The use of behavioural sciences in targeted health messages to improve the participation in cervical and breast screening programmes.

A thesis by

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Declaration

I hereby declare that this thesis and the research it describes are the products of my own work and that where it has been the result of collaboration with others, this is fully described. References from work by other researches are fully acknowledged in accordance with standard referencing practice.

Sarah W. Huf

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Thesis abstract

The aim of this thesis was to examine the effects of behaviourally informed interventions deployed in text message reminders and invitation letters on the participation in cervical and breast cancer screening.

Cancer screening saves lives through detecting cancer or precancerous changes early, when medical intervention is more likely to reduce morbidity and mortality. A key factor in the success of any screening programme is public participation. Although some individuals may object to cancer screening, evidence suggests that public support for cancer screening provision in the UK is above 90%. Yet despite this, participation rates across all three cancer screening programmes (breast, cervical and colorectal) remain lower than expected given reported intentions.

This thesis explores the role of decision making – both reflective and automatic in the context of cancer screening behaviour and highlights the potential for the application of behavioural economic theory and behavioural science to inform intervention design aimed at increasing cancer screening uptake. Through the application of frameworks informed by behaviour change theory, three randomised controlled trials were designed to test the impact of behavioural interventions on participation rates in regional cervical and breast cancer screening programmes within the London area. The intervention design of each trial focused on the message content within either text message reminders or invitation letters. The first randomised controlled trial (RCT) tested different behaviourally-informed invitation letters in cervical screening and found that a shortened letter that contained a loss framed message has a small but significant positive impact on cervical screening rates. The second RCT tested different text message reminder content against a no-text message control and found that text message reminders can improve participation in cervical cancer screening. However, the content of such text message reminders further affects screening participation behaviour. The final RCT tested the effect different behaviour message content in text message reminders for timed appointments in the breast screening programme. No significant difference in breast screening participation was noticed as

a result of the message content within text message reminders. However, due to logistical barriers encountered during the trial, which included a reconfiguration of regional screening services, this study had to be closed early, prior to the sample size being reached and was therefore underpowered.

This research highlights the importance of the message content within health communications in cancer screening to improve participation rates. Exploratory subgroup analyses within these trials, indicates that different subgroups of women with common characteristics such as age, level of deprivation or previous exposure to cancer screening affected which message content was most effective and improving cancer screening participation.

Table of Content

List of Tables

List of Figures

1. Introduction

1.1. Summary

Much evidence has shown that human behaviour is not always in line with our behavioural intentions. Both the fields of behavioural economics and health psychology have explored how different psychological factors may act as facilitators or barriers to choosing healthy behaviours. Participation in cancer screening is one such behaviour, where evidence shows that the vast majority of the public supports participation(1), however the proportion of eligible individuals who regularly engage with cancer screening falls below both the national targets as well as the proportions of the public who report intending to attend.(1-5)

Cervical and breast screening can significantly reduce morbidity and mortality rates through early diagnosis and treatment.(6-10) However, the success of cancer screening is being adversely affected by low participation rates.(11) This introduction chapter explores the issue of low participation rates in cervical and breast cancer screening and provides an overview of known behavioural barriers to participating in cancer screening. Behavioural economic (BE) theories that are relevant to low participation rates in screening are explored, along with a discussion and evaluation of how these theories might be utilised to inform intervention design based on predictable but irrational cognitive biases and heuristics that impact upon attendance.

An intervention design tool for behaviour change, the MINDSPACE framework, is reviewed in the context of cancer screening behaviour. This framework utilises BE theory to provide a toolkit that aids intervention design aimed at changing behaviour. Evidence from previous research is then showcased and mapped onto relevant MINDSPACE tools to highlight how items included in the framework have been utilised in previous cancer screening participation research. However, potential limitations of the framework are also discussed and an alternative framework, the Theoretical Domains Framework (TDF), is introduced as an alternative framework to

inform intervention design. This chapter concludes by outlining novel intervention techniques informed by the MINDSPACE framework, which have the potential to be tested within randomised controlled trials conducted as part of this thesis.

