8% for those with an abnormal result. This study raises the possibility of a bi-directional relationship between perceived risk and CRC screening uptake. It also suggests that the construct is amenable to change. The use of manual workers (a possible marker for low SES) was particularly pertinent to the current thesis; however the findings were limited because of the male only sample.

Improving risk comprehension is important as people are generally poor judges of their objective susceptibility to health outcomes. A consistent finding is that samples[1] report an optimistic bias when they are asked about their risk of CRC (Lipkus et al., 1996; Robb et al., 2004a). This phenomenon is defined as 'the mistaken belief that one's chances of experiencing a negative event are lower than

[1] Optimistic bias is generally observed in samples rather than individuals as it is difficult to prove that a single individual is correct or incorrect in their estimate. However, by the definition of 'average', a normal distribution in perceived risk should be observed across a sample.

one's peers' (Weinstein, 1980). A particularly innovative study performed among 10,551 UK participants in the FS screening trial provides evidence for this observation (Robb, Miles, & Wardle, 2004b). Using the rare opportunity of combining trial outcome results with socio-cognitive data, Robb and colleagues found only modest associations between perceived and objective risk. For example, 23.1% of respondents that reported a low perceived risk had an abnormal finding during the examination, compared with 28.9% of those with high perceived risk. Improving people's perception of risk is an important task for risk communication research.

2.4.2 Worry

Cancer worry can be defined as 'an emotional reaction to the threat of cancer' (Hay, Buckley, & Ostroff, 2005). Although distinct from dispositional worry (Jensen, Bernat, Davis, & Yale, 2010), there is little clarity on the difference between the terms cancer anxiety, worry and fear (Consedine, Magai, Krivoshekova, Ryzewicz, & Neugut, 2004). Several reviews and studies have suggested a link between cancer worry and CRC screening uptake (Hay et al., 2005; Moser, Mccaul, Peters, Nelson, & Marcus, 2007; Sutton et al., 2000). However, researchers have hypothesised that there may be a U-shape relationship between screening uptake and cancer worry (Hay et al., 2005). Empirical data suggests that particularly high or low levels of worry are detrimental to CRC screening uptake, while a moderate level of worry may encourage participation (Sutton et al., 2000).

Attempts to discuss CRC and CRC screening with the public should therefore be wary of causing excessive amounts of worry. This is particularly important to ensure that people are able to make an informed choice about screening participation (Ramirez & Forbes, 2012). Furthermore, high levels of worry are a frequently cited barrier to screening uptake among ethnic minority (Dein, 2004; Good, Niziolek, Yoshida, & Rowlands, 2010; Khankari et al., 2007), low SES (Logan & McIlfatrick, 2011; Wardle, McCaffery, Nadel, & Atkin, 2004) and low education groups (Han, Moser, & Klein, 2007; Lindholm, Berglund, Kewenter, & Haglind, 1997; McQueen et al., 2008; Sach & Whynes, 2009). A careful balance must be struck between increasing the threat of the disease, without causing emotional harm.

2.4.3 Attitudes and beliefs

Attitudes have been interpreted and assessed in a number of different ways. Findings from a large (n=2024) population-representative UK study suggest people generally have very positive attitudes towards screening, with nearly 90% of respondents stating that 'screening is almost always a good idea' (Waller, Macedo, & Wardle, 2012). However, such findings disguise strong negative views that people also possess about cancer and attempts to detect it.

The prevailing lay perception of cancer is of an inexorable condition with arduous treatments and disappointing outcomes (Hellman, 2005; Simon, 2004; Sontag, 1983), and this is particularly so among low SES groups (Rutten, Hesse, Moser, McCaul, & Rothman, 2009). Some of the reported beliefs have been termed fatalistic, defined as the perception that *'*death is inevitable when cancer is present*'* (Powe, 1995). High levels of fatalism have been associated with low participation in CRC screening and early detection behaviours (Beeken, Simon, von Wagner, Whitaker, & Wardle, 2011; Gorin, 2005; Powe, 1995). Ethnic minorities, lower SES groups and people with low health literacy have also reported higher levels of cancer fatalism (Beeken et al., 2011; Morris et al., 2013; Niederdeppe & Levy, 2007; Powe, 1995). Its importance is highlighted by a postal survey administered from UK General Practices showing that fatalism mediated the relationship between SES and FOB test completion (Miles, Rainbow, & von Wagner, 2011). Self-report studies are likely to underestimate the prevalence of fatalism because of poor response rates to surveys about cancer among those with negative beliefs about the disease.

Self- and response-efficacy are also important beliefs in relation to CRC screening participation. These constructs are central to SCMs such as social-cognitive theory (Bandura, 1977, 1986), the HAPA (Schwarzer, 1992, 2001) and the Theory of Planned Behaviour (Ajzen, 1985, 1991, 2005). In a CRC context, self-efficacy refers to the belief that one can complete a screening test successfully, whereas response-efficacy refers to the belief that screening is effective at detecting cancer early. According to the HAPA, self-efficacy helps the individual plan their behavioural response if response-efficacy is sufficiently high. It also prevents competing secondary intentions from distracting the individual during behavioural enactment (Schwarzer, 2008; Shah, 2005).

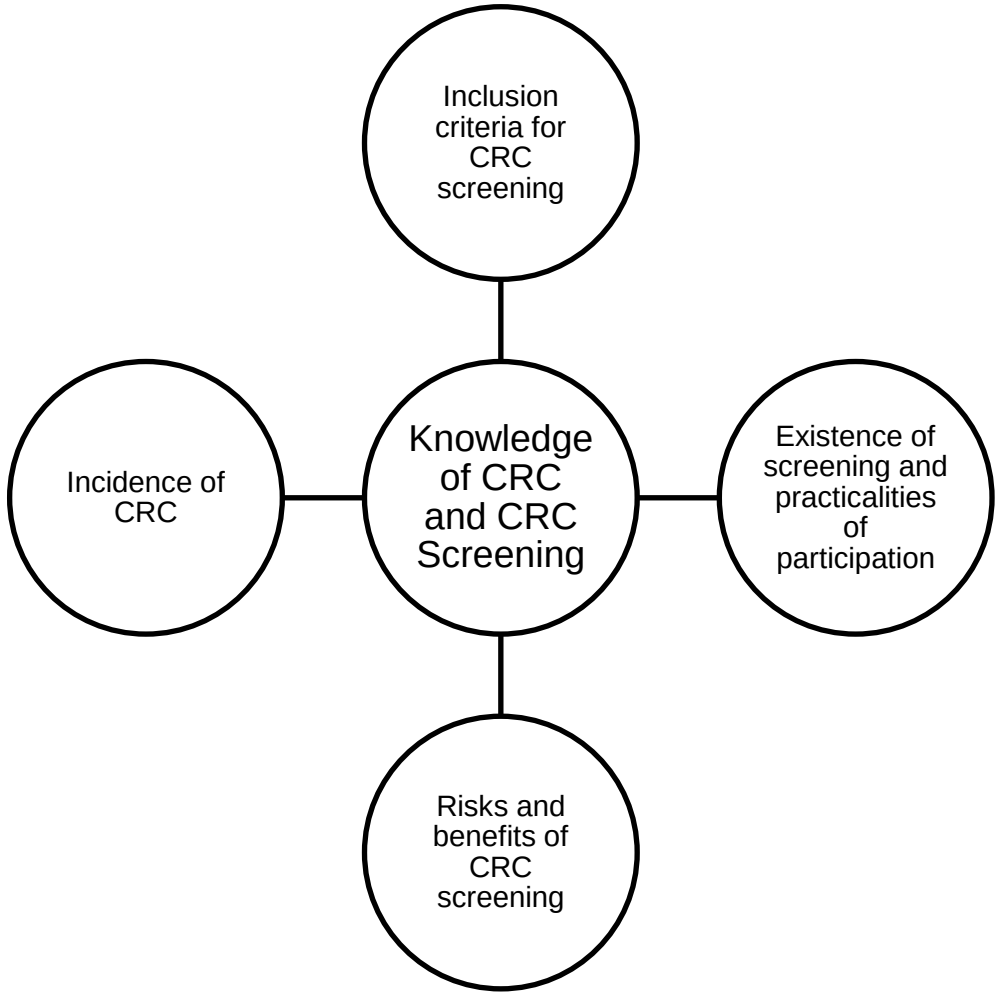
Higher levels of self-efficacy therefore increase the likelihood of intention being translated into action. A comprehensive literature review showed that 9 (64%) studies found a positive relationship between self-efficacy and FOBt screening and no studies identified a negative relationship (Kiviniemi et al., 2011). A handful of studies have shown that response-efficacy contributes to explanations for screening uptake, however it remains an under investigated concept (Kremers, Mesters, Pladdet, van den Borne, & Stockbrügger, 2000; Mack et al., 2009; McQueen, Tiro, & Vernon, 2008; Ritvo et al., 2008; Severino, Wilson, Turnbull, Duncan, & Gregory, 2009). It is unclear whether high response-efficacy is simply a reflection of generally positive views about screening or if it should be treated as a distinct construct.

2.4.4 Knowledge about CRC and CRC screening

There is little consensus on what people should know about CRC screening prior to making a decision. Using the UK General Medical Council's guidelines (General Medical Council, 2008), Smith and colleagues have argued that core knowledge includes understanding the risks (i.e. false-positives and false-negatives) and benefits (i.e. mortality reduction) of screening. (S. K. Smith, et al., 2012) They also argue in a subsequent overview of their work in communities with low health literacy, that understanding the 'gist' of screening may be adequate to engage in the decision-making process (S. K. Smith, Nutbeam, & McCaffery, 2013).

A systematic review of the decision aid literature suggested additional aspects of knowledge should be measured including why a screening test has been offered (i.e. the incidence of the disease), who it has been offered to (i.e. the age range and gender of the population being screened) and what the test entails (i.e. where it is performed and how often) (Mullen et al., 2006). All of these components of knowledge are important in order to make an informed decision about CRC screening participation (General Medical Council, 2008; Ramirez & Forbes, 2012). However, some may be more relevant for CRC screening than for other cancers. Differences in knowledge and awareness of CRC and CRC screening between population sub-groups may help to explain SES inequalities in uptake. A summary of the different aspects of knowledge in a CRC screening context can be found in Figure 2-6.

Figure 2-6 Aspects of knowledge that contribute to global understanding of CRC and CRC screening



2.4.4.1 Incidence of colorectal cancer

Cancers of the breast and lung attract a disproportionate amount of media coverage (Blanchard, Erblich, Montgomery, & Bovbjerg, 2002; Clarke & Everest, 2006; Lantz & Booth, 1998), but CRC tends to be neglected (Gerlach, Marino, & Hoffman-Goetz, 1997). This may contribute to low awareness of the high incidence of CRC observed in the general population (Dolan et al., 2004; Jalleh et al., 2010; Shokar, Vernon, & Weller, 2005). For example, a UK-based population survey showed that only 16% of people perceived CRC to be one of the three most common cancers and 40% believed it to be a common male cancer. Increasing awareness that it is a common cancer among both men and women should therefore be a priority.

Awareness of the incidence of CRC is poorer among lower SES groups. Juszcyk and colleagues observed that lower SES groups were significantly less likely to be aware that CRC is a common male cancer (Juszczyk, Simon, Waller, Ramirez, & Wardle, 2011). Similarly, a US study demonstrated that 9% of people with low health literacy had not heard of CRC, compared with just 2.5% of those with adequate health literacy (Dolan et al., 2004).

2.4.4.2 Existence of CRC screening tests and programmes

People who want to reduce their risk of CRC must first be aware of the options available to them. Following the introduction of an FOBt screening programme in Australia, Jalleh and colleagues observed that <25% of survey respondents reported FOBt as a method for checking for CRC (Jalleh et al., 2010). A random sample of members of a US health insurance company (n=1013) showed that while most people had heard of a colonoscopy (92.5%), there were differences between low (82.9%) and high (93.9%) health literacy groups (Morris et al., 2013).

A study in the UK used data from two samples to investigate ethnic differences in awareness of the programme. The first sample contained both white and non-white respondents (ONS sample), while the second purposively recruited ethnic minorities (Ethnibus). Across both samples, less than 30% of respondents were aware of the NHS BCSP compared with over 80% for the breast and cervical programmes (Robb et al., 2010). In the Ethnibus sample, awareness was significantly different across ethnicities and was particularly poor in Pakistani and Chinese ethnic groups.

Interestingly, similar ethnic differences were observed regarding awareness of the breast and cervical programmes.

Increasing awareness of the NHS BCSP is likely to increase engagement with the invitation materials when they are sent. Deficits in this aspect of knowledge are particularly important as they may explain why CRC screening uptake is substantially lower than other NHS cancer screening programmes.

2.4.4.3 Inclusion criteria for CRC screening

The NHS BCSP is the first cancer screening programme to be offered to men as well as women in England. It is therefore important that both sexes are aware that the screening invitation is relevant to them (Chapple, Ziebland, Hewitson, & McPherson, 2008). CRC screening programmes may pose particular challenges for men. Qualitative data from deprived communities in the US has suggested that anatomical knowledge may be lacking, with men often confusing cancers considered to be 'below the belt' (Fernandez et al., 2008; Gany et al., 2013; O'Malley, Beaton, Yabroff, Abramson, & Mandelblatt, 2004). The problem may also be an issue in the UK as ~20% of the population believe there is an organised prostate screening programme (Robb et al., 2010). This figure was shown to be particularly high among ethnic sub-groups, such as African Caribbean people (65%).

Understanding the risk factors for CRC and why particular groups (e.g. older people) are invited is an important part of screening knowledge. In a population-representative UK sample, respondents who were not prompted recalled 1.4 risk factors for the development of CRC (Power, Simon, Judzczyk, Hiom, & Wardle, 2011), although when they were prompted with a checklist, awareness was higher. The most commonly cited risk factor (family history) was still only recalled by 65.3% of the sample. Factors such as alcohol, physical activity and diet were reported by less than 50% of the sample. Lower SES groups were significantly less aware than those from less deprived backgrounds.

Of most importance to the NHS BCSP, is that less than 3% of the population reported age as a risk factor unprompted and only 45.3% reported it when prompted (Power et al., 2011). In a separate report, 35% of white people correctly identified

the correct starting age for CRC screening compared with 17% of non-white individuals (Robb et al., 2010). A sample purposively recruiting ethnic minority groups reported within the Robb manuscript showed that just 6% of respondents correctly provided the correct starting age.

Perceiving CRC screening invitations to be irrelevant is a reported barrier to participation among non-responders (Chapple et al., 2008). Highlighting that both men and women of a certain age are eligible for CRC screening may increase the salience of the screening offer and increase engagement with the programme. Effective communication is required to convey the message.

2.4.4.4 Harms and benefits of CRC screening

Understanding the harms and benefits of a medical procedure is important aspect of consent (General Medical Council, 2008). In addition, perceiving that the benefits of CRC screening outweigh the costs is a key determinant of uptake (Sutton et al., 2000; Wardle, McCaffery, Nadel, & Atkin, 2004). A particularly interesting study used structural equation modelling to demonstrate the effect of perceived risks and benefits in explaining the SES gradient in uptake within the UK FS trial (Whitaker et al., 2011). The authors showed that lower SES was associated with lower perceived benefits and more perceived harms, and that this (along with the tendency to have a present time orientation) mediated the relationship between SES and screening uptake. This study was important as it raises the possibility that the immediacy of the risk and/or benefit may be weighted differently, and in turn this may contribute to SES inequalities in uptake.

Interventions that improve understanding of the risk/benefit relationship have been shown to harm response-efficacy and screening participation rates. For example, Smith and colleagues developed an FOBt screening decision aid that presented absolute risk and benefit information using natural frequencies (e.g. 1 in 1000) (S. K. Smith et al., 2010). A moderately sized (n=572) randomised trial of the decision aid compared with the standard Australian screening information was performed among communities with low health literacy. Findings from the trial showed that overall knowledge and the likelihood of making an informed decision was higher in the decision aid group. However, attitudes and uptake were lower with 59% of the intervention group completing test kits compared with 75% in the control group.

A qualitative follow-up study indicated that the booklet may have been intimidating for groups with low health literacy that lacked statistical proficiency (S. K. Smith, et al., 2012). For example some participants felt it was intended for people with a 'high IQ' and not for the 'average person walking down the street'. Inspecting the booklet, this perspective can be sympathised with[1]. Although written in simple language, the volume of text and diagrams that the reader must process makes it a difficult document to follow. The male version is 33 pages long and contains a flow chart of 8 questions that must be answered in order to be navigated to one of 6 different risk scenarios. Although comprehension is an important outcome in itself, interventions manipulating any aspect of knowledge should consider the effect that excessive information can have on behavioural outcomes.

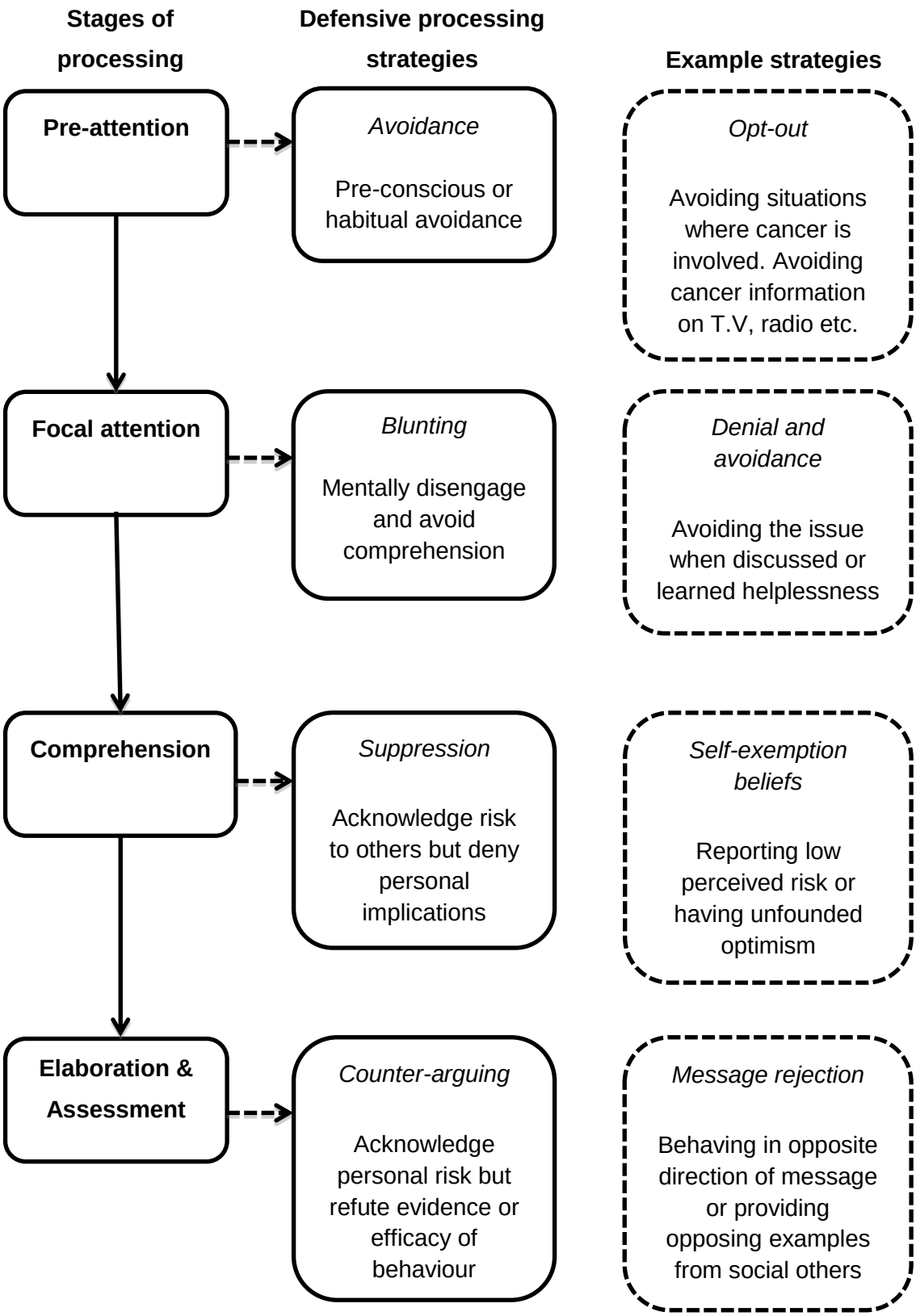
2.4.5 Informational avoidance and other defensive processes

The importance of delivering the correct amount of information is particularly important in a cancer context. The excessive fear of cancer in comparison with other conditions can lead to avoiding information about the disease (Case, Andrews, Johnson, & Allard, 2005; McCloud, Jung, Gray, & Viswanath, 2013; Miles, Voorwinden, Chapman, & Wardle, 2008). The Extended Parallel Process Model (EPPM) argues there are two parallel responses to threatening information: danger control and fear control (Witte, 1992, 1994). When a message is perceived as threatening, behavioural responses are evaluated. If perceived efficacy is high, and the advantages of ignoring the message are low, adherence to the message is triggered (i.e. danger control). However, when the perceived efficacy of the response is low or the advantages of avoidance are high, fear control strategies are used. The term defensive processing is used to represent the fear control pathway.

The model shown in Figure 2-7 is based on the work of Greenwald and Leavitt (1984; 1988) who proposed that people move through a stages when processing information: pre-attention; focal attention; comprehension; and elaboration. As each stage is passed, the level of involvement increases, as does the attention capacity required to process the information. The model argues that as involvement increases, the ability of the message to affect the reader grows stronger. Of interest to health communicators are the defensive processes that individuals use to prevent progression through these stages (marked in the dashed boxes).

[1] The male and female versions of the decision aid are available here: (http://sydney.edu.au/medicine/public-health/step/publications/decisionaids.php)

Figure 2-7 Defensive processing model adapted from McQueen et al., 2013



McQueen and colleagues adapted this model for the context of CRC screening (McQueen, Vernon, & Swank, 2013). According to McQueen's model, at the pre-attention stage individuals selectively attend to incoming stimuli (e.g. the word cancer); failing to become sufficiently involved in the message if it does not create an emotional response or habituation to the stimuli has occurred. To prevent further processing, strategies can be used to 'opt-out' of exposure.

Miles, Voorwinden, Chapman & Wardle (2008) showed in a UK study of older adults (age 50-70 years) that over one-quarter (26.7%) of respondents used strategies such as avoiding radio or TV programmes that contained cancer information. A US study of health insurance subscribers noted similar levels of information avoidance in relation to diseases/illnesses that the person did not have (Morris et al., 2013). Interestingly, respondents with low health literacy were more likely to report avoiding this kind of information than high health literacy groups (31.5% vs. 21.9%). However, caution should be taken, as at least some of these strategies are said to be 'pre-conscious'. Self-report questionnaires may therefore underestimate the prevalence of 'opt-out' strategies.

With this in mind, von Wagner and colleagues reported an objective measure of informational avoidance as part of an interactive computer-based study (von Wagner, Semmler, Good, & Wardle, 2009). Participants were asked to open links to excerpts from 'The Facts' booklet and browse the information. Findings indicated that only 28% of participants opened all of the links, and those with low health literacy were more likely to avoid the information. This study was particularly innovative as participants were unaware that their avoidance behaviours were being recorded, thereby providing a more valid assessment of informational avoidance.

The McQueen model suggests that if opt-out strategies are not used, information is processed at the focal attention stage. At this point, the individual is consciously aware of the stimuli, but may attempt to blunt the message by avoiding the issue when it is discussed. A seminal review of the cancer literature showed that 'blunters', as assessed by the 'Monitor-Blunter Style Scale (MBSS) (Miller, 1987), were less adherent to treatment recommendations and were less knowledgeable about the disease (Miller, 1995). Awareness of blunting responses may be an important aspect of information design that can have concomitant effects on these outcomes.

Messages that reach the comprehension stage of the model may be acknowledged, but suppressed through self-exemption strategies. People can use various biases to exempt themselves from the threat discussed. For example, as found by Robb and colleagues in a UK study, people often report unjustified levels of optimism about their risk of getting cancer (Robb et al., 2004a, 2004b). The assertion that this can lead to disengagement with information processing provides some justification for targeting perceived risk within communication interventions.

If blunting does not occur, the message is likely to reach the elaboration and assessment stage where it is compared to current motivation, beliefs and values. If there is coherence between the two, message acceptance is more likely to occur; if there is discord, message rejection may ensue. One example of a strategy used during message rejection is to counter-argue by providing isolated arguments (e.g. anecdotes) that refute the message (Fagerlin, Wang, & Ubel, 2005). Providing messages that demonstrate the importance of screening, while also maintaining an unpersuasive stance may help to reduce counter-arguing.

McQueen's framework should be credited with amalgamating a large field of research and applying it directly to CRC screening. The model provides a useful theoretical overview that can explain why people react poorly to cancer communications. It highlights the importance of designing information so that it is attended to (pre-attention and focal attention), while also conveying an objective message that does not cause a reactive response (comprehension and elaboration and assessment). Despite this, it lacks empirical support. McQueen's development of an accompanying defensive processing measure may go some way to addressing this problem over the coming years (McQueen et al., 2013).

2.4.6 Health literacy and cancer communication

Throughout this chapter, a number of studies have been cited which indicate that health literacy can affect CRC decision-making and responses to cancer communications. This includes poorer awareness of the disease (Dolan et al., 2004; Gany et al., 2013), greater experienced burden when processing CRC information (S. K. Smith, et al., 2012; von Wagner et al., 2009), less awareness of the available tests (Morris et al., 2013) and greater levels of informational avoidance (Morris et al., 2013; von Wagner et al., 2009).

The definitions of health literacy have been contested (S. G. Smith, Curtis, Wardle, von Wagner, & Wolf, 2013; Sørensen et al., 2012) but the Institute of Medicine (IOM) statement is most widely used: 'the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions' (Ratzan & Parker, 2000). The skills involved in being 'health literate' go beyond reading and writing but also include cognitive skills such as working memory, recall and numeracy (Wilson et al., 2010; Wolf et al., 2012). Recent surveys have demonstrated that over 10% of the UK adult population lack health literacy skills, and nearly a quarter possess only basic numeracy skills (Department for Business Innovations and Skills, 2011; von Wagner, Knight, Steptoe, & Wardle, 2007).

Health literacy can be influenced by SES markers including income, SES, education, and reading and writing abilities (Department for Business Innovations and Skills, 2011; Ibrahim et al., 2008; von Wagner, Steptoe, Wolf, & Wardle, 2008). For example, von Wagner and colleagues showed that 98% of people earning more than the modest sum of £20,000 had adequate health literacy, compared with 84% of those earning less than £10,000 (von Wagner et al., 2007). A similar gradient was observed with education, where 98% of those with an A-level or university education had adequate health literacy compared with 91.8% among those with a GCSE level of education and 71.8% in those with no formal qualifications. This study was particularly useful as it was performed in a nationally representative sample, increasing the likelihood that these estimates are accurate.

A number of useful guides provide guidance on how the needs of people with low health literacy can be considered within health communications (DeWalt et al., 2010; McCaffery et al., 2012; Plain English Campaign, 2011). The associations with CRC screening uptake and SES make health literacy a particularly attractive target for a public health intervention. The relative novelty of the health literacy field provides scope for further research in the area.

Chapter 3. Communication strategies and interventions in colorectal cancer screening

Chapter 2 established that disparities in knowledge and awareness of colorectal cancer (CRC) and CRC screening may be contributing to broader inequalities in uptake. However, the scale and resource-intensive nature of the National Health Service Bowel Cancer Screening Programme (NHS BCSP) limits the extent of communication with the public. It also limits the extent to which communication interventions can be evaluated within the programme. High intensity interventions involving face-to-face interactions (Green et al., 2013) or community-based initiatives (Foster, Scott, & Addington-Hall, 2010; S. G. Smith, Rendell, George, & Power, submitted) are likely to only reach a minority of population sub-groups. There is therefore a demand for a low cost, easily administered communication strategy that adequately conveys the screening offer to all population sub-groups within the administrative organisation of the NHS BCSP.

European Union (EU) guidelines recommend that all organised screening programmes should provide information materials at the invitation stage (Austoker, Giordano, Hewitson, & Villain, 2012). The aim of such information is to improve understanding of the aims, benefits and disadvantages of screening. However, the finding that lower socioeconomic status (SES) groups actively avoid information about cancer (McCloud et al., 2013; McQueen et al., 2013; Morris et al., 2013; von Wagner et al., 2009) and that materials rarely meet readability guidelines (Agarwal, Hansberry, Sabourin, Tomei, & Prestigiacomo, 2013) suggests careful attention should be paid to this part of the screening process. The mass dissemination of cancer control information within organised screening programmes has the potential to create or exacerbate communication inequalities (Viswanath et al., 2012).

3.1 Information materials used in the NHS BCSP

The NHS BCSP uses several print-based materials to inform the public about CRC screening. The main information material is ‘Bowel Cancer Screening: The Facts’ (see appendix A). ‘The Facts’ booklet is a 15 page document that provides information about CRC and the benefits and risks of CRC screening. It is published by the Department of Health, who received advice from the Cancer Research UK Primary Care Education Group during its development. It is the only CRC screening

information certified by the NHS cancer screening committee. The booklet has been translated into 20 different languages that are available on request. It is also available in British Sign Language, braille, audio and large print. The readability of 'The Facts' booklet is 62.4 according to the Flesch-Kincaid reading ease formula, which corresponds to a reading age of approximately 13-15 years (Flesch, 1948). This formula has a theoretical range of 0 (very difficult) to 100 (very easy). An approximate rule of thumb suggests documents in the public domain should achieve a score of 70 or higher (Vahabi & Ferris, 1995). Considering that one in six adults in the UK have a literacy level of below an eleven year old, over 10 million people might be expected to struggle when reading this level of document (Department for Business Innovations and Skills, 2011).

The standard version of 'The Facts' booklet is sent two weeks prior to the screening kit, along with an invitation to participate in CRC screening. This invitation letter briefly describes why people are invited to participate in the NHS BCSP, how the screening process works and who should be contacted to answer further questions. The letter contains sentences in 20 languages sign-posting the Freephone number. The readability of the letter according to the Flesch-Kincaid score is 70.1 (reading age: 13-15 years).

After two weeks, the screening kit is sent through the post and pictorial instructions are provided. The text used within these instructions is minimal and has been written with the needs of people with low health literacy in mind, as demonstrated by its readability score (Flesch-Kincaid Reading Ease = 84.9, reading age = 11-12 years). It is also available in a number of different languages, braille, audio and large print.

3.1.1 Evaluating the information materials used in the NHS BCSP

The public have a strong desire to be well informed about the benefits and risks of participating in screening programmes (Jepson, Hewison, Thompson, & Weller, 2007; Schwartz, Woloshin, Floyd, & Welch, 2004). For example population-representative UK data showed that over three-quarters of the population want full information about the risks and benefits of CRC screening when being invited to participate (Waller et al., 2012).

However, experimental research by von Wagner and colleagues that was discussed in the previous chapter showed that people do not always elect to read all of the information they are provided with (von Wagner et al., 2009). Interestingly, groups with low health literacy were also found to experience greater cognitive burden when reading the information, as measured by the time taken to read each link. After browsing the information, only half of the sample was able to answer 3 out of 9 basic knowledge questions correctly. This study suggests strategies to discourage informational avoidance and improve knowledge translation are needed to progress the field.

Concerns have also been raised in a qualitative focus group study about the complexity of 'The Facts' booklet. Woodrow and colleagues invited people who had either participated in the English BCSP Pilot or were naïve to the screening process to comment on the booklet. The study identified concern that the length and complexity of the information may discourage people from reading it. This is neatly summarised in the following quote:

> *'I don't know how you make it much shorter but it's the user friendliness to people who honestly would never read anything unless they were forced'* (Non-participant in screening, Male, from Woodrow et al., 2008)

In a similar study, Chapple and colleagues interviewed a sample predominantly composed of people who had participated in Faecal Occult Blood test (FOBt) screening (Chapple et al., 2008). Within the qualitative data, the authors identified possible difficulties with the instructional leaflet sent to participants with their kits. For example, one interviewee did not participate because she was uncertain about the length of time over which screening could occur[1]. As with all qualitative data, these examples form a minority of comments from a selective group of participants. However, when considered at a population level, a substantial proportion may be failing to comprehend the screening offer because of the information materials provided by the NHS BCSP.

In addition to providing the public with information about the NHS BCSP, 'The Facts' booklet can affect motivation to take up the screening offer. For example, findings from Woodrow and colleagues suggested people perceived information about the

[1] People are given 14 days to complete a sample once starting a screening kit, and therefore it does not have to occur on consecutive days.

incidence of CRC to be motivating. However, information on colonoscopy risk and the potential embarrassment of collecting faecal samples was considered off-putting, and may decrease screening uptake (Dolan et al., 2004; Reynolds, Consedine, Pizarro, & Bissett, 2013).

It appears that there is a high demand from the public for good quality information about CRC screening. However, when supplied with detailed information, not everyone benefits. People's ability to comprehend the screening offer may also be impaired because of how it is presented. There is evidence to suggest that the length and complexity of the information may be problematic, particularly for those with a low level of health literacy. There must therefore be a careful balance between satisfying the public's expressed preference for information, and accommodating the variation in people's ability to process difficult and unfamiliar text.

Limitations in the methodology of the published literature suggest these findings may be underestimating the size of the problem. For example, data are based on selective populations that have previously been invited and participated in CRC screening (Chapple et al., 2008; Dolan et al., 2004). This can bias the sample, as screening participation is associated with strong (often positive) beliefs towards CRC screening (Robb et al., 2013). The views and opinions of people who are naïve to the screening process may be less biased.

These studies often made use of qualitative methods such as focus groups and semi-structured interviews. Qualitative methods can make it difficult to disclose issues around comprehension, particularly among those with low health literacy skills (Paasche-Orlow & Wolf, 2008; Wolf et al., 2007). However, quantitative studies come with their own limitations such as the high levels of literacy required to complete lengthy questionnaires. There is a need for future research that addresses these limitations. Research methods that limit participant burden, but still provide explicit commentary on the specific areas of 'The Facts' booklet that are not well comprehended, are needed. Until then, content revision cannot occur and the design of communication materials will remain unguided.

3.2 Communication interventions within organised CRC programmes and trials

As shown in the summary of the trials in Table 3-1, using written information to communicate with the public about screening is not a new approach. Since the early clinical trials of FOBt screening in the 1980s, a number of studies have reported the use of health communication interventions to increase uptake of CRC screening. Following the introduction of organised CRC screening programmes in the UK, renewed attention has been given to this approach as it is often the only option that allows low cost, mass communication within the confounds of relatively inflexible programmes. The following will outline relevant UK-based trials that have evaluated new or amended health communication materials in CRC screening clinical trial and programme settings.

3.2.1 Study findings and conclusions

Education materials were tested in a sub-sample of a clinical trial that administered FOBt kits from general practitioners in Nottingham (Hardcastle et al., 1986). Men and women aged 45-74 (n=12,785) were allocated to receive either an educational letter about CRC and CRC screening (intervention group) or standard information from their family doctor. The content of both the educational letter and standard information was not discussed in the manuscript. Despite this lack of overt development, findings suggested that providing the educational letter led to a 9.7% difference in uptake in favour of the intervention group. Although the large sample size would provide sufficient power to detect socio-demographic differences in response to the intervention, no analysis was provided.

Similar, but slightly less favourable findings were observed in a sub-study of the UK FS screening trial (Atkin et al., 2001; Atkin et al., 2010). Wardle and colleagues provided a useful example of a health communication trial that addressed socio-cognitive constructs such as perceived risk, negative attitudes and knowledge, while also providing sufficient information to allow an informed decision to be made (Wardle et al., 2003). Findings showed that the intervention group had a 3.6% higher level of uptake compared with a control group who were provided with only a standard screening invitation. There was a suggestion that the booklet was more effective at increasing uptake among socially deprived groups, although the study was not powered for sub-group analyses.

Table 3-1 Summary of trials evaluating health information interventions

Context	Study	Strategy	Design	Population	Main finding	Strengths/Limitations
Invitations sent from primary care (FOBt)	Hardcastle et al., 1986	Educational letter	Randomised design. Educational letter + standard invitation vs. standard information alone	Men and women aged 45-74 years recruited from GP practices in England (n=12,785)	Educational letter + standard invitation had higher uptake vs. standard information alone (47.7% vs. 38%).	Trial setting
FS screening trial	Wardle et al., 2003	Educational booklet	Randomised design. Educational booklet (2-3 weeks before screening invite) vs. standard invitation.	Men and women aged 55-65 recruited from 14 trial centres in England. Participants were considered hard-to-reach because they had previously stated that they would 'probably' take up an FS screening offer (n=2,966)	Group given educational brochure had higher uptake than standard care (54.5% vs. 49.9%). Trend towards a greater effect among more deprived group.	Motivated sample
Invitations sent from primary care	Nichols et al., 1986	Educational booklet	Educational booklet tested in 3 scenario: 1) General Practice invite+test kit 2) General	Men and women aged 40-70 years recruited from GP practices in England	No significant effects of the intervention were shown in any context (data not available due to unreadable	Trial setting

Context	Study	Strategy	Design	Population	Main finding	Strengths/Limitations
(FOBt)			Practice invite+appointment with healthcare professional and 3) invite during routine consultation	(n=25,852)	manuscript).	
Invitations sent from primary care (FOBt)	Pye et al., 1988	Educational booklet	Randomised design. 5 scenarios: i) FOBt + GP letter ii) FOBt + GP letter + educational leaflet iii) FOBt + GP letter + symptom questionnaire iv) educational leaflet 2 weeks before FOBt + GP letter v) symptom questionnaire two weeks prior to FOBt and doctors letter	Men and women aged 50-74 years recruited from GP practices in England (n=3,860)	Uptake was significantly lower in all intervention groups (ii-v) compared to control (i).	Good description of intervention.

Context	Study	Strategy	Design	Population	Main finding	Strengths/Limitations
National screening programme	Hewitson et. al., 2011	GP invitation and/or low literacy information leaflet	Factorial randomised design: i) GP endorsement ii) Low literacy information leaflet iii) GP endorsement + low literacy information leaflet iv) Standard care	Men and women aged 60-75 from the Southern hub of the NHS BCSP (n=1,288)	Main effect of the GP endorsement (5.8% difference vs. control) and information leaflet (6.0%). There was a stronger effect when combined (11.8% difference).	Performed in the screening programme. ~100% ascertainment of intervention effect

Additional data from socio-cognitive measures assessed in an accompanying questionnaire indicated that the intervention was working via the hypothesised mechanisms. For example differences in favour of the intervention group were observed for attitudes towards screening, cancer fear and fatalism. This study suggests that educating the public can improve uptake by reducing negative beliefs about CRC and improving the perceived efficacy of screening. However, the study was performed with a sample of individuals who said they would 'probably' rather than 'definitely' take up the offer of screening (n=2,966), as only people with an intention to be screened were invited to participate in the clinical trial (Atkin et al., 2010). The effectiveness of the leaflet on those with a lower level of intention is therefore unknown.

Results in a trial of over 23,000 people aged 40-70 in a General Practice (GP)-led CRC screening trial were less positive (Nichols et al., 1986). Nichols and colleagues used a factorial design to test an educational booklet in three different scenarios: i) General Practice invitation + test kit; ii) General Practice invitation + appointment with healthcare professional/pick up test kit; iii) invitation during routine consultation. The letter of invitation explained the benefits of early detection, and provided advice on faecal sampling. The intervention booklet contained information about bowel disorders and the CRC screening test. Findings showed that the intervention had no effect on uptake in any of the invitation conditions. It is understandable that in such a large trial there were no socio-cognitive data available. However, the lack of supplementary developmental studies or pilot testing of the communication materials prohibits an understanding of why the intervention failed to increase uptake. This issue must be addressed in future health communication trials.

More worryingly, communication interventions can have negative effects on screening uptake. Within the Nottingham trial (Hardcastle et al., 1996), Pye and colleagues randomised participants to one of four intervention groups, two of which were provided with health information booklets (Pye, Christie, Chamberlain, Moss, & Hardcastle, 1988). In comparison with the study by Nichols and colleagues, more detail was given to the content of the leaflet. Topics included information on the value of early detection, the asymptomatic nature of CRC, the role of screening in detecting CRC and a description of the screening test. Despite this, compared to a control group who received a standard GP invitation, the intervention group had a

level of uptake that was 9% lower. A smaller 4% difference was observed when the information was given two weeks prior to the invitation letter.

The contexts in which these trials were run have implications for how generalisable the data are. The control groups in each of these studies received a personal invitation from their GP practice. Provision of information that is more personally relevant is likely to increase how much it is processed (Petty & Cacioppo, 1986). Indeed, personal invitations from a healthcare professional have been linked to higher uptake in organised programmes (Cole et al., 2007; Hewitson, Ward, Heneghan, Halloran, & Mant, 2011), randomised trials (Senore et al., 2010) and opportunistic settings (Zajac et al., 2010).

Despite this, there is evidence to suggest that uptake can be affected by improving the communication materials, even in the presence of a GP endorsement. For example, Hewitson et al., (2011) undertook an intervention that aimed to address barriers specific to groups with low health literacy. The authors designed a simple leaflet that included motivational messages and statements that reinforced the effectiveness of CRC screening. The intervention did not suffer from the limitation noted among other studies in that a small pilot was performed prior to the main trial. This showed that the majority of people considered the leaflet to be easy to read, sufficiently detailed and useful. Results of the trial demonstrated that the low literacy leaflet group had a 6% higher level of uptake than a control group who were sent standard materials. There was an 11.8% difference among those receiving both a GP recommendation and the low literacy leaflet, indicating that the effects of the intervention were independent.

This study suggests there is scope for improving the NHS BCSP to accommodate the communicative needs of those with low health literacy. However, it is possible this study underestimated the influence that poor health literacy skills can have on screening uptake. The study was conducted in the Southern hub of the screening programme, which is notably more affluent than the other hubs (Logan et al., 2012). Screening uptake is also higher. Furthermore, the study revised an instructional leaflet that uses diagrams and limited text; factors shown to aid comprehension, particularly among groups with low health literacy (Brotherstone, Miles, Robb, Atkin, & Wardle, 2006; McCaffery et al., 2012). A greater effect on screening uptake could

therefore be achieved by addressing the part of the information materials with the lowest readability i.e. ‘The Facts’ booklet.

Overall, these studies provide mixed support for the capacity of health communication materials to increase uptake of CRC screening in the UK. The most noticeable limitation (that also applies to health communication trials generally) is that the studies gave limited detail about the development process that was undertaken (Wilson et al., 2012). An additional limitation was that only one study examined differences in response to the intervention across the SES spectrum (Wardle et al., 2003), although another purposely addressed commonly cited barriers of groups with low health literacy (Hewitson et al., 2011). Further research investigating how the SES gradient in CRC screening uptake can be improved is required.

Another factor that should be considered when interpreting the results of these studies is that they were often embedded within clinical trials. Selection biases whereby higher recruitment of people who are white, younger, healthier and with a higher income are common in clinical trials (Murthy, Krumholz & Gross, 2004; Townsley, Selby, & Siu, 2005; UyBico, Pavel, & Gross, 2007). Studies performed within national programmes where participants have not opted to take part in a trial may produce more valid and generalisable data (Hewitson et al., 2011).

Aims and overview of the thesis

Chapter 1 provided a background to colorectal cancer (CRC) and highlighted that it is a major cause of mortality in the United Kingdom (UK). Evidence is presented showing that lower socioeconomic status (SES) groups are less likely to survive 5 years post-diagnosis than higher SES groups. This association is linear, with decreases in survival between each quintile of neighbourhood deprivation.

Chapter 2 described how the CRC screening programme operates in England. A current problem is that uptake of CRC screening is low, particularly in comparison with the breast and cervical screening programmes. SES inequalities in screening uptake are also apparent. I provided a theoretical and empirical account of the socio-cognitive correlates of uptake that may contribute to explaining low participation among deprived groups. I noted that knowledge about CRC and CRC screening is poor, particularly in groups with low health literacy. This problem may be compounded by defensive processing of information related to CRC.

The low uptake of CRC screening compared with other screening modalities has led to calls from policy makers and academic researchers for theoretically driven interventions to be designed and evaluated. In line with the Marmot review of SES inequalities, such interventions should aim for a levelling of the SES gradient in health outcomes, so called ‘proportionate universalism’ (Marmot et al., 2010). However, the scale, resources and organisation of the National health Service Bowel Cancer Screening Programme (NHS BCSP) limit the scope for public health interventions.

The low level of involvement from healthcare professionals within the invitation stages of the NHS BCSP means that the programme relies on health communication materials to convey the aims, advantages and disadvantages of the programme. Chapter 3 provided a review of the literature evaluating these materials. Chapter 3 also contained an overview of a number of UK-based interventions that have used communication interventions to increase CRC screening uptake. In these interventions, successful attempts have been made to address the information needs of lower SES and health literacy groups. A similar intervention addressing the most literacy intensive aspect of the programme (i.e. ‘The Facts’) has the potential to reduce screening inequalities.

Aim of thesis

This thesis aims to design and evaluate a brief ('gist-based') information leaflet that improves understanding by lower SES groups and thereby reduces the SES gradient in CRC screening uptake. A particular aim of the research is to improve uptake among people who are being invited for the first time as previous screening behaviour is one of the strongest predictors of repeat participation (Steele et al., 2010a; UK Colorectal Cancer Screening Pilot Group, 2004). First time invitees are also more likely to be guided by written communication materials, as they have yet to go through the decision-making process that precedes CRC screening participation.

The design and evaluation process was guided by a tripartite framework for the evaluation of patient information leaflets (Garner, Ning, & Francis, 2012). This framework suggests that in order for a health communication intervention to be successful, the information it contains should be: i) readable; ii) comprehensible, and iii) able to communicate its message effectively.

Designing a 'gist-based' information leaflet

Explicit, constructive commentary that supports content revision of the NHS BCSP information booklet, 'Bowel Cancer Screening: The Facts' remains elusive. It is therefore unclear which aspects of the screening offer people are failing to comprehend while reading the materials. Study 1 (Chapter 4) aimed to address this gap in the literature by using a psychological technique known as the 'think-aloud' method. This method entails the verbalisation of a person's thoughts that would normally be silent, while enabling them to continue reading the information they are presented with.

Study 1 objectives: To identify areas of the 'The Facts' booklet that were difficult to read, confusing to the reader or detrimental to motivation using a mixed-methods analysis. Quantitative analysis allocated the data into a typology of utterances developed prior to analysis. Qualitative (thematic) analysis provided in-depth observations of the content most problematic to participants.

Using the findings of study 1, best practice guidelines from the fields of cognitive psychology, health literacy and information design were used to complement a

theory-based approach to designing a 'gist-based' information leaflet. In Chapter 5, I discuss the theoretical observations from a model of medical decision-making (Fuzzy-Trace Theory) and use empirical evidence from these fields to design the leaflet. A cross-cutting theme throughout the design process is how the leaflet can be optimised for those with lower levels of health literacy.