1.2. Background

Evidence has shown that population-level screening offered to 'at-risk' groups determined by age and gender for breast, cervical and bowel cancer screening can significantly reduce morbidity and mortality rates, through early diagnosis and treatment.(7, 8, 11-13) In 1968, *Wilson et al.* (14) recognised that the success of any screening programme relies on a number of factors, such as the disease should be an important health problem, it should be detectable through a test at a latent early stage and a successful treatment should be available (see Figure 1.1) In their paper 'Principles and practice of screening for disease' published by the WHO, the authors also acknowledged that acceptability to the public is a key principle of a good screening programme as it plays an important role in encouraging cancer screening participation rates.(14) This is not surprising, as for a cancer or precancerous change to be detected early through screening, individuals need to be willing to participate and be screened.

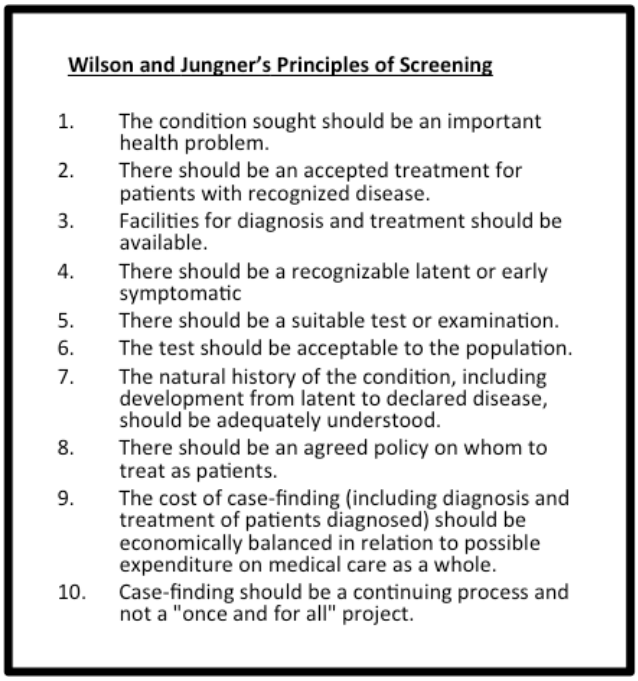


Figure 1.1 Wilson and Jungner's 'Principles of Screening' published in 1968 by the World Health Organisation. (6)

The importance of high participation rates was recently reiterated by *Landy et al.*(11), who modelled that if 100% of eligible women regularly attended cervical screening, then 83% of cervical cancer deaths could be prevented compared to the current

estimated rate of 70% avoided mortality.(11) However, achieving 100% of regular cancer screening participation is unrealistic for a number of reasons. Firstly, all cancer screening tests are associated with some risk, such as receiving a false negative test result that misses a cancer, or a false positive test result that may lead to further unnecessary investigations and treatment. Secondly, screening tests may detect a cancer that would not affect the individual in their lifetime, as it may for example be a slow growing, non-aggressive cancer. As a result there is a risk of harm from unnecessary further invasive tests or cancer treatments and the associated anxiety, whilst the outcome in terms of mortality is not altered through taking part in screening for such individuals. This is particularly the case for breast cancer screening, where an on-going public debate led to an independent review in 2012, which concluded that on balance breast screening provided more benefits than risks and should continue to be offered (See section 1.2.2 below). Thirdly, some individuals might feel that their risk of cancer is lower than their risk of succumbing to other pre-existing health conditions. Therefore, some individuals who consider these factors, may way up their personal risks and benefits and consciously decide to not take part in cancer screening, as they feel the benefits do not outweigh these risks.(15)

However, evidence from a large weighted study that conducted face-to-face interviews with 1,895 screening-eligible individuals who were selected using random location sampling from across England, Scotland and Wales found that the vast majority (approximately 90%) of the public believe that participating in screening is almost always a good idea.(1)

Furthermore, non-attendance at screening is often not linked to explicit and thoughtful consideration of the benefits and drawbacks of screening, but is commonly associated with cognitive factors such as forgetfulness (16-18), being too busy to make an appointment (18, 19), not feeling at risk of cancer (18, 20), practical barriers such as transport (21-23) or were deterred by emotional consequences such as anxiety about pain (18), embarrassment (16, 19) and a possible cancer diagnosis (19). This evidence therefore suggests that the majority of individuals often do not arrive at their decision to take part in cancer screening because they rationally, carefully and unemotionally weighed up the potential benefits and risks of cancer screening.(17, 18, 24, 25) In fact, research suggests that of those not attending screening only around 12% felt they made an informed decision not to.(26) This is unlikely to be due to lack of exposure

to such information, as much emphasis has been placed on providing all individuals invited to cancer screening with a full and balanced account of the risks and benefits of taking part. This was recently highlighted in the UK Department of Health's response to the House of Commons Science and Technology Committee report on National Health Screening, which lists the need for balanced and scientifically accurate information to be provided to all eligible members of the public invited to screening.(27) The report made specific reference to the need for inclusion of harms as well as the benefits in any health communications on screening including the invitation to screening, information leaflets and any follow-up information provided to the public.(27)

Indeed, some research has focused on how to provide full and balanced information to enable informed decision-making in the context of cancer screening. (28-30) However, this has also highlighted that although providing balanced information can improve knowledge and enable informed decision-making, this does not necessarily result in widespread adequate levels of knowledge amongst people receiving this information. *Hersch et al.* found that in the context of breast screening, providing women balanced information including on over-diagnosis, cancer mortality reduction and false positive rates of screening only resulted in 29% of women reaching 'adequate knowledge' levels compared to 17% in the control. Furthermore, only 24% made an informed choice compared to 15% in the control.(30) *Baena-Canada et al.* reported similar low knowledge rates in individuals allocated to the intervention of receiving the Nordic Cochrane Centre Information leaflet on breast cancer screening, with only 18.1% reaching 'good knowledge' levels compared to 8.4% the control arm.(31) The field of behavioural economics (BE) outlines how people often make irrational decisions, despite ample exposure to information and opportunity to assess the information provided. This irrational decision-making process can be heavily influenced by environmental context, predictable personally held biases and the emotional state in which the decision is made. This chapter will outline how the decision to take part in cancer screening is particularly vulnerable to factors that may lead to irrational decision-making, and begin to describe how the understanding of such factors might be utilised in trial intervention design to enable behaviour change.

1.2.1. Aims of this chapter

This chapter will summarise the effectiveness of cervical and breast cancer screening and the current trends of public participation rates. A narrative review of the literature will be presented, exploring known barriers and enablers of participation in cervical and breast screening and summarise traditional approaches used within the programmes to change behaviour and improve participation. This chapter will also outline the theoretical basis of Behavioural Economics (BE) and how certain elements apply to preventative health behaviours such as participation in cancer screening. It will summarise and review the MINDSPACE framework, which was devised to guide behaviour change intervention design that is grounded in BE theory and will review examples of the use of such techniques that have successfully improved cancer screening participation.(32)

1.2.2. Evidence of effectiveness of cervical and breast cancer screening

Substantial evidence supports the provision of cancer screening for breast, cervical and bowel cancer, provided through the National Health Service (NHS) cancer screening programmes for 'at risk' groups across the UK.(7, 8, 11-13) As the thesis did not investigate bowel screening, only evidence supporting the effectiveness of breast and cervical screening will be discussed in this section.

Cervical screening

In 2014, there were 3,224 new cervical cancer cases recorded in the UK. In the same year 890 women died of cervical cancer nationally.(33) The NHS cervical screening programme (NHSCSP) was introduced in England in 1988. Evidence suggests that cervical screening provides a 64% to 82% relative reduction in the risk of being diagnosed with cervical cancer in women who are screened compared to those who are not. (9) It was estimated by *Peto et al.* that around 4,500 lives are saved each year in England alone through the cervical screening programme.(13) A further recent study by *Landy et al.* (11) highlighted the importance of increasing participation rates in cervical screening by modelling that an estimated 83% of cervical cancer deaths

could be prevented, compared to the current estimated rate of 70%, if 100% of eligible women attended regularly.(11) In terms of the true effect of increasing screening participation rates to 100% in women of screening eligible age, Landy et al. estimated that the current mortality rate would drop by approximately half the current rate.(11)