Evaluating the readability, comprehensibility and communicative effectiveness of a 'gist-based' leaflet

In accordance with the Garner framework, study 2 (Chapter 6) evaluated the readability and comprehensibility of the gist leaflet. Using a user-testing methodology, the gist leaflet was tested in a series of cognitive interviews performed in rounds of approximately 8-10 participants. Volunteers were asked to read through the gist leaflet and answer a series of true or false statements developed for the purpose of this study. Each statement had to be answered correctly by at least 80% of participants for the leaflet to be deemed legible, clear, and easy to read. Failure to reach this threshold led to changes being made to the content and design of the leaflet. This was followed by an additional round of testing with new participants. This process continued until the threshold was met and the leaflet was deemed fit-for-purpose.

Study 2 objectives: To report the readability of the gist-based leaflet using the Flesch-Kincaid readability formula. I also used a user-testing methodology to test the comprehensibility of the leaflet in a sample purposively recruited from lower SES areas.

Study 3 (Chapter 7) tested the comprehensibility and communicative effectiveness of the gist leaflet. Using General Practices (GPs) in deprived areas as a source of participants with low health literacy, I undertook a randomised controlled trial of the gist leaflet. Participants approaching screening age were randomly allocated to either a control condition (Facts booklet only) or intervention group (Gist leaflet + Facts booklet), and asked to complete a questionnaire after reading the leaflets.

Study 3 objectives: To test the communicative effectiveness of the leaflet in a community-based randomised control trial by observing the effect that the gist leaflet had on screening intention. The communicative effectiveness and comprehensibility of the gist leaflet was also tested using the following secondary outcomes:

perceived readability; perceived usefulness; knowledge; perceived risk; and worry about CRC. The extent to which the intervention addressed inequalities was tested by monitoring the effectiveness of the intervention in low and high numeracy groups.

Following the comprehensive testing of the leaflet in studies 2 and 3, the impact of the gist leaflet was evaluated in a national cluster randomised controlled trial within the NHS BCSP. Randomisation was by day (10 days), stratified by screening hub (five hubs). People invited to CRC screening during the study period were allocated to either the control condition (Facts booklet only) or intervention group (Gist leaflet + Facts booklet).

Study 4 objectives: To ascertain the communicative effectiveness of the gist leaflet in a national cluster randomised controlled trial. I aimed to investigate the effect of the gist leaflet in reducing the SES gradient in CRC screening uptake using objectively recorded uptake data. Secondary outcomes included overall uptake, and the effectiveness of the gist leaflet among gender and age sub-groups, and screening type and round. A sub-sample analysis was performed on individuals in the first screening round.

Findings of the review chapters and studies are discussed in Chapter 9, alongside the theoretical and policy implications of the thesis. Future directions of this work are noted.

Chapter 4. How do people interpret information about colorectal cancer screening: observations from a think-aloud study (Study 1)[1]

4.1 Introduction

As discussed in Chapter 3, the information materials associated with the National Health Service Bowel Cancer Screening Programme may negatively affect screening participation due to their length and complexity, particularly among groups with low health literacy (S. K. Smith, Trevena, Nutbeam, Barratt, & McCaffery, 2008). However, the programme is heavily reliant on such materials to convey the aims, benefits and risks of screening. Research that provides an insight into the thought processes that occur while reading this information is needed. Using a method used by communication experts will allow me to identify the precise areas of the information which are considered problematic by the user.

4.1.1 The think-aloud method

The think-aloud method was first proposed in 1920 by behavioural psychologist John Watson as a way of accessing 'inner speech'. It entails the verbalisation of a person's thoughts that would normally be silent, while enabling them to continue with the primary task (such as completing a puzzle, calculating a mathematical sum or reading textual information). Essentially the utterances (i.e. the verbalised thoughts) represent the current contents of short-term memory, providing access to cognitive processes that occur during a task (Ericsson & Simon, 1993).

While some have argued it to be a form of introspection (Schooler, 2011), others disagree (Ericsson & Fox, 2011), pointing instead to a recent meta-analysis demonstrating think-aloud and introspective methods to be statistically and conceptually unique (Fox, Ericsson, & Best, 2011). The distinction hinges on the issue of 'reactivity', which refers to the idea that verbalising ones thoughts significantly alters the cognitive processes that create them, thus reducing the validity of the method for accessing concurrent thinking. Using data from over 3,500 participants and 94 think-aloud studies, the meta-analysis demonstrated that for

[1] A version of this chapter has been published in *Health Expectations* (S. G. Smith et al., 2013) (see appendix B).

studies where participants are required only to verbalise their thoughts (i.e. think-aloud), no consistent reactivity was shown, although performance tasks was consistently slower (Fox et al., 2011). Reactivity was however shown when participants were asked to describe or explain their thoughts (i.e. introspect) while continuing with the task.

There have been applications of the think-aloud method to a wide range of topic areas. One area where the think-aloud method has been applied is in the comprehension of written information. However, there has been little use of the method for this purpose in the health communication field, where attention has instead focused on assessing the validity of questionnaire items (French, Cooke, Mclean, Williams, & Sutton, 2007). A notable exception to this is a study reported by Scott and colleagues who used the think-aloud method to evaluate a newly designed patient education leaflet on the topic of oral cancer. Using a sample of patients who were at high risk of oral cancer, the authors used the think-aloud method to elicit a range of comments that enabled improvements to be made to the content and layout (Scott, Weinman, & Grunfeld, 2011).

The think-aloud method has the potential to be a useful tool to investigate comprehension barriers among groups with low health literacy. One advantage is that it can be framed in terms of testing the material, rather than the person being interviewed. Another advantage is that it allows the person to vocalise their exact thoughts on the information, with very little input from the interviewer. This overcomes a limitation of most qualitative studies (e.g. semi-structured interviews and focus groups) which tend to impose the views of the interviewer onto the subject (Chapple et al., 2008; Jepson et al., 2007; Woodrow et al., 2008). The potential to analyse the data using both quantitative and qualitative techniques provides additional validity to the findings. The technique has however rarely been used among groups with lower levels of health literacy who can find reading intimidating.

4.1.2 Aims of the study

I aimed to investigate how people interpret the National Health Service Bowel Cancer Screening Programme (NHS BCSP) information booklet ‘Bowel Cancer Screening: The Facts’ by using the ‘think-aloud’ method. The study will provide the basis for the design of a ‘gist-based’ information leaflet, which will be discussed in

subsequent chapters. Following the literature identified in previous chapters, I had a specific objective to identify areas of the existing booklet that were difficult to read, confusing to the reader or detrimental to motivation. The secondary objective was to identify additional responses to the information using a more in-depth qualitative analysis.

4.2 Method

4.2.1 Participants

Following ethical approval (ref: 2247/002), 21 participants were recruited through various organisations. Purposive sampling from deprived groups was undertaken because of the established link with health literacy (Boxell et al., 2012; Ibrahim et al., 2008; von Wagner et al., 2007) and colorectal cancer (CRC) screening uptake (Davis et al., 2001; von Wagner, et al., 2011a).

The first group to be approached was ContinYou. This organisation is an education charity, working with children and adults from deprived communities across the United Kingdom (UK). They specialise in lifelong learning courses and work closely with the jobseeker's agency. They provided contact details for age-appropriate individuals who were subsequently approached by telephone and mail. The company experienced financial difficulties during the recruitment process and were unable to fulfil the quota that was requested.

Social Action for Health (SAfH) was therefore approached approximately two-thirds of the way through recruitment. SAfH is a non-governmental organisation working in community health development within deprived communities in London (Hackney and Tower Hamlets). They run a number of chronic disease self-management courses, and support groups and provide advice on a range of public services. The contact details of individuals who had contact with SAfH since 2008 were stored on a database. I was provided access to this database and invited participants who were the appropriate age by telephone. Those who were interested and met eligibility criteria were sent an information sheet, my contact details and personalised directions for the SAfH head office.

The Third Age Project (TAP) was also approached for their assistance at the same time as SAfH. TAP are a community organisation working in the area of public

health and service engagement. They are located in a deprived community in the Kings Cross and Euston area of London. Recruitment was facilitated by enclosing a leaflet within their monthly newsletter that is sent by mail. Unfortunately, no participants responded to this invitation. Because of these recruitment difficulties, the Health Behaviour Research Centre participant panel was used to supplement recruitment. This is a panel that have previously participated in health research and agreed to be contacted again.

Men and women aged 45-60 years (i.e. before the age at which CRC screening is offered in England) with no known CRC diagnosis, severe cognitive impairment or English language issues were approached via mail or telephone. Individuals who were approached by mail were sent a consent form that contained a request for their contact details and a return envelope. Over the telephone, people were asked a series of screening items to ensure that they met eligibility criteria. These criteria were chosen to ensure that participants were relatively naïve to the processes of CRC screening and the accompanying information materials. Three participants completed interviews, but were subsequently excluded because one was unable to read and two had severe cognitive impairments. These participants had been recruited directly by ContinYou.

Participants were paid £20 for their time and travel expenses. Interviews took place in the ContinYou and SAfH head offices, as well as community spaces and university meeting rooms. The study documents provided to participants are shown in appendix C-H.

4.2.2 Procedure

Eligible participants were consented on the day of the interview. Participants completed a brief socio-demographic questionnaire and a health literacy assessment and then continued to the think-aloud interview. In line with best reporting methods for think-aloud studies (Fox et al., 2011), the statement in Figure 4-1 was read to participants prior to starting. This was adapted from the instructions used in studies by (Ericsson & Simon, 1993) and (Crain-Thoreson, Lippman, & McClendon-Magnuson, 1997).

Figure 4-1 Participant instructions for think-aloud study

‘In this exercise we are interested in what you think about when you read information. In order to do this I’m going to ask you to THINK-ALOUD as you read through some information. What I mean by think-aloud is that I want you to tell me EVERYTHING you are thinking from the time you reach a red dot. I would like you to think-aloud CONSTANTLY from the time you reach a red dot until you have finished telling me what you are thinking. I don’t want you to plan out what you say or try to explain to me what you are saying. You may want to make predictions about what you are reading, rephrase what you think the text is saying, share an story that describes something in the text that you’re familiar with, remark on something in the text that is confusing, or say something else that helps you understand the text you’re reading better. Just act as if you are in the room speaking to yourself. It is most important that you keep talking. If you are silent for any long period of time I will prompt you by saying ‘Please carry on thinking out loud’.

Participants were asked to practice on a control leaflet (‘recycle to save the environment’), which contained three prompts before reading ‘Bowel Cancer Screening: The Facts’, October (2010) version. After participants had completed three successful utterances, they were deemed ready to participate. If they did not reach this threshold during the practice session, the procedure was explained again and they were given additional time to practice.

This study used a ‘marked protocol’ in which participants were prompted to make a comment every time they encountered a small red dot in the leaflet. I placed a total of 66 prompts at the end of bullet points and short paragraphs (i.e. 2 short sentences). Where lengthy paragraphs were included (i.e. 2-3 longer sentences), a prompt was placed after each sentence in the paragraph. A marked protocol was used as it has previously elicited more instances of confusion and miscomprehension, a primary aim of the study (Crain-Thoreson et al., 1997).

4.2.3 Sample size

When determining the sample size for think-aloud studies, Nielsen (1994) argued that a single test subject yields up to a third of usability problems, while after as few as 5 participants, most issues are identified (Nielsen, 1994). This indicates that each participant produces a large amount of data and a large sample size is not needed to detect the majority of usability problems. We therefore recruited a sample of 15-20 participants to ensure the aims of our study were met. Saturation (i.e. when no new information is gained after several consecutive interviews) was used as the marker to cease recruitment.

4.2.4 Measures

4.2.4.1 Participant characteristics

Age, gender, marital status, first language, living arrangement, employment, education level, and screening history (women only) was recorded. An experience with cancer score was computed by assessing personal diagnoses of cancer (1 point) and/or knowing someone who had been diagnosed with cancer (1 point). Education was coded as basic high school qualifications (i.e. no formal qualifications, GCSEs or basic work qualifications), advanced high school qualifications (A-levels or advanced work qualifications), and university educated.

Health literacy was assessed using the UK version of the Test of Functional Health Literacy in Adults (UK-TOFHLA) which has a numeracy and literacy section (von Wagner et al., 2007). The numeracy section involves tasks relating to date and time calculation, computation of medication dosage, and patient navigation. The literacy section is based on the 'cloze' procedure. Three passages of text (instructions on how to prepare for an X-ray, eligibility for NHS prescriptions and a consent form for surgery) of increasing difficulty are given to the participant and every fifth word is missing. Where a word is missing a blank line is drawn and 4 possible words that could be used are provided. A score of 100 is calculated, with each section having a maximum score of 50. Scores are converted into three groups: inadequate (0-59), marginal (60-74), and adequate (75-100) health literacy (Parker, Baker, Williams, & Nurss, 1995).

4.2.5 Analysis

Interviews were audio recorded and transcribed. Occasions when participants deviated from the text (i.e. failed to read the text or misspoke) were coded as reading mistakes. After this, prompted and unprompted utterances (any statements made following a passage of text) were coded. Participants were not instructed to make unprompted utterances prior to starting the interview. However there was author consensus that unprompted utterances, when made, were not substantially different from prompted utterances. All utterances were therefore combined and analysed together. All analyses were performed in NVivo 9.

This study used a mixed-methods approach to analyse the data. Firstly, a coding framework was developed in consultation with previous literature (Crain-Thoreson et al., 1997) and the research team (see Table 4-1). A content analysis was then performed, with utterances allocated to at least one theme. An utterance could be coded into several themes if deemed necessary. However, where possible, multiple coding was kept to a minimum. An utterance could also be split into several sections if the participant was discussing several aspects of the text. Two of the transcripts (>10% of the data) was second coded by an additional researcher (GV) in order to assess inter-rater reliability. Reliability was found to be adequate to excellent (K = 0.5-1.0).

In addition to the content analysis, an in-depth thematic analysis was conducted to provide insight into the sub-themes contained within the framework. Thematic analysis is used to identify, analyse and report patterns (themes) within data (Braun & Clarke, 2006). While the majority of the comments were brief, and provided little insight past surface-level meaning, a thematic analysis allowed exploration of deeper level meanings of some comments. This approach was taken as the aims of the study were to extract general perceptions about 'The Facts' booklet, rather than understand individual experience with the information.

To increase the validity of the thematic analysis, I and an additional researcher (CvW) were responsible for analysing the transcripts. I first analysed each interview and extracted themes. Together, we then analysed the extracted themes across transcripts using the constant comparison method (Strauss, 1987). To increase the validity further, additional experts were consulted to suggest alternative themes

within the data and to assess whether the suggested themes were adequately represented by the quotes.

Table 4-1 Think-aloud coding framework

Name of theme	Description
Deep processing	An inference based on the text, which goes beyond repetition
	Rephrasing of the text, which goes beyond repetition
	An anecdote which explains the text
Surface processing	Repetition or very near repetition of the text
	Self-reported learning
	Self-reported previous knowledge
Miscomprehension	Confusion about a statement
	An incorrect statement following a passage of text
	Asserts that factual information is opinion
Emotional (negative)	A negative reaction with at least one emotion in the sentence
	Person mentions the information makes them feel the opposite of a positive emotion
Emotional (positive)	A positive reaction with at least one emotion in the sentence
	Person mentions the information makes them feel the opposite of a negative emotion
Unanswered questions	An individual has unanswered questions following a passage
Layout	An individual comments on the layout of the information
Unnecessary information	Comments that indicate the information is unnecessary
Decrease motivation	An individual remarks that something in the text would be demotivating to screening participation
Increase motivation	An individual remarks that something in the text would be motivating to screening participation

4.3 Results

4.3.1 Participant characteristics

Eighteen participants (mean age = 55 years [range 48-60]) took part. As indicated by Table 4-2, the sample was mixed; participants predominantly spoke English as a first language, were of White ethnicity, had a mixed level of education and most had experience of cancer in some form. Despite the purposive sampling methods used, several markers of socioeconomic status (SES) indicated that a biased sample was recruited. For example, nearly 90% of participants had 'adequate' levels of health literacy, 50% were university educated and ethnic minorities (11%) were underrepresented.

Table 4-2 Participant characteristics in Think-Aloud study

	N (%)
Gender	
Male	7 (39)
Female	11 (61)
Marital Status	
Married/living with partner	6 (33)
Single/Divorced/Separated	9 (50)
Widowed	3 (17)
English as first language	18 (100)
Living arrangement	
Own home/mortgage	9 (50)
Renting / Other	9 (50)
Employment	
Currently employed	10 (56)
Unemployed / Disabled or too ill to work	6 (33)
Retired	2 (11)
Education	
≤ Basic high school qualifications	4 (22)
Advanced high school qualifications or equivalent	5 (28)
University educated	9 (50)
Health literacy	
Adequate	16 (89)

	N (%)
Inadequate/Marginal	2 (11)
Ethnicity*	
White	15 (83)
Non-white	2 (11)
Cancer experience	
0	2 (11)
1	13 (72)
2	3 (17)
Breast screening history**	
Yes	11 (100)
No	0 (0)
Cervical screening history**	
Yes	10 (91)
No	1 (9)

* 1 participant elected not to answer this item ** Women only

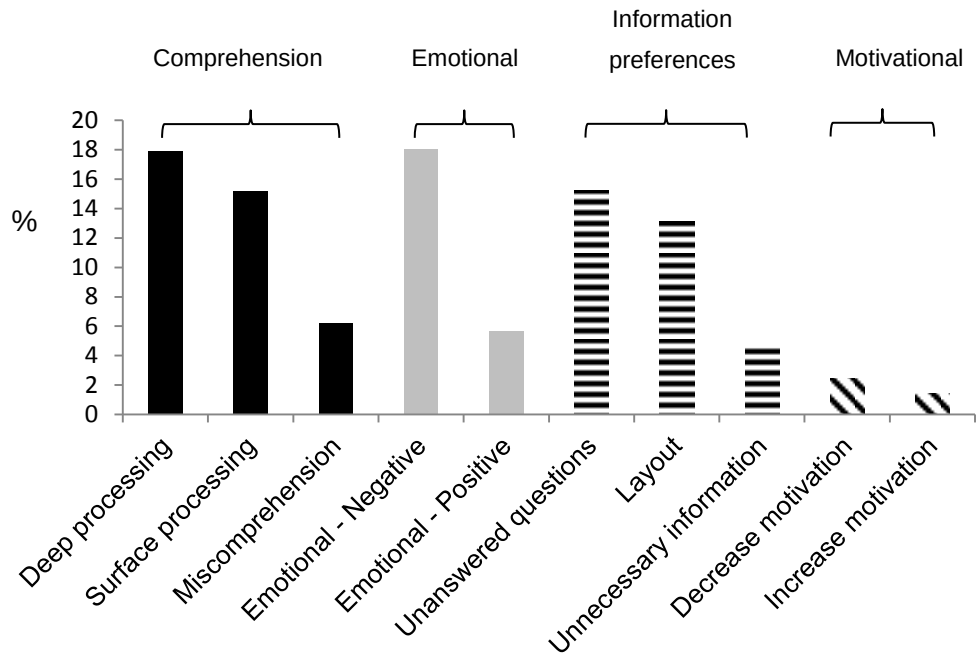
4.3.2 Content analysis

In the 18 interviews, 270 reading mistakes were recorded (mean = 15 per person; range = 0-59). The interviews yielded 776 coded utterances (mean = 43.1 per person; range = 8-95), which were analysed within the pre-determined framework.

There was substantial variation in the types of comments made by participants. As shown in Figure 4-2, the comprehension theme was largely made up of comments which implied a higher level understanding (i.e. deep processing; 17.9% of all comments), or repetitions of the text and unsubstantiated self-reported knowledge (i.e. surface processing; 15.2%). Miscomprehension was less common (6.2%), however this still amounted to 48 instances of mistakes or self-reported lack of understanding. There was a high number of comments in the emotional theme. Emotionally negative statements were three times more common than emotionally positive statements (18.0% and 5.7%, respectively). The information preferences theme suggested that people desired further information on specific aspects of the booklet (unanswered questions: 15.2%), while others suggested improvements to the style and layout of the booklet (layout: 13.1%). A minority of statements

questioned the necessity of certain information that they had just read (unnecessary information: 4.8%). Utterances rarely alluded to whether the participant felt motivated (1.4%) or demotivated (2.5%) by information in the booklet.

Figure 4-2 Summary of themes made by participants



4.3.3 Qualitative analysis

Quotes are presented in relation to three key themes, which were guided by the content analysis.

4.3.3.1 Difficulties with numerical information

The use of numbers to convey risk information in 'The Facts' booklet is common, which participants often considered to be unnecessary. For example, one participant preferred to think categorically about the efficacy of screening to reduce CRC deaths (i.e. anything is better than nothing), rather than in numerical terms (i.e. a 16% reduction):

> 'I know we have to have…the evidence and that, but I think if I hadn't done research myself…I would just find that got in the way really. This thing about 16%. What's 16%? What does it mean to the person on the street? I know anything is better than nothing for reducing the risk of dying, but surely it should be a lot more percentage than that, but is it

something that I want to know about?' (QE, 50 years, female, university educated).

The use of numerical information to convey the lifetime incidence of CRC as 1 in 20 led to confusion. For example, one participant largely overestimated the likelihood of being diagnosed with CRC as a result of an information processing error:

'That's about, yea, that's one in 4 of the population isn't it?' (IT, 51 years, male, advanced high school qualifications)

The frequency of different screening outcomes proved difficult to interpret. The booklet explains that following a Faecal Occult Blood (FOB) test, approximately 98 out of 100 people will receive a normal result (no blood found), four out of 100 will receive an unclear result (a small amount of blood), and two out of 100 receive an abnormal result (blood was found, further investigation is required). However, there was confusion as to whether the 'normal' prevalence figure includes those that have previously received an unclear result:

'Does that equate with the 98 out of 100 in the previous paragraph? Something, somewhere doesn't seem quite. Four people out of 100 and then we had 98 out of 100, anyway, not quite sure about that' (WW, 56 years, female, university educated)

As with the FOB results section, colonoscopy outcomes were misinterpreted. The booklet explains that one person out of 10 will be diagnosed with cancer, four people out of 10 will have a polyp removed, and five people out of 10 will have nothing found. In this instance, the participant appears to discount the number of people receiving a polyp diagnosis, thus overestimating the prevalence of cancer following an abnormal FOB result:

'Half of people that go for these colonoscopes [sic] don't have cancer? And the other half do? Hmm' (IT, 51 years, male, advanced high school qualifications)

4.3.3.2 Unfamiliar topics and complex terminology

Participants questioned whether it was necessary to have such a long and complex booklet to inform people about the NHS BCSP. The introduction of unfamiliar topics and scientific terminology also led to comprehension difficulties for all educational levels:

> 'This is an awful lot for people to read, this is just handed out? Hell of a lot to read isn't it?' (OU, 54 years, female, university educated)

> 'A bit difficult to understand, if you're not up to date with those kind of informations' (RT, 58 years, female, basic high school qualifications)

In particular, discussion of polyps when describing the purpose of bowel cancer screening led to confusion about the link between polyps and bowel cancer. One participant argued that it may be best to avoid the inclusion of polyps, particularly as the main purpose of reading 'The Facts' booklet is to find out specifically about bowel cancer:

> 'Funny, sort of early on to talk about the alternative to cancer… I think it's quite good if you're actually worried about it…there's nothing wrong with that but I don't quite see the point in it. People wanting to go for a bowel cancer screening must surely be wanting to know about bowel cancer. Anything else can be sorted out at some other stage' (TU, 59 years, male, basic high school qualifications).

> '…that [bowel polyps] is getting quite complicated, that's something that I don't know whether I want to know necessarily or that maybe I do?' (TU, 59 years, male, basic high school qualifications)

The terminology used in 'The Facts' booklet led to difficulties with pronunciation. As show in Table 4-3 words such as colonoscopy, colonoscope and colorectal were frequently pronounced incorrectly and this led to interruptions in reading.

Table 4-3 Prevalence of mistakes or deviations from text

Word or phrase	n
Polyp	7
Faecal	9
Adenoma	10
Colorectal	10
Colonoscope	11
Colonoscopy	49

Participants argued that a leaflet which aimed to provide complex and technical information would benefit from the use of vernacular language as opposed to scientific terminology:

> '…I would prefer a more high level definition of what the bowel is actually. This just seems to provide too much detail…' (SM, 51 years, male, university educated)

There was also difficulty when remembering and describing the difference between the possible outcomes of an FOB test:

> 'Right there's a lot there so did I read that there is a difference between unclear and abnormal? I can't remember now.' (TU, 59 years, male, basic high school qualifications)

Despite the bold text within this paragraph describing the exact meaning of abnormal, it was easily misinterpreted as the definite identification of a malignancy or polyp:

> 'So that's good, it gives you all of the different results of the testing…normal, you're not going to have any more tests for two years. If it's unclear you have another one to make sure it's nothing suspicious and if it's abnormal you've definitely got something that needs further investigation.' (CW, 56 years, female, university educated)

One quote demonstrated how much care needs to be taken over the wording of statements in communication materials. The participant TU observed contradictory statements in 'The Facts' booklet (on pages 5 and 6). The first statement indicated that FOB screening does not diagnose CRC and the second statement states clearly that it does (see appendix A). This led the participant to comment:

> 'Oh, it doesn't [detect bowel cancer] does it? Because it says directly above it that this doesn't detect bowel cancer' (TU, 59 years, male, basic high school qualifications)

Some aspects of the booklet were however considered to be useful to improve comprehension. For example, the use of illustrations and summary boxes increased the ease with which information was processed:

> 'Ok, yea, that's a useful summary and I'm quite pleased with that little boxed text provided' (SM, 51 years, male, university educated)

To improve the booklet further, it was recommend that when technical phrases are introduced, the most familiar word should be used first, and the more technical phrase included within brackets that follow:

> 'I'm wondering sometimes with these things whether it isn't better to have the common word before the technical, so piles (haemorrhoids), just because seeing those words that are hard to pronounce can put you off.' (OU, 54 years, female, university educated)

4.3.3.3 Emotional responses

As demonstrated by the quantitative analysis, there was a mixture of emotionally negative and positive comments. For example, some participants found the scientific explanations of cancer interesting, and somewhat reassuring:

> 'Yea that's interesting, I've never really known an awful lot about cancer, and how it spreads and what happens so that again seems to make it quite sensible and slightly not too scary. Because obviously everybody talking about cancer, everybody gets very 'the big C'' (WW, 56 years, female, university educated)

Despite the reassurance offered by these explanations, the colonoscopy risk information frequently led to negative emotional responses. In particular, the risk of death (1 in 10000) led some to question why this may occur:

> 'Oh, oh that is shocking. That is shocking. I'd like to know more, now that's been said…what on earth would they have had to do for that to happen – whether a heart attack, or a shock to the body or you perforate the liver or something that's vital to keep you alive' (CW, 56 years, Female, university educated)

> 'God, I didn't know that. Bloody hell!' (TU, 59 years, male, basic high school qualifications)

Others questioned the necessity of including such information, preferring instead to supply it on a 'need to know' basis or in a less prominent position:

> 'I'd write it in small and I'd write it at the end...It wouldn't be something massive, I don't think it, anything put there to make people more worried about the procedure, the procedure's complicated enough' (JS, 52 years, male, advanced high school qualifications)

In line with previous reports of stool-based testing, the test was often considered to be distasteful but unavoidable:

> 'Yea I think that probably, there's nothing else you can do about it but it is rather embarrassing and unpleasant' (BD, 56 years, female, basic high school qualifications)

One participant commented that the description evoked unpleasant images about the procedure that may induce aversion to participation:

> 'Ok, yea, wipe the samples on a special card…I'm getting a bit unpleasant mental images of that procedure' (SM, 51 years, male, university educated)

4.4 Discussion

This study of 18 adults who were naïve to CRC screening explored how people interpret the information booklet provided to invitees of the English NHS BCSP information booklet, 'Bowel Cancer Screening: The Facts' using the think-aloud method. Despite the extensive testing process the information went through (Woodrow et al., 2008) and its approval by the plain English campaign, this mixed-methods analysis suggests it may not always meet the information needs of people invited to take part in CRC screening.

Participants made on average 15 reading mistakes during the task, and in line with previous research, unfamiliar terminology such as colonoscopy, colorectal and adenoma were particularly problematic (O'Connell et al., in press; S. K. Smith et al., 2008). The introduction to the function of the colon and rectum and the adenocarcinoma sequence necessitated the use of such terminology, leading some participants to question whether it should be included. Importantly, these basic scientific explanations stretched the capabilities of even highly educated participants. Participants recommended that numerical information about unclear results and colonoscopy risk was reduced or simplified.

It was surprising that the booklet elicited frequent emotional responses, the majority of which were negatively framed such as fear of the possible outcomes and worry following risk information. As with previous qualitative research, risk information relating to colonoscopy was considered to be particularly shocking and in some cases unwanted (Woodrow et al., 2008). However, in Woodrow and colleagues study, only a minority of the sample were found the hold such views. The quantitative element of the current study demonstrates clearly that such views may be more prevalent than previously thought.

In line with previous questionnaire-based research, the disgust and 'messiness' of the FOB testing procedure was a common reaction and could potentially act as a barrier to screening (Chapple et al., 2008; Dolan et al., 2004; von Wagner, Good, Smith, & Wardle, 2012). Despite the higher prevalence of negative emotional responses, very few utterances suggested that this information was demotivating.

Thematic analysis indicated that the booklet was well-designed in terms of text size, colour and visual clarity. In line with previous research conducted within a flexible

sigmoidoscopy screening pilot, the use of diagrams to explain anatomical information improved knowledge and was considered beneficial (Brotherstone et al., 2006). Furthermore, the use of a summary box after the results section was useful and helped to clarify uncertainties. The provision of communication materials that offer a similar function (i.e. briefer, more accessible information) may therefore aid knowledge translation. However, care should be taken to ensure that such information is comprehensible to the target population.

In keeping with this, participants perceived 'The Facts' booklet to be too long. One solution put forward by participants was to limit the provision of information to a 'need to know' basis. For example, risk information about colonoscopy could be supplied at a later date, only to those that receive an abnormal screening result. Limiting the amount of information people are required to process may reduce the burden placed on individuals (particularly those with low health literacy) during the decision-making process. In turn, more cognitive resources can be allocated to processing information that is considered to be important to the public (e.g. the aims, advantages and disadvantages of screening (Waller et al., 2012).

4.4.1 Strengths and limitations

This study used a novel method to evaluate the quality of written information in the largest organised cancer screening programme worldwide. While others have successfully used the technique to qualitatively analyse health communication materials outside of a screening context, to my knowledge this is the first to use a mixed-methods approach (Scott et al., 2011). These analyses have enabled me to present a broad overview of public perceptions of the information materials, as well a more detailed analysis of the underlying factors which may contribute to decision-making in screening. The inclusion of people that spoke English as a first language allowed me to focus on literacy and not translation, which are considered to be separate issues (S. K. Smith et al., 2008). Participants were approaching screening age, but had not yet been screened which prevented biases that may occur in individuals with more experience of the screening procedure and information materials.

An objective of the study was to identify difficulties with reading and evaluating the materials. However, participants with a low level of education found this method troublesome and contributed less to the discussion. For example, of the 20

presented quotes, only 7 (35%) were from people with a basic levels of education. Low disclosure of miscomprehension may be because of the stigma associated with poor basic skills (Paasche-Orlow & Wolf, 2008; Seligman et al., 2005). Supporting this, a number of interviewees reported that this approach was quite intimidating and stressful. The present study shows that amendments are required if the think-aloud method is to be used by groups with low health literacy.

Attempts to improve the method should focus on reducing the cognitive burden of the task, perhaps by removing the requirement to read out loud or simplifying the requirements. For example, Pander Maat and Lentz have developed a version of the task whereby participants were asked to place their own marks on the text as they progressed silently through the material (Pander Maat & Lentz, 2007). These marks were then assessed by the interviewer and a short semi-structured interview was performed to identify the difficulties with the marked sections. Additional prompts with shorter intervals could also be used to reduce the cognitive burden of the task.

The use of a 'marked protocol' whereby participants are instructed to make utterances at certain points in the booklet was used here. This method appeared to encourage utterances throughout the interview and ensured a sufficient amount of data for both qualitative and quantitative analysis. However, it may also have introduced bias by encouraging comments at points in the booklet dictated by the researchers, and discouraging them at others. Establishing study designs and methods that place participants at ease when disclosing comprehension difficulties should be a primary goal for health communication methodologists.

A selection bias in the sample reported here was also likely. The number of low SES participants, as assessed by a range of markers, was not representative of the general population. The recruitment of minority groups is a well-recognised problem, and despite a number of recruitment strategies being used, difficulties occurred (Yancey, Ortega, & Kumanyika, 2006). The sample was also relatively experienced with cancer and cancer screening. For example, a nationally representative sample of UK older adults reported that 74% of the sample knew someone with cancer or had been diagnosed themselves, compared to 89% in this study (Williams, Beeken, & Wardle, 2013). There were also a high percentage of women who had previously participated in both breast (100%) and cervical (91%) cancer screening

programmes. This familiarity with cancer and cancer screening may have accounted for the relative lack of negative statements and could limit the degree to which these findings are generalisable outside of the study population.

4.4.2 Conclusion

The think-aloud method enabled me to identify specific areas of the existing information materials that were difficult to read, confusing to the reader and detrimental to motivation. I also observed strong emotional responses to some aspects of the screening process. However, the method was less effective at eliciting comprehension difficulties among groups with low health literacy, who found the task burdensome. Problems with 'The Facts' booklet are likely to be even more prevalent among socially deprived groups where basic skills are often more limited. Information materials designed with these findings in mind may aid knowledge translation and reduce the cognitive burden when making CRC screening decisions.

Chapter 5. The development of a 'gist-based' supplementary colorectal cancer screening information leaflet[1]

5.1 Introduction

Evidence provided in previous chapters suggested that differences in uptake of CRC may be partially due to differential understanding of the colorectal cancer (CRC) screening offer. To help address communication inequalities, information should be design that is more accessible to general public. In turn, deprived groups that tend to rely on lay networks for health information (Kontos, Emmons, Puleo, & Viswanath, 2011) will be exposed to accurate information that counters negative and erroneous beliefs that are more prevalent among such groups (von Wagner, Good, Whitaker, & Wardle, 2011b).

A health communication intervention such as this fits with the National Health Service (NHS) national cancer strategy which aims to tackle inequalities in cancer outcomes (Department of Health, 2011). In particular, the strategy calls for 'improve[d] access to screening programmes for all groups' (page 8). A gist-based information leaflet tailored to groups with low health literacy may be one way to reduce inequalities in understanding of screening. At this point, it is important to note that the gist leaflet will not replace the existing booklet. While most people will not read all of the information provided in 'The Facts' booklet (von Wagner et al., 2009), the screening programme insists that it is given to all people who are invited to ensure that they are able to make an informed decision about participating (Ramirez & Forbes, 2012).

5.1.1 Design of the gist-based information booklet: A Fuzzy-Trace Approach

5.1.1.1 Background to Fuzzy-Trace Theory

Fuzzy-Trace Theory (FTT) is a theory of judgement and decision-making (Reyna & Brainerd, 1995; Reyna, 2004). It has recently been applied to the field of medicine and health (Reyna, 2008). It is a dual-processing theory which proposes that information is encoded into memory in two parallel forms: a gist representation and a verbatim representation. Gist representations are defined as vague, qualitative

[1] A version of this chapter has been published in Patient Education & Counseling (S. G. Smith et al., in press).

concepts capturing the bottom-line meaning of information. As such, they are subjective to the individual and affected by a range of different core values. In turn, these core values are influenced by factors such as emotional state, general world view, literacy and numerical ability. In contrast, verbatim representations are precise and quantitative and said to capture the surface form of the information (i.e. they are literal). For example, an individual reading 'The Facts' booklet would first read about the efficacy of Faecal Occult Blood (FOB) screening in reducing CRC deaths. A verbatim representation of this would be 'FOB screening reduces my chances of dying from bowel cancer by 16%'. In comparison, a gist representation might be, 'my chances of dying would be lower if I take part in FOB screening'.

Gist representations are formed along a continuum (analogous to scales of measurement), which range from the simplest to most complicated i.e. categorical, ordinal and interval (see example in Table 5-1). People exhibit a consistent preference to use the simplest form of gist available when making a judgment or decision (Reyna & Brainerd, 1991, 1995) particularly at older ages (Reyna, 2011). For example, in a sample of students and physicians making judgements on the cardiac risk of 9 hypothetical patients, better discriminatory decisions resulted from processing information in an 'all-or-none' fashion, as opposed to weighing up several details at once (Reyna & Lloyd, 2006).

Table 5-1 Example representations in Colorectal Cancer Screening context

Ordinal	'My risk of getting bowel cancer is high'
Ratio	'My risk of getting bowel cancer is higher than others'
Interval	'My risk of getting bowel cancer is 1 in 20'

Gist representations of information are only as good as the understanding of the material being processed (Pieterse, de Vries, Kunneman, Stiggelbout, & Feldman-Stewart, 2013). Indeed, studies have shown that decision-makers will tend to pay less attention to, and allocate less weight to concepts that they do not understand (Hsee, Loewenstein, Blount, & Bazerman, 1999). Therefore, poor comprehension of health information by those with low health literacy and/or numeracy suggests health communication materials should accommodate all skill levels. FTT argues that by presenting information in a format more closely aligned with preferred processing styles (i.e. gist), gist retrieval will be improved and the cognitive burden

placed on the reader will be reduced (Elwyn, Stiel, Durand, & Boivin, 2011).This will be particularly true for people with lower levels of health literacy and numeracy (Berkman, Sheridan, Donahue, Halpern, & Crotty, 2011; S. G. Smith, von Wagner et al., 2012; von Wagner et al., 2009).

This point is demonstrated in Table 5-2 which includes some example gist representations, values and corresponding decisions within the context of screening (Reyna, 2008). In the first column is the gist representation formed after reading health information such as 'The Facts' booklet. The core values of the individual are then consulted and amalgamated to form a decision about screening. The importance of knowledge is demonstrated by the different decisions formed in response to the final two gist representations in Table 5-2. Here, although the gist extracted from the information is identical, the knowledge that 'early is better' results in a different decision about screening. Ensuring adequate level of knowledge in the target population is therefore of paramount importance.

Table 5-2 Example gist, values and corresponding decisions in Colorectal Cancer Screening

Gist representation	**Core values / knowledge**	**Decision**
Feel okay or take a chance on not feeling okay*	Better to feel okay	Do not screen
My risk of CRC is high	Better to be low risk	Choose screening
The FOB test does not reduce my risk of CRC very much	Only worth doing if it makes a difference	Do not screen
Screening detects disease early*	Early is better	Choose screening
Screening detects disease early*	Not sure what early means	Do not choose screening

* = Source: Reyna (2008)

Ideally, gist-based information should be presented by itself without any literal information, so as not to overburden the reader (Reyna & Brainerd, 1991). However,

where it is not possible to completely remove verbatim information (e.g. a national screening programme), it is recommended that gist information is provided as a supplement rather than in the same block of text (Zikmund-Fisher, 2013).

5.1.1.2 Fuzzy-Trace Theory and health information

Most official health information is presented in a detailed and literal format (Agarwal et al., 2013; Cressey, 2012), despite the consistent preference for using the gist of information to make decisions (Reyna & Brainerd, 1991; Reyna & Lloyd, 2006; Reyna, 2011, 2012). There is a growing awareness of the tendency by policy makers to provide large amounts of information and choice to consumers in order to facilitate informed decision-making. However, this tendency can have the unintended effect of interfering with decision-making processes; a so called 'less-is-more' phenomenon (Hibbard & Peters, 2003; Peters, Klein, Kaufman, Meilleur, & Dixon, 2013; Reyna & Brainerd, 1991; Schwartz, 2011; Zikmund-Fisher, Fagerlin, & Ubel, 2010).

For example, in a series of hypothetical medical decision-making tasks, Peters and colleagues showed that participants who were presented only with essential information were better able to comprehend the data and made better decisions as a result (Peters, Dieckmann, Dixon, Hibbard, & Mertz, 2007). The 'less-is-more' effect was particularly strong when the information that was removed contained numerical details and for those with low levels of numeracy. FTT would argue that these results are because providing verbatim information adds a further step into the process of extracting a meaningful gist from health information (Reyna, 2008).

The reviews and studies cited above have implications for the design of health information (Elwyn et al., 2011). Firstly, they suggest that gist representations of the key information should be considered as the driving force behind judgements and decisions. Enhancing the gist so that it is more apparent may therefore increase the role that it plays in forming judgements. Secondly, the removal of verbatim information (e.g. numerical risks), may improve the ease with which the gist is extracted from information. This improvement may be particularly apparent for low literacy and numeracy groups, making FTT an interesting theoretical model on which to base an intervention aiming to tackle SES inequalities.

5.1.2 Information design process

5.1.2.1 Informed decision-making

It is important to recognise the policy context in which the gist leaflet will be based. There is on-going debate on the best approach to take when informing the public about screening (Entwistle et al., 2008). Until recently, a didactic approach to screening recommendations, known as the 'be screened' approach was taken. However, concerns have been raised that this approach overplays the benefits of screening and underestimates the risks (Gotzsche, Hartling, Nielsen, Brodersen, & Jorgensen, 2009; Jørgensen, Klahn, & Gøtzsche, 2007).

The emergence of the informed decision-making (IDM) literature has led to interest in respecting personal autonomy, with an emphasis on the individual being responsible for making an informed decision based on available facts. An informed decision occurs when 'an individual understands the disease/condition…and also comprehends what the clinical service involves, including its benefits, risks limitations alternatives and uncertainties; has considered his or her own preferences; believes he or she has participated in decision-making at a level that he or she desires; and makes a decision consistent with those preferences' (Rimer, Briss, Zeller, Chan, & Woolf, 2004).

The current policy for screening communications endorsed in the United Kingdom (UK) cancer strategy is to 'empower the greatest number possible…to make an informed choice to participate in cancer screening' (Department of Health, 2011). Although this appears a somewhat conflicted approach, I consulted guidelines from the General Medical Council to ensure the gist leaflet would be accommodated within this policy context (General Medical Council, 2008). To ensure that the process of informed decision-making would still be met for invitees to CRC screening, the gist leaflet was designed to supplement, rather than replace the existing booklet. While this is not the ideal situation according to FTT, it represents a compromise for using psychological theory within the constraints of an organised healthcare system. Recent communication guidance from the EU and England's National Health Service (NHS) informed decision-making initiative were referred to throughout (Austoker et al., 2012; Ramirez & Forbes, 2012).

5.1.2.2 Consultation of best practice guidelines

Best practice guidelines from the fields of information design, cognitive psychology and health literacy were used to complement a theory-based approach during the design phase (Abraham & Kools, 2011; DeWalt et al., 2010; McCaffery et al., 2012; Plain English Campaign, 2011). As will be discussed in the following sections, these guidelines provided empirical evidence on the layout, presentation, language, phrasing and design of the gist leaflet.

5.1.2.3 Consultation of Experts

Specialist screening practitioners. Prior to starting the design process, 11 Specialist Screening Practitioners (SSPs) were interviewed to discuss their views on the development of the gist leaflet. These interviews focussed on three key areas: i) what parts of 'The Facts' booklet they felt members of the public found difficult to understand ii) what information contained in 'The Facts' booklet they felt was essential to know prior to making a decision about CRC screening participation iii) how acceptable they found the idea of providing supplementary information to the public as part of their invitation and iv) whether they had any advice on ways in which to provide this information. The SSPs were not consulted after the design phase had begun.

Expert panel. A panel with expertise in health services research, epidemiology, public health, behavioural science, decision-making, communication and literacy formed this panel. It included my supervisors (Professor Jane Wardle, Dr Christian von Wagner), the principal investigator on the programme grant (Professor Rosalind Raine), health psychology researchers (Dr Lesley McGregor and Dr Gemma Vart) and the project manager (Ms Mary Thomas).

The panel met frequently throughout the design process. Meetings took place in person, via e-mail and in smaller groups where specific expertise was needed. The meetings involved me presenting feedback from participants (study 2) and highlighting areas of the gist leaflet that needed improving. Chaired by me, the panel's role was to use their specific area of expertise to make suggestions in response to public feedback. For example, I consulted the individuals with expertise in decision-making and health services research if it was uncertain whether changes

made to the gist leaflet met principles of informed decision-making. Where there was disagreement among the group on how to present information, or if aspects of the leaflet were questioned, I took responsibility for finding the empirical evidence to support the final decision. I also took responsibility for implementing the recommendations from the expert groups. Although feedback from the group was an important contribution to the final leaflet, I was responsible for the final version. No lay members were present on this expert panel; however they were consulted during the advisory group meeting and were recruited to be part of the evaluation stages reported in studies 2, 3 and 4.

Advisory group meeting. During the design phase, a version of the leaflet was presented at the ASCEND advisory group meeting. ASCEND is the title of the National Institute of Health Research (NIHR) programme grant in which this thesis is embedded. This meeting was a multidisciplinary group of experts and lay members of the public. This provided an opportunity to receive feedback during the design phase, and ensure that the leaflet would be acceptable to those administering it (i.e. the hub directors), as well as the target audience.

5.1.3 Factors considered in the design of the leaflet

The following is a description of the factors that were considered in the design of the gist leaflet. Versions of the leaflet can be found in studies 2, 3 and 4.

5.1.3.1 Numerical information

As discussed above, there is evidence to suggest that attempts to encourage further understanding of risk information through the provision of numbers may be misguided. The empirical evidence to support the provision of numerical information for improving medical decision-making is scarce. Furthermore, it is possible that the provision of excessive numerical information can 'hurt rather than help' this process (Hibbard & Peters, 2003; Peters et al., 2007, 2013; Reyna & Brainerd, 1991; Schwartz, 2011; Zikmund-Fisher et al., 2010). Specifically, in a CRC screening context it has been shown to increase the prevalence of negative attitudes about CRC screening (Miles, Rodrigues, & Sevdalis, in press). At the same time, it is important that information is not so oversimplified that it is no longer accurate or fails to enable people to make an informed decision about screening (Ramirez & Forbes, 2012). Concerns that simplifying health information might disadvantage certain

groups are alleviated by the finding that low literacy messages can improve knowledge even among more educated samples (S. W. Smith et al., 2013).