Breast screening

In 2014, there were 55,222 new cases of breast cancer were recorded in the UK. In the same year 11,433 women died of breast cancer, (34) making it the most common cancer affecting women in the UK with one in eight women developing cancer in their lifetime. The NHS breast screening programme (NHSBSP) was introduced in the same year as the NHSCSP and was available across the UK by the mid-1990s.(35) Unlike screening for cervical cancer however, there has been much on-going international debate on the potential benefits and risks of taking part in breast screening. In 2011, a Cochrane review concluded that breast screening provided a 15% relative reduction in risk of dying from breast cancer but at a 30% relative risk of over-diagnosis, i.e. a diagnosis of breast cancer in a women who will not die of the disease in her lifetime.(36) As a result Cancer Research UK (CRUK) and the UK Department of Health jointly commissioned an independent review based on UK data to establish the evidence for and against breast screening.(6, 35) The review panel carried out a meta-analysis of 11 RCTs, which found an estimated 20% relative reduction of the risk of dying from breast cancer for women who attend breast screening.(6) The report extrapolated that for every 1 death prevented through screening, 3 women were over-diagnosed and over-treated. Overall, the panel concluded that the UK breast screening programme provides significant benefit despite of the risk of over-diagnosis and should be continued.(6) In light of the on-balance supportive evidence for both breast and cervical screening, the NHS continues to offer these as part of its national cancer screening programmes.

1.2.3. Cervical and Breast screening practice in England

Cervical screening is offered to woman aged 24-49 years and 50-64 years every three or five years respectively. Women due for screening are identified by their local screening hub as due for a cervical smear test. An invitation letter is sent from the hub inviting them to make an appointment with their general practitioner (GP) or family planning clinic. Women are given 18 weeks to have a smear test, after which non-attenders are sent a reminder letter. At 32 weeks the screening episode is closed and women who have not attended will be invited again at the next routine age-appropriate time interval.

By contrast, breast cancer screening is offered to women aged 50-70 years old, every 3 years, although a national age-extension rollout is underway that invites women aged 47-49 and 71-73 years. Women are sent an invitation letter with a timed appointment offer. The practice for non-attenders varies regionally. Some regions will send a reminder to women who did not attend their appointment, asking them to contact the screening service and make an appointment. In other regions, women who did not attend may be offered a second timed appointment. SMS reminders are used in some regions to further improve participation, at the discretion of the local hubs.

1.3. Current trends in participation rates

Coverage and Uptake definitions

National, regional and local cervical and breast screening rates are reported annually as ‘coverage’ rates. To be counted as ‘covered’ a woman has to have a test result reported within a screening interval appropriate for her age and the screening programme. This means that to be considered ‘covered’ within the NHSCSP, eligible women (i.e. have not had a hysterectomy and are not pregnant during the screening round for example) aged 24-49 would have been tested within the last 3.5 years and women aged 50-64 would have been tested within the past 5.5 years, as stipulated by the NHSCSP.

Within the NHSBSP, coverage refers to all women deemed eligible (i.e. have not had a bilateral mastectomy) aged 50-70, or aged 47-73 in age-extended areas, who have had a screening mammogram within the previous 3 years, as stipulated by the NHSBSP.

'Uptake' on the other hand, refers to the percentage of women screened within a particular invitation screening round. For example, this might include all women who had a cervical screen within 32 weeks of being sent an invitation letter. Uptake does not include opportunistic screening or self-referred screeners, though these screening occasions are included when assessing coverage. Therefore, uptake rates tend to be lower than coverage rates. As such, trials discussed in chapters 2, 3 and 5 will report the results as uptake rates at a defined time interval after exposure to an intervention. These are therefore not directly comparable to the regional coverage rates, however, interventions that improve uptake would be expected to impact overall coverage rates if implemented by local services. National data is reported as coverage and as a result national targets are also set for coverage rates rather than uptake and are 80% for cervical screening and 70% for breast screening.

Cervical screening coverage rates

The NHSCSP for England has seen a fall in national coverage rates over the past five years from 75.7% in 2011 to 72.7% in 2016.(2, 3) Whilst London coverage rates have consistently been below the national rates, in the same period they fell from 74.1% to 66.7%.(2, 3) The steeper drop seen in London may be in part a result of the NHSCSP's decision to change the definition of 'coverage' from 'within the last 5 years' in 2011 to 'age appropriate' as outlined in section 1.3 above. This reduced the required interval to 3.5 years for women aged 24-49 and increased the interval to 5.5 years for women aged 50-64. The NHSCSP retrospectively recalculated the national coverage rates to reflect the new definition for the national-level data. As a result the coverage rate in 2011 given the new definition was 75.7%, as opposed to 78.6% under the old definition. However, this was not recalculated at a regional level and therefore the London coverage of 2011 still includes women aged 24-49 who were considered 'up-to-date' with their screening test as defined as 'within 5 years' rather than 'within 3.5 years' as per the new definition. As a result the 2011 coverage rate for London

may reflect a higher rate as it included women who had been screened less than 3.5 years as per the new definition as well as women screened between 3.5 and 5 years prior to 2011. Despite this, coverage rates have dropped in London and fall consistently below the national average and target of 80%.

Breast screening coverage rates

As for cervical screening, the national breast screening coverage fell from 77.4% in 2011 to 75.5% in 2016, with its lowest rate of 75.4% in 2015. Therefore between 2011 and 2016 coverage rates have shown an absolute drop of almost 2%.(4, 5) Over the same time period coverage rates in London were relatively static at 69.3% in 2011 and in 2016, but these rates are well below the national average (See Figure 1.2).(4, 5) The West of London comprises of six boroughs including Ealing, Hillingdon, Hounslow, Hammersmith and Fulham, Kensington and Chelsea and Westminster. These boroughs are served by a single screening hub called the West of London Breast Screening Service (WoLBSS), which has seen particularly low coverage rates. In 2011, WoLBSS' coverage stood at 66.6% rising slightly to 66.8% by 2016, yet these rates were lower than the London and national average for the same time period as well as the national target of 70% (See Figure 1.2).(4, 5)

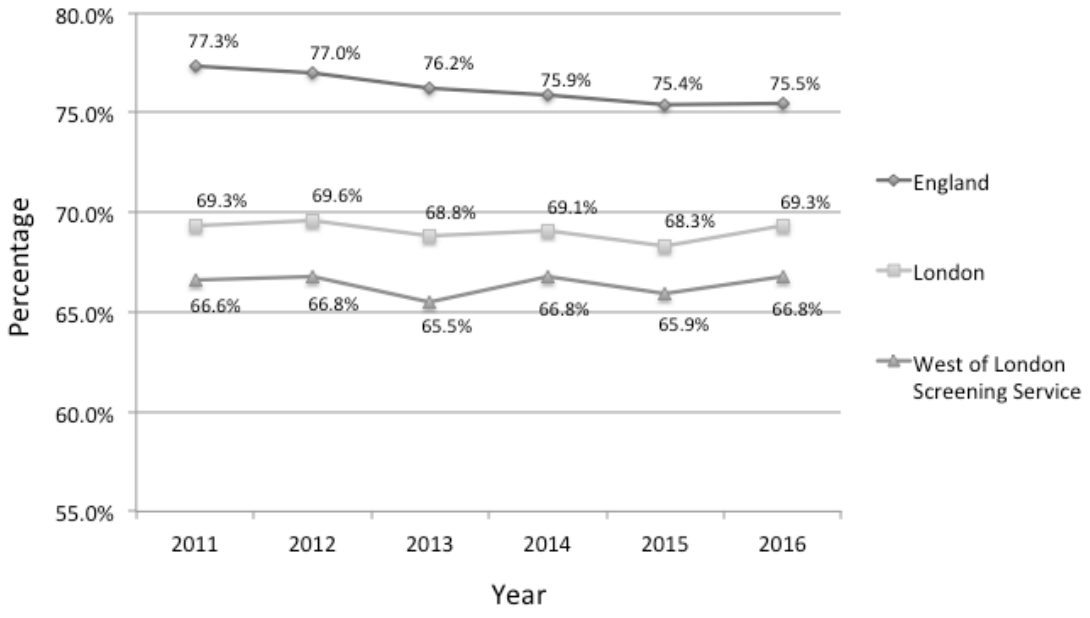


Figure 1.2 Breast cancer screening coverage 2011-2016. (4, 5)

This low baseline coverage rate was a key consideration for WoLBSS to be selected as the trial setting to improve breast screening uptake reported in chapter 5.