To overcome difficulties with processing numerical information, I attempted to encourage gist-based processing by providing a verbal description of the number which provides an evaluative label (i.e. gist) of the number (e.g. 'most people [98 out of 100]'). This approach has been used successfully in previous research (Berry & Hochhauser, 2006; Knapp, Gardner, Raynor, Woolf, & McMillan, 2010; Zikmund-Fisher, Fagerlin, Keeton, & Ubel, 2007). Broadly, findings indicate that comprehension of the information is improved, particularly for people with low numeracy (Peters et al., 2009). Furthermore, the same study suggested evaluative categories can increase deliberative processing of the numerical information. Numerical descriptors may also increase perceptions of risk, and as a result be more effective at altering behaviour than numerical information is isolation (Zikmund-Fisher et al., 2007). In line with current evidence, natural frequencies with the same denominator were used to present key numerical information (Galesic & Garcia-Retamero, 2010).

5.1.3.2 Reduction of concepts

In keeping with the 'less-is-more' approach, the leaflet was designed to encourage gist-based processing by removing specific concepts which were deemed ambiguous in the think-aloud study (Chapter 4). This resulted in four pages of text being used for the gist leaflet, compared with 15 pages in 'The Facts' booklet. An example of information that was streamlined was the role of FOB screening in preventing CRC (by removing polyps detected at follow-up colonoscopy). This was justified because of the unconvincing evidence that FOB-based screening reduces CRC incidence (Scholefield et al., 2012). The leaflet therefore focused on the primary mechanism by which FOB screening works; the early detection of colorectal adenomas. A further example of streamlining was the removal of academic references from within the text to accommodate the preferences of people with low health literacy (S. K. Smith et al., 2008).

After consultation with the expert panel, a decision was reached to remove any mention of 'unclear' results. This decision was made as it was considered confusing to the reader in the think-aloud study, without any additional benefit by its inclusion.

Its removal also fits with providing information in the most simple gist format (i.e. nominal), without overlapping categories (Reyna, 2008).

5.1.3.3 Navigation

Guidelines on the layout of health information designed for groups with low health literacy suggest providing essential information at the beginning of the text (McCaffery et al., 2012). This has been shown to improve comprehension and decision-making (Peters et al., 2007). To identify what was considered to be essential information, I searched the relevant literature to identify aspects of screening that are considered essential to make an informed decision (General Medical Council, 2008; S. K. Smith, et al., 2012). Interviews with the SSPs were also important to this process.

Information that was deemed essential to making a screening decision was presented on the front page. This included: i) the prevalence of the cancer; ii) how the test works iii) the efficacy of the test and iv) who is invited. To avoid the front page becoming too dense with information, additional essential information that could not be explained succinctly (i.e. in a single sentence) was contained in subsequent pages. This information included: i) the disadvantages of screening; ii) the possible outcomes iii) practical aspects of screening and iv) where more information can be found.

After providing the essential information on page 1, we aimed to improve the navigability of the information by providing 'sign-posting' to direct the reader to the location in the leaflet where more detailed information could be found (i.e. pages 2 and 3) (Dickinson, Raynor, & Duman, 2001). Page 4 was devoted to 'sign-post' other information sources (i.e. Bowel Cancer Screening: The Facts). As such, the booklet was designed to be a cascade of information formats ranging from the simplest gist-based information through to more detailed information for those that wanted it.

5.1.3.4 Language

Health literacy, EU and NHS guidelines suggest vernacular rather than formal language should be used where possible in cancer communication materials (Austoker et al., 2012; DeWalt et al., 2010; Plain English Campaign, 2011; Ramirez

& Forbes, 2012) (see Table 5-3 for examples that were implemented here). The use of words with multiple definitions (e.g. spot) may be confusing for the reader. However, this was accounted for by testing the comprehensibility of the leaflet (study 2). These guidelines also recommend that information should be written in short sentences and bullet point lists. Evidence from cognitive psychology suggests this reduces the cognitive burden of information by enabling participants to 'chunk' information and retain more in short-term memory (Wilson et al., 2010; Wolf et al., 2009). This is particularly important for people with poor basic skills due to the strong association between health literacy and cognitive ability (Wolf et al., 2012). Importantly, reducing the cognitive burden of information can increase subsequent recall and this is apparent for all health literacy groups (Freed et al., 2013).

Table 5-3 Comparison between formal and vernacular language

Word used in 'The Facts'	**Vernacular equivalent**
Colorectal	Bowel
Detect	Spot
Faeces/waste matter/stool/bowel motions	Poo
Colonoscopy	Further testing
Reduces	Lowers

5.1.3.5 Aesthetic appeal

The EU guidelines suggest that information materials should be appealing to the recipient (Austoker et al., 2012). The aim of this is to encourage engagement and processing of the information, and reduce immediate defensive reactions such as avoidance. In response to the guidelines, a blue background was used because experimental evidence has demonstrated that it invokes a lower disgust response (Curtis, Aunger, & Rabie, 2004), a frequently cited barrier to CRC and CRC screening participation (Chapple et al., 2008; Dolan et al., 2004; Reynolds et al., 2013; von Wagner et al., 2012).

Conclusion

In conclusion, this project is among the first to use empirical evidence behind FTT to create new health information. Mindful of the constraints of the National Health

Service Bowel Cancer Screening Programme (NHS BCSP) and the movement towards informed decision-making in healthcare, I demonstrated how gist-based information could be operationalised within the constraints of an organised healthcare system. This approach was deemed feasible by a multidisciplinary group of experts, including SSPs working in the programme and hub directors. The process was iterative and included multiple face-to-face meetings, e-mail contact and telephone calls with collaborators.

At all stages of the process, the latest empirical evidence from the fields of information design, cognitive psychology and health literacy were incorporated to create the gist leaflet. The information was largely based on 'The Facts' booklet, and did not provide any additional information beyond this. However, only essential information was used and presented to accommodate preference for gist-based processing. Care was taken to ensure that the leaflet met principles of IDM.

A strength of the design process was the involvement of academics and clinicians from a wide range of disciplines. Lay involvement was provided by two members of the public who were present at the advisory group meeting and they were named as collaborators on the NIHR Programme grant in which the project is based. Although this process used appropriate guidelines, the judgments regarding the design and content were largely made by me and the research team. To address this limitation, the leaflet must be evaluated to ensure it is readable, comprehensible and effective at communicating its message (Garner et al., 2012).

Chapter 6. Evaluating the readability and comprehensibility of a gist-based colorectal cancer screening information leaflet (Study 2)[1]

6.1 Introduction

The design of health communications interventions has often been atheoretical; relying on the use of readability statistics to indicate the quality of health information. In particular, interventions targeting groups with low health literacy have tended to shorten and remove words, with the assumption that the improved 'readability' will lead to greater comprehension and effectiveness of the intervention as a whole (Wolf et al., 2009). Attempts such as these have often been met with failure (Davis et al., 1998). Garner and colleagues argued that this is because they fail to utilise evaluative techniques beyond simple readability statistics (Garner et al., 2012).

The previous chapter discussed the design stages that were undertaken to develop a supplementary gist-based information leaflet for use in the National Health Service Bowel Cancer Screening Programme (NHS BCSP). Fuzzy Trace Theory (FTT), complemented by best practice guidelines, were used during this process. The following chapter will be based on the first two of three evaluative stages for patient information leaflets.

6.1.1 Stage 1: Readability

Readability has generally been assessed with the use of readily available readability calculators such as the Flesch Reading Ease score (Flesch, 1948), the Gunning-Fog Index (Laubach & Koschnick, 1977) and the Simple Measure of Gobbledygook (SMOG; McLaughlin, 1969). The formulae differ slightly, but there is a high degree of correlation between them and no one formula is better than another (Ley & Florio, 1996). While these measures perform a useful role in providing a rough guide to how readable a text is, they do not assess the texts comprehensibility. To use an example from Knapp and colleagues, the phrase 'injection by given be will medicine the' will achieve the same readability score as 'the medicine will be given by injection', despite the latter being obviously more comprehensible (Knapp, Raynor,

[1] A version of this chapter has been published in Patient Education & Counseling (S. G. Smith et al., in press) (see appendix I).

Silcock, & Parkinson, 2009). Readability statistics should therefore be used as an early guide in the evaluation of any health information material, but a high readability score should not be assumed to translate to a well-designed piece of health information.

6.1.2 Stage 2: Comprehensibility

After achieving a sufficient level of readability, it is important that the text is comprehensible to the reader. Garner and colleagues refrain from providing explicit guidance as to the type of methodology that could be used to assess comprehensibility. However, they provide an example similar to performance-based approaches described by Knapp and colleagues in various scenarios (Knapp et al., 2009; Knapp, Raynor, Silcock, & Parkinson, 2011; Raynor, Knapp, Silcock, Parkinson, & Feeney, 2011).

This method involves small cohorts of participants (n~10) reading through the information material to be tested in a one-to-one interview. After an initial familiarisation with the materials, participants are asked a series of questions based on the information they have just read. A brief semi-structured interview is also conducted, allowing participants to express any difficulties or problems that they perceive with the information. After testing the first cohort, the number of correct responses is summed and compared against a pre-defined threshold (usually 80% of participants have to find the information and answer correctly) (European Commission, 2006). If this threshold is not met, or if issues are raised in the interview, amendments are made and a new cohort of participants repeats the procedure.

While this is just one method of assessing comprehension, it is a potentially useful way of testing the effectiveness of health communication in a systematic manner. It also has the benefit of testing the information, as opposed to the participants themselves, thus reducing burden if they are unable to answer a question correctly.

6.1.3 Aims of current study

This study aimed to evaluate the readability and comprehensibility of the information leaflet with a user-testing method in a socially disadvantaged group. This stage of

evaluation was therefore targeting stages 1 and 2 of the framework outlined by Garner and colleagues (Garner et al., 2012).

6.2 Method

6.2.1 Participants

Twenty-eight participants were recruited via telephone, mail and face-to-face contact. As with the think-aloud study (Chapter 4), Social Action for Health (SAfH) and ContinYou were used to purposively sample from disadvantaged areas. Recruitment sites were specifically chosen in order to target and include the perspective of participants with low levels of basic skills. People meeting age criteria (age 45-59 year [i.e. before the age at which CRC screening is offered in England]) were approached to participate.

The recruitment difficulties noted in the previous study suggested that a different approach was needed. I therefore recruited a local business at the ContinYou site that was willing to provide a small number of age-appropriate administrative and factory-based employees for this purpose. I also attended a number of job seekers interviews in Coventry to recruit participants. Written consent during both recruitment strategies was taken in person at the time of the study interview.

Although both approaches assisted with recruitment, the majority of participants were provided by the SAfH site, particularly in the later rounds. They used a similar approach to recruitment that was discussed in study 1. However, they also supplemented this strategy by recruiting participants taking part in a locally run diabetes self-management class. Individuals meeting age criteria were approached by telephone and a list of contact details was provided to me by SAfH staff. I provided further information about the study and arranged a mutually convenient time to conduct the interview. Unfortunately, recruitment quotas in the early rounds were not met and the Health Behaviour Research Centre (HBRC) research panel was invited to participate by mail.

People were excluded if they were not being able to speak or read English, they had previous personal experience with colorectal cancer (CRC) or CRC screening, or had severe cognitive impairment. Exclusion criteria were assessed on first contact with the individual. Participants were paid £20 for their time and travel expenses.

The study was approved by the University College London research ethics committee (Reference: 2247/002).

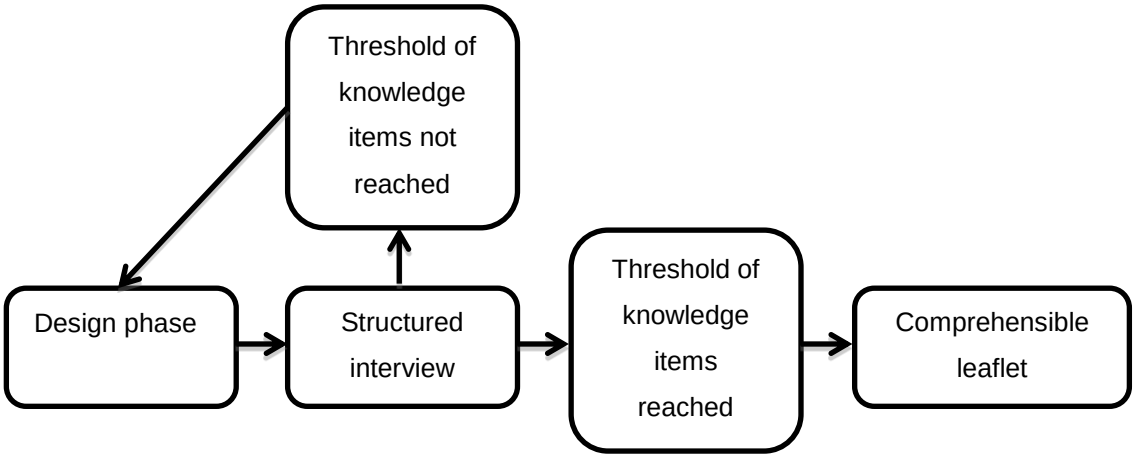
6.2.2 User-testing design and procedure

A mixed-methods, user-testing approach was used to assess the comprehensibility of the information leaflet (Knapp et al., 2009; Knapp et al., 2011; Raynor et al., 2011). In rounds of approximately 8-10 people, participants were asked to complete a brief socio-demographic questionnaire on arrival, followed by a health literacy assessment. They read through the gist-based leaflet for as long as they wanted, and completed a researcher-led comprehension test. The participant had access to the gist-based leaflet at all times. This was followed by a brief semi-structured interview (see Figure 6-1 for an overview of the topic guide). Following feedback from the comprehension test and the semi-structured interviews, the content and design of the gist leaflet was changed. Re-testing of the leaflet assessed the impact of revisions on a new set of participants, and was repeated in a continuous feedback loop until the threshold of knowledge items was reached (shown in Figure 6-2). For a copy of the study documents, please see appendix J-O.

Figure 6-1 Qualitative interview topic guide

Overall impressions of the leaflet
Use of language
Order of information
Use of headings
Use of the word ‘poo’ within a health context
Missing information
Size of the print
Ways to simplify the information
Any other changes that they would like to see

Figure 6-2 Procedure for user-testing a comprehensible leaflet



6.2.3 Outcome

The primary outcome was the percentage of participants correctly responding to eight true (T) or false (F) statements about CRC and CRC screening. In line with EU guidelines for medicinal package testing (European Commission, 2006), each statement had to be answered correctly by at least 80% of participants for our leaflet to be deemed legible, clear, and easy to read. The statements were based on the prevalence of CRC (1 statement), the practicalities of the program (4 statements), the benefits (i.e. risk reduction; 1 statement), and the risks of screening (i.e. false-positives and false-negatives; 2 statements). Measurement of these factors is in keeping with previous research that has assessed CRC screening knowledge (S. K. Smith et al., 2010) and the UK General Medical Council guidelines (General Medical Council, 2008). The phrasing and response options mirrored the gist-based style of the leaflet (Tait, Zikmund-Fisher, Fagerlin, & Voepel-Lewis, 2010a; Tait, Voepel-Lewis, Zikmund-Fisher, & Fagerlin, 2010b).

6.2.4 Data analysis

The Flesch-Kincaid formula (Kincaid, Fishburne, Rogers, & Chissom, 1975) was used to calculate the reading ease of the gist-based leaflet. Scores can range from 0-100, with higher scores indicating greater reading ease.

We calculated the total number of participants who answered each statement correctly (statement totals) as well as the mean number of statements correctly answered per participant (individual totals).

Data from the semi-structured interviews were digitally recorded, transcribed verbatim, and analysed using thematic analysis, which is a qualitative technique for identifying patterns (themes) within data (Braun & Clarke, 2006). Data analysis was performed after each round of interviews to pin-point the particular areas of the gist-based leaflet that caused difficulties with comprehension. Due to the time taken to perform the user-testing procedure and health literacy test, the interviews were short. Comments were therefore brief and could not be analysed past surface-level meaning.

I first analysed the interviews of participants who answered at least one comprehension item incorrectly, as they were most likely to have suggestions for improvements. Themes were extracted from these individual interviews and analysed using the constant comparison method (Strauss, 1987). After a list of potential changes was created, the final interviews were analysed to identify any remaining issues with the leaflet. The list of suggested changes was discussed among the wider study group. I was responsible for providing empirical evidence and guidelines during these meetings that would facilitate these changes being made. The experts were responsible for suggesting alternative actions in response to participant comments.

6.3 Results

6.3.1 Participant characteristics

The majority of participants were female (75%), employed (54%), white (54%), had a GCSE level of education or below (57%), adequately literate (82%), without a partner (68%), spoke English as a first language (75%), and had either received a cancer diagnosis themselves (11%) or knew someone that had (82%). As shown in Table 6-1, the majority had used written documents in their current of previous employment at least some of the time (75%). As rounds progressed, a greater proportion of participants had a lower level of education, marginal or inadequate health literacy scores, spoke English as a second language, or were from a minority ethnic group.

6.3.2 Round 1

6.3.2.1 Round 1- Quantitative findings

The version tested in this round can be found in Figure 6-3. The readability score of this version was 82.1, which corresponds to a reading age of approximately 9-10 years.

As demonstrated in Table 6-2, the majority of the statements were answered correctly by at least 80% of participants. However, two statements ('The FOB test is done at home' [T] and 'People with an abnormal result always have cancer' [F]), were answered correctly by less than 80% of participants. At an individual-level, participants were able to answer a mean of 7.2 out of 8 statements correctly (range = 5-8).

Table 6-1 Participant characteristics

	Round 1 (n = 6)	**Round 2 (n = 11)**	**Round 3 (n = 11)**	**Total (n = 28)**
Gender				
Male	2 (33)	4 (36)	1 (9)	7 (25)
Female	4 (67)	7 (64)	10 (91)	21 (75)
Marital status				
Married / living with partner	1 (17)	5 (45)	3 (27)	9 (32)
Single / Divorced / Separated	5 (83)	5 (45)	7 (64)	17 (61)
Widowed	0 (0)	1 (9)	1 (9)	2 (7)
English as first language				
Yes	6 (100)	7 (64)	8 (73)	21 (75)
No	0 (0)	4 (36)	3 (27)	7 (25)
Employment				
Currently employed	2 (33)	7 (64)	6 (55)	15 (54)
Unemployed / Disabled or too ill to work	3 (50)	4 (36)	5 (45)	12 (43)
Retired	1 (17)	0 (0)	0 (0)	1 (4)
Education				

	Round 1 (n = 6)	Round 2 (n = 11)	Round 3 (n = 11)	Total (n = 28)
≤ Basic high school qualifications	5 (83)	4 (36)	7 (64)	16 (57)
Advanced high school qualifications or equivalent	0 (0)	4 (36)	1 (9)	5 (18)
University educated	1 (17)	3 (27)	3 (27)	7 (25)
Health literacy[+]				
Adequate	6 (100)	9 (82)	8 (73)	23 (82)
Marginal/Inadequate	0 (0)	1 (9)	3 (27)	4 (14)
Ethnicity				
White	6 (100)	4 (36)	5 (45)	15 (54)
Non-White	0 (0)	7 (64)	6 (55)	13 (46)
Use of written documents				
All or most of the time	1 (17)	7 (64)	3 (27)	11 (39)
Some of the time	3 (50)	2 (18)	5 (45)	10 (36)
Hardly ever	2 (33)	2 (18)	3 (27)	7 (25)
Previous cancer diagnosis				
Yes	1 (17)	0 (0)	2 (18)	3 (11)
No	5 (83)	11 (100)	9 (82)	25 (89)
Know at least one person diagnosed with cancer				
Yes	5 (83)	8 (73)	10 (91)	23 (82)
No	1 (17)	3 (27)	1 (9)	5 (18)

[+] One participant refused to complete the TOFHLA health literacy assessment in round 2. % is reported for the total number of participants in this round. The total % also includes this individual.

6.3.2.2 Round 1: Changes to the leaflet

In response to the threshold not being met for the statement that 'the FOB test is done at home', we changed the word 'post' to 'home' in the following sentence to clarify where the test was completed: 'A FOB test kit with instructions is sent through to the home'.

More than 20% of participants did not correctly answer the statement that an abnormal test result does not necessarily mean cancer has been found. One participant commented:

> 'I do wonder about the fact that if you have an abnormal test that it doesn't necessarily indicate that you've got cancer. That's inferred but it doesn't necessarily say that' (AL, 55 years, female, degree level education).

To improve comprehension of the meaning of an abnormal result, we added the following sentence: 'An abnormal result does not always mean cancer has been found'.

The interviews demonstrated that the language used was easy to understand for the audience:

> 'It's quite well set out, and it's readable and gives you basically all the information' (WG, 58 years, female, no formal qualifications).

However, further changes were identified by participants that could make it more accommodating for groups with low health literacy:

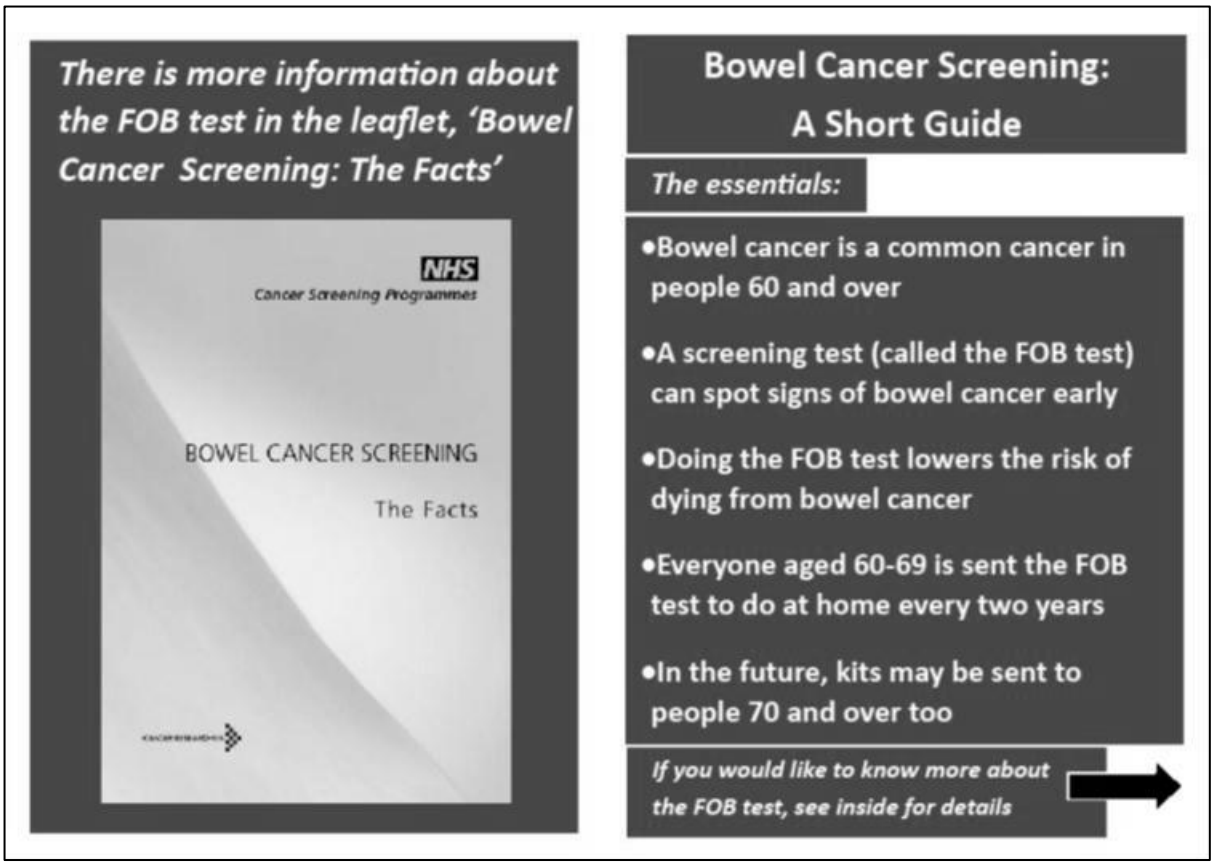
> 'There were a couple of words in it that I thought might need thinking about…'discuss', I wonder whether 'talk about' would be more appropriate?' (AL, 55 years, female, degree level education)

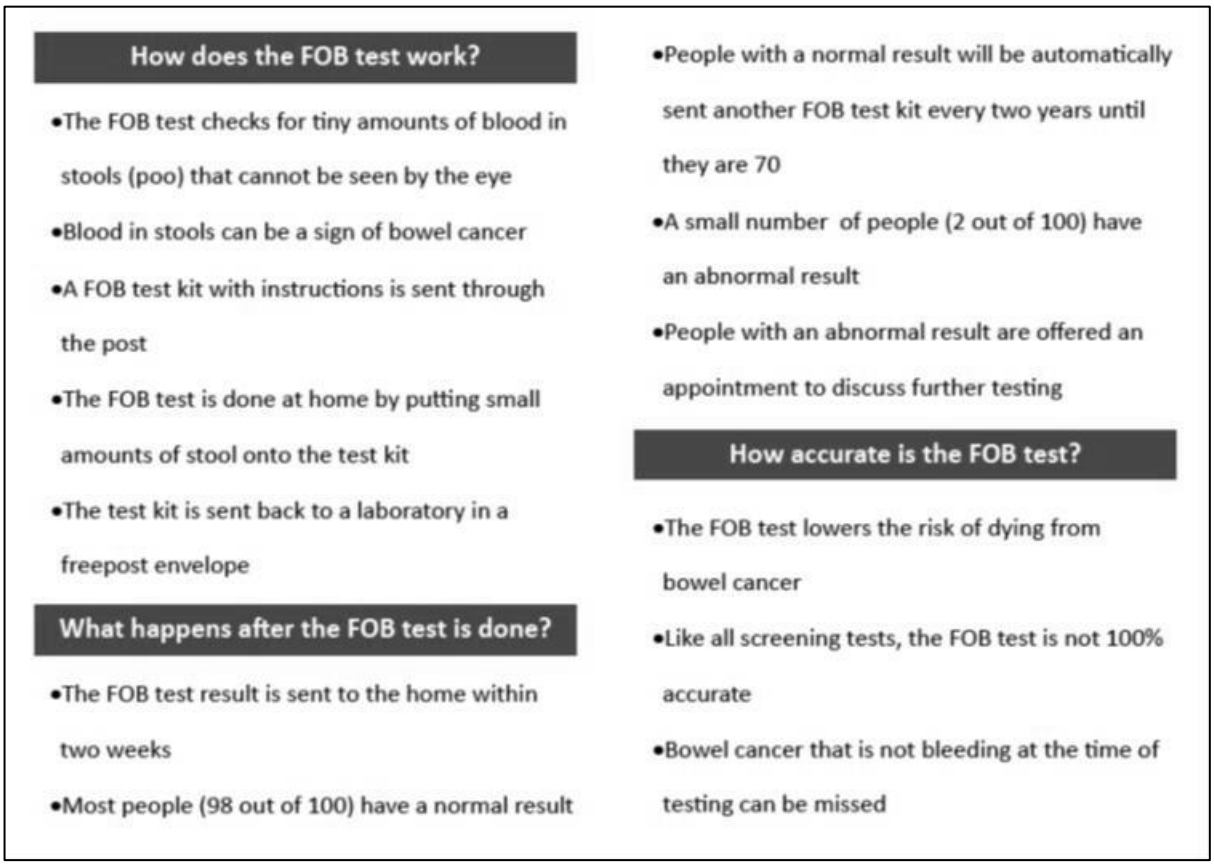
Several design changes recommended by the expert panel were undertaken prior to the second round of testing. These included: reducing the amount of dark blue space that was used within the leaflet; reducing the spaces within lines in paragraphs; expanding the spaces between paragraphs; and extending the space between bullet points and the start of sentences. These recommendations were made to improve the readability of the leaflet and make it more aesthetically appealing.

Table 6-2 Participant responses in rounds 1, 2 and 3

	Round		
	1	**2**	**3**
	Correct n (%)	**Correct n (%)**	**Correct n (%)**
1. Doing the FOB test lowers the risk of dying from bowel cancer [T]	6 (100)	11 (100)	11 (100)
2. The FOB test is done at home [T]	4 (67)	10 (91)	9 (82)
3. Most people who do the FOB test will receive an abnormal result [F]	5 (83)	9 (82)	9 (82)
4. Only women are sent a FOB test [F]	6 (100)	11 (100)	11 (100)
5. Bowel cancer is a common cancer in people over 60 [T]	6 (100)	10 (91)	10 (91)
6. People only need to do the FOB test once in their life [F]	6 (100)	10 (91)	11 (100)
7. The FOB test can miss bowel cancer [T]	6 (100)	9 (82)	9 (82)
8. People with an abnormal result always have cancer [F]	4 (67)	8 (73)	9 (82)

Figure 6-3 Version of the gist-based leaflet tested in round 1





6.3.3 Round 2

6.3.3.1 Round 2 - Quantitative findings

The version tested in this round can be found in Figure 6-4. The readability score for this version was not substantially different to the previous version (79.4).

As demonstrated in Table 6-2, nearly all statements were answered correctly by at least 80% of the participants. However, the statement on the meaning of an abnormal result remained problematic (8. 'People with an abnormal result always have cancer' [F]). At a participant level, a mean of 7.1 out of 8 statements were answered correctly (range = 4-8).

6.3.3.2 Round 2 – Changes to the leaflet

No explicit comments were made relating to the question that was not answered satisfactorily. However general changes that may improve comprehension and recall were made. These included changes to the layout of the leaflet that were made in response to difficulties with remembering all of the information they have just read:

> 'I think it's ok, but it's remembering what you read. If you read something and don't remember, it doesn't do you any benefit does it?' (DW, 52 years, female, no formal qualifications)

Changes included placing boxes around text that related to each sub-heading, reducing the number of bullet points on the final page, changing the colour of the background and increasing the size of the font on the front page to increase the readability of the text for readers with eyesight difficulties. Changes were also apparent on the final page which assisted participants when searching for the correct answer to the statement that did not meet the threshold:

> 'It's very clear. Maybe I would say, it could be done in more bigger letters, you know if somebody's old or something' (SF, 51 years, female, no formal qualifications)

The text relating to this statement was altered: ‘For most people, the follow-up test will show there is no bowel cancer’ in an attempt to improve comprehension.

Participants reported being confused about the age of eligibility for screening. To reduce this confusion, sentences discussing the age extension were removed:

> ‘That’s all clear and it’s explained further, all very simple. But this I couldn’t get [age extension]. That’s like a random statement. It’s not really backed up or [explained] why’ (VY, 45 years, male, advanced high school qualifications)

Participants also wanted reassurance that the test was simple, as some felt that it might be complicated and that people may be less likely to participate as a result. This resulted in changes to the text concerning the age that people are invited to screening, as well as an additional sentence highlighting ‘The FOB test is easy to do’.

The title of the booklet (‘A two minute guide’) was changed as this may have been perceived as intimidating by less literate and slower readers:

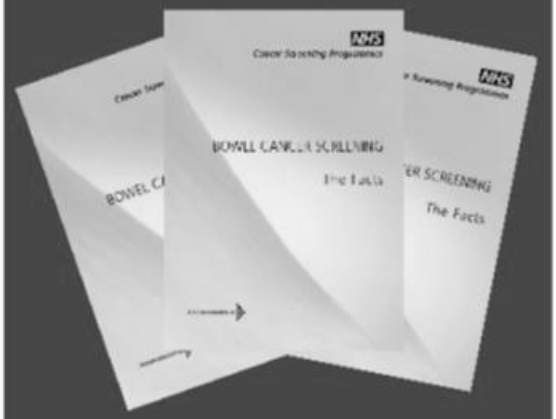
> ‘This is meant to be a two minute guide. Well people read at their own pace and you know they might think well, oh. A simple guide? Or is that being patronising…or the essentials?’ (FV, 55 years, female, degree level education).

The full title of the Faecal Occult Blood test was added in response to several participants questioning the phrase, FOB test:

> ‘I think the only thing is, FOB, what does that stand for?’ (WF, 58 years, male, no formal qualifications).

Figure 6-4 Version of the gist-based leaflet tested in round 2

For more information see the enclosed leaflet: *'Bowel Cancer Screening: The Facts'*



The NHS Bowel Cancer Screening Programme: A Two Minute Guide

The essentials:

- Bowel cancer is a common cancer in people aged 60 and over
- A screening test (called the FOB test) can spot signs of bowel cancer early
- Bowel cancer screening is meant for men and women, even if they do not have symptoms or bowel problems
- Doing the FOB test has been proven to lower the risk of dying from bowel cancer
- Everyone aged 60-69 is sent the FOB test to do at home every 2 years
- The screening programme is starting to send kits to people aged 70-74

If you would like to know more about the FOB test, see inside for details

How does the FOB test work?

- The FOB test checks for tiny amounts of blood in stools (poo) that cannot be seen by the eye
- Blood in stools can be a sign of bowel cancer
- A FOB test kit with instructions is sent through to the home
- The FOB test is done at home by putting small amounts of stool onto the test kit
- The test kit is sent back to a laboratory in a freepost envelope

What happens after the FOB test is done?

- The FOB test result is sent to the home within two weeks
- Most people (98 out of 100) have a normal result
- People with a normal result will automatically be sent another FOB test kit every two years until they are 70
- A small number of people (2 out of 100) have an abnormal result
- An abnormal result does not always mean cancer has been found
- People with an abnormal result are offered an appointment with a specialist to talk about further testing

How accurate is the FOB test?

- The FOB test lowers the risk of dying from bowel cancer
- Like all screening tests, the FOB test is not 100% accurate
- Bowel cancer that is not bleeding at the time of testing can be missed

To find out where you can get more information, see the back page

The decision was also made to move the narrative of the gist leaflet from third person to second person. This was done to enhance the sense that the invitation was personal to the recipient, as well as to improve the readability of the leaflet. This change was made after informally consulting members of the public and the expert panel.

Design changes made prior to the final round included: adding 'softer' boxes to the leaflet (i.e. text boxes with round edges were added); changing the colour of the 'sign-posting' arrow from green to blue; removing italicised text; and changing the colour to a lighter blue. These changes enhanced the aesthetic appeal of the gist leaflet. The additional space provided by the design changes allowed the text on the back page of the gist leaflet to be moved onto the third page. This was done to increase awareness of 'The Facts' booklet.

6.3.4 Round 3

6.3.4.1 Round 3 - Quantitative findings

The version tested in this round can be found in Figure 6-5. The readability score for this version was also not substantially different from the previous two rounds (81).

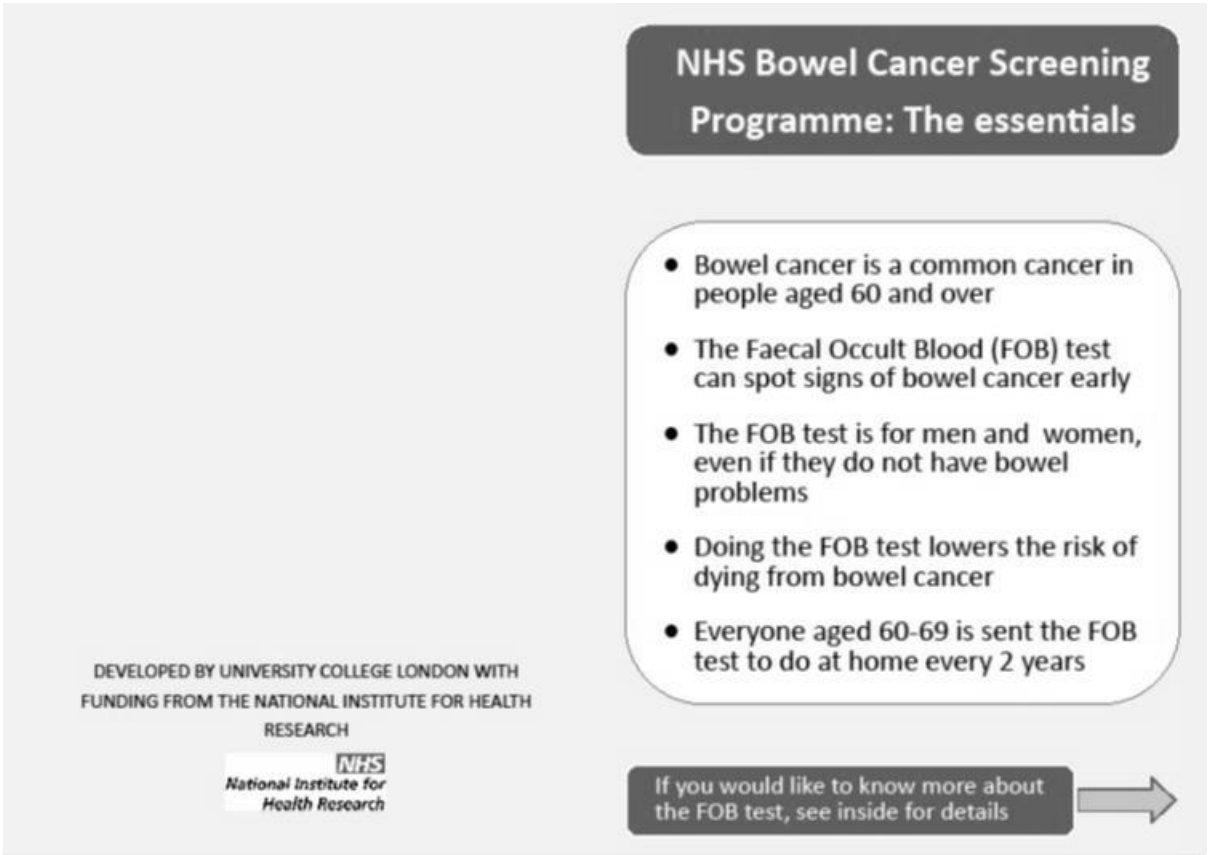
As demonstrated in Table 6-2, all statements were answered correctly at least 80% of the time. The pre-defined threshold was therefore met and the leaflet was considered 'fit-for purpose'. At a participant level, individuals were able to answer a mean of 7.2 out of 8 statements correctly (range = 6-8).

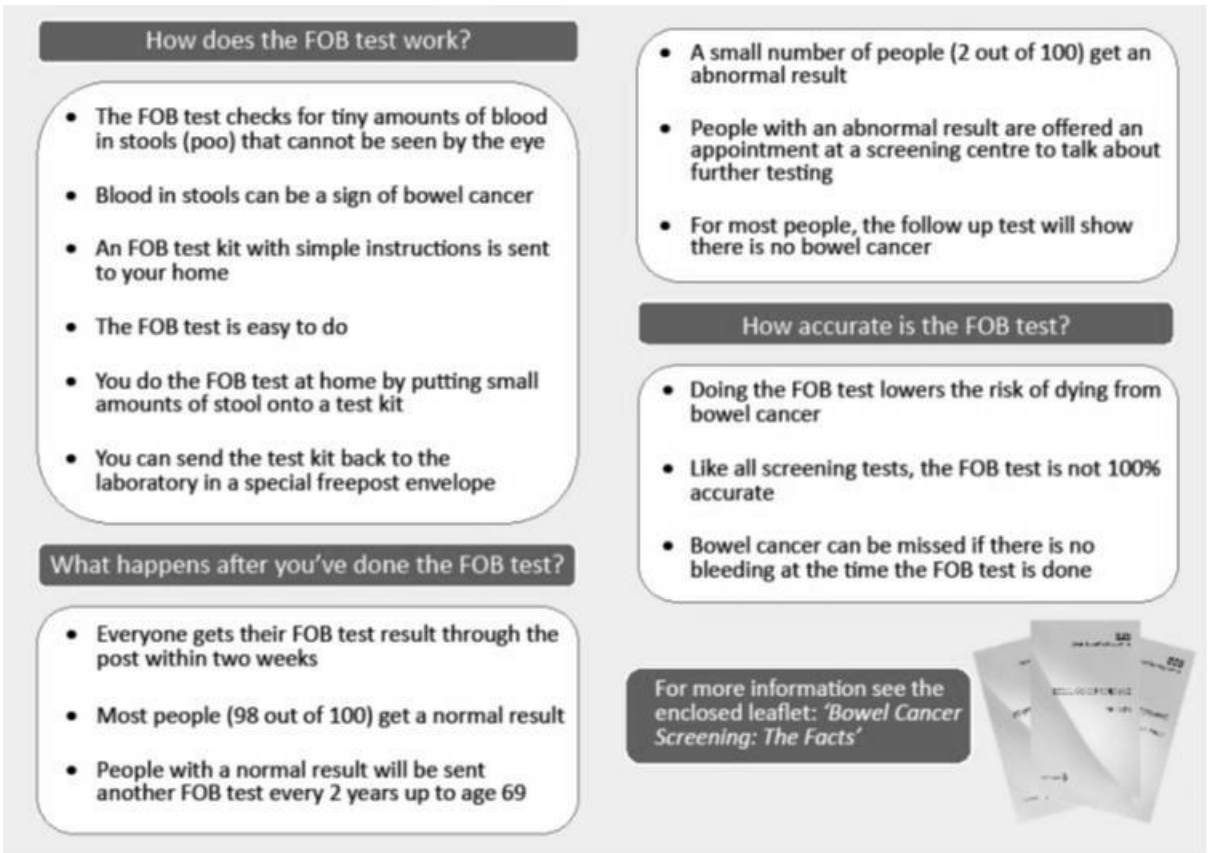
6.4 Discussion

6.4.1 Study findings

The objectives of this study were to design and user-test a 'gist-based' CRC screening information leaflet, which promotes comprehension of the screening offer. Principles of Fuzzy-Trace Theory complemented by best practice guidelines from the fields of information design, cognitive psychology and health literacy were used to design a gist-based information leaflet to provide accessible information about the aims, benefits and disadvantages of the English CRC screening programme.

Figure 6-5 Version of the gist-based leaflet tested in round 3





Readability scores indicated that the leaflet was suitable for people with low health literacy (e.g. reading age: 9-10 years), and may therefore increase the accessibility of the program to disadvantaged groups. The leaflet therefore met the first stage of the Garner framework for evaluating patient information leaflets (i.e. readability) (Garner et al., 2012).

The user-testing method employed to evaluate the second stage of the framework (i.e. comprehensibility) demonstrated that the leaflet was generally well comprehended in all rounds. Changes were made to several aspects of the leaflet in response to both the qualitative and quantitative data. In round 1, two statements did not meet the comprehension threshold. These related to where screening takes place and the meaning of an abnormal result. This finding was supported by qualitative data, which also highlighted additional text that could be simplified. Changes were made to the content of the leaflet and an additional round of testing was performed.

In round 2, responses to the abnormal result item were still not adequate. In this round, qualitative comments focused on the design and layout of the text. Changes made to the final version of the gist leaflet encouraged readers to 'chunk' information and made differences between sections more concrete. This reduced the cognitive load of the text, which may be a barrier to information processing among disadvantaged groups (Wilson et al., 2010; Wolf et al., 2009). In the third round of testing, the pre-defined threshold was met and the leaflet was considered to have met the comprehensibility stage of the Garner framework.

6.4.2 Strengths and limitations

This study was among the first to evaluate the comprehensibility of a health communication intervention designed using principles of FTT. The theory has been widely discussed in the literature over the last two decades (Reyna & Brainerd, 1995; Reyna, 2008), however there have been few reports of public health interventions that have tested its hypotheses. While this leaflet had to supplement existing information materials and not act as an independent decision aid, it was reassuring that it met International Patient Decision Aid Standards criteria for the design of decision aids for groups with low health literacy. These criteria are that the leaflet is easily understandable by the target group and should have a readability of a grade 8 or equivalent (McCaffery et al., 2012). The process of informed decision-

making is therefore unlikely to be compromised for individuals that prefer to read the gist leaflet only.

To my knowledge this is also the first study to incorporate a performance-based approach when evaluating a cancer communication intervention. Although others have taken similar approaches of adapting information so that it is 'culturally appropriate' in response to participant feedback, this has been performed in an unstructured manner (Cooperman, Efuni, Villagra, Duhamel, & Jandorf, 2013). The use of public feedback during the intervention design phase is becoming more common, and the findings of this study add support for this trend (Dowswell et al., 2012).

Although participants were less literate or educated than national estimates, the study would have benefited from the inclusion of more participants lacking these basic skills (European Commission, 2012; von Wagner et al., 2007). In addition, the use of the department research panel, which accounted for approximately 25% of participants, may have led to the sample being more invested in their wellbeing than the general population. An implication of these limitations is that the gist leaflet may not have addressed the concerns of those most in need of gist-based CRC screening information. The number of correct responses to the comprehension questions may have been lower if a sample with lower levels of health literacy had participated. This would have resulted in more rounds of testing and more changes being made to its current design. Further evaluation is clearly warranted before the leaflet can tested in a national sample.

Although difficult to achieve, the inclusion of low socioeconomic status (SES) groups within the initial stages of intervention design is recommended (Yancey et al., 2006). It also comes with rewards, as the inclusion of lower SES groups in the development stages can help to mitigate inequalities (Brown et al., 2012). Despite this, the majority of communication interventions fail to report on how they involved the target populations in their development. For example, a systematic review of print and multimedia health communication interventions observed that only 40% meet stage 1 of the Garner framework (readability) and only 17% report involving the public in the development of the intervention (Wilson et al., 2012). Although I attempted to address this weakness in the literature, different methodologies may be needed if the perspective of low literacy groups is to be fully ascertained.

Small sample sizes are the norm in user-testing studies, but chance variation between individuals means that the results may be less generalizable to the wider population. Although the methodology allows us to observe levels of comprehension, it does not consider the wider determinants of screening behaviour (von Wagner et al., 2011b). In addition, because of the length of the user-testing task and health literacy assessments, we did not ask respondents to elaborate on their open-ended statements. As such, the data were often brief utterances rather than in-depth comments.

A final limitation was that participants may have been less likely to disclose issues of miscomprehension or criticise the design of the leaflet while in the presence of a researcher involved in the project. Although every effort was made to place participants at ease in this setting, they may have felt under pressure to endorse the design and content of the leaflet. This may have resulted in fewer design changes than would have been undertaken had participants been more forthcoming with criticisms.

6.4.3 Future research

A larger study that is performed with respondents from deprived backgrounds is needed to ensure that the gist leaflet is meeting the communicative needs of all groups. Previous studies have achieved high recruitment rates from General Practices (Robb, Campbell, Evans, Miles, & Wardle, 2008; Wardle et al., 2003). Purposive sampling from practices in deprived areas may therefore help to recruit a more representative sample. This method has the added benefit of allowing the efficiency of recruitment to be monitored empirically.

In order to assess the next stage of the Garner framework (communicative effectiveness), future work should collect quantitative data on outcomes known to be associated with CRC screening behaviour. The comprehensibility of the intervention should also be confirmed on a larger sample, to reduce bias inherent in small scale studies. A study design which enables conclusions to be drawn about the additive effect of the gist leaflet should be used, as the gist leaflet has been designed to supplement rather than replace the existing materials.

6.4.4 Conclusion

In conclusion, I have shown that it is possible to use FTT as a guiding framework to design gist-based CRC screening information that is comprehensible to all health literacy groups. Best practice guidelines were useful supplements to this theory-driven process and they provided explicit guidance on how to address comprehension difficulties specific to groups with low health literacy. Further testing of the leaflet is now required to assess whether the gist leaflet is successful at affecting screening uptake.