Many population factors affecting cancer screening participation are common to both breast and cervical screening. Geographical variation in participation rates, such as the consistently low participation rates seen in London in both screening programmes, is only one element in a complex pattern of screening participation behaviour amongst women in England.(4, 5, 37) Coverage rates also vary considerably by age (3, 5), ethnicity (38), socio-economic status(38, 39), previous screening exposure (38, 40, 41) and personal beliefs and barriers(42). In both cervical and breast cancer screening programmes, eligible women in younger and older age groups tend to have lower participation rates than those in the middle age ranges.(3, 5) Women from ethnic minority groups, (38, 43, 44), as well as women from lower socio-economic groups generally have lower participation rates in both breast and cervical cancer screening.(38, 39) This is not a problem that is unique to the UK population, as much evidence from the US has also shown similar trends.(43) Women being invited for their first cervical or breast screen also have lower participation rates than women being invited for a routine interval recall.(3, 5, 38) However, evidence from breast screening has also shown that women who have attended in the past are more likely to attend in the future.(40, 41) This highlights the possible opportunity of targeting first time invitees on increasing participation in future screening opportunities.

The varied participation rates identified in different subgroups can be a challenge to address, as individual-level personally-held drivers of and barriers to screening can also influence the decision to be screened. These factors might be practical (e.g. distance to the screening facility and transport (21-23)), cognitive (e.g. forgetfulness (16-18)) or emotional barriers (e.g. anxiety about the anticipation of pain, embarrassment, or a cancer diagnosis (16, 18, 19, 45)) and will be discussed in more detail below. The prevalence and strength of the various barriers may also differ between individuals considering participating in screening. Such barriers highlight that the decision of whether to participate in screening may not always be reached by carefully weighing up the benefits and risks of screening in terms of reducing the risk of dying from cancer, the risk of over-diagnosis and over-treatment or the risk of false negatives and positives. Instead, such barriers highlight that how we behave is often

determined through the use of cognitive mental shortcuts also known as heuristics or systematic predictable personal biases. An example might be that previous screening behaviour (i.e. attendance vs. non-attendance) predicts future screening behaviour.(40, 41, 46, 47) This is an example of the status quo bias, in that when faced with a decision, individuals are prone to select what they chose previously.(48) The resulting screening behaviour may therefore not always be a rational decision. This is supported by evidence that suggests that almost 90% of non-attenders don't feel they made an informed decision to not attend.(26) Section 1.4 therefore provides an overview of the health psychology literature on barriers to screening and gives an overview of the field of health behavioural economics and how this can contribute to the explanation of screening participation behaviours.

1.4. Behavioural science and cancer screening participation

Much on-going and previous research has investigated factors affecting cancer screening participation, and intervention design targeting cancer screening participation. This research has largely arisen from the discipline of health psychology (HP) of which one focus has been to map out different psychological behavioural barriers that affect the decision to be screened. Another area of HP research has focused on the use of informed choice and decision support tools with the aim of providing easily comprehensible, full and balanced information on the benefits and harms of cancer screening to help decision-making. (27-31, 49, 50) *Barnes et al.* however, suggests that such decision support tools rely on the assumption that by providing better information, patients will make decisions that are rational, evidence-based and consistent with their personal values and beliefs.(51) The discipline of BE challenges the assumptions of rational human decision making and instead proposes that humans do not always make decisions based on sound reasoning, after carefully weighing up the evidence available for and against. BE therefore places more emphasis on the more automatic or irrational decision making process.(52) This section outlines these two different approaches to understanding screening non-attendance.

1.4.1. A review of psychological barriers and enablers to screening participation highlighted in the health psychology literature

A large body of evidence in the field of health psychology has highlighted a wide variety of factors affecting cervical and breast screening participation rates. These factors will be explored below, under the categories of practical, cognitive and emotional factors.(45)

Practical factors

Practical factors describe logistical barriers and enablers experienced by individuals when trying to attend screening, or considering attending screening. Such barriers include the distance to screening centres, accessibility to transport, ability to take time off work or access childcare, ability to make a screening appointment and language barriers.