Chapter 7. Evaluating the comprehensibility and communicative effectiveness of a gist-based colorectal cancer screening information leaflet: a randomised controlled trial (Study 3)

7.1 Introduction

Chapter 5 reported on the design of the gist-based leaflet, and the first two evaluative stages of the Garner framework were reported in Chapter 6 (study 2) (Garner et al., 2012). This demonstrated that the leaflet was adequately readable and comprehensible to the population, justifying further evaluation of the third and final stage of the framework.

7.1.1 Stage 3: Communicative effectiveness

The third stage assesses how effective the information is at communicating the message intended by the author. This stage goes beyond the textual analysis approach of stages 1 and 2 and considers cognitive, social and emotional reactions to the leaflet. The methods used to evaluate the previous stages do not consider these outcomes, making the results less generalisable outside of the study setting. To assess the communicative effectiveness of the leaflet, the user is placed in the wider context in which the leaflet is presented making this part of the evaluation a more thorough and valid test.

Garner and colleagues (2012) suggest one of the most concrete strategies to assess the communicative effectiveness of an information leaflet is to measure 'simulated behaviour' (Hrisos et al., 2009). Here, participants are given a hypothetical scenario and asked to report their intention to act in response to the behaviour discussed in the information. Psychological theories presented in Chapter 2 suggest that intention to perform a behaviour is commonly used as the most proxy marker of behaviour (Ajzen, 1985, 1991, 2005; Rosenstock, 1966, 1974; Schwarzer, 1992, 2001, 2008). Furthermore, there is evidence to suggest screening intention may be particularly useful in a CRC screening context because of the smaller intention-behaviour gap that is observed in comparison with other behaviours (Cooke & French, 2008). Intention may therefore be a useful outcome to assess stage 3 of the evaluation.

Garner and colleagues also recommend that the antecedents of intention are monitored when evaluating the communicative effectiveness of an information leaflet. The aforementioned psychological theories suggest perceived risk is a strong correlate of intention. It has also been shown in empirical studies to be associated with colorectal cancer (CRC) screening behaviour (Dillard, Ferrer, Ubel, & Fagerlin, 2012; Janz et al., 2007; Janz, Wren, Schottenfeld, & Guire, 2003; Sun, Basch, Wolf, & Li, 2004; Tessaro, Mangone, Parkar, & Pawar, 2006). Perceived risk may be a particularly relevant factor to consider here as the most evident manipulation within the gist leaflet is to increase the ease through which risk information is extracted from the text. In turn, Fuzzy-Trace Theory (FTT) stipulates this will increase assimilation of the information leading to greater perceptions of risk (Reyna, 2008, 2012).

Finally, Garner and colleagues recommend that consideration should be given to the social context in which the information is presented. The gist leaflet aims to address socioeconomic status (SES) inequalities in screening uptake and was therefore designed using techniques that will improve comprehension among those with poor basic skills. This study also considered the role of social context by purposively sampling from General Practices based in deprived neighbourhoods.

7.1.2 Aims of the current study

The primary aim of this study was to use a parallel randomised controlled trial to assess the communicative effectiveness of the gist leaflet. An intervention group (gist leaflet + 'The Facts' booklet) was compared against a control group ('The Facts' booklet only) on screening intention and perceived risk. In keeping with similar evaluations and the design of the gist leaflet, I monitored levels of worry about CRC to ensure that any increases in intention and perceived risk did not also result in worse emotional outcomes (Robb, Miles, Campbell, Evans, & Wardle, 2006; S. K. Smith et al., 2010; Wardle et al., 2003).

A secondary aim of the study was to evaluate the comprehensibility of the gist leaflet in a larger and more representative sample than that reported in Chapter 6 (study 2). Comprehensibility measures (perceived readability, usefulness and objective knowledge) were therefore collected. To consider the social context in which the gist leaflet was delivered and establish whether the gist leaflet addresses

communication inequalities, primary and secondary outcomes were monitored for high and low numeracy participants.

I hypothesised that screening intention (primary outcome), comprehensibility (perceived readability, usefulness and objective knowledge) and perceived risk would be significantly higher among the intervention group. I also predicted that levels of worry about CRC would not be affected by the intervention. Finally, I predicted an interaction between the study group and numeracy, whereby differences in study outcomes between the intervention and control groups would be significantly greater among participants with low numeracy.

7.2 Methods

For a copy of the completed Consolidated Standards of Reporting Trials (CONSORT) checklist, please see appendix P.

7.2.1 Study design

A multicentre parallel randomised trial design was used. Individuals were randomised by household, in order to avoid inter-household contamination of the intervention. Participants were allocated to two groups (control group: 'The Facts; booklet only; intervention group: 'The Facts' booklet + gist leaflet) on a 1:1 allocation ratio. The study was registered as a trial on the ISRCTN database (ISRCTN62215021) and was given ethical approval by the Proportionate Review Sub-committee of the National Research Ethics Service Committee Yorkshire & The Humber - Leeds West, on 7 February 2012 (Reference: 12/YH/0106).

7.2.2 Participants and Setting

Primary care General Practices in the north of England (Greater Manchester and Liverpool) were identified in January 2012 by the Primary Care Research Network (PCRN). Using the Index of Multiple Deprivation score (a neighbourhood deprivation score based on several SES markers), the PCRN systematically approached the most deprived practices to recruit them for the study. The most deprived practice was approached first and this continued until sufficient practices had been identified. Three deprived practices agreed, and one additional practice in an affluent area was recruited. One practice in Liverpool was composed of two combined practices, with patients eligible to be treated at both. This practice was treated as a single practice.

A list of all men and women aged between 45-59.5 years registered with the GP practices was created. This age group was used as they had not previously been invited to CRC screening and had no experience with the procedure or the information materials. At each practice, General Practitioners (GPs) were invited to exclude patients who were unsuitable for taking part. This included patients who had severe cognitive impairments, vulnerable groups (e.g. those with a recent diagnosis of cancer or other significant illness), those who were under CRC surveillance and patients who were not able to read English[1]. Participants were not offered any incentive for taking part in the study.

7.2.3 Randomisation and blinding

Eligible patients at each practice were randomised to either the intervention or control group, with households always allocated to the same study group to limit contamination. I used random number generation software (http://bit.ly/SoIYLA) to generate a restricted randomisation sequence for participant group allocation. The type of restricted randomisation used was the blocking method. This type of randomisation ensures close balance of numbers in each group, which was needed to ensure adequate study materials were printed. Blocking limits the unpredictability of randomisation, but this bias was reduced by the use of random blocks (Moher et al., 2010).

Using the random sequence, I was responsible for assigning participants to the appropriate study group and performing the mail-out of study materials from the General Practice. At all practices, an additional researcher was available to help with this process (HB, SM, HC). Group allocation was not concealed at any stage after the random sequence was generated. It was also not possible to be blind to the group allocation at data entry or analysis stage as some questions were only included for one study group. Participants were not aware of a comparator group. Randomisation occurred prior to consent, which was assumed following the return of a completed questionnaire.

[1] Although an exclusion criteria, it was not possible to be certain that all non-English speakers were excluded due to inconsistencies with GP records

7.2.4 Study groups

7.2.4.1 Control group

Letters containing a study invitation letter from the General Practice, a questionnaire, and an example 'screening pack' were sent to all control participants. To increase the ecological validity of the study, 'screening packs' were as similar as possible to a real screening invitation (i.e. they included an National Health Service [NHS] envelope and a real screening invitation letter watermarked with 'example'). They also included a copy of the current patient information booklet ('Bowel Cancer Screening: The Facts'). Participants were sent a reminder pack approximately 3 weeks after their initial invitation containing a reminder letter from the General Practice, a questionnaire and an example screening pack[1]. All materials were delivered by second class post at the same time. For a copy of the study documents, see appendix Q-V.

7.2.4.2 Intervention group

The intervention group was provided with the same materials as the control group. In addition to these materials, a gist leaflet was contained within the example screening pack.

7.2.5 Measures

All outcome measures were assessed in the same questionnaire.

7.2.5.1 Primary outcome

Screening intention. The primary outcome measure for this study was intention to be screened using the item 'Imagine you have just turned 60 and have received the bowel screening test kit (FOB test kit) in the post, would you do the test?'. Responses were dichotomised to reflect high intention ('yes, definitely') and low intention ('definitely not', 'probably not', 'yes, probably').

[1] The practices and staff were not always able to accommodate the preferred dates of the mail-outs.

7.2.5.2 Secondary outcomes

Comprehensibility and usefulness. For each information booklet, participants in the intervention group were asked on a 7-point scale the extent to which the booklet was: (1) 'hard to read' or (7) 'easy to read' and (1) 'not at all useful' or (7) 'useful'. This item was created for the purposes of this study.

Gist knowledge. In line with the aim of the gist leaflet, knowledge was assessed using a method which captures whether participants have understood the 'gist' of the information (S. K. Smith, et al., 2012; Tait et al., 2010a; Tait et al., 2010b). I developed nine items (see Table 7-1) that assessed 'essential' knowledge required in order to make a screening decision, with each having a 'true', 'false' and 'don't know' response. These items reflect 'core' knowledge outlined by the General Medical Council's screening guidelines (General Medical Council, 2008), and reviews on knowledge measures within the informed decision-making and screening literature (Mullen et al., 2006; S. K. Smith, et al., 2012). The reliability of the scale was adequate (α = 0.73).

Table 7-1 True or false gist knowledge items

Item	**Concept**
Doing the FOB test lowers the risk of dying from bowel cancer	Risks and benefits of screening
The FOB test is done at home	Practical aspects of screening
Most people who do the FOB test will receive an abnormal result	Risks and benefits of screening
Only women are sent a FOB test	Inclusion criteria for screening
Bowel cancer is a common cancer in people over 60	Incidence of cancer
People only need to do the FOB test once in their life	Practical aspects of screening
The FOB test can miss bowel cancer	Risks and benefits of screening
People with an abnormal result always have cancer	Risks and benefits of screening
People aged 60-74 years are sent the FOB test	Inclusion criteria for screening

All items could be answered correctly using the information provided to both the control and intervention groups, and the questions were not asked in the order that information was presented in the information booklets. One point was given for a correct response. A total score was calculated from a sum of all responses. Smith and colleagues recommended a pass mark of 50% for 'adequate' gist knowledge and therefore participants in this study must answer at least 5 items correctly (55.5%) to be classified as having adequate gist knowledge (S. K. Smith, et al., 2012). Sensitivity analyses using different thresholds were performed.

Perceived risk. Two perceived risk items were included (Dillard et al., 2012). Absolute risk question was assessed with the item: 'If I never do the FOB screening test, I think my chances of dying from bowel cancer would be…', with responses ranging on a 7-point scale from 'almost zero' to 'almost certain'. Comparative risk was assessed by the item: 'Compared to others of the same sex and age my chances of getting bowel cancer are…', with responses ranging on a 5-point scale from 'much below average' to 'much above average'.

Colorectal cancer worry. Worry was assessed using the item, 'How worried are you about getting bowel cancer' on a 4-point scale from 'not worried at all' to 'very worried' (Sutton et al., 2000).

7.2.6 Participant characteristics

Individual-level data were available for age, gender, number of invitees in a household and neighbourhood deprivation scores from General Practice records. Non-responder analyses used this data.

Age, gender, marital status (married, unmarried), ethnicity (white, black, south asian and other), employment status (employed [full-time, part-time or self-employed], unemployed, full-time homemaker, retired, student, disabled or too ill to work), educational achievement (no formal education, some formal education [below degree], degree level education) were recorded in the questionnaire. Objective numeracy was assessed using the item 'which of the following numbers represents the biggest risk of getting a disease?', '1 in 100', '1 in 1000', or '1 in 10' (Lipkus et al., 2001). Participants were scored as either correct (high numeracy) or incorrect (low numeracy).

7.2.7 Quality assurance

Quality assurance based on guidelines for health behaviour interventions were in place during the study (Bellg et al., 2004). These assessed whether the intervention was a) delivered as intended and b) received as intended. To assess whether the intervention was delivered as intended, participants allocated to different conditions were sent questionnaires that were either yellow or green. When questionnaires were returned, I observed whether the colour of the questionnaire corresponded with the group that the participant was allocated to. Intervention delivery was also assessed by observing the correspondence between practice and questionnaire data for age and gender. If there were discrepancies in the data, the participant was excluded. For example, this occurred if the questionnaire was completed by a male, but was recorded as being sent to a female.

To assess whether the intervention was received as intended, participants were asked the question: 'Have you read the orange leaflet, 'Bowel Cancer Screening: The Facts', found inside the NHS envelope' (Olamijulo & Duncan, 2001). A similar question was asked about the gist leaflet. Response options were: 'no', 'I have read part of it', 'I have read it all', 'I have read it all more than once'.

7.2.8 Methods to increase response rates

Using a Cochrane systematic review as a guide, strategies were implemented to increase response rates (Edwards et al., 2009). These included naming a university sponsor, using a trusted logo (National Health Service) on the outgoing envelope, stating that the data will be kept confidential and providing a reminder for non-responders. Specific strategies employed within the reminder included stating that others had replied to the questionnaire and providing a second copy of the questionnaire (Sahlqvist et al., 2011). This latter technique has been shown to be particularly useful at recruiting groups with a low level of education (Hoffman, Burke, Helzlsouer, & Comstock, 1998). Low literacy versions of scales/items were used wherever available. When they were not available, small wording changes were made to items to improve readability. As shown in Table 7-2, the questionnaire and gist leaflet had superior readability to 'The Facts' booklet and the invitation letters, although all were considered to be readable to a lay audience (Vahabi & Ferris, 1995).

7.2.9 Sample Size

The planned national trial of the gist leaflet (Chapter 8) aimed to detect a 3% difference in uptake between the study groups (Brentnall, Duffy, Baio, & Raine, 2012). To account for the assumed intention-behaviour gap, the current study aimed to achieve a 5% difference in intention between the two study groups (Sheeran, 2002; Power et al., 2008). To detect this effect size (w=0.12), 818 respondents were needed, assuming 80% power and a one-sided significance level of p=0.05. Using conservative estimates, approximately 4400 individuals would need to be approached to recruit this number, assuming a 20% response rate. Although higher responses have been noted in a similar study, this was not performed in deprived areas (Robb et al., 2008).

Table 7-2 Readability of study materials

Study material	**Flesch Reading Ease Score (0 [hard] -100 [easy])**
Questionnaire	80
Invitation letter	63.2
Reminder letter	64.7
Facts booklet	62.4
Gist leaflet	84.5

7.2.10 Analysis

7.2.10.1 Using GP practice records

A response rate was calculated using the number of invitations administered as the denominator and the number of questionnaires returned (after exclusions) with primary or secondary outcome data. Differences in response rates between the practices were calculated using chi-square. To calculate whether there were differences in response between gender, household size and deprivation, chi-square was used. An independent t-test was used to calculate differences in age between responders and non-responders. GP practice data were used to perform these analyses, but were not used any further as socio-demographic data provided in participant questionnaires was more comprehensive.

7.2.10.2 Using questionnaire data

The acceptability of the intervention was assessed by determining the proportion of participants who reported reading the leaflet. Comparisons between low and high numeracy groups were performed using chi-square analyses.

The dataset was inspected to ensure that it met parametric assumptions. For these assumptions to be met the data had to be normally distributed, be at least interval level, be independent and have homogenous variance. Histograms and P-P plots were used to test for the assumption of normal distribution. Where the normal distribution assumption was not met, data were dichotomised. The Levene's test was used to test for homogeneity of variance in Analysis of Variance (ANOVA) models, and corrected if violated. The assumptions of parametric data (e.g. normal distribution) are less important for logistic regression analyses, however additional assumptions are relevant (Field, 2009). These assumptions (linearity, independence of errors and multicollinearity) were not violated in these analyses.

The reliability of the gist knowledge scale was assessed using Cronbach's alpha. The validity of the scale was assessed by observing the Pearson's correlation matrix, followed by a Maximum Likelihood Principal Components Analysis (Wentzell, Andrews, Hamilton, Faber, & Kowalski, 1997).

Screening intention, perceived readability, perceived usefulness and knowledge were dichotomised and group differences were assessed using chi-square. Perceived risk and worry items were normally distributed and were analysed as continuous outcomes using independent t-tests. To investigate interactions between the effect of the intervention and numeracy with dichotomous outcomes, logistic regression was used. For continuous outcomes, ANOVA was used. Data were analysed using SPSS version 21.

Qualitative data were reported for the intervention group only, as they were the only group that were able to comment on both information booklets. Data were coded according to whether the comment was 'positive', 'neutral', 'negative' or 'unrelated' (see Table 7-3). Approximately 20% of comments were second coded by an additional researcher (GV) to ensure inter-rater reliability. Individual comments that support this framework and the findings of the quantitative analysis are presented.

Table 7-3 Coding framework for qualitative data

Positive	A comment that is only positive about the leaflet
Neutral	A comment that is neutral about the leaflet
	A comment that contains positive and negative comments
	A comment that suggests more information added
Negative	A comment that is only negative about the leaflet
Unrelated	A comment unrelated to the booklets (e.g. questionnaires etc).

7.2.11 Missing data

Missing data[1] were generally low (see Table 7-4). Missing data on all primary and secondary outcomes (except gist knowledge) were considered to be missing at random and pairwise deletion was used during data analysis (Tabachnick & Fidell, 2013).

Table 7-4 Number and % of missing data on primary and secondary outcomes

Construct	**N (%)**
Intention	2 (0.2)
Perceived readability (gist leaflet)	20 (4.0)
Perceived usefulness (gist leaflet)	33 (6.6)
Perceived readability ('The Facts' booklet)	21 (4.2)
Perceived usefulness ('The Facts' booklet)	31 (6.2)
Total gist knowledge score+	37 (3.8)
Comparative risk	28 (2.9)
Absolute risk	12 (1.2)
Colorectal cancer worry	19 (2.0)

+ Missing data prior to transformation

Missing gist knowledge data were considered to be missing not at random if at least 5 items out of a possible 9 were completed. Participants who had not answered any gist knowledge items were excluded for all gist knowledge outcomes (n=6). Missing

[1] Missing data can be classified as missing in three different ways. Missing at random means that the propensity for data to be missing is not related to the missing data, but is related to the observed data. Missing completely at random means that the data are not related to any other data, missing or observed; the probability of missingness is the same for all units. Missing not at random means that even after accounting for observed information, the absent value is still dependent on the missing data itself.

data for the remaining participants were dealt with by transforming total scores to account for the number of items that were responded to. This enabled participants with a small amount of missing data to be allocated a score from 0-9.

There was a large amount of missing data on the numeracy item (10.5%). These data were also considered to be missing not at random. All analyses involving numeracy coded missing data as incorrect, however sensitivity analyses were performed that excluded participants with missing data. Unless otherwise stated, it should be assumed that this sensitivity analysis yielded similar results.

7.3 Results

7.3.1 Sample size and response rates

Participants were recruited between July, 2012 and March, 2013. Questionnaire responses were accepted until May, 2013. Individuals (n=4452) were randomised by household (n=3706). As shown in the CONSORT diagram (Figure 7-1), a total of 2216 people were allocated to the control group and 2236 to the intervention group. A total of 3631 (81.6%) reminders were sent (control group = 1808 [81.6%]; intervention group = 1823 [81.5%]) approximately three weeks after the initial invitation (median = 22 days [range = 22-41 days]).

Respondents were excluded from the analysis if questionnaire data on age and gender did not match General Practice records (n = 26) or if they did not receive the study materials as intended (e.g. incorrect address [n=22]; death prior to invitation [n=1]). These exclusions were approximately equal for both study groups. After exclusions, a sample of 4403 remained and was used as the denominator for calculating response. A total of 964 questionnaires providing data on either primary or secondary outcome data were returned, giving a response rate of 21.9%. The response rate varied between the practices (Liverpool a [18.1%], Manchester [13.0%], Liverpool b [19.6%], Stockport [31.8%]; $\chi^2(3) = 128.76$, $p < 0.001$). No harms were reported in either study group.

Table 7-5 reports the characteristics of individuals that received the allocated intervention for each recruitment site[1]. The data shows more males than females were randomised in the Manchester and Liverpool (b) practices and there were

[1] Data sourced from GP practices

more two person households in Stockport. As expected, individuals from the Stockport practice were from more affluent neighbourhoods.

Figure 7-1. CONSORT diagram

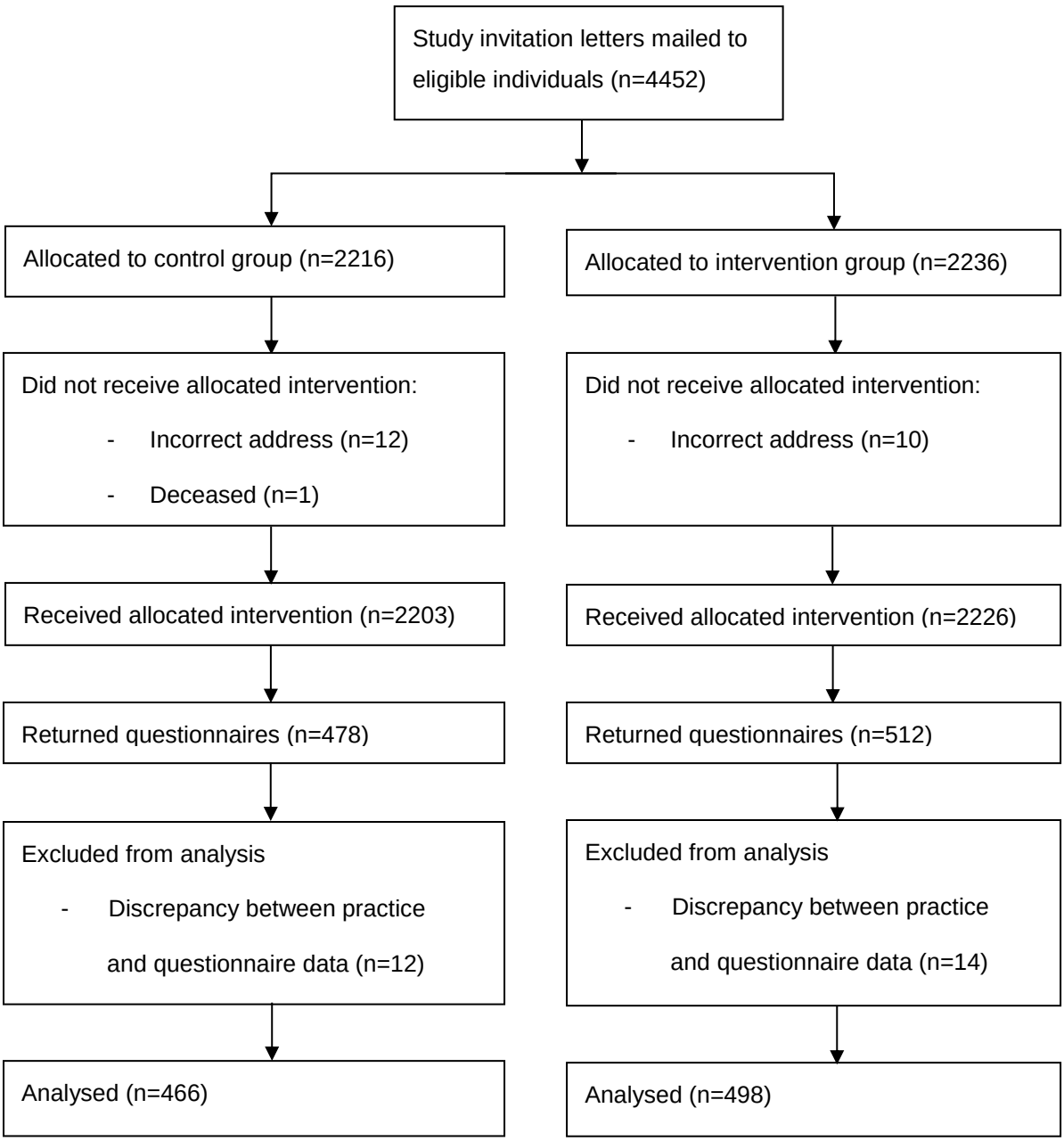


Table 7-5 Characteristics of invited sample by recruitment site (n=4452)

	Liverpool (a) (n=1105)	**Manchester (n=806)**	**Liverpool (b) (n=1142)**	**Stockport (n=1399)**
	N (valid %)	**N (valid %)**	**N (valid %)**	**N (valid %)**
Gender				
Male	551 (49.9)	498 (61.8)	688 (60.2)	683 (48.8)
Female	554 (50.1)	308 (38.2)	454 (398)	716 (51.2)
Number in household				
1	794 (71.9)	603 (74.8)	930 (81.4)	657 (47.0)
2	302 (27.3)	174 (21.6)	209 (18.3)	715 (51.1)
3	9 (0.8)	21 (2.6)	3 (0.3)	27 (1.9)
4	0 (0)	8 (1.0)	0 (0)	0 (0)
IMD score Quintiles				
1 (low deprivation)	0 (0)	7 (0.9)	0 (0)	989 (70.8)
2	67 (6.1)	178 (22.1)	163 (14.4)	386 (27.6)
3	259 (23.4)	320 (39.8)	335 (29.6)	16 (1.1)
4	138 (12.5)	269 (33.4)	421 (37.2)	6 (0.4)
5 (high deprivation)	641 (58.0)	31 (3.9)	212 (18.7)	0 (0)
Age[+]	51.7 (4.2)	50.7 (4.1)	50.9 (4.2)	51.1 (4.0)

+ Mean and standard deviation reported b Sample size varied for IMD due to incomplete data (Liverpool[a] = 1105, Manchester = 805; Liverpool [b] = 1131; Stockport = 1397)

General Practice records indicated the characteristics of the study groups were comparable (see Table 7-6). Responders were significantly more likely to be female ($\chi^2(1) = 16.09$, $p < 0.001$), older ($t(4401) = 6.16$, $p < 0.001$), from an affluent neighbourhood ($\chi^2(1) = 115.07$, $p < 0.001$) and be in a home with two or more invitees ($\chi^2(1) = 4.05$, $p = 0.044$).

Table 7-6 Characteristics of randomised individuals (n = 4452)

	All (n = 4452)	**Control (n=2216)**	**Intervention (n=2236)**
	N (valid %)	**N (valid %)**	**N (valid %)**
Gender			
Male	2420 (54.5)	1194 (53.9)	1226 (54.8)
Female	2032 (45.6)	1022 (46.1)	1010 (45.2)
Number in household			
1	2984 (67)	1476 (66.6)	1508 (67.4)
2	1400 (31.4)	714 (32.2)	686 (30.7)
3	60 (1.3)	22 (1.0)	38 (1.7)
4	8 (0.2)	4 (0.2)	4 (0.2)
IMD score Quintiles			
1 (low deprivation)	996 (22.4)	473 (21.4)	523 (23.5)
2	794 (17.9)	412 (18.7)	382 (17.1)
3	930 (21.0)	462 (20.9)	468 (21.0)
4	834 (18.8)	420 (19.0)	414 (18.6)
5 (high deprivation)	884 (19.9)	441 (20.0)	443 (19.9)
Age[+]	51.1 (4.1)	51.2 (4.1)	51 (4.2)

+ Mean and standard deviation reported

Questionnaire data indicated that a high proportion of participants were married (66.9%), white (83.8%), in employment (72.2%) and had either some formal education (49.9%) or a degree level education (36.5%) (see Table 7-7). Despite the relatively educated sample, a high proportion of the sample answered the numeracy item incorrectly (35.3%) or did not provide an answer (10.5%). The sample was relatively even with regard to gender (51.4% female) and age group (45-49, 32.7%; 50-54, 34%; 55-59, 33.3%).

Table 7-7 Participant characteristics for total sample

	Total sample
	N (valid %)
Gender	
Male	466 (48.6)
Female	493 (51.4)
Age	
45-49	313 (32.7)
50-54	325 (34)
55-59	319 (33.3)
Marital status	
Married	640 (66.9)
Unmarried	317 (33.1)
Ethnicity	
White	799 (83.8)
Black	42 (4.4)
South Asian	58 (6.1)
Other	55 (5.8)
Education	
No formal education	128 (13.6)
Some formal education	471 (49.9)
Undergraduate or higher	345 (36.5)
Employment status	
Employed	689 (72.2)
Unemployed	95 (10.0)
Full-time homemaker	44 (4.6)
Retired	37 (3.9)
Student	5 (0.5)
Disabled	84 (8.8)
Numeracy	
Correct	523 (54.3)
Incorrect	340 (35.3)
Missing	101 (10.5)

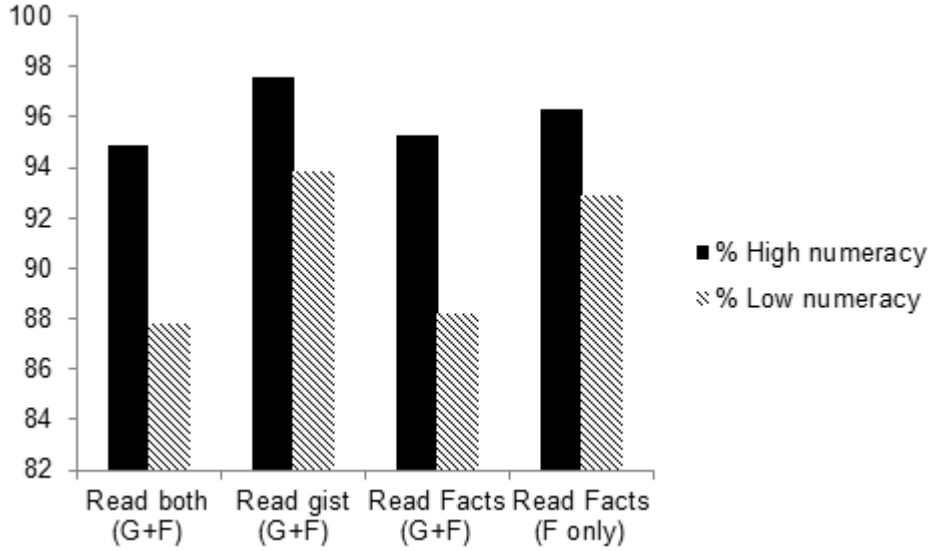
Note: n may not round to 964 due to missing data. Where missing data is > 10% a ‘missing’ category is presented

7.3.2 Acceptability of the intervention

In the whole sample, 93.0% reported that they read at least some of their allocated information materials, and those with low numeracy were less likely to have read them (90.0% vs. 95.6% [5.6% diff]; $\chi^2(1) = 11.52$, p = 0.001). The intervention group were significantly less likely to have read their allocated materials than the control group (91.4% vs. 94.8%; $\chi^2(1) = 4.52$, p = 0.034).

Intervention group participants were more likely to read at least some of the gist leaflet (95.8%) than 'The Facts' booklet (91.8%). Of those that did not read 'The Facts' booklet (n=41), 53.7% reported reading the gist leaflet instead. Whereas, of those that did not read the gist leaflet (n=21), 9.5% read 'The Facts' booklet instead. As shown in Figure 7-2, intervention group participants with low numeracy were slightly less likely to read the gist leaflet (93.9% vs. 97.6% [3.7% diff]; $\chi^2(1) = 4.34$, p = 0.037), but were even less likely to read 'The Facts' leaflet (88.2% vs. 95.3% [7.1% diff]; $\chi^2(1) = 8.29$, p = 0.004).

Figure 7-2 Percentage of participants reporting reading their allocated materials by numeracy group



The control group showed high adherence to reading at least some of 'The Facts' booklet (94.8%) and there was no difference between the low and high numeracy groups (96.3% vs. 92.9% [3.4% diff]; $\chi^2 = 2.75$, p = 0.097 (see Figure 7-2).

7.3.3 Primary and secondary outcomes

Analyses comparing group differences in primary and secondary outcomes were performed (see Table 7-8).

Table 7-8 Differences between study groups on primary and secondary outcome measures

Variable	Intervention group (N=496)	Control group (N=462)	Significance
	%	%	
Intention	75.7	73.8	$\chi2(1) = 0.45$, p = 0.50
Gist knowledge	95.2	90.9	$\chi2(1) = 6.74$, p = 0.009
	Mean (SD)	Mean (SD)	
Perceived risk (comparative)	2.90 (0.83)	2.93 (0.76)	t(933.45) = 0.568, p=0.57
Perceived risk (absolute)	3.82 (1.01)	3.73 (1.03)	t(950) = -1.377, p=0.169
Worry	1.90 (0.73)	1.84 (0.69)	t(943) = -1.373, p=0.170

Intention. A large proportion of the sample said they 'definitely' (74.7%) or 'probably' (22.9%) intended to participate in CRC screening, and very few reported that they would 'probably not' (1.6%) or 'definitely not' (0.8%) participate. There were no significant differences between the two groups in the proportion of participants who definitely intended to participate ($\chi^2(1) = 0.45$, p = 0.50).

Perceived readability and usefulness. Participants in the intervention group provided perceived readability scores on a 1 ('not easy') to 7 ('easy') scale. Scores for the gist leaflet (mean = 6.56, SD = 1.04) and 'The Facts' booklet (mean = 6.35, SD = 1.20) indicated both were skewed towards being easy to read. This ceiling effect led me to dichotomise this outcome into whether individual scores favoured a particular leaflet. The majority of participants reported the same readability score for both leaflets (79.3%), but more participants found the gist leaflet easier to read (16.9%) than 'The Facts' (3.8%).

On a similar scale from 1 ('not useful') to 7 ('useful'), a ceiling effect was also observed with both leaflets considered to be very useful (gist mean = 6.45, SD =

1.13; Facts mean = 6.44, SD = 1.13). Using the same dichotomy, the majority of participants reported the same usefulness score for both leaflets (86.0%), with the remaining evenly distributed between scoring the gist leaflet as more useful (6.0%) or 'The Facts' booklet as more useful (8.0%).

Knowledge. The correlation matrix showed significant correlations between the knowledge items (range r=.12-.45, all ps < 0.001). An initial analysis was run to obtain eigenvalues for each component of the data. Eigenvalues were above 1 for two components, and 45.9% of variance was explained. Inspection of the scree plot suggested justification in retaining only a one-factor solution and this explained 33.8% of the variance. The factor loadings for this solution ranged from 0.30-0.65.

The sample had high knowledge (mean = 7.70, SD = 1.74, out of a possible 9). Using the pre-defined threshold, a high proportion of the sample (93.1%) were classified as having 'adequate' gist knowledge. The intervention group were significantly more likely to have adequate gist knowledge (95.2%) than the control group (90.9%; $\chi^2(1) = 6.74$, p = 0.009). Sensitivity analyses using more conservative thresholds for 'adequate' gist knowledge yielded similar proportional differences, although significance levels varied (see Table 7-9).

Table 7-9 Sensitivity analysis for gist knowledge

Adequate knowledge threshold	**Intervention (N = 496) (% correct)**	**Control (N = 462) (% correct)**	**Difference (%)**	**Significance**
4-9	96.4	95	1.4	$\chi^2(1) = 1.063$, p = .303
5-9	95.2	90.9	4.3	$\chi^2(1) = 6.742$, p = .009
6-9	91.9	87.9	4	$\chi^2(1) = 4.366$, p = .037
7-9	84.9	81.2	3.7	$\chi^2(1) = 2.343$, p = .126

Gist knowledge score data were rounded to whole numbers where transformations occurred.

Table 7-10 Correlation matrix for knowledge scale

	Lowers risk	**At home**	**Abnormal result**	**Only women**	**Common cancer**	**Once in life**	**Miss bowel cancer**	**Abnormal always cancer**	**Age 60-74**
Doing the FOB test lowers the risk of dying from bowel cancer	-								
The FOB test is done at home	.19***	-							
Most people who do the FOB test will receive an abnormal result	.16***	.18***	-						
Only women are sent a FOB test	.16***	.24***	.37***	-					
Bowel cancer is a common cancer in people over 60	.19***	.20***	.12***	.24***	-				
People only need to do the FOB test once in their life	.18***	.25***	.30***	.39***	.21***	-			
The FOB test can miss bowel cancer	.13***	.25***	.27***	.24***	.27***	.33***	-		
People with an abnormal result always have cancer	.13***	.26***	.33***	.45***	.14***	.44***	.37***	-	
People aged 60-74 years are sent the FOB test	.23***	.27***	.20***	.30***	.25***	.25***	.27***	.22***	-

* = $p < 0.001$

Perceived risk. The comparative risk scores on a 5-point scale indicated that participants typically felt that they were at 'average' risk of CRC (mean = 2.91, SD = 0.80). The modal response reflected this (average; 56.5%), although more participants indicated that they were 'below average' risk (25.1%) than 'above average' risk (18.3%). The average absolute risk on a 7-point scale was 3.78 (SD = 1.02) which indicates a 'moderate' level of perceived risk. This was also reflected in the modal response ('moderate'; 47.1%), but there was a higher proportion of participants reporting less than moderate risk (35.5%) than above moderate risk (17.4%). The sample therefore demonstrated an optimistic bias on both perceived risk outcomes.

There was no support for the hypothesis that perceived risk would be increased by the intervention, as shown by the non-significant differences on the comparative risk ($t(933.45) = 0.57$, $p = 0.57$) and absolute risk ($t(950) = -1.38$, $p = 0.169$) outcomes.

Worry about CRC. As expected, worry about CRC was low (mean = 1.87, SD = 0.72). These levels indicated that people were on average 'a bit worried' about getting CRC. A breakdown of the scale suggested that most of the sample were either 'not worried at all' (29.8%) or 'a bit worried' (56.4%) and few participants were 'quite worried' (10.7%) or 'very worried' (3.1%). In line with the aims of the gist leaflet, no increase in worry about CRC was seen in the intervention group ($t(943) = -1.37$, $p = 0.170$).

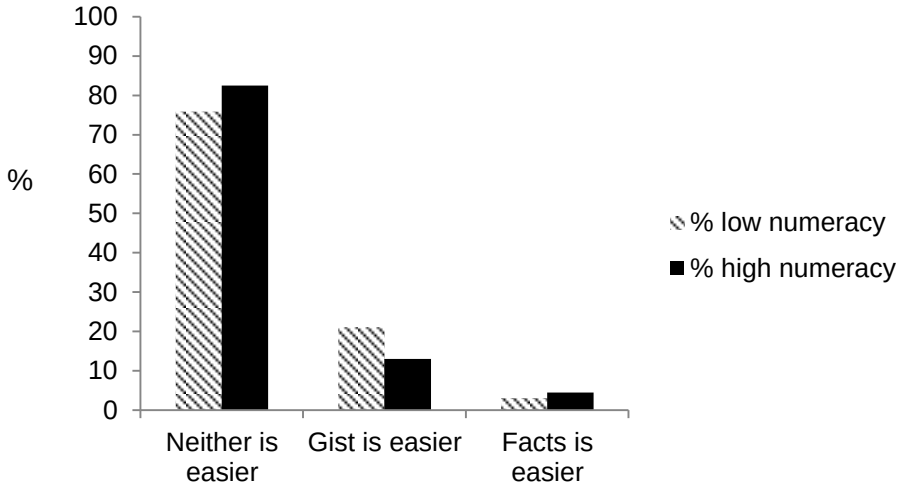
7.3.4 The effect of the intervention in groups with different levels of numeracy

Analysis of the study outcomes by numeracy group was performed (see Table 7-11). Participants with low numeracy were less likely to say they would 'definitely' participate in CRC screening (71.2% vs. 77.7% [6.5%]; $\chi^2(1) = 5.40$, $p = 0.020$). As shown in Figure 7-3, there was a non-significant difference between the numeracy groups in their perceived readability of the communication materials ($\chi^2(1) = 5.81$, $p = 0.055$). Those with low numeracy were less likely than high numeracy participants to find both leaflets equally readable (75.9% vs. 82.5% [6.6% diff]), more likely to find the gist leaflet easier to read (21.1% vs. 13% [8.1% diff]) and approximately as likely to find 'The Facts' easier to read (4.5% vs. 3.1% [1.4% diff]).

Table 7-11 Study outcomes by numeracy group

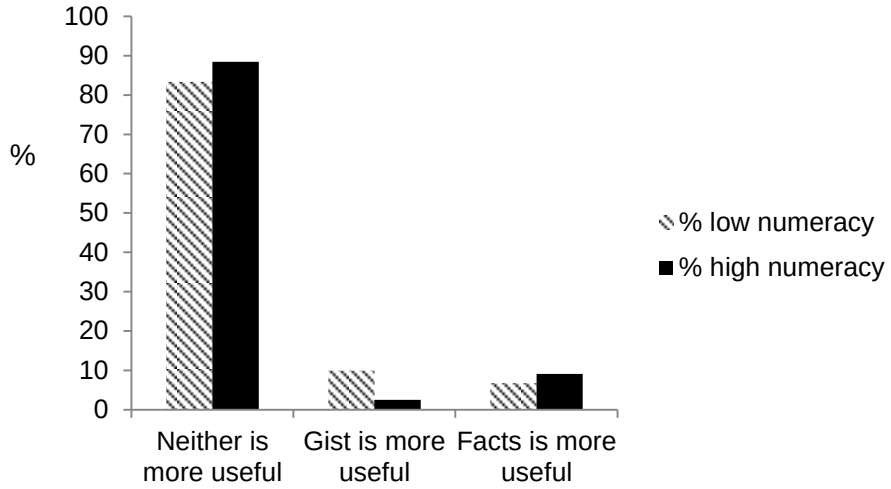
Variable	Low numeracy (N=441)	High numeracy (N=523)	Significance
	%	%	
Intention	71.2	77.7	$\chi^2(1) = 5.40$, p = 0.020
Gist knowledge	89.0	96.6	$\chi^2(1) = 21.34$, p <0.001
	Mean (SD)	Mean (SD)	
Perceived risk (comparative)	2.87 (0.77)	2.95 (0.82)	t(934) = 1.45, p = 0.149
Perceived risk (absolute)	3.84 (1.05)	3.73 (1.0)	t(950) = -1.71, p = 0.087
Worry	1.90 (0.75)	1.85 (0.68)	t(943) = -1.13, p = 0.260

Figure 7-3 Proportion of individuals with low and high numeracy in each readability category



There was a significant difference in the perceived usefulness of the communication materials by numeracy group ($\chi^2(2) = 11.79$, p = 0.003). As demonstrated in Figure 7-4, participants with low numeracy were slightly less likely to find both leaflets equally useful (83.3% vs. 88.5% [5.2% diff]), more likely to find the gist leaflet useful (9.9% vs. 2.5% [7.4% diff]) and approximately as likely to find 'The Facts' booklet more useful (6.8% vs. 9.1% [2.3% diff]).

Figure 7-4 Proportion of individuals of low and high numeracy who found each booklet more useful



Participants with low numeracy were significantly less likely to have adequate gist knowledge (89.0% vs. 96.6% [7.6% diff]; $\chi^2(1) = 21.34$, $p < 0.001$). Both numeracy groups reported an 'average' level of comparative risk (low numeracy mean = 2.87, SD = 0.77; high numeracy mean = 2.95, SD = 0.82; t(934) = 1.45, p = 0.149). Similarly, both sets of individuals reported a 'moderate' level of absolute risk (low numeracy mean = 3.84, SD = 1.05; high numeracy mean = 3.73, SD = 1.0; t(950) = -1.71, p = 0.087). Worry scores for both numeracy groups indicated that they were both 'a bit worried' about getting bowel cancer (low numeracy mean = 1.90, SD = 0.75; high numeracy mean = 1.85, SD = 0.68; t(943) = -1.13, p = 0.260).

The effect of the intervention was not moderated by numeracy for any primary or secondary outcome: intention (OR = 1.02, p = 0.936), gist knowledge (OR = 0.42, p = 0.130), comparative risk (F(1, 932) = 1.159, p = 0.282), absolute risk (F(1, 948) = 0.939, p = 0.333) and CRC worry (F(1, 941) = 0.35, p = 0.852).

7.3.5 Qualitative feedback

Participants made a total of 148 comments in the open-ended section of the questionnaire, of which 124 (83.8%) were related to the information booklets. Table 7-12 shows that the majority of comments were positive, however there were more negative comments related to 'The Facts' booklet than the gist leaflet. Inter-rater reliability of the comments demonstrated substantial agreement (*K* = 0.61*).*

Table 7-12 Number and % of comments related to each information booklet

	Gist leaflet (n=62)	**'The Facts' booklet (n=62)**
Positive comments	42 (67.7)	28 (45.2)
Neutral comments	17 (27.4)	14 (22.6)
Negative comments	3 (4.8)	20 (32.3)

7.3.5.1 Qualitative feedback: 'The Facts' booklet

The negative feedback centred on the length of the booklet, with some stating they were unable to read to the end:

> *'Too long and repetitive. Became boring and I wanted to stop reading it and skip the final pages'* (56 years old, female, low numeracy, intervention group).

> *'I started scanning parts of the (orange) booklet. This information was over the top and repeated too many times. I would get bored of reading in the orange booklet and may run the risk of missing an important piece of information'* (54 years old, male, low numeracy, intervention group).

There was also concern regarding the use of numerical information. This led to miscomprehension of the possible outcomes from an FOB test:

> *'Too much risk analysis. Arithmetic appears to be wrong. If 98% receive a normal result how can 4% receive an unclear result and 2% an abnormal result? Total 104%?'* (57 years old, male, low numeracy, intervention group).

The positive comments on 'The Facts' booklet focussed on its 'plain English' language and how it might complement the gist leaflet by providing detail that some may want:

'The orange leaflet takes things up nicely from where the blue left off. I like that the orange leaflet gives details of organisations that give you support and can answer further questions' (51 years old, female, high numeracy, intervention group).

7.3.5.2 Qualitative feedback: The gist leaflet

The comments were generally positive about the gist leaflet. Its simplicity and lack of complex terminology was noted:

'The blue leaflet is simple and to the point and explains enough facts clearly without going over the top' (54 years old, male, low numeracy, intervention group).

In line with the aim of the booklet, participants appreciated that the gist leaflet provided essential information needed to make a screening decision, and that more information could be found elsewhere:

'A good introductory leaflet which made me curious for more information' (52 year old, female, low numeracy, intervention group)

'Good summary - gives readers key points without being too wordy and importantly directs them to further information' (59 year old, female, low numeracy, intervention group)

7.4 Discussion

This study reports on a multicentre randomised controlled trial evaluating the communicative effectiveness and comprehensibility of the gist-based leaflet. The leaflet was compared against 'The Facts' booklet among a diverse sample of participants approaching screening age from four General Practices in England.

7.4.1 Acceptability of the intervention

The response rate of the study was 22% and participants were more likely than non-responders to be female, older, from an affluent neighbourhood and be living in a household with two or more invitees. However, compared with population estimates

of adults living in the relevant local authorities (Stockport, Liverpool and Manchester[1]), unemployment was closely matched to the characteristics reported in this study (present sample 10% vs. area average 11%). Similar observations are made for ethnicity, with 85% self-reporting as white in the local authority data, compared with 84% in the study. The present study also recruited slightly more participants with no formal education compared to 'economically active' adults in the areas (14% vs. 11%[2]).There are no UK data related to this numeracy item. However, a higher proportion of respondents answered the item incorrectly than in a nationally representative US sample (35.3% vs. 22.6%) (Ciampa, Osborn, Peterson, & Rothman, 2010).

The majority of participants read at least some of the materials they were allocated to, although the provision of two booklets led to fewer participants in the intervention group reading their allocated materials. This is an important finding to consider as it emphasises the possibility that providing supplementary information may exacerbate literacy barriers within the National Health Service Bowel Cancer Screening Programme (NHS BCSP). Added to this, people with low numeracy were less likely to read the information materials, and the difference between the numeracy groups was larger for 'The Facts' booklet than the gist leaflet. This finding supports the observation that lower health literacy groups are more likely to engage in defensive processing strategies such as information avoidance (Morris et al., 2013; von Wagner et al., 2009). Supplementing the programme with additional information may reduce the likelihood that it will be read, but 'The Facts' booklet may be a more important problem to tackle than the gist leaflet.

No differences in cancer-specific worry were observed between the study groups, indicating that no psychological harm was caused by the intervention.

7.4.2 Communicative effectiveness

As observed in previous research, nearly three-quarters of the sample responded that they would 'definitely' participate in CRC screening (Power et al., 2008). In keeping with previous literature, low numeracy participants expressed less interest in CRC screening, although intentions were still high (Ciampa et al., 2010). This

[1] Area average data are sourced from NOMIS (http://bit.ly/13ymGY2) and should be considered for illustrative purposes only as the measures may not be directly comparable.
[2] Data were unavailable for 45-59 year olds, and so are compared against 40-64 year olds.

may have led to an underestimation of the intervention effect as there were no significant differences between the intervention and control groups with regard to screening intention. The null effect of the intervention on this outcome was consistent across low and high numeracy groups. Further research is needed to determine whether the communicative effectiveness of the leaflet is more effective when it is tested in a less motivated sample.

Consistent with previous research, the sample generally considered themselves to be at lower than average risk of CRC (Robb et al., 2004a, 2004b). This optimistic bias was observed regardless of numeracy level. The manipulation of risk information in the gist leaflet was intended to improve the ease with which the information was processed; however the study groups reported similar scores on the risk measures. The assumption that providing a descriptive context for the numerical information would be particularly useful for low numeracy groups was also not upheld (Peters et al., 2009). As assessed by these outcomes, the gist leaflet cannot be considered to have met the criteria set by the third stage of the Garner framework.

In addition to skewed intention and perceived risk responses, there may be further explanations for the null effects of the intervention. In the absence of literature testing similar interventions, the study was reliant on guidelines to estimate a feasible increase in screening participation (i.e. 3%) (Halloran, 2009). While such increases are realistic, they are more likely to be seen in trials where the control group do not receive any educational intervention (Wardle et al., 2003). This may be particularly true in the current study, where the supplementary gist leaflet had to be accompanied by the 'The Facts' booklet in order to meet principles of informed decision-making (Austoker et al., 2012; Ramirez & Forbes, 2012).

Gist-based risk information can be presented without numerical details (Reyna & Brainerd, 1991). Although this approach can increase perceived risk (Berry & Hochhauser, 2006), a recent taxonomy suggests the complete removal of numerical detail may only be appropriate in specific circumstances (Zikmund-Fisher, 2013). The CRC screening context is unlikely to be considered suitable, as most adults want full information about the risks and benefits of CRC screening (Waller et al., 2012). Research investigating how health communication can be designed to

ensure that perceived risk is affected, without compromising informed decision-making, is warranted.

A further possibility is that the threat of CRC was not sufficiently salient because the decision to screen was anticipated rather than current. Individuals who do not consider CRC screening to be salient with their view of how to protect and maintain their health report lower perceived risk of CRC (Vernon et al., 2001). Interventions that increase disease salience have also been shown to have concomitant effects on perceived risk (Dillard, Fagerlin, Dal Cin, Zikmund-Fisher, & Ubel, 2010; McQueen, Kreuter, Kalesan, & Alcaraz, 2011). The gist leaflet may be more effective at increasing perceived risk when tested among a group of people with high disease salience.

7.4.3 Comprehensibility

Within-group comparisons demonstrated that 'The Facts' booklet was strongly approved of with regard to readability and usefulness. However, more participants perceived the gist leaflet to be easier to read and these differences were particularly pronounced among those with low numeracy. Although there were no significant differences with regard to the perceived usefulness of the leaflets in the whole sample, low numeracy individuals favoured the gist leaflet on this outcome. These findings provide some evidence that the gist leaflet could address communication inequalities in the NHS BCSP.

The importance of addressing communication inequalities was demonstrated by the finding that participants with low numeracy had significantly lower levels of gist knowledge. Encouragingly, the intervention group were found to have significantly higher gist knowledge than the control group, and these improvements were equal for low and high numeracy groups. This is an important outcome in itself as previous educational interventions have been shown to exacerbate communication inequalities (Boxell et al., 2012). This intervention may have been less effective than the gist leaflet as it did not place such a strong emphasis on the comprehension barriers reported by groups with low health literacy (e.g. complex terminology was used throughout). It also went through a less extensive developmental process, highlighting the importance of following models such as the Garner framework when evaluating health communications.

7.4.4 Qualitative analysis

Qualitative analysis supported findings from study 1 (Chapter 4) and the quantitative analysis reported here. A reliable and simple coding framework showed that there were more positive comments and fewer negative comments about the gist leaflet than 'The Facts' booklet. 'The Facts' booklet was considered to be too long and as noted in study 1, there were problems in understanding the numerical presentation of screening outcomes. Respondents noted that the gist leaflet contained less complex terminology and would make a useful addition to the existing screening information. The comprehensibility findings provided further evidence that the gist leaflet met the comprehensibility stage of the Garner framework.

7.4.5 Strengths and limitations

A strength of the research was the randomised controlled design, which is considered the gold standard method in most contexts for evaluating public health interventions (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996). The validity of the study's findings were increased through the use of multiple recruitment centres, as single centre studies have been shown to inflate the effect of the intervention in both pharmacological and non-pharmacological randomised controlled trials (Bafeta et al., 2012; Dechartres, Boutron, Trinquart, Charles, & Ravaud, 2011). This study design enabled me to observe the impact of the gist leaflet against a group provided with the existing information materials. Although this may have limited the effect of the intervention, it gave strength to claims that the benefits seen in terms of comprehension were real added effects.

The study was somewhat successful in recruiting low SES participants compared with population estimates of unemployment, ethnicity, education and US estimates of numeracy (Ciampa et al., 2010). The quantitative data in this study allowed the views and opinions of all participants to be weighted equally, overcoming a limitation of study 1 and 2 where highly educated participants were seen to disproportionately contribute to the study findings. The collection of qualitative data that supported quantitative findings should also be noted as a strength.

Although the representation of low SES groups was greater than the previous studies, people living in deprived neighbourhoods were still less likely to respond to the study invitation. The ascertainment of the intervention's effect was therefore

recorded in an unrepresentative sub-sample of the eligible population. This may go some way to explaining why there was a ceiling effect observed in the intention and knowledge outcomes. This finding highlights the need to observe the effect of the intervention among those who did not consent to participate in questionnaire-based research.

It should also be noted that the study took place in GP practices that were willing to take part in research. Centres such as these have been shown to be different to practices who do not participate in trials with regard to general achievement scores[1] and composition of ethnic minorities in the area (Down et al., 2009). Ascertainment of the study effect among members of the public who are not registered with practices familiar with research is therefore needed.

Despite using methods to increase response, rates of return were lower than expected. For example in a UK-based randomised trial of a CRC risk communication intervention, 60% of participants returned a completed questionnaire (Robb et al., 2008). Questionnaire length is unlikely to explain response differences between the studies as they were of similar length. However, the communication materials used by Robb and colleagues may have induced less cognitive burden. In their study, participants were randomised to three study groups: a control group (no information); a 'risk factors' group (leaflet about the risk factors for CRC and incidence of the disease); and a 'risk factors + screening information' group (risk factors leaflet + 120 words about CRC screening tests). Both information leaflets achieved a Flesch readability score that was superior to 'The Facts' leaflet (Robb et al., = 75.5 vs. 'The Facts' leaflet = 62.4). Although the gist leaflet was superior to all of the materials (84.5), the need to read 'The Facts' leaflet may have reduced response rates in this study.

An additional factor that may explain differences in participation between the two studies is the deprivation scores noted at the recruitment sites. The present study purposively sampled from three practices that were based in areas with high levels of neighbourhood deprivation. Robb and colleagues did not report IMD data, prohibiting direct comparison. However, observing the locations of the two studies it is fair to assume that the General Practices reported here were based in more deprived neighbourhoods.

[1] As measured by ascertainment of Quality and Outcomes Framework points

The recruitment of individuals who had not previously been screened was considered both a strength and limitation of the study. On the positive side participants were not biased by previous exposure and past behaviour. However, participants were younger than those who would normally be invited to participate in the NHS BCSP and the decision was anticipated rather than current. This forced me to rely on a proxy marker of behaviour (i.e. screening intention). Although the factors involved in intention and screening behaviour are similar, they may not always overlap (Power et al., 2008; Schwarzer, 2001; Shah, 2005). Further investigation with objective screening uptake data may be warranted.

A further issue with using participants who were naïve to the CRC screening process in this study was that they may have responded to the questionnaire differently to those with more experience. Vernon and colleagues investigated this topic by assessing whether responses to measures of barriers, benefits, self-efficacy and optimism were different according to level of experience with CRC screening (never screened, overdue for screening and currently screened) (Murphy et al., 2013). They showed that although most items and factors were similar, the never screened group responded differently to the barriers scale than the currently screened group. The screening categories may not be directly comparable to those reported here. However, it suggests that questionnaire responses may not always represent people who are of screening age. It may have been interesting to recruit a sample that had previously been screened so that this limitation could have been investigated further.

Finally, the majority of outcomes reported in this study were from valid scales. However some items (e.g. readability and usability) and scales (e.g. gist knowledge), were designed for the purposes of this study. The gist knowledge items were true or false items that were not difficult to answer. This may explain why a ceiling effect was observed for this outcome. However, the items were purposely designed so that they could assess the essential information needed to make a screening decision. Further research using samples of different ages, deprivation levels and ethnicities are required to confirm the reliability and validity of these measures.

7.4.6 Conclusion

In conclusion, this study did not support hypotheses related to the communicative effectiveness of the gist leaflet. The final stage of the Garner framework was therefore not met. The second stage (comprehensibility) of the evaluation was confirmed following positive effects for perceived readability, perceived usefulness and gist knowledge. Improvements to comprehensibility outcomes were particularly apparent among low numeracy individuals. The provision of two information materials may decrease the likelihood that they will be read, although the gist leaflet appeared to be favoured when people were given the option.

Chapter 8. Evaluating the communicative effectiveness of a gist-based colorectal cancer screening information leaflet: A national cluster randomised controlled trial (Study 4)

8.1 Introduction

Chapter 6 (study 2) and Chapter 7 (study 3) demonstrated that the gist leaflet was readable and comprehensible to a sample of individuals that were approaching screening age. The low response rate in study 3 meant that ascertainment of the study effect was limited to a self-selected, motivated group of individuals, although it benefited from the collection of detailed socio-cognitive outcome data. Further research was needed using a study design that provided objective screening uptake data for a greater proportion of the eligible sample.

In line with the overall aim of the thesis, the focus of study 4 was to investigate the effect of the gist leaflet on socioeconomic status (SES) inequalities in uptake and uptake overall. However, the study design provided the opportunity to observe the effect of the intervention on other population sub-groups such as sex, age and previous screening behaviour. While this was not a primary focus of the gist leaflet, there was justification for investigating whether these effects were present.

As discussed in previous chapters, differences in health literacy have been observed by sex and age, with men and older groups less likely to achieve adequate level. For example, a nationally representative survey of the United Kingdom (UK) (n=759) showed that men were more than twice as likely to have limited health literacy (von Wagner et al., 2007). In comparison with the youngest age group (18-44 years; 5.7%), the oldest age group (65+; 30%) were much more likely to have limited health literacy skills. This raises the possibility that a health communication intervention, designed with the principles of health literacy in mind, may be more beneficial to older individuals and men. Reyna has also argued that preferences for gist-based information increase with age (Reyna, 2011). The gist leaflet may therefore complement this preference by being a more accessible resource on which to base their screening decision.

A further factor that will be investigated is past behaviour. Previous screening participation is a strong determinant of repeat uptake (Steele et al., 2010a). This emphasises the importance of improving participation rates among those invited for the first time. Furthermore, people naïve to a behaviour may be more likely to seek information to assist with the decision-making process (Betsch, Haberstroh, Glöckner, Haar, & Fiedler, 2001; Verplanken, Aarts, & Van Knippenberg, 1997; Wahlich, Gardner, & McGowan, 2013). The effect of a health communication intervention may therefore be modified by previous exposure to screening information and the behaviour itself. A final reason for investigating screening history is that the gist leaflet was designed and evaluated with participants who had not previously been invited to screening (studies 1, 2 and 3). Their views and opinions may therefore be different to those who had previously participated, making the gist leaflet more suitable for their needs.

8.1.1 The current study

The aim of study 4 was to evaluate the communicative effectiveness of the gist leaflet in a national sample. A randomised controlled trial was used to compare objectively recorded colorectal cancer (CRC) screening uptake between an intervention group (standard information + gist leaflet) and a control group (standard information only).

The primary hypothesis of this study was that the SES gradient would be reduced in the intervention group compared with the control group. The prediction was for a progressively greater impact of the intervention across progressively lower SES quintiles. I also predicted that uptake would be higher in the intervention group overall, and that this effect would be moderated by sex, age, screening type and screening round. A planned sub-sample analysis on individuals invited for the first time was performed.

8.2 Methods

A copy of the completed Consolidated Standards of Reporting Trials (CONSORT) checklist is in appendix W. Statisticians associated with the ASCEND programme were consulted throughout the design phase of this study. They were responsible for

producing the randomisation sequence and performing the sample size calculation (Brentnall, et al., 2012).

8.2.1 Study design

The study was designed in collaboration with the managers and directors of the five screening hubs, Connecting for Health (who are responsible for the Bowel Cancer Screening System [BCSS]) and Real Digital International, who are responsible for sending the materials at three of the screening hubs (London, Southern and Eastern). The study design was adapted to accommodate the operating systems and processes of the NHS BCSP. The scale of the programme and the differences in management between the hubs mean that it was not possible to use an individually randomised design. Instead, a cluster randomised controlled trial was used, whereby randomisation occurs by another unit. In this case the unit of randomisation was composed of the 10 days over which the intervention ran, stratified by the five hubs (North-West hub, London hub, North-East hub, Eastern hub and Southern hub), such that there were 50 day/hub clusters.

The study was approved by the National Research Ethics Service London – Harrow Committee (Reference: 12/LO/1396) and is a registered clinical trial (ISRCTN74121020). Activities of the National Health Service Bowel Cancer Screening Programme (NHS BCSP) are covered by National Information Governance Board (NIGB) approval with regard to the handling of patient-identifiable data (Ref: PIAG 1-08(a)/2003).

8.2.2 Sample and setting

The study covered the working period of the 5th-16th November, 2012. Dates were selected to avoid annual holidays, when uptake can be inconsistent. All individuals invited to the NHS BCSP during the study period were effectively eligible to participate in the study. Inclusion criteria for a CRC screening invitation were being aged 59-74[1] and registered with a General Practitioner (GP). Individuals were excluded (and would not normally receive an invitation) if they were not registered

[1] Or 69 in the areas where the age extension has not been implemented. Note also that some individuals aged 59 that are approaching their 60th birthday are invited to participate in screening.

with a GP, or they had previously opted out of screening. Individuals were asked not to complete a Faecal Occult Blood test (FOBt) kit if they have been referred for an investigation of the bowel, have previously had bowel surgery, or have had a colonoscopy in the past two years. No additional inclusion/exclusion criteria were used that would not apply to the usual screening invitations. Individuals were not given any incentive as part of the study.

8.2.3 Randomisation and Blinding

A week before the start of the intervention, the randomisation sequence was generated by the ASCEND statistician (Prof Stephen Duffy) and sent to Connecting for Health, Real Digital International and the North-East and North-West hubs. Real Digital International are responsible for the administration of screening kits at the Southern, Eastern and London hubs. Necessary data (e.g. the numbers expected to be invited during the intervention period) were provided by the BCSS who are responsible for the logistical organisation of the programme (see Chapter 2 for a comprehensive description of how the screening programme is organised and the roles played by RDI and the BCSS).

For each hub, a set of ten random numbers were generated. For each set of random numbers, a day was allocated to intervention or control based on whether it was above or below the median of the random numbers. The decision to allocate either the intervention or control to below the median was determined by a coin toss (personal communication, Duffy).

The hubs and Real Digital International were not blind to randomisation; however the possibility of biasing participation was minimal due to the lack of direct contact with participants (Puffer, Torgerson, & Watson, 2003). Individuals were not aware of a comparator unless a member of their household also received an invitation during the study period that contained different information materials. There were approximately ten mailroom staff members at each hub (or Real Digital International's distribution centre) who were responsible for printing and packing the screening invitations. These individuals were not blind to group allocation and I was not blind to group allocation at the analysis stage.

8.2.4 Study groups

8.2.4.1 Control group

Individuals were sent the standard screening invitation two weeks prior to their screening kit. It was sent in an NHS envelope that contained an invitation letter and 'The Facts' booklet. After two weeks, an FOBt kit was sent through the post with a brief instructional leaflet. If there was no response after 4 weeks, a reminder letter and another FOBt kit were sent. For a copy of the study documents, see appendix S-V, X[1] and Y.

8.2.4.2 Intervention group

The intervention group received the gist leaflet within the same envelope as 'The Facts' booklet, but there were no other differences. The envelopes delivered to the study groups were the same size and shape.

8.2.5 Study variables

All study variables were based on individual-level data. Data from the trial were uploaded onto the Bowel Cancer Screening System (BCSS), which is the centralised system for screening invitations and is linked to general practices around the country. The BCSS contains detailed information on screening history, as well as who is eligible to be invited in the near future. Data from the BCSS were downloaded after 18 weeks so that the dataset could include uptake data. The downloaded data were sent to the Southern hub to be anonymised and cleaned. The ASCEND study office were sent this version of the dataset.

8.2.5.1 Study arm

Study arm (intervention or control) was calculated by the ASCEND statistician. Based on the date of invitation (ascertained from BCSS data) and the hub code, they used the randomisation schedule given to the hubs and Real Digital

[1] Minor changes were made to the leaflet reported in Chapter 8 after consultation with the research team.

International to compute which cluster the individual was based in (see appendix Z for an example of the randomisation schedule).

8.2.5.2 Uptake

Screening uptake was defined as returning an adequate FOBt kit within 18 weeks of being sent an invitation. 'Adequate' in this context was defined as reaching a definitive FOBt outcome of either 'normal' (no further clinical investigation required) or 'abnormal' (referral for further testing, usually colonoscopy). The variable was computed using data on the outcomes of all screening kits completed within this screening round. For example, a participant would be classified as not returning an adequate kit if they received an unclear result from their first test kit and then failed to complete a subsequent screening kit.

8.2.5.3 Deprivation

IMD scores were calculated based on the smallest geographical unit available to the screening programme (Lower Super Output Area [LSOA]). Super output areas were created by the Office for National Statistics to ensure stability when reporting area-based statistics. There are 32,844 LSOAs in England, with a minimum population of 1,000 and a maximum of 3,000 (400-1200 households) (Office for National Statistics, 2011b). The LSOA has previously explained area-level inequalities in bowel cancer screening uptake (von Wagner et al., 2011a). IMD quintiles were created based on sample data.

8.2.5.4 Gender

Gender was ascertained from General Practice records and uploaded onto the BCSS system.

8.2.5.5 Age

Age was also ascertained from General Practice records and uploaded onto the BCSS system. Individuals were recoded into the following age bands (59-64; 65-69;

70-74). Although screening is offered from the age of 60, some people may be invited in the days before their 60th birthday and were therefore coded as age 59.

8.2.5.6 Screening type

The BCSS records previous screening uptake, which allowed invitees to be coded as undergoing either prevalence or incidence screening. The term 'prevalence screening' is used to indicate the first time of screening, and the term 'incidence screening' is used to refer to subsequent screens (Steele et al., 2010a). For example, a person accepting a screening invitation for the second time would undergo prevalence screening if they had not been screened before or incidence screening if they had responded to the previous invitation.

8.2.5.7 Screening round

The BCSS also records the round in which the individual has been invited to. There have been 5 rounds of screening since the screening programme started in 2006. However, the majority of people would not have been invited to all of these rounds. I therefore categorised people as being a 'round 1 invitee' or a 'round 2+ invitee'. This is slightly different to the prevalence/incidence categorisation as screening round refers to whether the individual has previously been invited as opposed screened.

8.2.6 Study outcomes

8.2.6.1 Primary outcome

The primary outcome in the study was the proportion of people in each Index of Multiple Deprivation (IMD) quintile returning an adequate FOBt test kit.

8.2.6.2 Secondary outcomes

The overall proportion of people adequately screened was used as a secondary outcome. The extent to which the intervention's effect on uptake was moderated by

sex, age (59-64 vs. 65-69 vs. 70-74), screening type (prevalence screening vs. incident screening) and screening round (round 1 vs. 2+) was also monitored[1].

8.2.7 Sample Size

The principal statistician involved in the ASCEND project was responsible for formulating the sample size calculation. The following is a summary of the factors that were considered. Full details of the sample size calculation can be found in Brentnall et al., (2012).

There are different baseline uptake rates, socioeconomic profiles and population sizes in each of the different hubs. Separate sample sizes were therefore calculated, with each assuming the composition of one of the five hubs (see Table 8-1). The final calculation assumed the composition of the hub that required the largest sample (North-West). This is because whatever the underlying uptake rate, socioeconomic profile, or population size of the hub, there would be an adequate number of individuals invited to detect the anticipated effect.

Because the study randomised by day, and there is variation in the number of invitations sent per day, an inflation factor of 1.7 was included. Assuming $\alpha=0.05$ and power $(1-\beta)=0.9$, the number of individuals in each arm of the trial needed to detect a 1-2-3-4-5% difference in uptake in the least to most deprived IMD quintile respectively was 46,000 people in total (23,000 per arm). Due to the volume of invitations sent out by each hub during a working week (70-80,000), this sample would be achieved within 5 days. However, this would lead to an insufficient number of clusters and possibly create bias (Campbell, Donner, & Klar, 2007; Donner & Klar, 2004). The intervention therefore ran for 10 days, providing a sample of approximately 140-160,000.

[1] Screening type and screening round are sometimes collectively referred to as 'screening variables' or 'screening-specific variables'.

Table 8-1 Sample size required at each hub

Hub sample size was based on	N required per arm (excluding variance factor)	N required per arm (including variance factor)
North-West	13500	23000
London	12200	20740
North-East	11700	19890
Eastern	5400	9180
Southern	4500	7650

8.2.8 Quality assurance

To ensure that the helpline call centres were adequately equipped to deal with any additional calls they received as a result of the intervention, a list of frequently asked questions was developed by an ASCEND staff member (GV) who had experience of working on the screening helpline (see appendix AA). Along with other ASCEND researchers, I visited each of the hubs before the start of the trial to present the study design and ask for feedback on the logistics of the trial from hub staff and managers. At the time, the hubs were asked to record any feedback they received from members of the public as part of this process evaluation (see appendix BB).

An assessment of whether the intervention was a) delivered as intended and b) received as intended, was included. The process varied by hub:

Real Digital International Hubs. To ensure the leaflet was received as intended, a monitor letter was sent at the beginning and end of letters printed that day (60 monitor letters). Two letters were used to ensure that the appropriate materials were included within the entire batch. The monitor letters were sent to Professor Wendy Atkin at the trial office at Imperial College London. The randomisation schedule was also placed at the packing machines every day during the trial to ensure the correct materials were sent. Quality assurance checklists were also signed and counter-signed and e-mailed to the trial office daily.

North-Western Hub. In addition to printing and sending a monitor letter with each batch of letters (10 monitor letters), additional fidelity checks were put in place.

These included taking photographic evidence of the contents of the letters each day, and signing a log book to note what materials were included on that day. These additional fidelity checks were sent to the trial office daily.

North-Eastern Hub. The North-Eastern hub elected to print one monitor letter at the beginning of each batch of letters during the trial (10 monitor letters). No additional fidelity checks were in place at this hub during the trial period.

8.2.9 Data extraction

As demonstrated in Figure 8-1, raw data from the trial were extracted by Connecting for Health in March and sent to the Southern hub to be anonymised.

8.2.10 Analysis

Anonymised data were downloaded from the BCSS after 18 weeks. This was sent to a statistician employed on the project at the Southern Hub (Julia Snowball). She was responsible for data cleaning and liaising with the screening hubs regarding missing data. The dataset was then forwarded to a statistician working at UCL who was responsible for calculating the study arm variable. Following this, a dataset containing the following variables was securely sent to my e-mail account: age at invitation, sex, Index of Multiple Deprivation (IMD) score, hub code, screening episode, adequate screening status and intervention group. The statisticians therefore did not carry out any statistical analysis on these data before it was made available to me. I performed all analyses contained within this thesis.

Socio-demographic data across the study arms was described. Uptake between socio-demographic and screening groups was examined using chi-square analysis. Differences between the two arms of the trial were analysed using logistic regression. The primary logistic regression analyses were unadjusted, but secondary analyses adjusted for sex, age, IMD score (quintiles), screening round and hub (Spiegelhalter, Abrams, & Myles, 2003). To test for interactions between study arm and demographic/screening variables, ‘intervention group x variable’ interactions were computed and entered into the model predicting CRC screening uptake. The main effects of the intervention were calculated using logistic regression (Wald statistic). The assumptions of logistic regression were not violated.

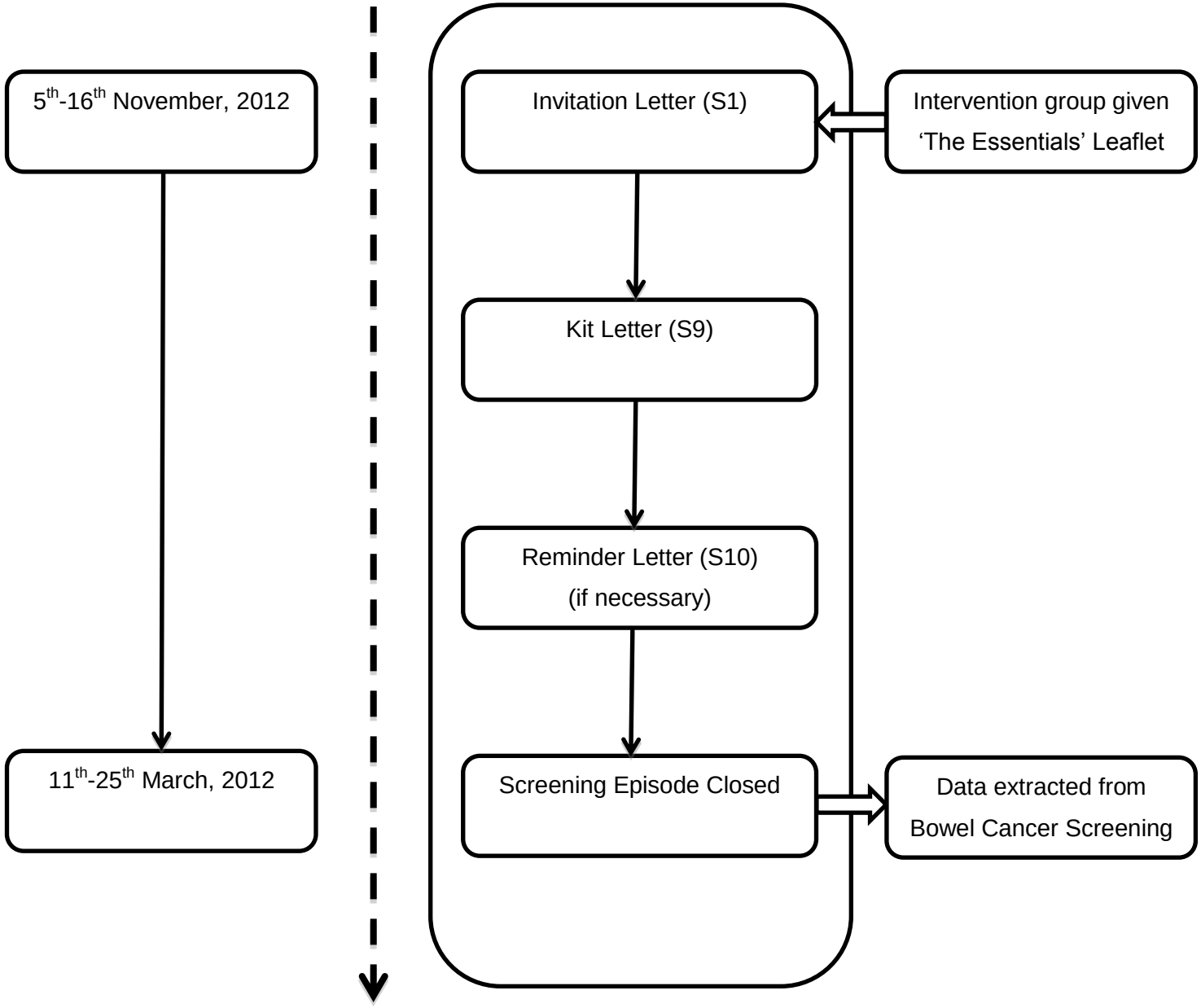


Figure 8-1 Organisation and schedule of the national trial

8.2.11 Missing data

Missing data for all study variables were minimal. Outcome data were not available from the screening hubs for 41 (0.03%) people, and 271 (0.16%) individuals lived in postcodes where IMD scores could not be calculated. There were a similar amount of missing data in both study groups. Missing data were treated as missing not at random, but were not imputed, because the missing data were minimal and because no other measures of SES could be used in estimation models to impute missing data. Missing IMD scores were therefore deleted pairwise. Uptake of individuals with missing IMD data was comparable to individuals in the second most affluent quintile (data not shown).

8.3 Results

As shown in the CONSORT diagram (Figure 8-2), a total of 163,566 individuals were randomised to the intervention group (n=79,134) or control group (n=84,432). Analysable data provided by the five screening hubs were available for 163,525 (99.97%) individuals.

As shown in Table 8-2, individuals were mainly from the younger age groups (age 59-64 [42.5%]; 65-69 [36.1%]) and had been invited at least once before (screening round 2+ [84.4%]). There were slightly more individuals invited for incident (53.3%) than prevalence (46.7%) screening. As expected, there were differences in the number of individuals invited from each screening hub, with the North-West hub inviting the most (28.6%) and London the least (8.6%). The numbers of men and women was similar. IMD quintiles were created using the study dataset and were therefore equal for each category.

Seventy-five of the 80 monitor letters were received by the study office and contained the appropriate study materials. The remaining monitor letters were not returned and it is unknown whether the appropriate intervention was supplied. No other problems with the implementation of the study were noted and no phone calls referring specifically to the gist leaflet were reported by the hubs.

Figure 8-2. CONSORT diagram

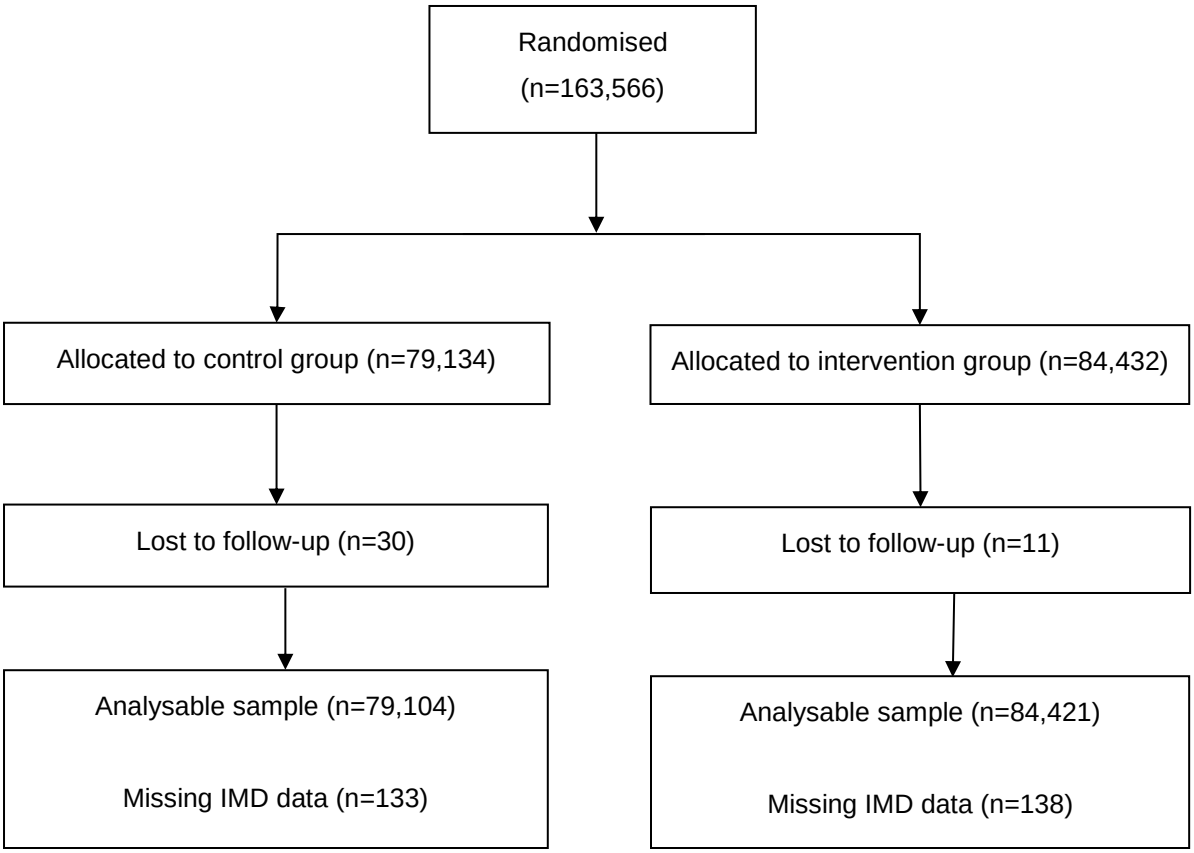


Table 8-2 Descriptive data of whole sample

	All (n=163525) N (valid %)	Control group (n =79104) N (valid %)	Intervention group (n =84421) N (valid %)
Sex			
Male	83866 (51.3)	38433 (48.6)	41226 (48.8)
Female	79659 (48.7)	40671 (51.4)	43195 (51.2)
Age			
59-64	69509 (42.5)	33589 (42.5)	35920 (42.5)
65-69	59086 (36.1)	65-69 (35.9)	30707 (36.4)
70-74	34930 (21.4)	17136 (21.7)	17794 (21.1)
Hub			
North-West	46838 (28.6)	24369 (30.8)	22469 (26.6)
Southern	41655 (25.5)	21004 (26.6)	20651 (24.5)
London	14052 (8.6)	6636 (8.4)	7416 (8.8)
North-East	26472 (16.2)	12858 (16.3)	13614 (16.1)
Eastern	34508 (21.1)	14237 (18.0)	20271 (24.0)
IMD score[+]			
1 (Affluent)	32746 (20.1)	16279 (20.6)	16467 (19.5)
2	32645 (20.0)	15681 (19.9)	16964 (20.1)
3	32576 (20.0)	15255 (19.3)	17321 (20.6)
4	32642 (20.0)	15372 (19.5)	17270 (20.5)
5 (Deprived)	32645 (20.0)	16384 (20.7)	16261 (19.3)
Screening type			
Prevalence	76363 (46.7)	36961 (46.7)	39402 (46.7)
Incidence	87162 (53.3)	42143 (53.3)	45019 (53.3)
Screening round			
1	25444 (15.6)	12410 (15.7)	13034 (15.4)
2 or more	138081 (84.4)	66693 (84.3)	71387 (84.6)

+ Numbers do not sum to 100% due to rounding.

8.3.1 Primary and secondary outcomes for whole sample

Table 8-3 shows overall uptake figures for the whole sample and all study sub-groups. Unadjusted analyses reporting the effectiveness of the gist leaflet are presented throughout. As shown in Table 8-4, no changes to statistical significance were observed in adjusted analyses.

Table 8-3 Uptake for whole sample and sample sub-groups

	N (% uptake)	Univariate comparisons
Overall sample	163525 (57.5)	-
IMD score+		
1 (Affluent)	32746 (66.2)	$\chi^2(4) = 4021.53$, $p < 0.001$
2	32645 (62.8)	
3	32576 (60.1)	
4	32642 (54.6)	
5 (Deprived)	14362 (44.0)	
Sex		
Male	79659 (55.8)	$\chi^2(1) = 204.47$, $p < 0.001$
Female	83866 (59.2)	
Age		
59-64	69509 (54.7)	$\chi^2(2) = 528.04$, $p < 0.001$
65-69	59086 (61.0)	
70-74	34930 (57.4)	
Screening round		
1	25444 (49.1)	$\chi^2(1) = 885.05$, $p < 0.001$
2+	138081 (59.1)	
Screening type		
Prevalence	76363 (26.0)	$\chi^2(1) = 58470.10$, $p < 0.001$
Incidence	87162 (85.2)	

8.3.1.1 Primary outcome

Uptake by socioeconomic status. There was a strong SES gradient observed in uptake during the study period, ranging from 66.2% through 62.8%, 60.1%, 54.6%

and 44.0% in the least to most deprived quintiles respectively ($\chi^2(4) = 4021.53$, $p < 0.001$). There were no significant differences in the effectiveness of the intervention to increase uptake among any of quintiles 2 to 5 compared to the most affluent quintile (quintile 1) (see Table 8-4).

8.3.1.2 Secondary outcomes

Overall uptake. Overall uptake was 57.5% and did not differ between the intervention group and control group (57.7% vs. 57.4% [0.3% diff]; Wald statistic = 2.261; OR = 1.015 [95% CI = 0.995-1.035], p = 0.133).

Uptake by sex. Uptake among women (59.2%) was significantly higher than men (55.8%; $\chi^2(1) = 204.47$, $p < 0.001$). The effect of the intervention was similar for men (intervention group = 56.0% vs. control group 55.4% [0.6% diff]) and women (intervention group = 59.3% vs. 59.2% [0.1% diff]). The interaction between sex and intervention group was not significant (Wald statistic = 0.915; OR = 1.019 [95%CI = 0.980-1.060], p = 0.339).

Uptake by age. Uptake varied by age group ($\chi^2(2) = 528.04$, $p < 0.001$). However, the effect was not linear. Individuals in the youngest age group (59-64) were the least likely to be adequately screened (54.7%), followed by the oldest group (70-74; 57.4%) and then the middle group (65-69; 61.0%). The effect of the intervention was similar for individuals aged 59-64 (intervention group = 55.0% vs. control group = 54.3% [0.7% diff]), 65-69 (intervention group = 60.9% vs. control group = 61.2% [0.3% diff]) and 70-74 (intervention group = 57.8% vs. control group = 56.9% [0.9% diff]). The interaction between age and intervention group was not significant (65-69 vs. 59-64: Wald statistic = 3.529; OR = 0.958 [95% CI = 0.916-1.002], p = 0.060; 70-74 vs. 59-64: Wald statistic = 0.076; OR = 1.007 [95% CI = 0.956-1.061], p = 0.782).

Screening type. Uptake in the prevalence round of screening (26.0%) was significantly lower than the incident round (85.2%; $\chi^2(1) = 58470.10$, $p < 0.001$). The effect of the intervention was similar for individuals in the prevalence round (intervention group = 26.2% vs. control group = 25.7% [0.5% diff]) and incidence round (intervention group = 85.3% vs. control group = 85.1% [0.2% diff]). The interaction between screening type and intervention group was not significant (Wald statistic = 0.331; OR = 1.015 [95% CI = 0.966-1.066], p = 0.565).

Table 8-4 Descriptive analysis and univariate interaction effects for the total sample

	Control N=45369	Intervention N=48729	Univariate unadjusted interactions (variable x intervention group)		Univariate adjusted interactions (variable x intervention group)	
	N (% of uptake)		OR (95% CI)	p value	OR (95% CI)	p value
Sex						
Male	21303 (55.4)	23107 (56.0)	1.019 (0.980-1.060)	0.339	1.018 (0.978-1.059)	0.385
Female	24066 (59.2)	25622 (59.3)	Ref	Ref	Ref	Ref
Age						
59-64	18245 (54.3)	19760 (55.0)	Ref	Ref	Ref	Ref
65-69	17371 (61.2)	18688 (60.9)	0.958 (0.916-1.002)	0.060	0.962 (0.920-1.007)	0.098
70-74	9753 (56.9)	10281 (57.8)	1.007 (0.956-1.061)	0.782	1.019 (0.967-1.074)	0.480
IMD score+						
1 (Affluent)	10775 (66.2)	10893 (66.2)	Ref	Ref	Ref	Ref
2	9840 (62.8)	10662 (62.9)	1.006 (0.944-1.073)	0.854	0.995 (0.933-1.061)	0.879
3	9174 (60.1)	10413 (60.1)	1.001 (0.939-1.067)	0.978	1.008 (0.946-1.075)	0.804
4	8373 (54.5)	9459 (54.8)	1.014 (0.952-1.080)	0.666	0.999 (0.938-1.065)	0.979
5 (Deprived)	7145 (43.6)	7218 (44.4)	1.034 (0.970-1.101)	0.302	0.971 (0.911-1.035)	0.369
Round						
1	6003 (48.4)	6483 (49.7)	1.050 (0.995-1.107)	0.078	0.964 (0.913-1.018)	0.187
2+	39366 (59.0)	42246 (59.2)	Ref	Ref	Ref	Ref

	Control N=45369	Intervention N=48729	Univariate unadjusted interactions (variable x intervention group)		Univariate adjusted interactions (variable x intervention group)	
	N (% of uptake)		OR (95% CI)	p value	OR (95% CI)	p value
Screening type						
Prevalence	9496 (25.7)	10333 (26.2)	1.015 (0.966-1.066)	0.565	0.978 (0.929-1.029)	0.391
Incidence	35873 (85.1)	38396 (85.3)			Ref	Ref

Adjusted analyses control for sex, age, IMD score (quintiles) screening round and hub.

Uptake by round. Individuals receiving their first screening invitation were significantly less likely to be adequately screened than those in subsequent rounds (49.1% vs. 59.1%; $\chi^2(1) = 885.05$, $p < 0.001$). The effect of the intervention was similar for individuals in the first screening round (intervention group = 49.7% vs. control group = 48.4% [1.3% diff]) and second (or more) screening round (intervention group = 59.2% vs. control group = 59.0% [0.2% diff]). The interaction between screening round and intervention group was not significant (Wald statistic = 3.116; OR = 1.050 [95% CI = 0.995-1.107], p = 0.078).

8.3.2 Sub-sample analysis: Round one invitees

The interaction between screening round and intervention group was not significant in the main analysis. However, because I was particularly interested in the response to the intervention among people invited to screening for the first time, additional sub-group analyses were undertaken. Uptake rates of people invited to their first round of screening are shown in Table 8-5. Table 8-6 shows the effect of the intervention by SES, sex and age.

Uptake by socioeconomic status. Uptake among individuals invited in the first round ranged from 57.9% through 55.0%, 51.4%, 45.9% and 36.7% in the least to most deprived quintiles respectively. The effect of deprivation on uptake was significant ($\chi^2(4) = 591.38$; $p < 0.001$). There were no significant differences in the effectiveness of the intervention to increase uptake among quintiles 2-5 compared to the most affluent quintile (quintile 1).

Overall uptake. Uptake was 49.1% and was significantly different between the intervention and control groups (intervention group = 49.7% vs. control group = 48.4% [1.3% diff]; Wald statistic = 4.752; OR = 1.056; 95%CI = 1.006; p = 0.029).

Uptake by sex. Uptake among women (52.2%) was significantly higher than men (46.0%; $\chi^2(1) = 98.77$, $p < 0.001$). The intervention was more effective at increasing uptake among men (intervention group = 47.4% vs. control group = 44.5% [2.9% diff]) than women (intervention group = 52.1% vs. control group = 52.3% [0.2% diff]; Wald statistic = 5.692; OR = 1.127 [95%CI = 1.022-1.244], p = 0.017).

Table 8-5 Overall uptake of round 1 invitees and sub-group differences

	N (% uptake)	Univariate comparisons
Overall sample	25444 (49.1)	
IMD score+		
1 (Affluent)	4900 (57.9)	$\chi^2(4) = 591.38$; $p < 0.001$
2	4924 (55.0)	
3	4893 (51.4)	
4	5196 (45.9)	
5 (Deprived)	5485 (36.7)	
Sex		
Male	12749 (46.0)	$\chi^2(1) = 98.77$, $p < 0.001$
Female	12695 (52.2)	
Age		
59-64	22528 (49.3)	$\chi^2(2) = 8.76$, $p = 0.013$
65-69	373 (42.9)	
70-74	2543 (47.5)	

Uptake by age. Uptake varied significantly by age ($\chi^2(2) = 8.76$, $p = 0.013$). The effect was not linear and did not follow the same pattern observed among the whole sample. Individuals in the youngest age group (59-64; 49.3%) had the highest uptake, followed by the oldest age group (70-74; 47.5%) and then the middle age group (65-69; 42.9%). Very few individuals aged 65-69 were invited to screening for the first time (n=373).

Individuals in the 70-74 age group (intervention group = 50.3% vs. control group = 44.6% [5.7% diff]) were significantly more likely to be affected by the intervention compared with the 59-64 age group (intervention group = 49.8% vs. control group = 48.8% [1.0% diff]; Wald statistic = 4.952; OR = 1.205; [95%CI = 1.023-1.421], p = 0.026). The difference between the 65-69 age group (intervention group = 40.0% vs. control group 45.9% [5.9% diff]) compared with the 59-64 age group was not significant (Wald statistic = 1.744; OR = 0.755 [95% CI = 0.499-1.142], p = 0.183).

Harms. No harms were reported during the course of this study.