Accessibility of transport and travel distance

Evidence shows particularly in breast cancer screening that an increase in the distance from the screening service can detrimentally affect participation rates. In a study of 34,868 women in the north of England who lived more than eight kilometres away from their local screening service were significantly less likely to attend than women who lived less than two kilometres away (OR 0.89 (95% CI 0.81 to 0.99).(22) Furthermore, women who live in isolated communities (21) or women who do not have access to available transport are also less likely to attend. (21, 53) However, no distinction is made in either of these papers whether the transport barrier to due to a lack of access to personal private transport, which may be a barrier experienced more frequently by women of lower SES, or whether such transport barriers are due to a lack of public transportation infrastructure geographically. However, further evidence has shown that women who have access to a private car are more likely to attend.(54) Conversely, reducing the burden of arranging transport has shown some promise in improving participation. Some evidence has shown that providing workplace

screening opportunities, (23) or providing transportation (55) can improve uptake in breast screening.

Childcare

Evidence has also shown that women with children can see finding childcare as a barrier to attending both cervical and breast cancer screening.(56, 57) Some evidence has indicated that providing assistance with childcare can improve participation particularly for women from more deprived backgrounds.(55) However, it is also possible that some women, who have children, may be aware that nulliparity is associated with a slightly higher biological risk of developing breast cancer. Such women might have a lower perceived personal risk which may contribute to lower participation rates in women with children.(58)

Access to services and availability of appointments

A lack of access to physicians and not having a primary care provider (47) as well as a lack of recommendations by a patient's physician or primary care provider (21, 47, 54, 59) have shown to reduce participation rates in breast and cervical a screening. Self-reported ability to make an appointment has also frequently been cited as a barrier for women seeking both breast and cervical screening. (18, 19, 21, 42)

Time pressures

A number of papers have shown that some women perceive their work, social and family time pressures as a barrier to making time for screening, reporting that they feel that they are 'too busy' to be able to attend. (17, 18, 23, 24, 60, 61)
Feldstein et al. found that in particular younger women were more likely to report not having enough time to attend mammographic screening.(24) Evidence has shown that women's perception of their workplace environment can influence their attendance at screening.(23) As a result initiatives such as work place mammography programmes have been tested. *Glanz et al.* found that work environment characteristics such as employer policies and location of screening facilities are key in implementing successful work site mammography programmes. (23)

Language barrier

Language can act a barrier to screening (62, 63) and research using translated information in cervical screening including leaflet, GP-letters, and screening invitations have also shown an increase in participation.(64)

Financial concerns

Financial constraints as well as the fear of potential costs have been cited as a cause for low participation rates in cancer screening.(17, 23, 47, 56, 65) However financial concerns tend to be cited as a bigger barrier to participation in countries outside the UK where cancer screening and potential subsequent further investigations and treatments are paid for by the healthcare consumer and / or their insurance company.

Cognitive factors

Cognitive barriers include factors such as levels of knowledge of existing screening programmes and eligibility, judgement of personal risk perception as well as the ability to remember to make an appointment and attend the screening test. Yet it may also include judgements about the accuracy of the screening test in terms of the risk of over-investigation following an abnormal test result, where there is in fact no cancer, or over-diagnosis of a cancer that would not affect the individual in their lifetime, but also the perceived risk of missing a cancer.

Knowledge

Much evidence has shown that a lack of awareness of the screening programmes has often been cited as a key factor affecting participation. (21, 47, 59, 63, 66, 67) *Schueler et al.* found that women who had low levels of knowledge of breast screening (i.e. knowledge of screening guidelines, self-examination) were half as likely to attend.(47) Further evidence suggests that a lack of awareness of risk factors is also associated with lower screening rates.(67) This may be related to a woman's perceived risk, as women who are not aware of the risk factors may also have lower risk perceptions as compared to women who are aware of the risk factors. (17, 19, 42)

Perceived risk

Evidence shows that women who have low levels of perceived risk of developing breast or cervical cancer are also less likely to attend screening.(18, 20) Further

evidence also highlighted that a woman's low perceived risk might be associated with whether or not they perceive themselves to have risk factors such as a family history (17), their sexual activity (cervical screening) (19, 42) or because they have not experienced any concerning symptoms (42). In the case of CS, this should also be considered in the context of the recent introduction of the HPV vaccination for adolescent girls and the effect this introduction may have on perceived risk and future screening intention. Some work has indicated that women may perceive to be at lower risk as a result of receiving the HPV vaccination and may therefore me less likely to attend.(68-70) However, other studies have indicated the opposite is true. (71, 72) However, as the first cohort of adolescent girls offered the vaccination in the UK has only recently reached the CS eligible age, this is not considered further in this thesis.