Table 8-6 Descriptive analysis and univariate interaction effects for the sub-sample of round 1 invitees

	N (% of uptake)		Univariate unadjusted interactions (variable x intervention group)		Univariate adjusted interactions (variable x intervention group)	
	Control N=6003	**Intervention N=6483**	**OR (95% CI)**	**p value**	**OR (95% CI)**	**p value**
Sex						
Male	2776 (44.5)	3084 (47.4)	1.127 (1.022-1.244)	0.017	1.128 (1.021-1.247)	0.018
Female	3227 (52.3)	3399 (52.1)	Ref	Ref	Ref	Ref
Age						
59-64	5373 (48.8)	5744 (49.8)	Ref	Ref	Ref	Ref
65-69	84 (45.9)	76 (40.0)	0.755 (0.499-1.142)	0.183	0.811(0.531-1.239)	0.333
70-74	546 (44.6)	663 (50.3)	1.205 (1.023-1.421)	0.026	1.183 (1.002-1.398)	0.048
IMD score+						
1 (Affluent)	1374 (57.2)	1464 (58.6)	Ref	Ref	Ref	Ref
2	1258 (53.5)	1451 (56.4)	1.063 (0.906-1.247)	0.456	0.950 (0.809-1.115)	0.528
3	1220 (51.3)	1297 (51.6)	0.957 (0.816-1.123)	0.592	1.066 (0.908-1.251)	0.434
4	1169 (45.6)	1218 (46.2)	0.968 (0.827-1.133)	0.682	1.051 (0.897-1.231)	0.539
5 (Deprived)	974 (36.2)	1038 (37.2)	0.986 (0.842-1.155)	0.861	1.022 (0.872-1.197)	0.790

Adjusted analyses control for sex, age, IMD score (quintiles) screening round and hub.

8.4 Discussion

This study reports the findings of a national cluster randomised controlled trial evaluating the effectiveness of a supplementary gist-based information leaflet to increase CRC screening uptake in the NHS BCSP. As in study 3, the intervention group were provided with both the gist leaflet and 'The Facts' booklet and this was compared against a control group receiving 'The Facts' only. The large sample size (n=163,525) provided sufficient power to investigate whether the intervention was successful at reducing SES inequalities in CRC screening uptake. The large sample also enabled me to investigate whether the intervention was modified by age, sex, screening type and screening round. A particular focus of the study was to investigate the effect of the gist leaflet among people invited to CRC screening for the first time. Sub-sample analyses were therefore performed with this group.

8.4.1 Overview of sample

Average uptake of screening in the whole sample was 57.5% and this is comparable to figures observed after the third round of the English bowel cancer screening pilot (58.7%; Moss et al., 2012). Uptake was graded by SES, ranging from 44.0%-66.2% in the most to least deprived quintile, and this is similar to the most comparable data which was reported by the Scottish programme (Information Services Division, 2013b). Uptake was also higher in women and among those aged 65-69 years.

Among the sub-sample of individuals invited for the first time, overall uptake was slightly lower than previously published figures (49.1% vs. 53.6%) (von Wagner et al., 2011a). Uptake in the most affluent quintile was also lower than previously reported in the national data (57.9% vs. 61.1%), whereas the most deprived quintile in this sample had higher uptake figures (36.7% vs. 35.0%). The SES gradient in this sample was therefore less pronounced than has previously been observed, but this was mainly due to a lower level of uptake among the most affluent. Uptake differences between men and women were comparable to national estimates. This is the first time uptake data from the older group (70-74) has been reported, and this showed that older groups were almost as likely as the youngest group to take up the screening offer.

8.4.2 Study findings

There was no evidence that the intervention either increased uptake overall or reduced the SES gradient in screening uptake in the whole sample. Analysis of the secondary outcomes showed the effect was similar for sex, age, screening type and screening round. These findings were maintained in adjusted analyses controlling for sex, age, IMD score (quintiles) screening round and hub. On the basis of these results, there is no evidence that the gist leaflet achieved the communicative effectiveness stage of the tripartite Garner model (Garner et al., 2012).

As mentioned in the introduction, I was particularly interested in investigating the effect of the gist leaflet among people invited for the first time. This is because the information needs of people are likely to be altered by their level of experience with the programme. For example, there is evidence that people who have established patterns of behaviour are less likely to seek information about the behaviour in question (Betsch et al., 2001; Verplanken et al., 1997; Wahlich et al., 2013). It may therefore be possible that groups invited for the first time are more reliant on guidance from official communication than others who have previously made a decision about CRC screening.

The sub-sample analysis showed that the intervention did not affect the SES gradient in uptake. There was however a small but significant difference in uptake (1.3%) in favour of the intervention. This effect was smaller than the predicted difference (3%) and the extent to which it was clinically meaningful is unclear (Halloran et al., 2012). It is perhaps best to conclude that the addition of gist-based information to the standard materials used in the NHS BCSP is likely to have little impact on overall screening uptake and will not reduce the SES gradient.

The difference in uptake between the intervention and control group was 0.2% for women, and 2.9% for men. This finding was particularly welcome as women are consistently more likely to respond to the first CRC screening invitation (Hardcastle et al., 1996; UK Colorectal Cancer Screening Pilot Group, 2004). For example, uptake for men in the first round of the NHS BCSP was 51.0% compared with 56.4% in women (von Wagner et al., 2011a). Similar figures were noted in the current dataset. The provision of gist-based information to first round invitees may therefore help to narrow the observed gender differences in the programme.

To my knowledge, there have been no reports of sex differences in gist-based processing. However, national estimates show men are more likely to have limited health literacy (von Wagner et al., 2007). It is therefore possible that men are more able to engage with the gist leaflet because of its superior readability. Sex differences in informational avoidance have rarely been reported, but where they have they appear to suggest that women are more likely to avoid cancer information (McCloud et al., 2013). It is therefore possible that men will be more affected by supplementary screening information. The sample reported by McCloud and colleagues were cancer survivors, and therefore the type of information they were avoiding was likely to be very different to the population being included here. Further investigation among the screening eligible population is needed to ascertain whether avoidance of cancer screening information can explain socio-demographic differences in uptake, and responses to health communication interventions.

An additional group that might benefit from gist-based information in the first round of screening was older individuals. For example, significant effects were noted for the 70-74 age group who demonstrated a 5.7% difference in uptake between the intervention and control, compared with a 1.0% difference among the 59-64 age group. The age effect is an important finding considering the on-going extension of the screening programme. It also supports the positive association between older age, preferences for gist-based processing (Reyna, 2011) and poor health literacy skills (von Wagner et al., 2007). The age effect can also be explained by differences in the design of the gist leaflet. For example, the text size used in the gist leaflet was larger than 'The Facts' booklet. This may have made it easier to read for older adults who are more likely to have eyesight difficulties (Owen et al., 2012; Rudnicka et al., 2012). Working memory has also been shown to decrease in older age (Singh-Manoux et al., 2012). Therefore the shorter and less cognitively burdensome gist leaflet may have been more suitable for older adults. Collecting cognitive measures when evaluating similar cancer communication interventions may help to answer these questions (Wilson et al., 2010).

The differential impact of the gist leaflet among older groups and men invited for the first time demonstrates that it is possible to affect CRC screening uptake by changing the information that is provided as part of the invitation. One limitation of the age effect is that the number of 70-74 year olds invited for the first time is small and will eventually vanish once the age extension is fully rolled out. In this instance,

the resources required to tailor information to specific age groups invited for the first time may therefore not be worthwhile. Interventions among other socio-demographic groups may however be warranted.

Further research is required to investigate who is in need of informational support and at what stage of the screening process. Identification of such groups opens the possibility of disseminating different information materials (also known as tailoring) depending on factors such as previous screening experience. The Elaboration Likelihood model suggests that providing information that is more personally relevant increases cognitive activity and the likelihood it will be processed (Petty & Cacioppo, 1986). In turn, tailoring can lead to more thought being given to health messages, and more evaluation of their content. Although it may be logistically challenging, I would suggest that the NHS BCSP should at least discuss the possibility of tailoring information within the programme.

8.4.3 Strengths and limitations

This study addressed a limitation of study 3 as it collected objective rather than self-reported outcome data. It also overcame the problem of a highly motivated sample being recruited, as participation did not require any additional effort such as completing a questionnaire. Ascertainment of the study effect was achieved for over 99% of the eligible population.

A parallel randomised controlled trial could not be performed and a cluster randomised trial was the strongest alternative. One advantage of this design includes the ability to develop quality assurance measures which monitor intervention fidelity. The trial monitor levels showed that the intervention was delivered with a high level of fidelity. It is therefore feasible to run interventions within highly organised screening programmes without affecting usual practice. The disappointing outcome of the trial should not detract the NHS BCSP from working with academic researchers to evaluate changes to the information materials used in the programme.

There are several disadvantages of cluster randomised trials. These include compromised statistical efficiency due to clustering, which increases the sample size required to achieve appropriate power (Campbell et al., 2007; Donner & Klar, 2004). This was addressed in the sample size calculation and the trial surpassed its

recruitment target (Brentnall et al., 2012). A further limitation is the possibility that the study groups became contaminated, such that individuals in the control group were exposed to the intervention (e.g. two household members receiving their invitations at a similar time). While this limitation is noted, it would also have applied to other study designs, including parallel randomised controlled trials. The study did not suffer from other common limitations of randomised trials such as allocation concealment, and missing follow-up data. This provides support for the validity of the findings.

A further limitation of using a cluster randomised controlled trial is the possibility that internal factors of the cluster affected the outcome. For the years of 2011-2012 a researcher from the ASCEND team (GV) identified 149 research initiatives related to CRC screening and 206 screening promotion activities nationwide. With such a large number of concurrent activities it is highly likely that some were present during the study period. This is important as these events may have acted as a 'cue to action', triggering higher screening uptake on that day. In turn, this may have biased the study in favour or against the intervention. The natural fluctuation in uptake within the hubs and the large number of heterogeneous events makes it impossible to control for their effect on the intervention. This bias would have been less apparent if a parallel design was used.

It should be noted that although several demographic variables were reported (i.e. age, sex and neighbourhood deprivation), no data were available on other factors that have been associated with screening participation such as ethnicity, marital status and individual-level deprivation (e.g. education and income). It may be possible to use this data to perform secondary analyses on some of these variables. For example, data from the hubs could be used to calculate which households received multiple invitations during the study period (as a proxy for relationship status). However, no protocol for this was in place at the start of the ASCEND programme.

A further limitation was that no socio-cognitive data were recorded in this study, thereby limiting the extent to which screening uptake could be explained beyond socio-demographic correlates. Socio-cognitive data is logistically challenging to collect due to confidentiality issues in the NHS BCSP and the complexity of sending

additional materials during the invitation stage. This limitation emphasises the importance of the data collected in previous chapters.

8.4.4 Conclusion

In conclusion, this national cluster randomised controlled trial observed that a supplementary gist-based leaflet had no effect on inequalities in screening uptake. There was also no effect of the intervention on screening uptake overall and this was not moderated by gender, sex, screening type or screening round. Although a small difference was observed in uptake overall among the sub-sample of individuals invited to screening for the first time, this effect was small and not clinically important. The larger effects seen in this sub-sample on gender and age may have useful implications for the NHS BCSP. Further research determining why these effects were only observed among first time invitees is required before widespread implementation.

Chapter 9. Discussion

9.1 Summary of the literature and aims

CRC is a major cause of cancer-related death in the United Kingdom (UK) (General Register Office for Scotland, 2012; Northern Ireland Statistics Research Agency, 2012; Office for National Statistics, 2012a). Survival from the disease is strongly associated with the stage of diagnosis, and earlier diagnosis may partially explain why higher socioeconomic status (SES) groups are more likely to live longer with the disease (Coleman et al., 2004). Poor uptake of colorectal cancer (CRC) screening by lower SES groups therefore has the potential to exacerbate inequalities in CRC survival (von Wagner et al., 2011a). It is vital to identify cost-effective and implementable strategies to level the social gradient.

A number of qualitative and quantitative studies suggest that one of the key determinants of non-participation in screening may be the inability to comprehend the screening offer (Chapple et al., 2008; Dolan et al., 2004; von Wagner et al., 2009). Poor background knowledge about CRC and low awareness of the National Health Service Bowel Cancer Screening Programme (NHS BCSP) contribute to this general low level of understanding (Dolan et al., 2004; Jalleh et al., 2010; Juszczyk et al., 2011; Shokar et al., 2005). The consistent finding that lower SES groups are less likely to comprehend to the CRC screening offer suggests strategies to address these deficiencies may have concomitant effects on reducing inequalities in screening uptake (Dolan, 2004; Morris et al., 2013; von Wagner et al., 2009).

Written information is the main strategy for informing the public about the aims, benefits and risks of screening because there is no healthcare professional contact as part of the initial CRC screening invitation. Written health communication strategies offer a cheap and accessible way of reaching a large number of people. Cost and reach are particularly important factors to consider for the NHS BCSP because it is the largest organised screening programme worldwide. Data from a number of clinical trials provide some support for the effectiveness of written communication in increasing CRC screening uptake (Hardcastle et al., 1986; Hewitson et al., 2011; Wardle et al., 2003). However, there have been few attempts to investigate SES differences in response to health communication strategies (Wardle et al., 2003).

People with low levels of health literacy have been shown to disproportionately struggle when reading health communication materials related to CRC screening. They are also more likely to avoid information related to cancer (Morris et al., 2013; von Wagner et al., 2009). Markers of SES such as education, income and ethnicity are closely linked with health literacy (Boxell et al., 2012; Ibrahim et al., 2008; von Wagner et al., 2007). Improving the readability and comprehensibility of health communications for people with low health literacy may reduce communication inequalities, and in turn result in a levelling of the SES gradient in CRC screening uptake.

These observations were used as the basis for this thesis, which aimed to design and evaluate a gist-based health communication intervention that reduced SES inequalities in CRC screening uptake. The Fuzzy Trace Theory (FTT) model was used to guide the development of the gist leaflet, as it provided a theoretical argument for simplifying health information for people with low levels of basic skills. Guidelines specifically targeted towards improving health communication for individuals with low health literacy were consulted throughout this process.

9.2 Summary of findings

The first study in this thesis (Chapter 4) used the think-aloud method to establish how people interpret the CRC screening offer when they read the existing information booklet, 'Bowel Cancer Screening: The Facts'. Eighteen participants were recruited from a number of sources. Despite attempts to recruit people who lacked health literacy skills, the resulting sample was highly educated and they disproportionately contributed to the findings.

Participants made on average 15 reading mistakes during the task, with terminology such as colonoscopy, colorectal and adenoma being particularly troublesome. The value of detailed biological processes such as the function of the colon and the adenocarcinoma sequence were questioned by participants. In addition, the range of numerical information throughout the booklet led to confusion and calls for it to be simplified. Participants commented that the booklet should be shorter for fears that a lengthy complex document may inhibit individuals from processing the most relevant text.

The think-aloud study provided detailed commentary on areas of the booklet that were considered unnecessary, confusing and poorly designed. However, because of the underrepresentation of low health literacy groups, the study did not provide relevant data to the extent that I thought it might at the start of the study. Although I was able to consult other relevant literature and speak to Specialist Screening Practitioners (SSPs) who work in the programme, by using data from Study 1 I may have failed to adequately address comprehension barriers that are experienced by those with the lowest levels of health literacy.

Nonetheless, using the resources available to me, I developed a gist-based information leaflet that was guided by the FTT model. This was an iterative process that resulted in many changes that were informed by best practice guidelines for designing simplified health information. One issue that I faced during this process was the scarcity of research on how FTT should be conceptualised when designing CRC screening information. FTT has roots in child eye-witness testimony and basic cognitive psychology, and has only recently been applied to the field of medicine. Although the decisions I made during the design phase were informed by FTT research, I was forced to consider other factors such as the issue of informed decision-making and the requirements of the NHS BCSP. The gist leaflet may therefore not have been a true representation of FTT, but instead should be considered to be my best attempt to accommodate these often competing influences.

Study 2 used a performance-based approach to evaluate the gist leaflet's readability and comprehensibility. The method is based on principles of engineering (i.e. designing, testing and modifying prototypes), and has been applied to the evaluation of medication labels. In rounds of approximately 8-10 participants, the volunteers read the gist leaflet and answered a series of simple true or false statements about CRC and CRC screening. Using a pre-defined threshold (80% of participants had to answer each item correctly), the leaflet went through three rounds of testing before it was deemed comprehensible to the public and fit-for-purpose. Changes were made to the content, design and layout of the information in response to incorrect statements and qualitative data that were also collected. These changes were also informed by expert groups, best practice guidelines and FTT.

As with the think-aloud study, study 2 did not have a sufficient number of low literacy participants. Although this was improved in the later rounds of testing, the overall sample did not reflect the purposive nature of the recruitment methods used. The user-testing method was suited to people with low levels of basic skills, although the true/false responses may have led to artificially high levels of comprehension. The semi-structured interview that was performed after the user-testing was also more suited to educated participants. This is because they were more able and perhaps more willing to articulate issues they had with the gist leaflet, as well as offer solutions. Using mixed-methods was important as it allowed the perspective of both high and low literacy groups to be ascertained. However, participants with high health literacy are likely to have disproportionately influenced the study findings.

To investigate the communicative effectiveness of the gist leaflet and provide a more thorough test of the comprehensibility stage, study 3 was developed. This used a multicentre parallel randomised controlled trial recruiting from deprived General Practices in the north of England. In line with the framework, screening intention was the primary outcome and perceived readability and usefulness of the information, gist knowledge, perceived risk of CRC and worry about CRC were secondary outcomes. The extent to which the intervention addressed communication inequalities was investigated by monitoring the effect of the intervention for low and high numeracy groups.

The study groups were composed of an intervention group who were given the gist leaflet plus ‘The Facts’ booklet, and a control group who were given ‘The Facts’ booklet only. This study was therefore an important part of the evaluation as it was the first to investigate whether there was any added benefit of providing the gist leaflet to the established programme booklet. The decision to use the gist leaflet as a supplement was made early on in the development of the gist leaflet to accommodate concerns from the NHS BCSP committee that informed decision-making would be harmed as a result of providing gist-based information.

Although this decision was in keeping with the policy context of the screening programme, it led to a significant difference in the likelihood of participants reading the information materials they were allocated to. When offered the choice, participants were more likely to choose to read the gist leaflet than ‘The Facts’ booklet. This preference was particularly apparent among the low numeracy group.

Although these differences were small, it might be safe to assume that they may be more pronounced in a sample who are not invested in completing a questionnaire. Further consideration of whether the gist leaflet should supplement 'The Facts' booklet, or be delivered as a standalone leaflet is clearly necessary.

The readability and usefulness scores provided by participants indicated that both information materials were considered acceptable. However, in support of the superior Flesch-Kincaid readability scores, participants in the intervention group were more likely to report that the gist leaflet was readable. These effects were stronger for low numeracy groups providing evidence that it was more accessible for people with poor basic skills. Although the leaflets were considered equally useful, there was a tendency for low numeracy respondents to prefer the gist leaflet.

The intervention group were also more likely to have adequate knowledge. There were however no significant differences between the groups in intention or perceived risk. The gist leaflet therefore did not affect the socio-cognitive antecedents of behaviour in the way that was hypothesised at the beginning of the study. Collectively, the gist leaflet may marginally improve comprehension of the screening offer, but it is unlikely to affect inequalities in uptake because there was no effect on intention. It may also inadvertently decrease the likelihood that people will read the information they are provided with, thereby affecting informed decision-making.

The results of study 3 provided weak support for further evaluation without amendments to the gist leaflet, or consideration of the context in which it was delivered (i.e. as a supplement). However, as this project was part of a larger NIHR programme grant, there was pressure to deliver the planned programme of work. Also, the hubs and Real Digital International had undertaken a good deal of preparation for the national trial. Alterations to these plans would not have been possible without adding to the workload.

Despite these reservations, there was also some justification for continuing with the original plans. Study 3 was limited by a highly motivated and relatively educated sample who reported screening intention rather than objective uptake data. The decision was therefore made to continue with the original protocol (study 4); a national cluster randomised controlled trial recording screening uptake data. This

study design enabled me to ascertain the effect of the intervention in 99% of the eligible sample, and was therefore a more thorough test of the leaflet's communicative effectiveness. As with study 3, the control group were given the standard information and the intervention group were given standard information plus the gist-based leaflet.

The primary aim of this study was to assess to extent to which the leaflet reduced the SES gradient in CRC screening uptake. Secondary outcomes included overall uptake and uptake among population sub-groups (e.g. gender, age and screening history). As the design process was largely undertaken with individuals who had not been invited to CRC screening, sub-sample analyses were performed among first time invitees.

Disappointingly, data from the whole sample showed there were no significant differences between the intervention and control group on any of the outcome measures. In sub-sample analyses that only included individuals that were being invited for the first time, there was also no significant effect on the SES gradient. In the sub-sample there was a small significant difference in screening uptake between the study groups. However, the extent to which this was clinically meaningful is unclear. The intervention was also more effective among men and older individuals invited for the first time. Overall, the gist leaflet did not meet the requirements for all three stages of the Garner framework because the message did not result in behavioural differences among the predicted groups.

9.3 Implications of thesis and future directions

Findings from study 3 provided support for FTTs hypothesis that the provision of information in a format that encourages gist extraction can reduce the cognitive burden placed on the reader. Furthermore, data on some outcomes indicated this reduced cognitive burden was experienced to a greater extent among individuals with poorer numerical ability, which would also be predicted by FTT. There was also evidence to suggest that the provision of gist-based information increased knowledge over and above the standard information. FTT would predict this to happen because of the improved ease through which the gist could be extracted and encoded into memory.

There are several possible explanations for the null effect of the intervention on screening uptake. Throughout the design phase of the intervention, care was taken to ensure that the leaflet could be easily implemented within the NHS BCSP if it successfully reduced the SES gradient in screening uptake. To ensure the leaflet adhered to principles of informed decision-making, the decision was made to include 'The Facts' booklet with all screening invitations and treat the gist leaflet as a supplement, as opposed to a standalone leaflet (Ramirez & Forbes, 2012). However, evidence from study 3 suggested that this may have led to more informational avoidance, thereby diluting the effect of the intervention.

Providing gist information in isolation (i.e. not as a supplement) may further encourage engagement with the materials and facilitate gist-based decision-making. One possible compromise would be to only provide the gist leaflet to those that are being sent a reminder after four weeks of non-response. These individuals are sent an additional test kit, but not another copy of 'The Facts' booklet. The gist leaflet could therefore be delivered in isolation, which would still satisfy the need to provide invitees with the established materials. Although the current gist leaflet may need to be slightly adapted if it is used for these purposes[1], the NHS BCSP should consider testing this approach in future research.

Similarly, I made decisions regarding the content of the leaflet that might have been different in other health contexts. For example, when describing risk information, the simplest gist (i.e. categorical) could not be presented. Instead, numerical information was supplemented with a verbal descriptor (e.g. most people [98 out of 100]) to place the information in a more comprehensible context. Although this approach has been used successfully in a number of samples, it was not sufficient to influence intention or perceived risk in study 3 (Berry & Hochhauser, 2006; Knapp et al., 2010; Zikmund-Fisher et al., 2007).

FTT may be most suitable when it is ethical to present risk information in its most simple form. For example, this may occur when the risk of a side-effect is very minimal (e.g. medication side-effects) or if a decision is being made between two procedures with very similar outcomes (e.g. surgery vs. radiation therapy in prostate cancer). In both contexts, Reyna would argue that an informed decision is made

[1] It currently states that 'The Facts' booklet is enclosed, which would be incorrect if it was supplied in this context.

when there is awareness that a risk is present, and not simply when there is a recital of the verbatim risk (Reyna, 2012). Categorical risk information is therefore suitable to meet this purpose.

A further explanation for the null effect of the intervention on behaviour is that the gist leaflet altered representations at a surface-level, but core values held about cancer and cancer screening were more influential in the final screening decision. This fits with the FTT model which argues that for the gist to be used, core values and background knowledge must be consulted (Reyna, 2008, 2012). It is possible that if the two are discordant, then the resulting decision is more influenced by core values. Cancer is known to elicit strong emotional reactions in comparison with other health conditions (Hellman, 2005), particularly in disadvantaged groups (Dein, 2004). A combined approach of providing gist information that tackles established core beliefs may therefore be more effective at influencing screening behaviour. Supporting this, previous interventions that have increased CRC screening uptake have specifically addressed beliefs such as embarrassment, fatalism and fear (Wardle et al., 2003).

The difficulty however lies in designing an intervention that adequately informs the public about screening, addresses barriers to participation, and legitimises the option of not being screened. This conflict was present throughout the design stages of the gist leaflet and is an argument that is unlikely to be settled soon. To progress the field, policy makers, academic researchers and healthcare professionals should come together to classify where each screening programme stands on the issue of informed decision-making and screening promotion. Frameworks can then be developed to outline the type of interventions that may be permissible within each policy context.

The literature reviews and findings from the think-aloud study also have implications for the screening programme. These chapters suggest that the communication materials currently used in the NHS BCSP may not be adequately comprehended by the screening population. The frequent inability to understand ‘The Facts’ booklet and the generally poor knowledge about CRC and CRC screening calls into question the extent to which people are making fully informed decisions about CRC screening. This will be of particular interest following the publication of guidelines

outlining how informed decision-making can be encouraged within screening information (Ramirez & Forbes, 2012).

The high levels of affect reported in the think-aloud study support the notion that cancer is an emotive subject. Furthermore, it provides evidence for dual-processing theories which state that information is processed both rationally and emotionally (also known as type I and type II processing) (Epstein, 1998; Kahneman, 2012; Strack & Deutsch, 2004). Future work that aims to harness the emotional routes of information processing has the potential to impact the field of health communication. It is worth noting at this point that a national trial of an information leaflet that aims to achieve this goal was jointly funded by the NIHR as part of the programme of work reported here. In this intervention, narrative information on screening experiences provided by key informants will be included as a supplement to 'The Facts' booklet. This approach will be used as narrative information is more likely to access the emotional processing route (Shaffer & Zikmund-Fisher, 2013). The results are anticipated in the first quarter of 2014.

A published protocol of proposed work in the Scottish CRC screening programme is also making use of a dual-systems approach (O'Carroll, Steele, Libby, Brownlee, & Chambers, 2013). The authors propose to activate the emotional processing route by using an 'anticipated regret' intervention. Anticipated regret can be defined as 'the belief about whether or not feelings of regret will follow from inaction' (Sheeran & Abraham, 2005). Individuals can attempt to avoid experiencing regret if it is anticipated. For example, in this instance anticipated regret will be triggered by asking participants invited to CRC screening to answer two questions: 'If I did not complete and return my test kit, I would later feel regret' and 'If I did not complete and return my test kit, I would later wish I had'. This is a simple intervention that could be easily implemented within existing screening programmes. The results are anticipated in 2014.

Although I made use of the think-aloud findings when designing the gist leaflet, the method may not have identified all of the barriers experienced by people who lack basic skills. In addition to information processing difficulties, it is also possible that the low literate face other barriers when they engage with the screening offer. For example they may have more negative attitudes about cancer (Morris et al., 2013), have other competing demands and life stresses, or be less able to follow the

sampling instructions provided by the programme. From the perspective of literacy barriers within the NHS BCSP, the final point is particularly important. Hewitson and colleagues successfully improved uptake by making the sampling leaflet more literacy friendly (Hewitson et al., 2011). Although they did not report the effect of the intervention in reducing the SES gradient, it is possible that the sampling procedure is a more central barrier to people with poor basic skills than the ability to process 'The Facts' booklet.

An interesting focus group study from the US demonstrated that the use of 'wordless' instructions for Faecal Immunochemical Testing (FIT) kits was well received by a low literacy Latino population (Coronado et al., 2013). The use of diagrams instead of text has the advantage of reducing literacy barriers and enabling people of all cultures and languages to access the same information. Also, changes to the sampling leaflet could be evaluated easily, with no need to supplement the existing information. I believe the positive findings of Hewitson and colleagues should not be disregarded. Further investigation of its effect across the SES gradient is needed, followed by timely implementation if the results are successful at reducing inequalities

Study 4 observed that the gist leaflet was particularly effective among population sub-groups invited for the first time. As discussed previously, this could be a result of these individuals engaging with the materials more readily because of their lack of experience with this particular health decision. Research from a range of domains outside the screening context has shown that people with established and stable patterns of behaviour tend to be less receptive to new information (Betsch et al., 2001; Verplanken et al., 1997; Wahlich et al., 2013). Although this needs to be replicated in a CRC screening setting, more engagement with the information materials among people invited for the first time may explain why stronger effects were observed in this sub-group.

In round one invitees, the finding that the gist leaflet had a stronger effect on men than women may be a result of the lower levels of literacy that are observed in men (Department for Business Innovations and Skills, 2011; von Wagner et al., 2007). The gist leaflet may therefore have been easier for men to read, leading to greater engagement with the materials and the programme. Men may also be more affected by a cancer communication intervention because they are less likely to engage in

informational avoidance (McCloud et al., 2013). Together, these observations raise the possibility that providing gist-based information may reduce the small but important gender differences in screening uptake.

There was also a strong effect of the intervention among older groups invited for the first time. FTT argues that gist-based processing increases with age (Reyna, 2011). The gist leaflet may therefore have been more in tune with the processing styles of older groups. It is also possible that people in the intervention group were less confused by the age extension of the programme. The front page of the gist leaflet does not mention that screening has only recently been introduced for older groups. Therefore participants reading the gist leaflet may have felt that the screening invitation was relevant for all ages compared with those reading 'The Facts' booklet only. Improving the clarity of screening information may be particularly useful for older groups who have been shown to have lower levels of health literacy than their younger counterparts (von Wagner et al., 2007).

At present, the screening programme operates a 'one-size-fits-all' approach to information provision. This is necessary in such a large population-based programme, but the findings of this thesis highlight the difficulties that it causes for low SES groups. The search for an intervention that addresses SES inequalities in uptake continues. However, the effects observed for population sub-groups in study 4 support the assertion that differences in uptake can be addressed. Even simple tailoring (e.g. by gender) may be difficult to implement within national programmes, but the reward may justify these initial problems. Researchers should continue to work with the screening hubs to investigate ways in which simple and cost-effective interventions can be evaluated and implemented within the NHS BCSP.

Psychological theory provides support for the idea that tailored information is more likely to be processed. The Elaboration Likelihood Model (ELM) argues that information that is more personally relevant to the individual encourages processing and more thoughtful consideration of its content (Petty & Cacioppo, 1986). There is no shortage of systematic reviews and meta-analyses showing that tailored information is more effective at increasing behaviour change (Krebs, Prochaska, & Rossi, 2010; Noar, Benac, & Harris, 2007; Sohl & Moyer, 2007). However, the challenge would be to identify a form of tailoring that affected uptake, but could also be incorporated into a highly organised and rigid screening programme.

9.4 Strengths and limitations of thesis

9.4.1 Using psychological theory in a national screening programme

A strength of this thesis is that I have provided a foundation on which to build future FTT research protocols. Prior to the start of the thesis, FTT research was largely conceptual with very few studies implementing the theory in an applied area such as public health. Although, my interpretation of the theory was based in a CRC screening context, the research and methodologies presented here could be adapted for other health decisions. More generally, this process has also provided me, and perhaps others, valuable experience in how to adapt theory within the constraints of an organised system. This lesson will be applied to future research proposals.

A limitation that resulted from the scarcity of FTT research is that I was forced to make decisions using best practice guidelines from a range of different fields. The gist leaflet was an attempt at consolidating these recommendations into a coherent health communication intervention. However, the evidence base on which these recommendations were made was often weak and sometimes conflicting. It was frequently stated that more research was needed before explicit recommendations could be made (Abraham & Kools, 2011). Clearly more academic research is needed on the basics of information design and cognitive processing, particularly with a view to improving the situation for those with poor basic skills.

It was also challenging to amalgamate psychological theory within an organised cancer screening programme. For example, FTT often contravenes guidelines on informed decision-making (e.g. the use of verbal rather than numerical descriptors of risk). Despite evidence to suggest that gist-based information works best when used in isolation (Reyna & Brainerd, 1991), I was forced to use the gist leaflet as a supplement to the existing materials. This compromise between theory and policy meant that the gist leaflet may not have been a true reflection of FTT. It may also have meant that the public were provided with too much information, thereby countering any reduction in cognitive burden that was provided by the gist leaflet.

A final limitation in this area was that this series of studies was part of a larger NIHR programme grant. I was responsible for the development and evaluation of the gist leaflet, however the timescale of the grant meant that the leaflet had to be delivered

in a timely manner. Ideally, the findings from study 3 would have informed further changes that could have been incorporated into the design and content of the gist leaflet. However, this was not possible within the time frame of the grant. Further refinement of the gist leaflet may be needed before it is tested in other contexts.

9.4.2 Study designs and methods

A strength of this thesis was the use of novel methods and strong research designs. Throughout, I have been guided by a framework that provided a comprehensive overview of the theoretical approaches that should be used to ensure adequate evaluation of patient information (Garner et al., 2012). Recommended methods that should be used in the tripartite model were lacking. I was therefore able to suggest a series of techniques that could be used to evaluate the gist leaflet within each stage of the framework. The relative success of these studies varied, however it is certain that methods suitable for lower literacy groups are needed to develop the framework further.

9.4.2.1 The think-aloud method

Few studies have used the think-aloud method in a cancer communication context. Although similar unstructured approaches have been used to assess the 'cultural appropriateness' of information materials, none have reported both qualitative and quantitative data (Cooperman et al., 2013). Despite this advantage, a number of limitations with the think-aloud method were noted. Participants who had lower levels of education found the task of reading aloud intimidating, particularly in the presence of a researcher. This is likely to have altered their reading ability, as well reduced the likelihood that they would report issues with comprehension. It also excluded participants who were not able to read lengthy documents, as the study protocol required people to read 13 pages of text within the interview. It is unlikely that this structured approach is how most participants would choose to read health information.

These limitations were apparent in hindsight and it is now clear that other methodologies may yield different results, particular when there is a focus on literacy barriers. These observations do not preclude the think-aloud method from being used in other contexts, but care should be taken not to exclude target audiences from providing their perspective. Modifications of the method could also

be made, such as removing the requirement to read aloud or providing more breaks during the interview. Further methodological requirement is clearly needed to improve the validity of the findings.

9.4.2.2 User-testing

As with the think-aloud technique, the user-testing methodology has not previously been used in a cancer communication context. A number of limitations were noted following its use. The nature of the method required participants to answer 8 true or false questions about CRC and CRC screening. This procedure was framed as a 'test of the information material' and not of the individual being interviewed. Despite this, participants who were unfamiliar with tests and examinations may have felt under pressure to answer the items correctly. Participants were reassured throughout the study, but this pressure may have reduced how forthcoming they were when asked to disclose problems with the gist leaflet.

The use of true or false questions and small sample sizes meant that chance variation may have led to the gist leaflet being prematurely accepted as 'fit-for-purpose'. Although this limitation was lessened by the progressively greater representation of participants with a low level of education in rounds 2 and 3 of the study, it should be recognised as a problem of the method. One alternative could be to adapt the method and use open-ended questions with standardised marking criteria. In addition to making the task more difficult, it may also provide an insight into the thought processes that occur when answering the question.

It should be noted that participants were not exposed to 'The Facts' booklet during the user-testing study. This was a conscious decision, as I felt that data collection would be maximised if participants were only able to comment on one information leaflet. However, providing 'The Facts' booklet as well would have provided a more ecologically valid test of the gist leaflet. It would also have provided insight into how the public would cope with being provided two information materials instead of one. Again, this decision may have resulted in a premature acceptance of the gist leaflet's design and content. Future research should be aware of the context in which the intervention will be delivered throughout the design and evaluation stages.

9.4.2.3 Randomised controlled trials

A further strength of the thesis was that two studies used multicentre randomised designs. The randomised designs added validity to the conclusions of the studies and are considered the gold standard approach for testing public health interventions (Sackett et al., 1996). The use of multiple recruitment centres in all studies (but specifically studies 3 and 4) further increased the validity of the findings by reducing the likelihood that study effects would be artificially inflated (Bafeta et al., 2012; Dechartres et al., 2011).

It is often not feasible to collect socio-cognitive data within organised screening programmes. Study 3 was therefore used to provide complementary data for the national trial. However, this study was limited by the lack of follow-up and the use of screening intention as a proxy for screening participation. Despite the purposive sampling method used, study 3 was performed on a relatively educated and motivated sample. Combined, these limitations prevented me from examining the true effect of the gist leaflet on screening outcomes.

Although the data recorded in study 3 did not provide evidence for the communicative effectiveness of the gist leaflet, the national trial was still undertaken (Study 4). The size of the trial provided sufficient power to test novel hypotheses such as the extent to which the gist leaflet addressed SES inequalities in screening uptake. Similar studies investigating the effect of an intervention among low SES groups have shown encouraging trends, but were hampered by a lack of statistical power (Wardle et al., 2003).

Study 4 used a cluster randomised design as it was not feasible to run a parallel trial within the NHS BCSP. When the initial programme was funded, a parallel design was proposed to the National Institute of Health Research (NIHR). However, Real Digital International and the hubs requested that this was changed due to logistical challenges. Cluster designs have their own limitations including limited statistical efficiency that can be dealt with by using large samples and increasing the number of clusters (Campbell et al., 2007; Donner & Klar, 2004). This was achieved within study 4, thereby limiting the importance of this limitation. A more important point to note is the number of concurrent initiatives that were likely to have occurred during the study period. Cluster randomised trials are more susceptible to bias because of

differences between clusters (in this case days). Furthermore, these differences are difficult, if not impossible, to control for.

This highlights the important compromise that had to be made when developing this trial. On one side there was the argument that a trial should be designed optimally so that it has the best chance of demonstrating its true effect (i.e. a parallel design). On the other, there was the practical argument that the resources required to design the optimal trial would be so large that it may not be practicable. It also limits the extent to which interventions in the future could be evaluated within the national programme. In the end, we have to acknowledge that using a cluster design was a limitation of the trial and this should be considered when interpreting the findings.

Despite these limitations, study 4 was an interesting learning experience for all of those who were involved. It provided evidence that the collaborative efforts of hub staff and academics from a range of difference disciplines can come together to test interventions within the NHS BCSP. I hope that the hubs were also able to learn from the experience, and can accommodate future interventions within the screening programme.

9.4.3 Problems with recruitment

Recruitment difficulties were experienced for studies 1, 2 and 3. This was further exacerbated by the focus on SES inequalities as such groups are particularly difficult to recruit (Alcaraz, Weaver, Andresen, Christopher, & Kreuter, 2011; Ford et al., 2008). An implication of these difficulties was that the gist leaflet may not have addressed the concerns of those most in need of supplementary communication materials. Furthermore, the number of correct responses to the comprehension questions (Studies 2 and 3) may have been lower if a sample of individuals with lower levels of health literacy had participated. This would have resulted in more rounds of testing (Study 2) and more changes being made to its current design.

The most concerted efforts to address recruitment issues were made in study 3. A strength of using GP practices to identify participants was that a large sample of individuals based in deprived locations with accurate socio-demographic data could be approached. This reduced (but did not eliminate) the possibility of a self-selected sample because all eligible individuals at the practice were approached. Despite these efforts, poor recruitment rates meant that a study effect was not ascertained

for ~80% of the study population. In addition, those that did respond were less likely to read the information materials if they had low numeracy skills. Future research should not only investigate ways of recruiting members of the public with poor basic skills, but also identify strategies to reduce informational avoidance among those that have consented to participate (Howell & Shepperd, 2013).

9.4.4 Age of the samples

In line with the aims of the thesis, studies 1, 2 and 3 included participants that were under 60 years of age and that had no CRC screening experience. I was particularly interested in these individuals as a primary aim of the thesis was to improve participation rates among first time invitees. This is because data from the UK CRC screening pilot and Scottish programme showed that repeat screening was strongly associated with past behaviour (Steele et al., 2010a UK Colorectal Cancer Screening Pilot Group, 2004). Intervening at an early stage may therefore increase future screening behaviour.

Although the bias of using individuals with experience of the behaviour was removed, using people who were naïve to CRC screening had limitations. Evidence from a US study shows that screening experience can be an important factor in how people respond to items related to CRC screening (Murphy et al., 2013). Construal-Level Theory (CLT) suggests that people considering the possibility of being screened in the near future are more likely to construe the behaviour in concrete terms (Trope & Liberman, 2010). In contrast, people considering screening in the far future (like participants in study 3) are less focussed and tend to represent the behaviour abstractly. These phenomena are likely to affect questionnaire responses, and may explain the inflated estimates of intention that were observed.

Previous research has shown that screening naïve participants reported higher estimates of intention to be screened when the decision was framed in the distant future, as opposed to the immediate context (von Wagner Semmler, Power, & Good, 2010). Furthermore, it also led to individuals in the distal condition to focus on the long-term benefits and neglect the immediate disadvantages of screening. The high level of intention reported in study 3 suggests a similar phenomenon may have occurred in that sample. Identifying ways of making the screening decision seem more apparent to participants may increase the validity of self-reported screening

intention among screening naïve participants. Further research that attempts to achieve this may help to improve the developmental phase of intervention design.

9.4.5 Study outcomes

Studies 2 and 3 were able to record socio-cognitive data. These measures were used to improve the intervention, as well as provide explanations as to how the intervention was operating. This is important as it is logistically challenging and expensive to record such data within screening trials embedded within programmes. The complementary approach of performing separate studies with psychological and behavioural outcomes was a model that could be replicated in future evaluations of screening interventions.

A limitation of studies 2 and 3 was that the knowledge scales had not previously been validated. Although validated measures are ideal, researcher-generated scales are common in communication trials (Biesecker, Schwartz, & Marteau, in press). To improve the validity of the scales, experts in the field and specialist screening practitioners were interviewed to ensure content and face validity. Principal component analysis was also used in study 3, which showed a single underlying factor. Nonetheless, further validation is required in other samples and contexts.

9.5 Concluding remarks

This thesis reports on the design and evaluation of a gist-based information leaflet that aimed to reduce SES inequalities in screening uptake and improve comprehension of the CRC screening offer. Findings demonstrated that the leaflet had no effect on screening uptake, but it may have a small impact on public understanding of CRC and CRC screening. Although the results were disappointing, I hope I have contributed a series of innovative and methodologically rigorous studies to the field of health communication and that future research can make use of these findings.

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Smith SG, Rendell H, George H, Power E (revise and resubmit) Improving cancer control through a community-based cancer awareness initiative. *Preventive Medicine.*

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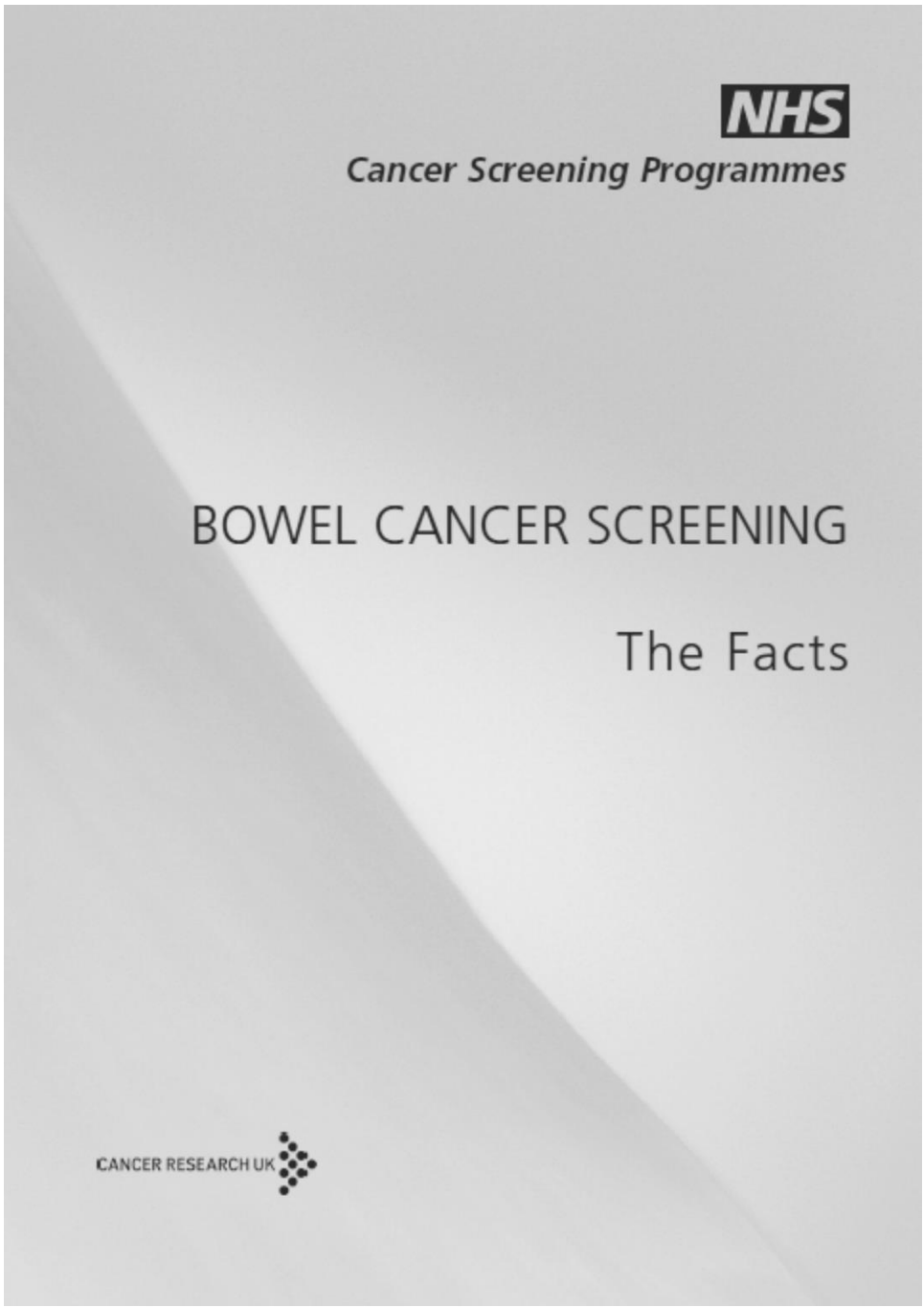
Appendix

Appendix A – 'Bowel Cancer Screening: The Facts'



What is the aim of this leaflet?

This leaflet gives you information about bowel cancer, and the benefits and risks of bowel cancer screening. It aims to help you make an informed choice about taking part in the NHS Bowel Cancer Screening Programme.

What is the purpose of bowel cancer screening?

- Bowel cancer screening aims to detect bowel cancer at an early stage (in people with no symptoms), when treatment is more likely to be effective.
- Bowel cancer screening can also detect polyps. These are not cancers, but may develop into cancers over time. They can easily be removed, reducing the risk of bowel cancer developing.

Is screening for bowel cancer important?

- About one in 20 people in the UK will develop bowel cancer during their lifetime.
- It is the third most common cancer in the UK, and the second leading cause of cancer deaths, with over 16,000 people dying from it each year (Cancer Research UK, 2005. *Cancerstats*).
- Regular bowel cancer screening has been shown to reduce the risk of dying from bowel cancer by 16% (Cochrane Database of Systematic Reviews, 2006. *Screening for colorectal cancer using the faecal occult blood test: an update*).

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. This age range is currently being extended to 60 to 74. People in the invitation age range are automatically sent an invitation, then their screening kit, so they can do the test at home. Your GP will provide your contact details, so it is important that he or she has your correct name and address.

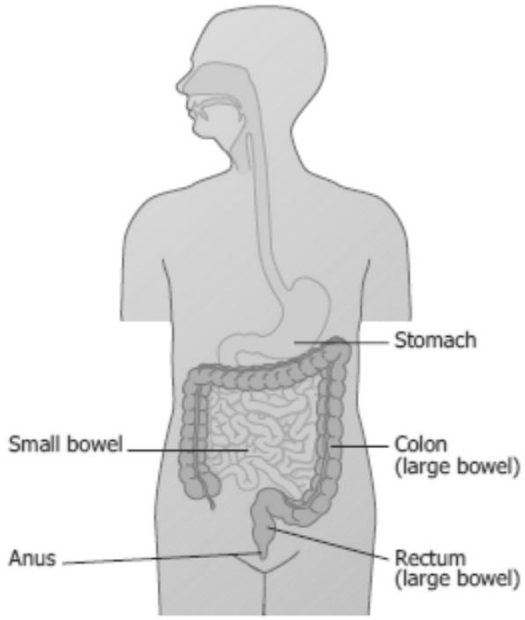
After your first screening test, you will be sent another invitation and screening kit every two years until you reach 69 (74 in areas where age extension has already started). If you are over the invitation age range, you can ask for a screening kit every two years by calling the Freephone number at the end of this leaflet (page 15).

What does the bowel do?

The bowel is part of our digestive system and is divided into the small and large bowel. The large bowel is made up of the colon and rectum.

Food passes from the stomach to the small bowel. After the small bowel takes nutrients into the body, any undigested food passes through the large bowel, where water is removed from the waste matter.

This waste matter is held in the rectum (back passage) until it leaves the body as bowel motions (also known as stools or faeces).



What is bowel cancer?

Bowel cancer is also known as colon, rectal or colorectal cancer. The lining of the bowel is made of cells that are constantly being renewed. Sometimes these cells grow too quickly, forming a clump of cells known as a bowel polyp (sometimes known as an adenoma). Polyps are not bowel cancers (they are usually benign), but they can change into a malignant cancer over a number of years. A malignant cancer is when cancer cells have the ability to spread beyond the original site and into other parts of the body.

Who is at risk of developing bowel cancer?

- Both men and women are at risk of developing bowel cancer.
- Your risk of developing bowel cancer increases with age. Eight out 10 people who are diagnosed with bowel cancer are over 60.
- People with a family history of bowel cancer have an increased risk of developing the disease.
- People who take little exercise, people who are overweight, and people who have a diet high in red meat and low in vegetables, fruits and fibre are all thought to have an increased risk of developing bowel cancer.

How does the screening test work?

- The screening test detects tiny amounts of blood, which you cannot normally see, in your bowel motions. It is called the **Faecal Occult Blood (FOB) test** ('occult blood' means hidden blood).
- Polyps and bowel cancers sometimes bleed, which is why we screen for blood in your bowel motions.
- **The FOB test does not diagnose bowel cancer**, but the results will tell you whether you need an examination of your bowel (a colonoscopy).

How is the screening (FOB) test carried out?

You carry out the FOB test in the privacy of your own home. The screening kit provides a simple way for you to collect small samples of your bowel motions. You wipe the samples on a special card, which you then send in a hygienically sealed Freepost envelope to a laboratory for testing. There are detailed instructions with each kit. You may think that doing the test sounds a bit embarrassing or unpleasant, but it will only take a few minutes and it is an effective way to detect bowel cancer early.

When do I get my results and what do they mean?

You should receive a results letter from the laboratory within two weeks of sending in your sample. There are three types of results you could receive.

- A normal result means that blood was not found in your test sample. Most people (about 98 out of 100) will receive a normal result. A small number of these people will have repeated the test due to an unclear result beforehand.

A normal result does not guarantee that you do not have or will never develop bowel cancer in the future, so being aware of the symptoms of bowel cancer (see page 11) is very important.

You will be offered bowel cancer screening again in two years.

- An unclear result means there was a slight suggestion of blood in your FOB test sample. This could have been caused by conditions such as haemorrhoids (piles) or stomach ulcers. **Receiving an unclear result does not mean you have cancer, just that you need to repeat the FOB test.**

If you receive an unclear result, you will be asked to complete the FOB test up to two more times. This is necessary because polyps and cancers do not bleed all the time and it is important to find out whether or not there is blood in your stools. About four people out of every 100 will initially receive an unclear result. Most people who repeat the test will then receive a normal result.

- An abnormal result shows that blood may have been found in your FOB test sample – **it is not a diagnosis of cancer, but it does mean that you will be offered a colonoscopy**. The abnormal result may have been caused by bleeding from bowel polyps, rather than a bowel cancer. It may also have been caused by other conditions, such as haemorrhoids (piles).

About two in every 100 people doing the test will have an abnormal result. Sometimes, someone with an abnormal result will have repeated the test due to a previous unclear result.

If you receive an abnormal result, you will be offered an appointment with a specialist screening practitioner at a local screening centre, to discuss having a more detailed examination of your bowel (a colonoscopy), to see whether or not there is a problem that may need treatment.

Summary of screening results

Normal	No further tests are needed. You will be invited to take part in screening again in two years.
Unclear	Repeat the FOB test.
Abnormal	You will be offered an appointment to discuss colonoscopy at a local screening centre.

What is a colonoscopy?

A colonoscopy is an investigation that involves looking directly at the lining of your large bowel. A thin, flexible tube with a tiny camera attached (a colonoscope) is passed into your back passage and guided around your bowel. If polyps are found, most can be removed painlessly, using a wire loop passed down the colonoscope tube.

These tissue samples will be checked for any abnormal cells that might be cancerous.

- About five in 10 people who have a colonoscopy will have a normal result (they do not have cancer or polyps).
- About four in 10 will be found to have a polyp, which if removed may prevent cancer developing.
- About one in 10 people will be found to have cancer when they have a colonoscopy.

A colonoscopy is the most effective way to diagnose bowel cancer. For most people, having a colonoscopy is a straightforward procedure. However, as with most medical procedures, there is the possibility of complications. These can include heavy bleeding (about a one in 250 chance) that needs further investigation or medical advice. The colonoscope can cause a hole (perforation) in the wall of the bowel (about a one in 1,000 chance). In extremely rare cases, colonoscopy may result in death. Current evidence suggests that this may only happen in about one in 10,000 cases.

For more information about colonoscopy, you can read our leaflet 'The colonoscopy investigation' (see page 15). We will also send this leaflet to anyone who is offered a colonoscopy appointment.
Remember, most people who complete the FOB test will not need a colonoscopy.

Do I have to have a colonoscopy if I have an abnormal FOB result?

If you have an abnormal result, you will be offered an appointment with a specialist screening practitioner. He or she will fully explain the colonoscopy procedure to you and assess your fitness for it. If you want to go ahead with the colonoscopy, the practitioner will book an appointment for you.

How reliable is bowel cancer screening?

- Bowel cancer screening has been shown to reduce the risk of dying from bowel cancer.
- Like all screening tests, the FOB test is not 100% reliable.
- There is a chance that a cancer can be missed if it was not bleeding when the screening test was taken.
- Bowel cancer may also start to develop in the two years between screening tests.
- It is important to be aware of the symptoms of bowel cancer in the two years between screening tests.

What are the symptoms of bowel cancer?

The most common symptoms of bowel cancer to look out for are:

- 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; and
- a lump in your abdomen.

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

What if I need treatment for bowel cancer?

In the unlikely event that you are diagnosed with bowel cancer, a team of specialists will look after you. They will make sure that you get the best care and treatment at all times.

If bowel cancer is detected at the earliest stage, there is over a 90% chance of survival (Cancer Research UK, 2005. *Cancerstats*).

The main treatment for bowel cancer is surgery. In some cases, chemotherapy or radiotherapy may be offered.

If the cancer is in a polyp that has been removed during colonoscopy, regular check-ups may be all that is needed.

Not all bowel cancers detected by screening can be cured.

What happens to my sample once it has been tested?

Once the FOB test sample has been analysed, the result is recorded onto a database and the sample card is destroyed. We regularly review all screening records as part of our aim to offer you a good quality service and to help increase the expertise of specialist staff. This means that staff who work elsewhere in the health service will need to see your records.

For more information on how we keep records, you can contact NHS Direct on 0845 4647.

Summary

Before deciding whether or not you want to take part in bowel cancer screening, you may like to consider some of the benefits and disadvantages, and think about what is important to you.

- Bowel cancer is the second most common cause of cancer deaths in the UK. Taking part in bowel cancer screening reduces your chances of dying from bowel cancer.
- Bowel cancer screening can also detect polyps that may develop into cancer over time. Removing polyps during a colonoscopy can reduce your chances of developing bowel cancer in the future.
- There is a chance that a cancer can be missed if it was not bleeding when the screening test was taken.
- An abnormal test result means that you will be offered a colonoscopy. Most people who have a colonoscopy will not have cancer. Although rare, there are risks associated with having a colonoscopy.
- Not all bowel cancers detected by screening can be successfully treated.
- Although some people may find completing the FOB test unpleasant, it can be done in the privacy of your own home.

This leaflet was developed by Cancer Research UK, in association with the NHS Bowel Cancer Screening Programme and with advice from the English Bowel Cancer Screening Pilot.

It was also developed through consultation with the following charities.

- Beating Bowel Cancer
- Bowel Cancer UK
- Cancerbackup
- Men's Health Forum

More information and support

If you have any questions, or would like more information about screening for bowel cancer, you can:

- contact your programme hub on Freephone 0800 707 60 60;
- talk to your GP;
- visit the NHS Cancer Screening Programmes website at www.cancerscreening.nhs.uk;
- visit the NHS Choices website at www.nhs.uk, or call 0845 46 47;
- visit the MacMillan Cancer Support website at www.macmillan.org.uk, or call 0808 808 0000;

- visit the CancerHelp website at www.cancerhelp.org.uk, or call 0808 800 4040;
- visit the Bowel Cancer UK website at www.bowelcanceruk.org.uk, or call 0800 8 40 35 40;
- visit the Beating Bowel Cancer website at www.beatingbowelcancer.org, or call 08450 719 300;

If you are 70 or over, (75 or over in areas where the age range has been extended), and would like a bowel cancer screening kit, please call Freephone 0800 707 60 60.

Bowel Cancer Screening – The Colonoscopy Investigation. Available at www.cancerscreening.nhs.uk/bowel/publications/colonoscopy-investigation.html

Published by the Department of Health in association with NHS Cancer Screening Programmes, with advice and support from the Cancer Research UK Primary Care Education Group.

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First Edition May 2006
Updated February 2011

If you require further copies of this title
visit **www.orderline.dh.gov.uk** and quote
273372/Bowel cancer The Facts or contact:
DH Publications Orderline
Tel: 0300 123 1002
Textphone: 0300 123 1003 (8am to 6pm, Monday to Friday)

273372/Bowel cancer The facts can also be made available on request in Braille, audio and large print.

www.cancerscreening.nhs.uk

Appendix C Consent form for think-aloud study

HEALTH BEHAVIOUR RESEARCH CENTRE
DEPARTMENT OF EPIDEMIOLOGY AND PUBLIC HEALTH

1-19 Torrington Place
University College London
London
WC1E 6BT
02076791940
c.wagner@ucl.ac.uk

Consent Form

CONFIDENTIAL

Title of Study: Interview about bowel cancer screening: The 'think aloud' study

Name of Chief Investigator: Dr Christian von Wagner
Name of interviewer: Mr Sam Smith

(Please tick box)

1 I confirm that I have read the information sheet for the above study and have had the opportunity to ask questions and have had these answered satisfactorily. ☐

2 I understand that my participation is voluntary and I am free to withdraw consent at any time, without giving a reason, without my medical care or legal rights being affected. ☐

3 I understand that data collected may be looked at by responsible representatives from the sponsor (UCL) for the purposes of monitoring and auditing to ensure that the study is being conducted properly. I give permission for these individuals to have access to relevant information. ☐

4 I understand my personal details such as my name and telephone number will not be revealed to people outside this study. ☐

Name of participant (Print)	Signature of participant	Date

Name of interviewer (Print)	Signature of interviewer	Date

Appendix D Participant information sheet for think-aloud study

HEALTH BEHAVIOUR RESEARCH CENTRE
DEPARTMENT OF EPIDEMIOLOGY AND PUBLIC HEALTH

UCL

PARTICIPANT INFORMATION SHEET

INTERVIEW ABOUT THE INFORMATION SUPPLIED TO INDIVIDUALS IN THE NHS BOWEL CANCER SCREENING PROGRAMME: 'THE THINK ALOUD STUDY'

What is the study about?

In this study we are investigating the public response to written information that is provided when people are invited to participate in the NHS Bowel Cancer Screening Programme. This invitation is given to people that are aged 60-69.

What will I have to do?

The research will explain everything you have to do throughout this study. However you will be asked to read parts of the information booklet and then speak your thoughts out loud. We do not want you to think too much about what your thoughts are, just your initial reaction.

You will then be given a pile of cards that contain the information you have just read. You will be asked to sort these cards into piles, again speaking your thoughts out loud while you do it. Everything will be explained to you in further detail during the study.

The whole process will be recorded so that we can look at what you have been saying afterwards. It should take approximately 1 hour to perform the tasks. **If you need reading glasses, please bring them with you when you come for your interview.**

What will happen to the results of the study?

The recordings will be transcribed and anonymised. Our findings will be written up for scientific journals and presented at academic conferences. You can request a lay summary of the results by using the contact details below.

Further information and contact details

Samuel Smith (Samuel.smith@ucl.ac.uk) – tel: 0207 679 1723

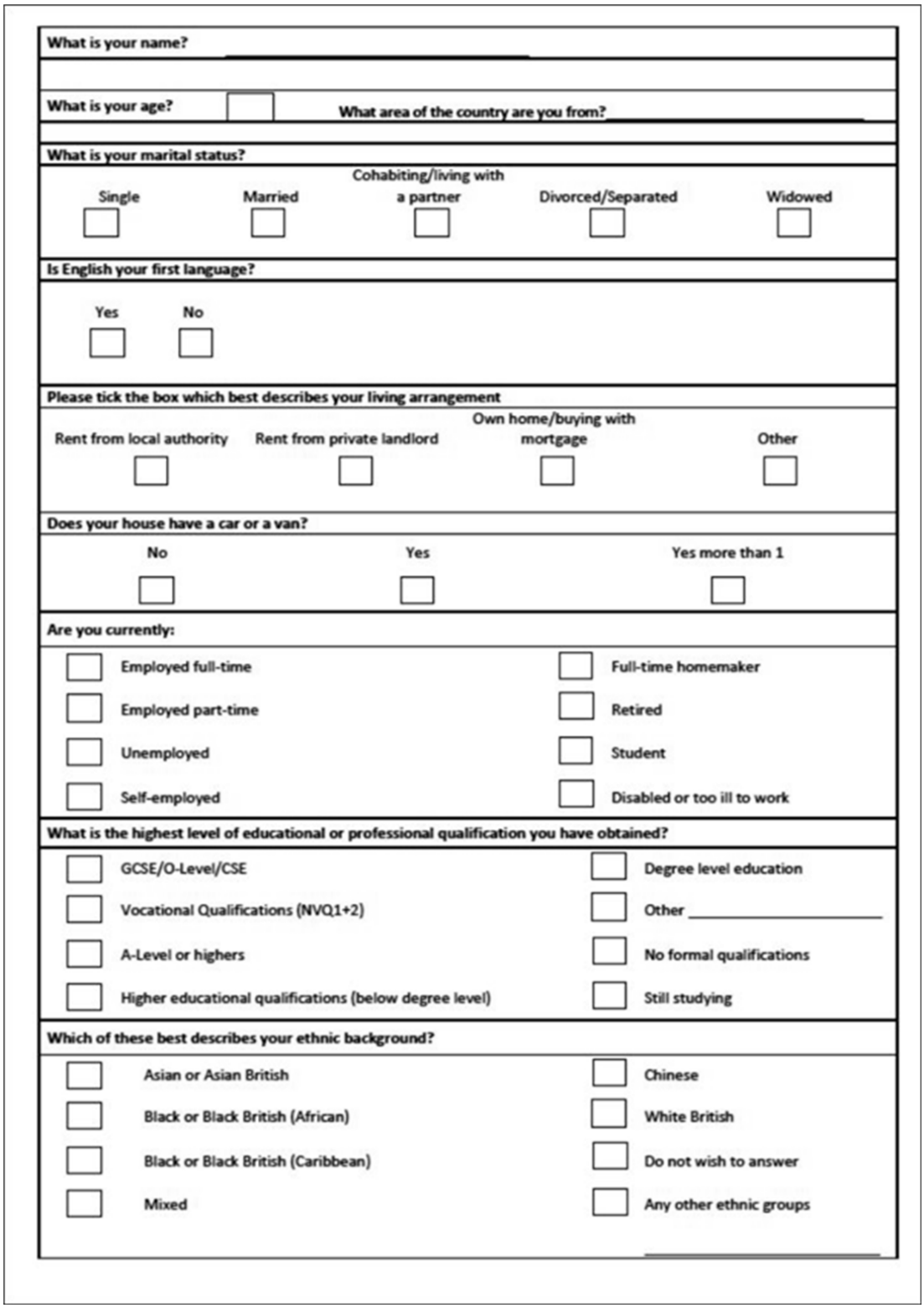
1-19 Torrington Place

Department of Epidemiology and Public Health

London

WC1E 6BT

Appendix E Participant demographics form for think-aloud study



What is your name? _____

What is your age? ☐ What area of the country are you from? _____

What is your marital status?

Single ☐ Married ☐ Cohabiting/living with a partner ☐ Divorced/Separated ☐ Widowed ☐

Is English your first language?

Yes ☐ No ☐

Please tick the box which best describes your living arrangement

Rent from local authority ☐ Rent from private landlord ☐ Own home/buying with mortgage ☐ Other ☐

Does your house have a car or a van?

No ☐ Yes ☐ Yes more than 1 ☐

Are you currently:

☐ Employed full-time
☐ Employed part-time
☐ Unemployed
☐ Self-employed
☐ Full-time homemaker
☐ Retired
☐ Student
☐ Disabled or too ill to work

What is the highest level of educational or professional qualification you have obtained?

☐ GCSE/O-Level/CSE
☐ Vocational Qualifications (NVQ1+2)
☐ A-Level or highers
☐ Higher educational qualifications (below degree level)
☐ Degree level education
☐ Other _____
☐ No formal qualifications
☐ Still studying

Which of these best describes your ethnic background?

☐ Asian or Asian British
☐ Black or Black British (African)
☐ Black or Black British (Caribbean)
☐ Mixed
☐ Chinese
☐ White British
☐ Do not wish to answer
☐ Any other ethnic groups _____

In general, how easy or hard do you find it to understand medical statistics?

Very easy ☐ Easy ☐ Hard ☐ Very Hard ☐

In general, would you say your health is...

Poor ☐ Fair ☐ Good ☐ Very Good ☐ Excellent ☐

Have you ever attended any of the following?

Breast cancer screening ☐ Cervical cancer screening ☐ Prostate Cancer testing (PSA – Men only) ☐

Have you ever been diagnosed as having cancer?

Yes ☐ No ☐ (If yes, name) _____

Have any of your friends or family members been diagnosed as having cancer?

Yes ☐ No ☐ (If yes, name of cancer) _____ Relationship with you _____

Have you been diagnosed with any chronic condition?

Yes ☐ No ☐ (If yes, name) _____

Have you been diganosed with any bowel conditions?

Yes ☐ No ☐ (If yes, name) _____

During the past 12 months, not counting times you went to accident and emergency, how many times did you go to a doctor, nurse of other health professional to get care for yourself?

None ☐ 1 time ☐ 2 times ☐ 3 times ☐ 4 times ☐ 5-9 times ☐

Have you ever looked for information about cancer from any source?

Yes ☐ No ☐ (If yes, where) _____

How much attendtion do you pay to information about health or medical topics on tv, radio, magazines or newspapers?

A lot ☐ Some ☐ A little ☐ Not at all ☐

Appendix F Researcher instructions for think-aloud study

Researcher Instructions

I'd like to speak to you today about Bowel Cancer Screening. We do not expect you to know anything about this topic, so do not worry if you don't. We are particularly interested in the information that is provided to people when they are invited to participate. To help us explore this issue, I'm going to take you through a series of exercises which will show us what your first impression of this information is.

Is that ok?

First round of think aloud

In this exercise we are interested in what you think about when you read information. In order to do this I'm going to ask you to THINK ALOUD as you read through some information. What I mean by think aloud is that I want you to tell me EVERYTHING you are thinking from the time you reach a red dot. I would like you to think aloud CONSTANTLY from the time you reach a red dot until you have finished telling me what you are thinking. I don't want you to plan out what you say or try to explain to me what you are saying. You may want to make predictions about what you are reading, repharase what you think the text is saying, share an story that describes something in the text that you're familiar with, remark on something in the text that is confusing, or say something else that helps you understand the text you're reading better. Just act as if you are in the room speaking to yourself. It is most important that you keep talking. If you are silent for any long period of time I will prompt you by saying 'Please carry on thinking out loud'

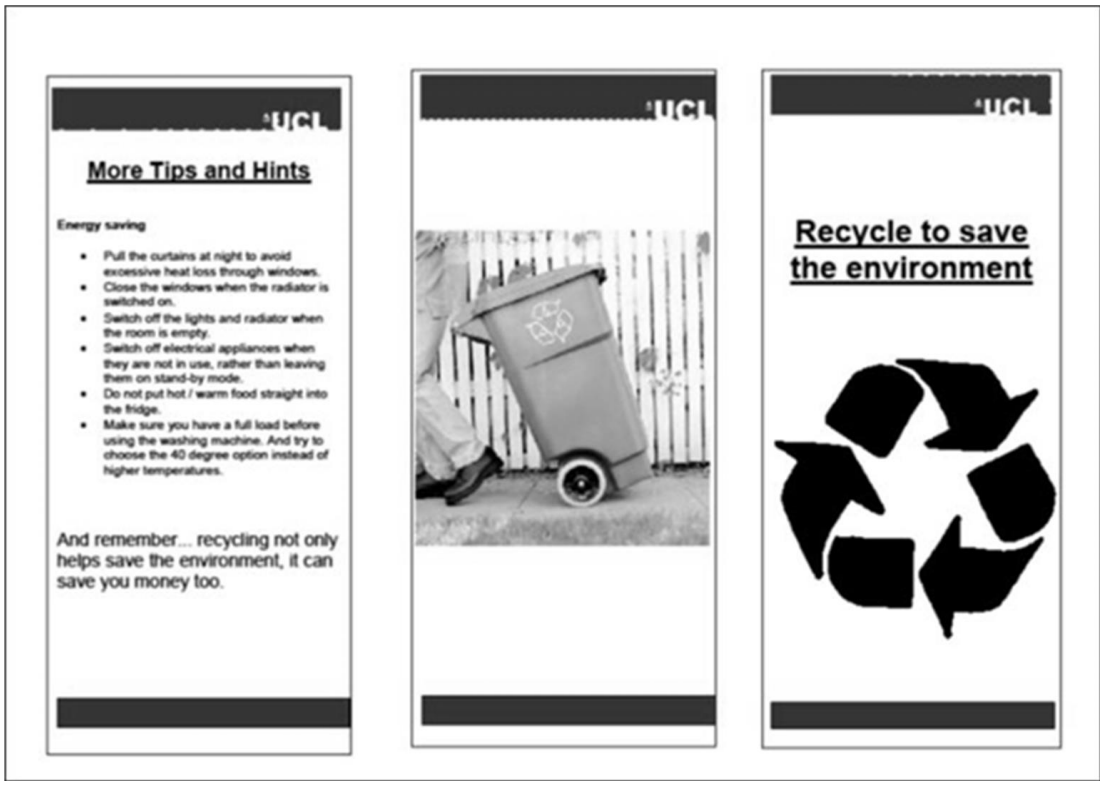
Do you understand what I want you to do?

Good, now we will begin with a practice leaflet.

Show recycling leaflet - ask participant to read at least first paragraph. If they understand the task and think aloud in the appropriate place, stop and move on to Bowel Screening booklet. If they do not understand, repeat the instructions and ask them to read the second paragraph.

Do you feel ready to try this technique on your own?

Appendix G Practice leaflet used in think-aloud study



UCL

More Tips and Hints

Energy saving

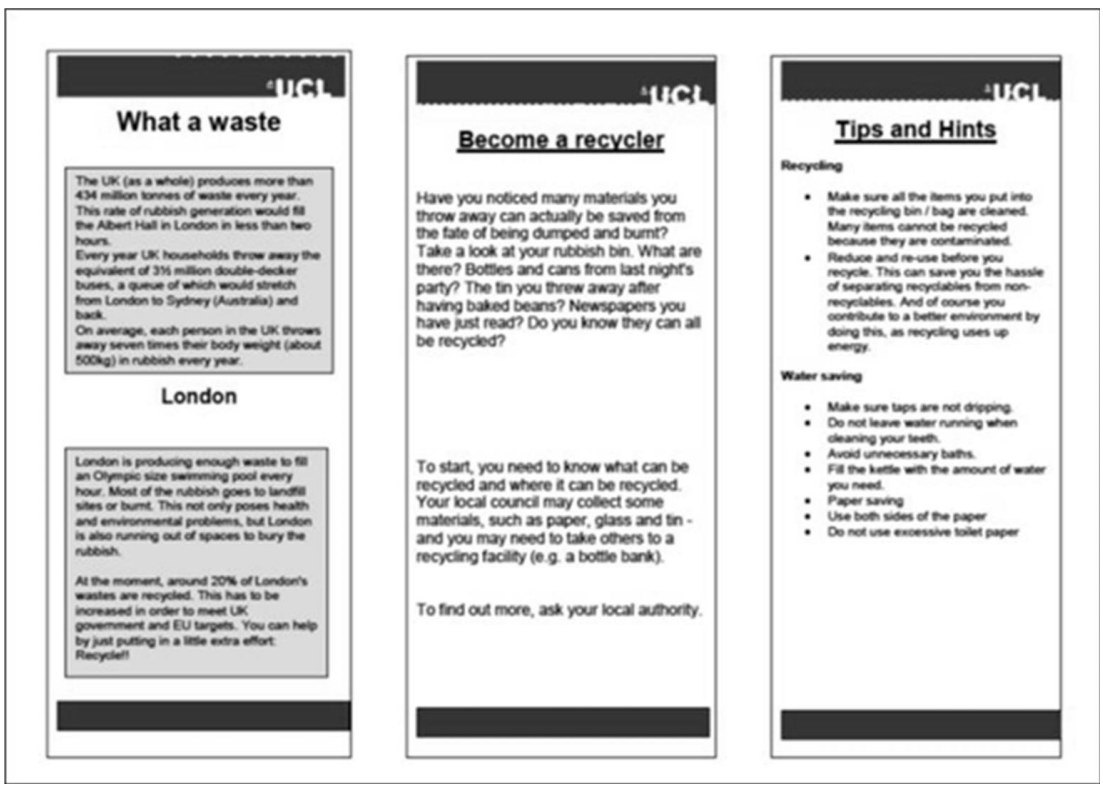
- Pull the curtains at night to avoid excessive heat loss through windows.
- Close the windows when the radiator is switched on.
- Switch off the lights and radiator when the room is empty.
- Switch off electrical appliances when they are not in use, rather than leaving them on stand-by mode.
- Do not put hot / warm food straight into the fridge.
- Make sure you have a full load before using the washing machine. And try to choose the 40 degree option instead of higher temperatures.

And remember... recycling not only helps save the environment, it can save you money too.

UCL

UCL

Recycle to save the environment



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What a waste

The UK (as a whole) produces more than 434 million tonnes of waste every year. This rate of rubbish generation would fill the Albert Hall in London in less than two hours.
Every year UK households throw away the equivalent of 3½ million double-decker buses, a queue of which would stretch from London to Sydney (Australia) and back.
On average, each person in the UK throws away seven times their body weight (about 500kg) in rubbish every year.

London

London is producing enough waste to fill an Olympic size swimming pool every hour. Most of the rubbish goes to landfill sites or burnt. This not only poses health and environmental problems, but London is also running out of spaces to bury the rubbish.

At the moment, around 20% of London's wastes are recycled. This has to be increased in order to meet UK government and EU targets. You can help by just putting in a little extra effort. Recycle!!

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Become a recycler

Have you noticed many materials you throw away can actually be saved from the fate of being dumped and burnt? Take a look at your rubbish bin. What are there? Bottles and cans from last night's party? The tin you threw away after having baked beans? Newspapers you have just read? Do you know they can all be recycled?

To start, you need to know what can be recycled and where it can be recycled. Your local council may collect some materials, such as paper, glass and tin - and you may need to take others to a recycling facility (e.g. a bottle bank).

To find out more, ask your local authority.

UCL

Tips and Hints

Recycling

- Make sure all the items you put into the recycling bin / bag are cleaned. Many items cannot be recycled because they are contaminated.
- Reduce and re-use before you recycle. This can save you the hassle of separating recyclables from non-recyclables. And of course you contribute to a better environment by doing this, as recycling uses up energy.

Water saving

- Make sure taps are not dripping.
- Do not leave water running when cleaning your teeth.
- Avoid unnecessary baths.
- Fill the kettle with the amount of water you need.
- Paper saving
- Use both sides of the paper
- Do not use excessive toilet paper

Appendix H Debrief form used in think-aloud study

HEALTH BEHAVIOUR RESEARCH CENTRE
DEPARTMENT OF EPIDEMIOLOGY AND PUBLIC HEALTH

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Thank you very much for taking part in this study.

What were the aims of this study?

The aim of this study was to develop our understanding of the issues that influence participation in the NHS Bowel Cancer Screening Programme, particularly in relation to the information materials that people are supplied with.

It is hoped that we can use this information to design interventions that may make it easier for people to participate, should they wish to do so in the future.

Where can I get more information about bowel cancer screening?

If you would like more information about bowel cancer screening then you can call the freephone telephone number 0800 707 60 60 who will be happy to assist you with any queries you may have. In addition you can go to the NHS Bowel Cancer Screening Programme website at: http://www.cancerscreening.nhs.uk/bowel/

How can I get more information on the study?

For further information on specific information please feel free to contact the researchers. If you are interested in our results, then let one of the researchers know and you will be emailed or sent by post the results of this study.

We would like to confirm that all the information that you have supplied is confidential and you will not be identified in any research.

If you have been distressed by any of the issues raised by participating in this project, please feel free to contact any of the researchers who will be happy to discuss any concerns or queries that you may have.

What are the researchers' contact details?

Sam Smith and Dr Christian Wagner

Email: Samuel.Smith@ucl.ac.uk – tel 0207 679 1723 c.wagner@ucl.ac.uk – Telephone: 0207 679 1940

We are psychology researchers at the Health Behaviour Research Centre, Department of Epidemiology and Public Health at UCL

Health Behaviour Research Centre
1-19 Torrington Place, University College London
London, WC1E 6BT

Thank you once more for taking part in this study.

Appendix J Participant invitation letter for user-testing study

HEALTH BEHAVIOUR RESEARCH CENTRE
DEPARTMENT OF EPIDEMIOLOGY AND PUBLIC HEALTH

UCL

«firstname» «lastname»
«address1»
«address2»
«address3»
«address4»
«postcode»

DATE

Dear «title» «lastname»,

Re: Interview about information materials given to individuals in the NHS Bowel Cancer Screening Programme: 'The Teach to goal study'.

The Cancer Research-UK Health Behaviour Research Centre would like to ask for your help with a research project on bowel cancer screening. I recently spoke to you on the phone about this project and here is some more information about it.

We are seeking volunteers for a study that is evaluating the quality of information materials that have been designed for the NHS Bowel Cancer Screening Programme.

Who do we want to speak to?

We are interested in speaking to individuals aged 45-59. We are offering **£10** to compensate for time and travel expenses.

What will I have to do?

You will be asked to read the information materials that are given to you. We will then ask you a series of questions on the topic of bowel cancer screening, as well as any recommendations you have for improvements that could be made to the leaflet. You do not need to have any experience of bowel cancer screening to take part in this study. In order to participate, you will be required to attend the ContinYou head office (see enclosed for a map and directions).

I would like to participate, what do I do next?

If you would like to participate, and have arranged a time to attend, you do not need to do anything else.

If you would like to participate, but have not arranged a time to attend, please call Sam Smith on 0207 679 1723 or E-mail: Samuel.smith@ucl.ac.uk.

Yours sincerely,

Sam Smith

Appendix K Participant consent form for user-testing study

Participant Consent form

Please complete this form after you have read the information sheet.

Title of the Project: *Interview about new information materials given to individuals in the NHS Bowel Cancer Screening Programme: 'The Teach to Goal study'.*

This study has been approved by the UCL Research Ethics Committee (Project ID: 2247/002)

Thank you for your interest in taking part in this research. Before you agree to take part, the person organising the research must explain the project to you. If you have questions, please ask the researcher before you decide whether to join in. If you decide to take part please read and sign the statement below.

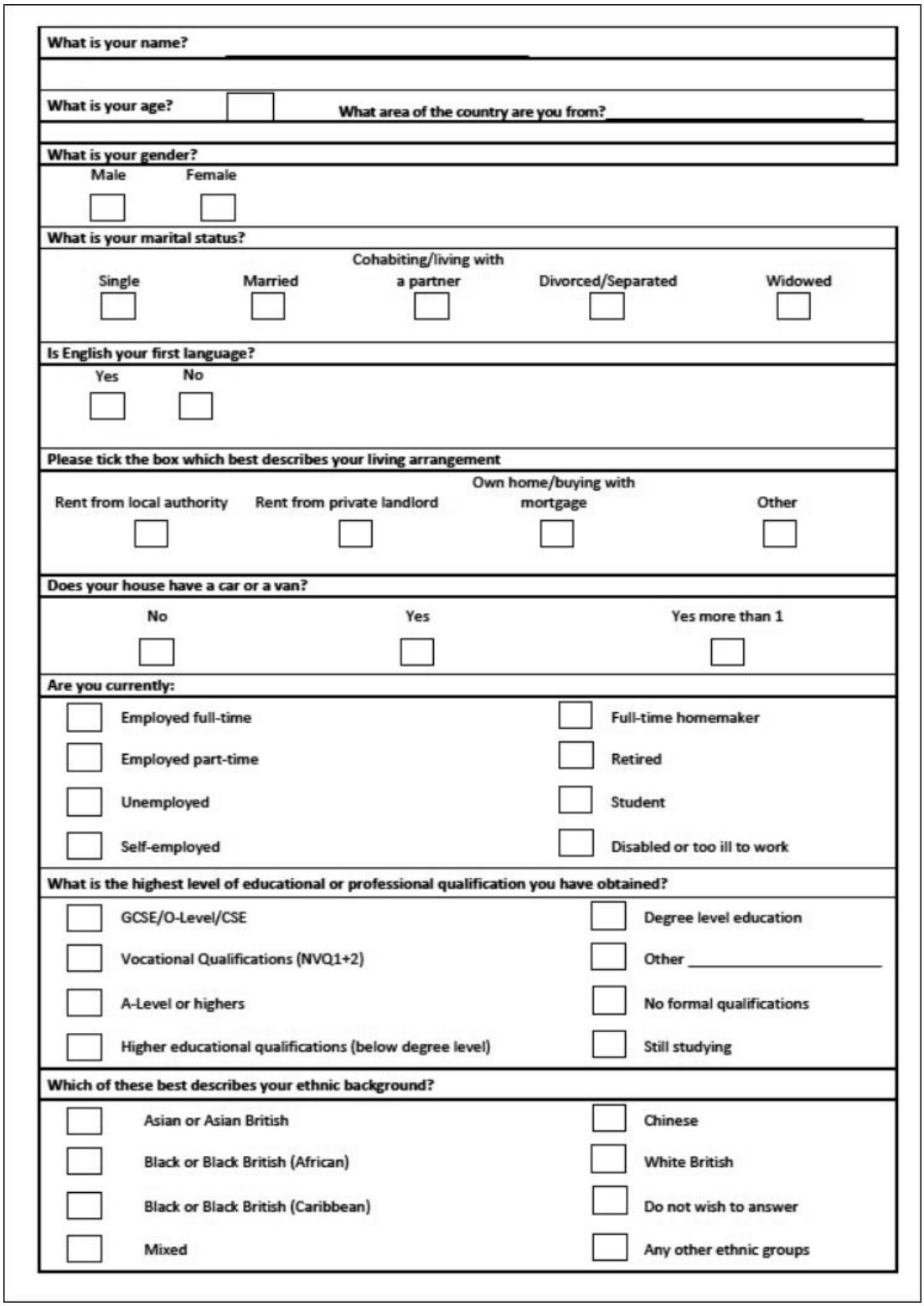
Participant's Statement

I,_____

- Have read the text contained on this consent form and in the information sheet and I understand what the study involves.
- Understand that if I decide that I no longer wish to take part in this project, I can notify the researchers involved and withdraw immediately
- Consent to the processing of my personal information for the purposes of this research study
- Understand that such information will be treated as strictly confidential and handled in accordance with the provisions of the data protection act 1998
- I agree that my non-personal research data may be used by others for future research. I am assured that the confidentiality of my personal data will be upheld through the removal of any identifiers
- Agree that the research project named above has been explained to me to my satisfaction and I agree to take part in this study.

Participant's signature:	Researcher's signature:
_____	_____
Date:	Date:
_____	_____

Appendix L Participant demographics for user-testing study



What is your name? _____

What is your age? ☐ What area of the country are you from? _____

What is your gender?

Male ☐ Female ☐

What is your marital status?

Single ☐ Married ☐ Cohabiting/living with a partner ☐ Divorced/Separated ☐ Widowed ☐

Is English your first language?

Yes ☐ No ☐

Please tick the box which best describes your living arrangement

Rent from local authority ☐ Rent from private landlord ☐ Own home/buying with mortgage ☐ Other ☐

Does your house have a car or a van?

No ☐ Yes ☐ Yes more than 1 ☐

Are you currently:

☐ Employed full-time
☐ Employed part-time
☐ Unemployed
☐ Self-employed
☐ Full-time homemaker
☐ Retired
☐ Student
☐ Disabled or too ill to work

What is the highest level of educational or professional qualification you have obtained?

☐ GCSE/O-Level/CSE
☐ Vocational Qualifications (NVQ1+2)
☐ A-Level or highers
☐ Higher educational qualifications (below degree level)
☐ Degree level education
☐ Other _____
☐ No formal qualifications
☐ Still studying

Which of these best describes your ethnic background?

☐ Asian or Asian British
☐ Black or Black British (African)
☐ Black or Black British (Caribbean)
☐ Mixed
☐ Chinese
☐ White British
☐ Do not wish to answer
☐ Any other ethnic groups

In general, how easy or hard do you find it to understand medical statistics?

Very easy ☐ Easy ☐ Hard ☐ Very Hard ☐

How often do you use long written documents in your current or previous job?

All of the time ☐ Most of the time ☐ Some of the time ☐ Hardly ever ☐

In general, would you say your health is...

Poor ☐ Fair ☐ Good ☐ Very Good ☐ Excellent ☐

Have you ever attended any of the following?

Breast cancer screening ☐ Cervical cancer screening ☐ Prostate Cancer testing (PSA – Men only) ☐

Have you, your family or close friends ever had cancer? (Tick all that apply)

Myself ☐ **My partner** ☐ **A close family member** ☐ **Other family member** ☐ **A close friend** ☐ **Other friend** ☐ **Prefer not to say** ☐

Have you been diagnosed with any chronic condition?

Yes ☐ No ☐ (If yes, name) _____

Have you been diganosed with any bowel conditions?

Yes ☐ No ☐ (If yes, name) _____

During the past 12 months, not counting times you went to accident and emergency, how many times did you go to a doctor, nurse of other health professional to get care for yourself?

None ☐ 1 time ☐ 2 times ☐ 3 times ☐ 4 times ☐ 5-9 times ☐

Have you ever looked for information about cancer from any source?

Yes ☐ No ☐ (If yes, where) _____

How much attendtion do you pay to information about health or medical topics on tv, radio, magazines or newspapers?

A lot ☐ Some ☐ A little ☐ Not at all ☐

Appendix M Participant instructions for user-testing study

TEACH TO GOAL SCRIPT

- Introduce self
- Explain information materials may be used in NHS Bowel Cancer Screening Programme
- We are testing them on members of the public
- You do not need any experience
- We would just like your opinion
- You will be asked to perform a series of tasks
- If you want to stop, just say so and we can
- Everything will be anonymous and confidential
- Tape record some parts

Task 1 – Consent form

Thank you

Task 2 – TOFHLA

Thank you

Task 3 – Read leaflet

Now, I'm going to ask you to read this leaflet. Imagine that you are 60 years old and have just been invited to participate in the NHS Bowel Cancer Screening Programme. Please read the information carefully and you will be asked a series of questions afterwards. I'll leave you alone to read the information, please let me know when you're finished.

Task 4 – Answer gist items

Great. I'll now ask you the questions. I'd first like you to show me where the answer is in the information materials. Then I would like you to explain what it is saying in your own words. I'm going to tape record this part of the interview.

Task 5 – Qualitative interview

Appendix N Knowledge statements used in user-testing study

NAME_____ DATE_____

E/D		Participant correct?	Find it?	Comments
E	Doing the FOB test lowers the risk of dying from bowel cancer	☐	☐	
E	The FOB test is done at home	☐	☐	
E	Most people who do the FOB test will receive an abnormal result	☐	☐	
E	Only women are sent a FOB test	☐	☐	
E	Bowel cancer is a common cancer in people over 60	☐	☐	
E	People only need to do the FOB test once in their life	☐	☐	
E	The FOB test can miss bowel cancer	☐	☐	
E	People with an abnormal result always have cancer	☐	☐	
D	What is the FOB test looking for?	☐	☐	
D	Why does the FOB test sometimes miss cancer?	☐	☐	
D	Where can people get more information about the FOB test?	☐	☐	

Appendix O Debrief form used in user-testing study

HEALTH BEHAVIOUR RESEARCH CENTRE
DEPARTMENT OF EPIDEMIOLOGY AND PUBLIC HEALTH

Thank you very much for taking part in this study.

What were the aims of this study?

The aim of this study was to develop and evaluate an information leaflet that will be given to people that are invited to take part in the NHS Bowel Cancer Screening Programme.

Where can I get more information about bowel cancer screening?

If you would like more information about bowel cancer screening then you can call the freephone telephone number 0800 707 60 60 who will be happy to assist you with any queries you may have. In addition you can go to the NHS Bowel Cancer Screening Programme website at: http://www.cancerscreening.nhs.uk/bowel/

How can I get more information on the study?

For further information on specific information please feel free to contact the researchers. If you are interested in our results, then let one of the researchers know and you will be emailed or sent by post the results of this study.

We would like to confirm that all the information that you have supplied is confidential and you will not be identified in any research.

If you have been distressed by any of the issues raised by participating in this project, please feel free to contact any of the researchers who will be happy to discuss any concerns or queries that you may have.

What are the researchers' contact details?

Sam Smith and Dr Christian Wagner

Email: Samuel.Smith@ucl.ac.uk – tel 0207 679 1723 c.wagner@ucl.ac.uk – Telephone: 0207 679 1940

We are psychology researchers at the Health Behaviour Research Centre, Department of Epidemiology and Public Health at UCL

Health Behaviour Research Centre
1-19 Torrington Place, University College London
London, WC1E 6BT

Thank you once more for taking part in this study.

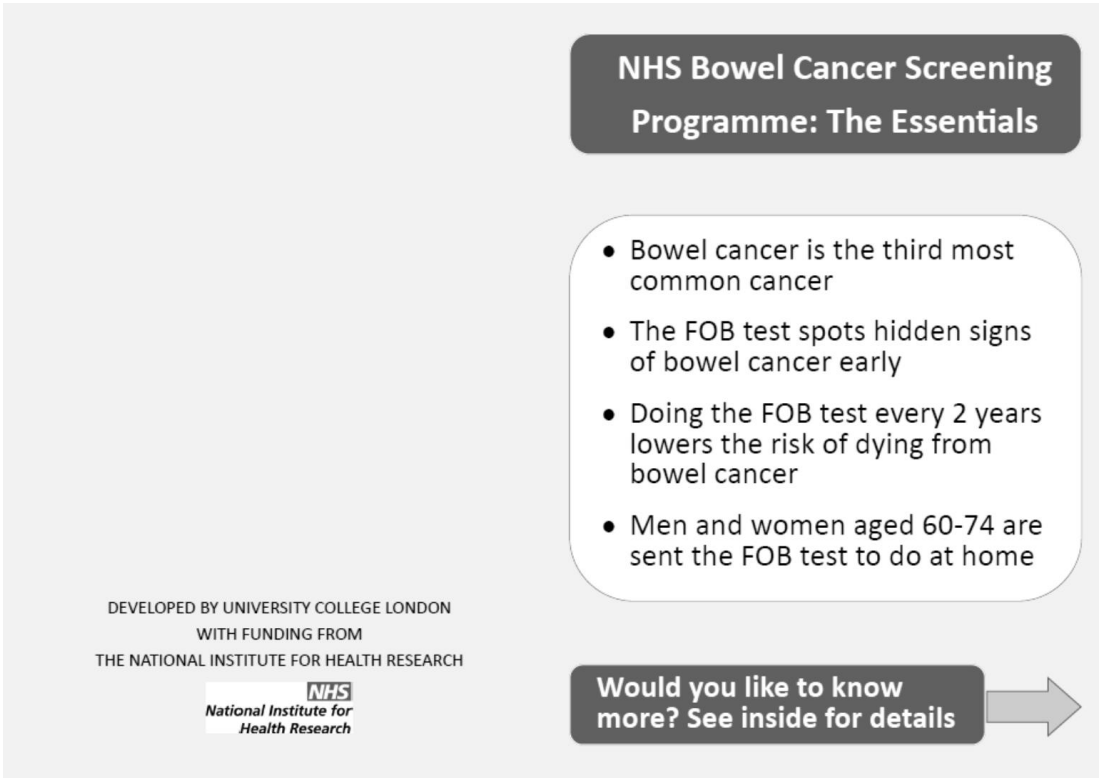
Appendix P Completed CONSORT checklist for community trial

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported?
Title and abstract			
	1a	Identification as a randomised trial in the title	YES
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	N/A
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	YES
	2b	Specific objectives or hypotheses	YES
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	YES
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	YES
Participants	4a	Eligibility criteria for participants	YES
	4b	Settings and locations where the data were collected	YES
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	YES
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	YES
	6b	Any changes to trial outcomes after the trial commenced, with reasons	YES
Sample size	7a	How sample size was determined	YES
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	YES
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	YES
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	YES
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	YES
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	YES
	11b	If relevant, description of the similarity of interventions	YES
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	YES
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	YES
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	YES
	13b	For each group, losses and exclusions after randomisation, together with reasons	YES
Recruitment	14a	Dates defining the periods of recruitment and follow-up	YES
	14b	Why the trial ended or was stopped	YES
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	YES
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	YES
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	YES
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	YES
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	YES
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	YES
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	YES
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	YES
Other information			
Registration	23	Registration number and name of trial registry	YES
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	YES

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix Q Gist leaflet used in community trial

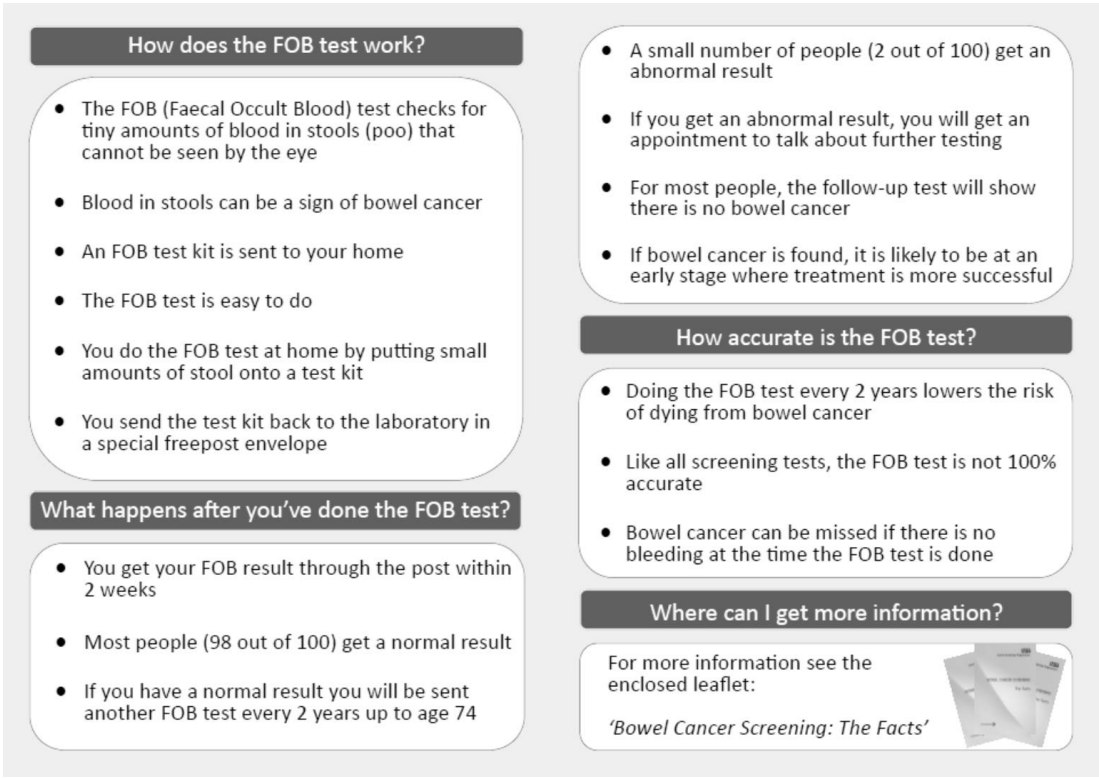


NHS Bowel Cancer Screening Programme: The Essentials

- Bowel cancer is the third most common cancer
- The FOB test spots hidden signs of bowel cancer early
- Doing the FOB test every 2 years lowers the risk of dying from bowel cancer
- Men and women aged 60-74 are sent the FOB test to do at home

DEVELOPED BY UNIVERSITY COLLEGE LONDON
WITH FUNDING FROM
THE NATIONAL INSTITUTE FOR HEALTH RESEARCH
NHS National Institute for Health Research

Would you like to know more? See inside for details



How does the FOB test work?

- The FOB (Faecal Occult Blood) test checks for tiny amounts of blood in stools (poo) that cannot be seen by the eye
- Blood in stools can be a sign of bowel cancer
- An FOB test kit is sent to your home
- The FOB test is easy to do
- You do the FOB test at home by putting small amounts of stool onto a test kit
- You send the test kit back to the laboratory in a special freepost envelope

What happens after you've done the FOB test?

- You get your FOB result through the post within 2 weeks
- Most people (98 out of 100) get a normal result
- If you have a normal result you will be sent another FOB test every 2 years up to age 74
- A small number of people (2 out of 100) get an abnormal result
- If you get an abnormal result, you will get an appointment to talk about further testing
- For most people, the follow-up test will show there is no bowel cancer
- If bowel cancer is found, it is likely to be at an early stage where treatment is more successful

How accurate is the FOB test?

- Doing the FOB test every 2 years lowers the risk of dying from bowel cancer
- Like all screening tests, the FOB test is not 100% accurate
- Bowel cancer can be missed if there is no bleeding at the time the FOB test is done

Where can I get more information?

For more information see the enclosed leaflet:

'Bowel Cancer Screening: The Facts'

Appendix R Study invitation letter

GP LETTER HEAD

Flat 1 Example Street
Example Town
Example City

Study number: XXXX

1st January, 2012

Dear Mr Example

Evaluation of NHS Bowel Cancer Screening patient information materials

Researchers at University College London (UCL) are organising a study that aims to find out how people respond to information about bowel cancer screening. We are helping with this study by inviting people, who are close to the age for bowel cancer screening, to complete a brief questionnaire which is enclosed. Also included with this letter is an NHS labelled envelope (containing information about bowel cancer screening) and a freepost return envelope.

Note: The letter inside the NHS labelled envelope is just an example. You are NOT being invited to participate in the NHS Bowel Cancer Screening Programme.

It is up to you to decide if you take part in this study or not:

- If you DO want to take part in this study please follow the instructions that are on the front cover of the questionnaire booklet. If we have not received a questionnaire from you within 2 weeks we will send you another as a reminder.
- If you DO NOT want to take part, please return the blank questionnaire in the freepost envelope provided (no stamp needed). This way, we know not to bother you with a reminder.

If you would like to know more about this study before deciding to take part or not, please contact Mr Samuel Smith at UCL on 0207 679 1723 / email: Samuel.smith@ucl.ac.uk. Please note that the researchers may use anonymised quotes of your answers to the questionnaire.

If you would like to know more about bowel cancer screening, call the NHS Bowel Cancer Screening helpline on 0800 707 60 60. You may also contact your GP if you have any concerns about bowel cancer or bowel cancer screening.

Yours sincerely,

Dr Example

Appendix S Mock reminder letter

GP LETTER HEAD

Flat 1 Example Street
Example Town
Example City

Study number: XXXX

1st January, 2012

Dear Mr Example

Evaluation of NHS Bowel Cancer Screening patient information materials

A few weeks ago we wrote to you about taking part in the above study. So far, not everyone who was invited to take part has responded. We are, therefore, sending you another copy of the NHS labelled envelope, questionnaire and freepost return envelope, in case the first copies have been mislaid.

Just to remind you, this study is being organised by researchers at University College London (UCL) and aims to find out how people respond to information about bowel cancer screening.

The practice is helping with this study by inviting people, who are close to the age for bowel cancer screening, to complete a brief questionnaire.

It is up to you to decide if you take part in this study or not.

- If you DO want to take part in this study please follow the instructions on the front cover of the questionnaire.

If you would like to know more about this study before deciding to take part or not, please contact Mr Samuel Smith at UCL on 0207 679 1723 / Samuel.smith@ucl.ac.uk

If you would like to know more about bowel cancer screening, call the NHS Bowel Cancer Screening helpline on 0800 707 60 60.

If you have already sent your questionnaire back, or if you do not wish to respond, please ignore this reminder and accept our apologies for any inconvenience caused.

Many thanks for your help.

Yours sincerely,

Dr Example

Appendix T Mock invitation letter

NHS
Cancer Screening Programmes

24 July 20XX

Bowel Cancer Screening Programme
Example Programme Hub
Example Hospital
Example Road
Example
XX45 6LE

Freephone: 0800 7XX 6X 6X

Mr/Mrs/Ms A N Example
22 Example Street
Example Town
Example
Example
XX12 3PL

S1 278/7/26

NHS No: 999 000 545

Dear Mr/Mrs/Ms A N Example

This is an invitation to take part in the NHS Bowel Cancer Screening Programme. The programme aims to detect bowel cancer early, when successful treatment and cure is more likely. Screening is offered every two years to people aged 60-69 who are registered with a GP in England. We are starting to extend the screening age range, so if you are aged 70-74, you are being invited as part of this process.

You will be sent a test kit with full instructions in about two weeks. The kit is simple to use in the privacy of your own home. If you want to be screened, wait until the kit arrives, follow the instructions, and return the kit in the **Freepost** envelope provided. You will get your results by letter within 2 weeks.

We do not have your medical history, and screening is not appropriate for everyone. **If you have already been referred to hospital for bowel investigations by your GP, or if you have had previous bowel surgery, then screening may not be appropriate for you. Please call us for advice.** If you don't wish to be screened, then please call and let us know. The **Freephone** number for all calls is at the top of this letter (calls are free from UK landlines).

If you need help from family or a carer in order to use the kit, please call us (or ask them to call us) for further important information. You can also use the **Freephone** number if you have any questions about taking part in the programme. Finally, please take the time to read the enclosed leaflet 'Bowel Cancer Screening The Facts', which may help to answer any questions you may have.

Yours sincerely

Hub Director

Appendix U Intervention group questionnaire

ID number:

Questionnaire

Evaluation of NHS Bowel Cancer Screening patient information materials

We would like to hear your views on bowel cancer and bowel cancer screening so that we can improve the information we give to others in the future. We are inviting all men and women aged 45-59 years from your GP practice to take part in a survey.

To take part, we ask that you:

1) Read through all the contents of the NHS labelled envelope
2) Complete this short questionnaire
3) Return the completed questionnaire in the freepost envelope provided (no stamp is required)

It is up to you to decide whether to take part or not. Your decision will not affect the quality of medical care you receive now or in the future.

The contents of the NHS labelled envelope are for you to read through only.

You will not be sent a screening test kit as part of this study.

When you reach your 60th birthday, the NHS will send you an FOB screening test kit.

If you have any questions please contact:

Samuel Smith
0207 679 1723
samuel.smith@ucl.ac.uk

Please answer all of the questions on each page

	No	I have read part of it	I have read it all	I have read it all more than once
Have you read the blue leaflet *'The NHS Bowel Cancer Screening Programme: The Essentials'*, found inside the NHS envelope?	☐	☐	☐	☐
Have you read the orange booklet, *'Bowel Cancer Screening: The Facts'*, found inside the NHS envelope?	☐	☐	☐	☐

Imagine you have just turned 60 and have received the bowel screening test kit (FOB test kit) in the post, would you do the test?

Definitely not	Probably not	Yes, probably	Yes, definitely
☐	☐	☐	☐

Remember, doing the test involves taking small amounts of your stools (poo) on three different days and putting them on the FOB test kit. Realistically speaking, how likely are you to do this?

Definitely not	Probably not	Yes, probably	Yes, definitely
☐	☐	☐	☐

Imagine you have just turned 60 and are making a decision about doing an FOB test kit…	Yes	Unsure	No
Do you know the benefits of doing an FOB test kit?	☐	☐	☐
Do you know the disadvantages of doing an FOB test kit?	☐	☐	☐
Are you clear about which benefits matter most to you?	☐	☐	☐
Are you clear about which disadvantages matter most to you?	☐	☐	☐
Do you have enough information about the FOB test?	☐	☐	☐

Compared to others of the same sex and age, my chances of getting bowel cancer are…

Much below average	Below average	Average	Above average	Much above average
☐	☐	☐	☐	☐

If I never do the FOB screening test, I would feel very vulnerable to bowel cancer

Strongly disagree	Disagree	Not sure	Agree	Strongly agree
☐	☐	☐	☐	☐

If I never do the FOB screening test, I think my chances of dying from bowel cancer would be…

Almost zero	Very small	Small	Moderate	Large	Very large	Almost certain
☐	☐	☐	☐	☐	☐	☐

	Strongly disagree	Disagree	Agree	Strongly agree
Doing the FOB test would be an important thing for me to do	☐	☐	☐	☐
Doing the FOB test would be disgusting	☐	☐	☐	☐
Doing the FOB test would be tempting fate	☐	☐	☐	☐
Doing the FOB test would make me anxious	☐	☐	☐	☐
Doing the FOB test would make me feel I was doing something positive for my health	☐	☐	☐	☐
Doing the FOB test would give me peace of mind	☐	☐	☐	☐
Doing the FOB test would make me worry more about bowel cancer	☐	☐	☐	☐
Doing the FOB test and receiving a normal result would reassure me that I do not have bowel cancer	☐	☐	☐	☐
I would be confident that I could do the FOB test correctly	☐	☐	☐	☐
I would be unlikely to have the time to do the FOB test	☐	☐	☐	☐
I would not have the privacy to do the FOB test	☐	☐	☐	☐
I would not want to keep small amounts of my stools on a card in the house	☐	☐	☐	☐
I would regret it if I did not do the FOB test	☐	☐	☐	☐
I would be embarrassed if others knew I had done the FOB test	☐	☐	☐	☐
I would do the FOB test because I would want to stay healthy for my family	☐	☐	☐	☐
The thought of bowel cancer scares me	☐	☐	☐	☐
I would only do the FOB test if I had symptoms of bowel cancer	☐	☐	☐	☐
I would be afraid of getting an abnormal result from my FOB test	☐	☐	☐	☐
Bowel cancer is a life-threatening illness	☐	☐	☐	☐
Bowel cancer cannot be cured no matter when it is found or how it is treated	☐	☐	☐	☐
I avoid information about cancer from the TV, newspapers and radio	☐	☐	☐	☐
If I feel healthy I do not go to the doctor for a routine check-up	☐	☐	☐	☐

	Strongly disagree	Disagree	Agree	Strongly agree
I like to ignore the fact that I could get cancer	☐	☐	☐	☐
The FOB test can't be that important because my GP has never told me I had to do it	☐	☐	☐	☐
The FOB test wouldn't affect my chances of dying from bowel cancer	☐	☐	☐	☐

I do not need to be screened for bowel cancer because I have regular bowel movements	☐	☐	☐	☐
I do not need to be screened for bowel cancer because I include enough fruit and vegetables in my diet	☐	☐	☐	☐
I do not need to be screened for bowel cancer because I don't eat too much red meat	☐	☐	☐	☐
I do not need to be screened for bowel cancer because I exercise regularly	☐	☐	☐	☐

What percentage of people in England, aged 60 to 74, do you think do the FOB test?

None	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

	True	False	Don't know
Doing the FOB test lowers the risk of dying from bowel cancer	☐	☐	☐
The FOB test is done at home	☐	☐	☐
Most people who do the FOB test will receive an abnormal result	☐	☐	☐
Only women are sent a FOB test	☐	☐	☐
Bowel cancer is a common cancer in people over 60	☐	☐	☐
People only need to do the FOB test once in their life	☐	☐	☐
The FOB test can miss bowel cancer	☐	☐	☐
People with an abnormal result always have cancer	☐	☐	☐
People aged 60-74 years are sent the FOB test	☐	☐	☐

Which of the following numbers represents the biggest risk of getting a disease?

☐ 1 in 100 ☐ 1 in 1000 ☐ 1 in 10

HERE ARE SOME QUESTIONS ABOUT YOU AND YOUR BACKGROUND

What is your age?

☐ years

What is your gender?

☐ Male ☐ Female

What is your marital status?

Single	Married	Cohabiting / living with partner	Divorced / separated	Widowed
☐	☐	☐	☐	☐

Which of these best describes your ethnic group?

☐ White British	☐ Caribbean	☐ Indian	☐ White and Asian	☐ Chinese
☐ White Irish	☐ African	☐ Pakistani	☐ White and Black Caribbean	☐ Any other
☐ Other White background	☐ Other Black background	☐ Bangladeshi	☐ White and Black African	
		☐ Other Asian	☐ Other Mixed	

Please tick the box which best describes your living arrangement:

☐ Rent: local authority / housing association / council ☐ Own your home / have a mortgage

☐ Rent: private landlord ☐ Other

Does your household have a car or van?

☐ No ☐ Yes, one ☐ Yes, more than one

Are you currently…? (please tick all that apply)

☐ employed full-time	☐ full-time homemaker	☐ disabled or too ill to work
☐ employed part-time	☐ retired	☐ self-employed
☐ unemployed	☐ student	

What is the highest level of educational or professional qualification you have obtained?

☐ GCSE / O-level / CSE	☐ Masters / PhD or equivalent
☐ Vocational qualifications (e.g. NVQ1+2)	☐ Other (Specify……)
☐ A-level or equivalent (e.g. NVQ3)	☐ No formal qualifications
☐ Bachelor Degree or equivalent (e.g. NVQ4)	

Would you say that for someone of your age, your own health, in general, is…?

Poor	Fair	Good	Excellent
☐	☐	☐	☐

Have you ever done any kind of test that involves taking a small amount of your stool (poo) before?

☐ Yes ☐ No ☐ Not sure

4

Have you ever had cancer?

Yes	No	Not sure
☐	☐	☐

If 'Yes', what type of cancer was it? (please print here)

_____

Have any of the following people ever been diagnosed with **bowel cancer**? (Please tick all that apply)

- ☐ Wife / Husband / Partner
- ☐ Family member (blood relative)
- ☐ Family member (non blood relative)
- ☐ Close friend
- ☐ Other friend
- ☐ Not sure

How worried are you about getting bowel cancer?

Not worried at all	A bit worried	Quite worried	Very worried
☐	☐	☐	☐

HERE ARE SOME QUESTIONS ABOUT THE INFORMATION GUIDES

For me, the blue leaflet, '*NHS Bowel Cancer Screening Programme: The Essentials*', was…

1	2	3	4	5	6	7
Easy to read						Hard to read
1	2	3	4	5	6	7
Useful						Not at all useful

For me, the orange booklet, '*Bowel Cancer Screening: The Facts*', was…

1	2	3	4	5	6	7
Easy to read						Hard to read
1	2	3	4	5	6	7
Useful						Not at all useful

If you have any other good or bad comments to make about the two information guides, please write them in the boxes below:

'NHS Bowel Cancer Screening Programme: The Essentials' (Blue leaflet)

'Bowel Cancer Screening: The Facts' (Orange booklet)

5

Thank you very much for taking the time to complete the questionnaire. Your answers are very important to our research.

Please return this questionnaire in the enclosed freepost envelope.
No stamp is required.

If you lose the freepost envelope please post to:

FREEPOST UNIVERSITY COLLEGE LONDON
(BOWEL SCREENING STUDY)

If you would like to receive a copy of the results from this study please tick here ☐

If you would like to be contacted about taking part in future studies please tick here ☐

If you ticked either of the boxes above please write down your contact details below. In order to keep our costs down, we would prefer to contact you by e-mail if this is possible.

Name: _____

Email address: _____

Address: _____

_____

_____

Telephone: _____

This page will be removed from the questionnaire as soon as the researchers receive it to make sure your questionnaire answers are treated confidentially.

The return of a completed questionnaire is confirmation of your consent to take part in the study and allows the researchers to use the personal information you provide in their research. This information will not be given to anyone outside University College London (UCL).

All data you provide to the researchers will be treated in the strictest confidence and will be stored securely in accordance with the Data Protection Act 1998.

7

Appendix V Control group questionnaire

ID number:

Questionnaire

Evaluation of NHS Bowel Cancer Screening patient information materials

We would like to hear your views on bowel cancer and bowel cancer screening so that we can improve the information we give to others in the future. We are inviting all men and women aged 45-59 years from your GP practice to take part in a survey.

To take part, we ask that you:

1) Read through all the contents of the NHS labelled envelope
2) Complete this short questionnaire
3) Return the completed questionnaire in the freepost envelope provided (no stamp is required)

It is up to you to decide whether to take part or not. Your decision will not affect the quality of medical care you receive now or in the future.

The contents of the NHS labelled envelope are for you to read through only.

You will not be sent a screening test kit as part of this study.

When you reach your 60th birthday, the NHS will send you an FOB screening test kit.

If you have any questions please contact:

Samuel Smith
0207 679 1723
samuel.smith@ucl.ac.uk

Please answer all of the questions on each page

	No	I have read part of it	I have read it all	I have read it all more than once
Have you read the orange booklet, *'Bowel Cancer Screening: The Facts'*, found inside the NHS envelope?	☐	☐	☐	☐

Imagine you have just turned 60 and have received the bowel screening test kit (FOB test kit) in the post, would you do the test?			
Definitely not	Probably not	Yes, probably	Yes, definitely
☐	☐	☐	☐

Remember, doing the test involves taking small amounts of your stools (poo) on three different days and putting them on the FOB test kit. Realistically speaking, how likely are you to do this?			
Definitely not	Probably not	Yes, probably	Yes, definitely
☐	☐	☐	☐

Imagine you have just turned 60 and are making a decision about doing an FOB test kit…	Yes	Unsure	No
Do you know the benefits of doing an FOB test kit?	☐	☐	☐
Do you know the disadvantages of doing an FOB test kit?	☐	☐	☐
Are you clear about which benefits matter most to you?	☐	☐	☐
Are you clear about which disadvantages matter most to you?	☐	☐	☐
Do you have enough information about the FOB test?	☐	☐	☐

Compared to others of the same sex and age, my chances of getting bowel cancer are…				
Much below average	Below average	Average	Above average	Much above average
☐	☐	☐	☐	☐
If I never do the FOB screening test, I would feel very vulnerable to bowel cancer				
Strongly disagree	Disagree	Not sure	Agree	Strongly agree
☐	☐	☐	☐	☐
If I never do the FOB screening test, I think my chances of dying from bowel cancer would be…				
Almost zero	Very small	Small	Moderate	Large	Very large	Almost certain
☐	☐	☐	☐	☐	☐	☐

	Strongly disagree	Disagree	Agree	Strongly agree
Doing the FOB test would be an important thing for me to do	☐	☐	☐	☐
Doing the FOB test would be disgusting	☐	☐	☐	☐
Doing the FOB test would be tempting fate	☐	☐	☐	☐
Doing the FOB test would make me anxious	☐	☐	☐	☐
Doing the FOB test would make me feel I was doing something positive for my health	☐	☐	☐	☐
Doing the FOB test would give me peace of mind	☐	☐	☐	☐
Doing the FOB test would make me worry more about bowel cancer	☐	☐	☐	☐
Doing the FOB test and receiving a normal result would reassure me that I do not have bowel cancer	☐	☐	☐	☐
I would be confident that I could do the FOB test correctly	☐	☐	☐	☐
I would be unlikely to have the time to do the FOB test	☐	☐	☐	☐
I would not have the privacy to do the FOB test	☐	☐	☐	☐
I would not want to keep small amounts of my stools on a card in the house	☐	☐	☐	☐
I would regret it if I did not do the FOB test	☐	☐	☐	☐
I would be embarrassed if others knew I had done the FOB test	☐	☐	☐	☐
I would do the FOB test because I would want to stay healthy for my family	☐	☐	☐	☐
The thought of bowel cancer scares me	☐	☐	☐	☐
I would only do the FOB test if I had symptoms of bowel cancer	☐	☐	☐	☐
I would be afraid of getting an abnormal result from my FOB test	☐	☐	☐	☐
Bowel cancer is a life-threatening illness	☐	☐	☐	☐
Bowel cancer cannot be cured no matter when it is found or how it is treated	☐	☐	☐	☐
I avoid information about cancer from the TV, newspapers and radio	☐	☐	☐	☐
If I feel healthy I do not go to the doctor for a routine check-up	☐	☐	☐	☐

	Strongly disagree	Disagree	Agree	Strongly agree
I like to ignore the fact that I could get cancer	☐	☐	☐	☐
The FOB test can't be that important because my GP has never told me I had to do it	☐	☐	☐	☐
The FOB test wouldn't affect my chances of dying from bowel cancer	☐	☐	☐	☐

I do not need to be screened for bowel cancer because I have regular bowel movements	☐	☐	☐	☐
I do not need to be screened for bowel cancer because I include enough fruit and vegetables in my diet	☐	☐	☐	☐
I do not need to be screened for bowel cancer because I don't eat too much red meat	☐	☐	☐	☐
I do not need to be screened for bowel cancer because I exercise regularly	☐	☐	☐	☐

What percentage of people in England, aged 60 to 74, do you think do the FOB test?

None	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

	True	False	Don't know
Doing the FOB test lowers the risk of dying from bowel cancer	☐	☐	☐
The FOB test is done at home	☐	☐	☐
Most people who do the FOB test will receive an abnormal result	☐	☐	☐
Only women are sent a FOB test	☐	☐	☐
Bowel cancer is a common cancer in people over 60	☐	☐	☐
People only need to do the FOB test once in their life	☐	☐	☐
The FOB test can miss bowel cancer	☐	☐	☐
People with an abnormal result always have cancer	☐	☐	☐
People aged 60-74 years are sent the FOB test	☐	☐	☐

Which of the following numbers represents the biggest risk of getting a disease?

☐ 1 in 100 ☐ 1 in 1000 ☐ 1 in 10

HERE ARE SOME QUESTIONS ABOUT YOU AND YOUR BACKGROUND

What is your age?

☐ years

What is your gender?

☐ Male ☐ Female

What is your marital status?

Single	Married	Cohabiting / living with partner	Divorced / separated	Widowed
☐	☐	☐	☐	☐

Which of these best describes your ethnic group?

☐ White British	☐ Caribbean	☐ Indian	☐ White and Asian	☐ Chinese
☐ White Irish	☐ African	☐ Pakistani	☐ White and Black Caribbean	☐ Any other
☐ Other White background	☐ Other Black background	☐ Bangladeshi	☐ White and Black African	
		☐ Other Asian	☐ Other Mixed	

Please tick the box which best describes your living arrangement:

☐ Rent: local authority / housing association / council ☐ Own your home / have a mortgage

☐ Rent: private landlord ☐ Other

Does your household have a car or van?

☐ No ☐ Yes, one ☐ Yes, more than one

Are you currently…? (please tick all that apply)

☐ employed full-time	☐ full-time homemaker	☐ disabled or too ill to work
☐ employed part-time	☐ retired	☐ self-employed
☐ unemployed	☐ student	

What is the highest level of educational or professional qualification you have obtained?

☐ GCSE / O-level / CSE	☐ Masters / PhD or equivalent
☐ Vocational qualifications (e.g. NVQ1+2)	☐ Other (Specify……)
☐ A-level or equivalent (e.g. NVQ3)	☐ No formal qualifications
☐ Bachelor Degree or equivalent (e.g. NVQ4)	

Would you say that for someone of your age, your own health, in general, is…?

Poor	Fair	Good	Excellent
☐	☐	☐	☐

Have you ever done any kind of test that involves taking a small amount of your stool (poo) before?

☐ Yes ☐ No ☐ Not sure

4

Have you ever had cancer?

Yes	No	Not sure
☐	☐	☐

If 'Yes', what type of cancer was it? (please print here)

_____

Have any of the following people ever been diagnosed with **bowel cancer**? (Please tick all that apply)

- ☐ Wife / Husband / Partner
- ☐ Family member (blood relative)
- ☐ Family member (non blood relative)
- ☐ Close friend
- ☐ Other friend
- ☐ Not sure

How worried are you about getting bowel cancer?

Not worried at all	A bit worried	Quite worried	Very worried
☐	☐	☐	☐

HERE ARE SOME QUESTIONS ABOUT THE INFORMATION BOOKLET

For me, the orange booklet, '*Bowel Cancer Screening: The Facts*', was…

1	2	3	4	5	6	7
Easy to read						Hard to read
1	2	3	4	5	6	7
Useful						Not at all useful

If you have any other good or bad comments to make about the booklet, '*Bowel Cancer Screening: The Facts*', please write them in the box below.

'Bowel Cancer Screening: The Facts' (Orange booklet)

Thank you very much for taking the time to complete the questionnaire. Your answers are very important to our research.

Please return this questionnaire in the enclosed freepost envelope.
No stamp is required.

If you lose the freepost envelope please post to:

FREEPOST UNIVERSITY COLLEGE LONDON
(BOWEL SCREENING STUDY)

If you would like to receive a copy of the results from this study please tick here ☐

If you would like to be contacted about taking part in future studies please tick here ☐

If you ticked either of the boxes above please write down your contact details below. In order to keep our costs down, we would prefer to contact you by e-mail if this is possible.

Name: _____

Email address: _____

Address: _____

_____

_____

Telephone: _____

This page will be removed from the questionnaire as soon as the researchers receive it to make sure your questionnaire answers are treated confidentially.

6

The return of a completed questionnaire is confirmation of your consent to take part in the study and allows the researchers to use the personal information you provide in their research. This information will not be given to anyone outside University College London (UCL).

All data you provide to the researchers will be treated in the strictest confidence and will be stored securely in accordance with the Data Protection Act 1998.

7

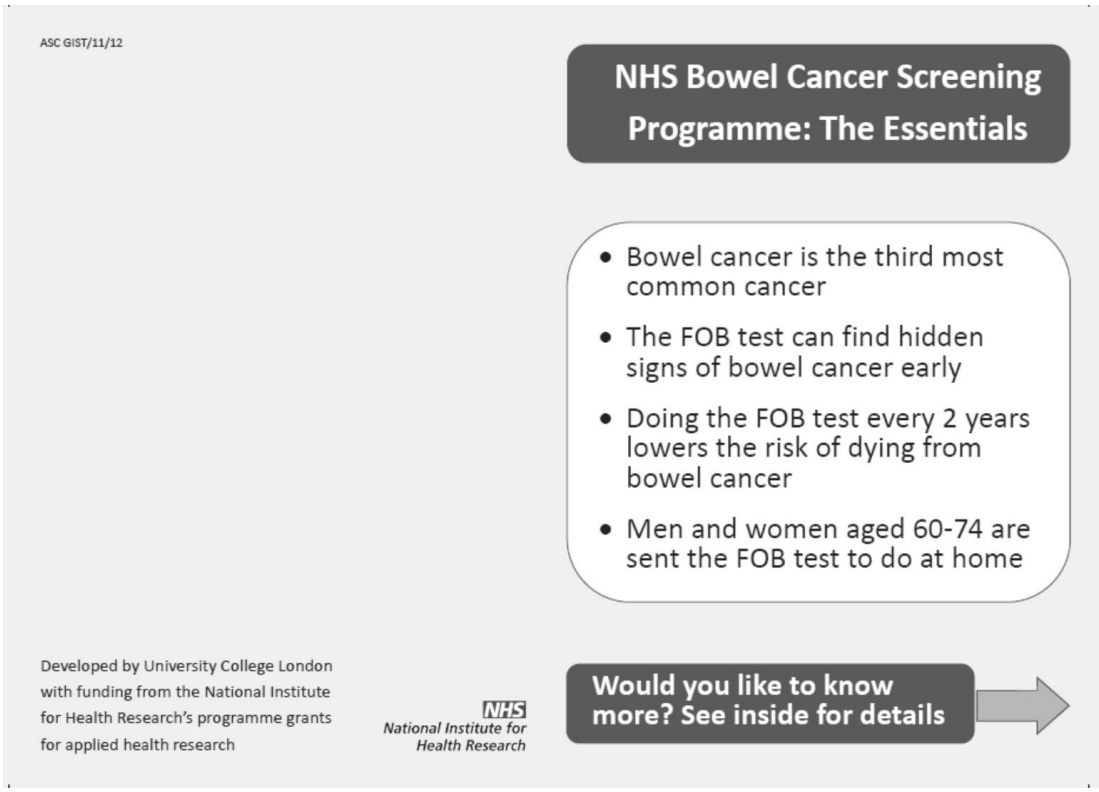
Appendix W Completed CONSORT checklist for national trial

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported?
Title and abstract			
	1a	Identification as a randomised trial in the title	YES
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	N/A
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	YES
	2b	Specific objectives or hypotheses	YES
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	YES
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	YES
Participants	4a	Eligibility criteria for participants	YES
	4b	Settings and locations where the data were collected	YES
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	YES
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	YES
	6b	Any changes to trial outcomes after the trial commenced, with reasons	YES
Sample size	7a	How sample size was determined	YES
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	YES
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	YES
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	YES
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	YES
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	YES
	11b	If relevant, description of the similarity of interventions	YES
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	YES
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	YES
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	YES
	13b	For each group, losses and exclusions after randomisation, together with reasons	YES
Recruitment	14a	Dates defining the periods of recruitment and follow-up	YES
	14b	Why the trial ended or was stopped	YES
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	YES
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	YES
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	YES
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	YES
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	YES
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	YES
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	YES
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	YES
Other information			
Registration	23	Registration number and name of trial registry	YES
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	YES

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix X Gist leaflet used in national trial



ASC GIST/11/12

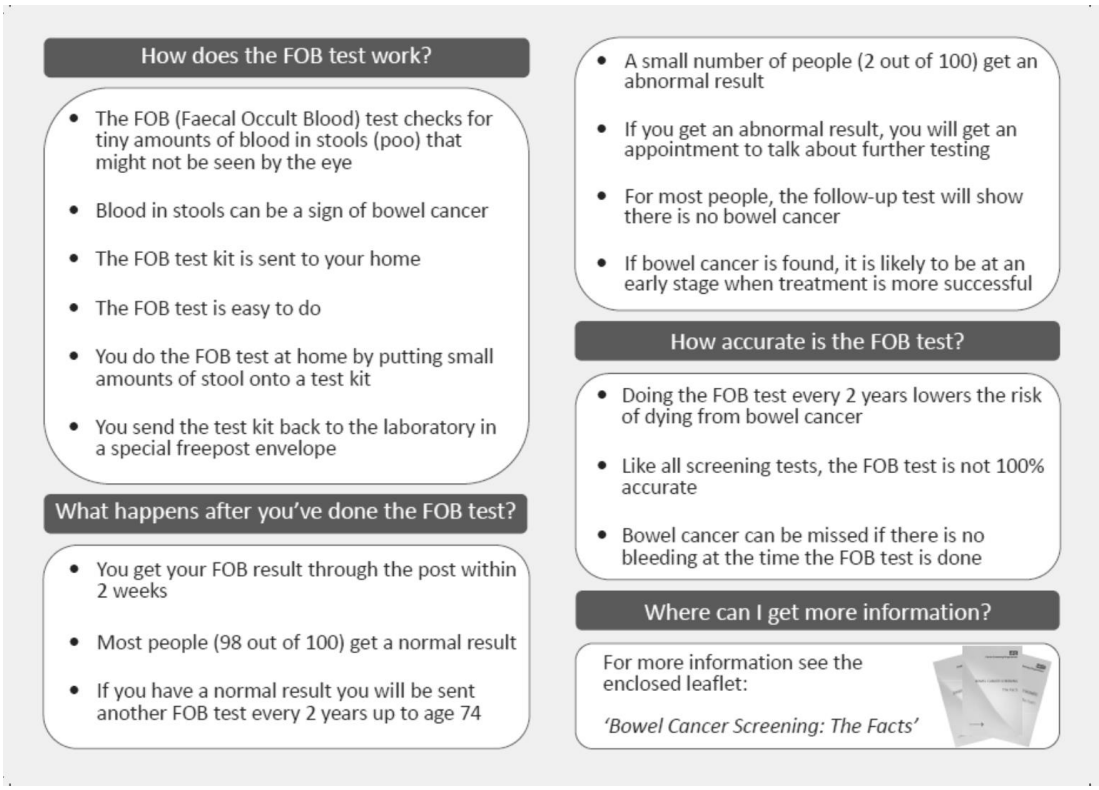
NHS Bowel Cancer Screening Programme: The Essentials

- Bowel cancer is the third most common cancer
- The FOB test can find hidden signs of bowel cancer early
- Doing the FOB test every 2 years lowers the risk of dying from bowel cancer
- Men and women aged 60-74 are sent the FOB test to do at home

Developed by University College London with funding from the National Institute for Health Research's programme grants for applied health research

NHS National Institute for Health Research

Would you like to know more? See inside for details



How does the FOB test work?

- The FOB (Faecal Occult Blood) test checks for tiny amounts of blood in stools (poo) that might not be seen by the eye
- Blood in stools can be a sign of bowel cancer
- The FOB test kit is sent to your home
- The FOB test is easy to do
- You do the FOB test at home by putting small amounts of stool onto a test kit
- You send the test kit back to the laboratory in a special freepost envelope

What happens after you've done the FOB test?

- You get your FOB result through the post within 2 weeks
- Most people (98 out of 100) get a normal result
- If you have a normal result you will be sent another FOB test every 2 years up to age 74
- A small number of people (2 out of 100) get an abnormal result
- If you get an abnormal result, you will get an appointment to talk about further testing
- For most people, the follow-up test will show there is no bowel cancer
- If bowel cancer is found, it is likely to be at an early stage when treatment is more successful

How accurate is the FOB test?

- Doing the FOB test every 2 years lowers the risk of dying from bowel cancer
- Like all screening tests, the FOB test is not 100% accurate
- Bowel cancer can be missed if there is no bleeding at the time the FOB test is done

Where can I get more information?

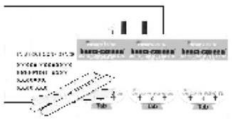
For more information see the enclosed leaflet:

'Bowel Cancer Screening: The Facts'

Appendix Y FOBt kit instructions

In your kit, you will find:

☑ A prepaid return envelope
☑ 6 cardboard sticks
☑ An orange and white cardboard test kit



Important:

Your kit will last for many months unopened, but it must be completed and received for testing **within 14 days** of the first sample being taken. Please note that kits will not be tested on weekends

1. Before doing the test

Get your kit ready to use before sitting on the toilet: take the kit out of the envelope and have two cardboard sticks ready.

Leave the side marked 'DO NOT OPEN' sealed, to ensure that your test results are not affected.

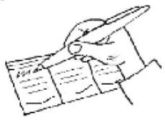
There are 3 parts to the kit, for 3 separate bowel motions.

Only open one flap at a time.

Do not separate the 3 parts.

2. Doing the test

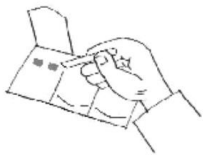
On the side with **your name printed on it**, write the date on flap 1 in the space provided.



- Peel back flap 1.
- You will see two small 'windows' on which to put your samples.
- Keep the kit and sticks within easy reach.

3. Collecting the first sample

- It is important that the bowel motion you take the sample from has not been in the toilet bowl, as this could affect the test result. Suggested ways to catch your sample are:
  - Folded pieces of toilet paper
  - Your hand covered in a small plastic bag
  - A clean disposable container
- Use a cardboard stick to take a small piece from the bowel motion you have just collected. Spread it thinly over the first window.



- Using another stick, take another sample from a different area of the bowel motion. Spread it thinly over the second window.

4. When you are finished

- Please wipe the sticks with toilet paper, wrap them up and dispose of them in an outside bin. **Do not** flush the cardboard sticks down the toilet.

- Close the flap, and tuck it under the orange tab to keep secure.
- **Do not** leave the kit in a warm place, or in direct sunlight, as this could spoil it. Wash your hands after use.

5. Collecting the second sample

- Write the date on flap 2.
- Repeat the test using the two windows under flap 2.

6. Collecting the third sample

- Write the date on flap 3.
- Repeat the test using the two windows under flap 3.

Note: Your samples do not need to be taken from three bowel motions in a row, but they must be from three separate motions.

Checklist ☑

- Have you put samples on all six windows? ☐
- Have you written the date on all three flaps? ☐
- Will the kit be received for testing **within 14 days** of the first sample being taken? ☐

If the answer is NO to <u>any</u> of the checklist questions, please contact the programme hub for advice: Freephone 0800 707 60 60, Textphone 18001 0800 707 60 60.

If the answer is YES to <u>all</u> of the checklist questions, put the kit in the prepaid envelope, seal it, and put it in the post. The envelope meets postal regulations, and is safe to send. But please make sure it is clean, in order to protect postal workers.

Any questions?

Contact the programme hub on
FREEPHONE 0800 707 60 60
Textphone 18001 0800 707 60 60

Calls will be dealt with in strictest confidence. Please do not feel embarrassed to ask for information or advice. Staff are there to help you.

This leaflet is also available in braille, audio CD and BSL DVD format.

Remember:
Store the kit away from sunlight and heat

NHS
Cancer Screening Programmes

NHS
Cancer Screening Programmes

NHS Bowel Cancer Screening Programme

This leaflet explains how to use the kit.
Please read carefully.

Appendix Z Example randomisation schedule

	Screening hub				
Date of invitation	North-West	Southern	London	North East	Eastern
05 Nov	Gist	Gist	Standard	Gist	Gist
06 Nov	Standard	Gist	Gist	Standard	Gist
07 Nov	Gist	Standard	Standard	Standard	Standard
08 Nov	Standard	Standard	Standard	Gist	Standard
09 Nov	Gist	Gist	Gist	Standard	Gist
12 Nov	Standard	Gist	Gist	Gist	Standard
13 Nov	Gist	Standard	Gist	Standard	Standard
14 Nov	Standard	Standard	Gist	Gist	Standard
15 Nov	Standard	Standard	Standard	Standard	Gist
16 Nov	Gist	Gist	Standard	Gist	Gist

Appendix AA Frequently asked questions provided to help-desk staff

'The Essentials' leaflet

'The Essentials' leaflet	ASCEND Interventions
Why do I have two information leaflets?	'The Facts' (orange) leaflet is the one sent out by the BCSP as standard. 'The Essentials' (blue) leaflet is a newly designed leaflet which provides a simple overview of the screening programme.
I have two information leaflets, which one should I read?	The choice is yours as to whether you read one/ both/ neither of the leaflets. 'The Essentials' (blue) leaflet was designed to give a simple overview of the BCSP, where as 'The Facts' provides more in-depth information. If you have any questions about any of the information in either leaflet , you can call us back on the Freephone number.
I think the leaflet is too patronizing	'The Essentials' (blue) leaflet was designed to give a simple overview of the BCSP. It uses terms that the general population, and people with no experience of bowel screening, will find easy to understand. Please feel free to ignore the leaflet.
What does it mean when it says 'the FOB test is not 100% accurate' ?	No test is 100% accurate, so a normal result does not mean that you do not have or will never develop bowel cancer. If you have any symptoms please contact your GP immediately.
What does the leaflet mean by 'follow-up test' ?	The follow-up test referred to in the leaflet is usually a colonoscopy. If you receive an abnormal result then an appointment will be made for you to see one of our specialist nurses at a clinic local to you. Here they will offer you a colonoscopy, which involves a small camera being passed up your bottom to allow the doctor to have a good look at the whole of your large bowel. (If the person requires further medical advice refer to a nurse.)
Why doesn't the leaflet explain what an 'unclear' result means?	'The Essentials' (blue) leaflet aims to summarise only the most common outcomes of completing a FOB test. Please see 'The Facts' booklet for more information of possible outcomes associated with completing a FOB test.
Why does the leaflet not talk about polyps?	'The Essentials' (blue) leaflet was designed to give a simple overview of the BCSP. Please see 'The Facts' booklet for more information about polyps.
It says in the leaflet that the FOB test is easy to use but I am finding it difficult	(Find out what they are finding difficult and offer help based on BCSP FAQs) E.g. Ask if they would like you to explain how to complete the kit/ need ideas on collecting faecal samples/ need the test kit instructions in a different language etc.
Can I get this leaflet in another language?	Unfortunately this leaflet is not available in any other languages at present but it may be in the future
I have received 'The Essentials' (blue) leaflet but my spouse/ partner/ friend has not. Why is that?	Everyone aged 60 or over is sent the BCSP invitation letter with 'The Facts' leaflet. However we are testing this ADDITIONAL leaflet at the moment as part of a trial which means that only half of those currently invited would receive the additional leaflet. We are only testing the leaflet for about 2 weeks so future invitations will not include this leaflet until the NHS has made a decision about including it permanently.
I have mislaid/ damaged 'The Essentials' (blue) leaflet I received	That is not a problem, we can send you another one out today.
I have not received 'The Essentials' (blue) leaflet. Please can you send it to me?	We cannot send the leaflet to you. We are testing this ADDITIONAL leaflet at the moment as part of a trial which means that only half of those currently invited would receive the additional leaflet. We are only testing the leaflet for about 2 weeks so future invitations will not include this leaflet until the NHS has made a decision about including it permanently.

'The Essentials' leaflet

'The Essentials' leaflet	ASCEND Interventions
My wife/partner spouse/ neighbour received 'The Essentials' (blue) leaflet which says people are screened between 60-74. I am 72 but have not received a test kit.	You may live in an area where the age extension, i.e. 70-74 has not been applied. If this is the case you can 'opt-in' to the screening programme. (Explain what completing the kit involves and what will happen if they have an abnormal result, i.e. colonoscopy.)
Why is there a code on the back of 'The Essentials' (blue) leaflet? Can I be identified by this?	The code simply specifies what type of leaflet it is. This is for office use only and you can not be identified with it.
How much money has 'The Essentials' (blue) leaflet cost the NHS?	The costs of the leaflet have been covered by the research team who developed the leaflet.
I have just received 'The Essentials' (blue) leaflet which mentions the word 'research'. Have researchers had access to my personal data?	No. Your name, age and address are the only details we have at the Bowel Cancer Screening Programme. This data is confidential which means it cannot be shared outside of the NHS. The letter you received containing 'The Essentials' (blue) leaflet was processed by the NHS.
I have just received 'The Essentials' (blue) leaflet which mentions the word 'research'. Is the Bowel Cancer Screening Programme a trial?	No. The programme started in July 2006 and has been gradually rolled out across the country. It is now a nation wide screening programme.

Please speak to your supervisor if there are any questions you feel unable to answer. Thank you

Appendix BB Process evaluation form provided to help-desk staff

Guidelines for 'The Essentials' Proforma

Dear Helpline Assistant,

To find out more about the effect of the ASCEND interventions on your Hub, we would like you to complete the proforma attached for every call you take **relating to the 'The Essentials'/ blue leaflet** sent out with the invitation letter (S1).

It would be very helpful if you could elaborate as much as possible when recording these types of calls.

To help you get started, please see the example below. We have tried to make the form simple and easy to complete; it should only take a few moments to fill in after each call:

If you should have any questions about how to complete the proforma, please ask your supervisor. Thank you in advance for your help with this research,

ASCEND project team

'The Essentials' proforma	Helpline Assistant Name: *A.SMITH*	Week beginning: *10.10.10*
DATE	Comments	
10.10.10	*Wanted translated version of 'The Essentials' leaflet*	
11.10.10	*Thought the leaflet was too patronizing*	
12.10.10	*Wanted to know why the leaflet does not talk about polyps*	

'The Essentials' proforma	Helpline Assistant Name:	Week beginning:
DATE	Comments	

NB: The ASCEND project team do not have access to the BCSS. Therefore this proforma should not identify individuals; please do not record any identifiable information on the form e.g. NHS numbers etc.