Forgetfulness

Forgetfulness is a common reason cited by women for not attending cancer screening.(16-18) A Dutch study showed that over 32% of non-responders reported that they forgot to make an appointment for their cervical screen.(16) Similarly, a study of Afro-Caribbean women in London showed that 28% 'didn't get round to [having a cervical smear]' (18) and a national survey in England found that 21% of women reported that they intended to, but did not get around to having a smear test.(19) This may have some crossover with a woman's perceived ability to make time in a busy schedule and the sense of value or priority they place on taking part in screening. This in turn may relate to how much priority a woman places on screening compared to other tasks or activities in her daily life.

Accuracy of the test

Concerns about the accuracy of the test itself tend to have been more often cited in mammographic screening than for cervical screening, which is consistent with the public debate discussed above which triggered an independent review of the efficacy of breast screening.(24, 47) A systematic review found that women who had negative beliefs towards the efficacy of breast screening were more than twice as likely to not attend screening.(47) However, some work has also shown that concerns over the accuracy of smear test can also pose a barrier to cervical screening.(19)

Emotional factors

Such barriers include a wide variety of emotional influences that can affect screening attendance by both improving and reducing participation rates. These factors include fears about the test itself in terms of embarrassment and pain but also of the potential diagnosis. Emotional factors also include the sense of the value placed on the test as well as the social environment in which they make such decisions.

Embarrassment

A number of studies have highlighted that women who anticipate feeling embarrassed or ashamed as a result of having a screening test are less likely to attend both in breast (17, 21, 46) and cervical screening (16, 18, 19, 45, 67, 73). A survey carried out by *Waller et al.* found that 29% of women surveyed, felt that being embarrassed during a cervical smear test was the strongest barrier to attendance.(19) A similar study from the Netherlands found that 16% of non-attenders admitted to being too embarrassed to have a smear test taken.(16) *Crump et al.* found that women who felt that having a mammogram is embarrassing were 2.8 times more likely to not attend screening.(17)

Pain

Much evidence highlights that women who anticipate experiencing pain during the test are less likely to attend both breast (65, 74) and cervical (17-19) screening. Some studies have shown that ethnic minority groups and women who are obese may experience more pain during mammograms.(24, 47) The potential detrimental impact of experiencing pain during screening was highlighted by *Whelan et al.* who found that women who experienced pain were 1.34 times more likely to not attend future screening rounds.(75)

Fears about a cancer diagnosis

Fear about a potential cancer diagnosis is a barrier common to both programmes.(19, 65, 73) Some evidence also suggests that this can affect women in different ways. For example, the fear of a cancer diagnosis may result in some women wanting to take action to detect cancer early through regularly attending cancer screening, whereas it may deter others from taking part in screening.(46) This discrepancy may be understood given the finding that women who have higher levels of cancer fatalism

are less likely to attend screening, although this is often moderated by ethnicity, age, income and level of education.(76) *Flynn et al.* investigated the effect of screening fatalism on clinical breast examination compliance in women of Latino and Anglo origin. The authors found that ethnicity indirectly moderated the effect of cancer fatality on compliance. However, the study also found that Latino women with lower education and income had higher levels of cancer fatalism, whereas in the Anglo subjects, older women and those with lower income had higher levers of cancer fatalism.(76)

Social networks and support

Some work has highlighted the positive influence of social networks, in that women who perceive that they have high levels of social support and positive role models and are able to talk to others about screening were more likely to attend screening.(73) Other evidence from outside the UK has suggested that perceptions of social influences may also be detrimental. A study conduced in Mexico highlighted that some non-attenders perceive that men would not want them to have cervical screening and have reported this as a barrier to attending.(67)

1.5. Behavioural economics in cancer screening.

The 'dual process model' outlines how humans make decision using broadly two processes; the 'reflective' (characterised as controlled, effortful, rule-based and deliberate) and the 'automatic' (characterised as fast, emotional, unconscious).(77) BE theory highlights how such decision-making, in particular the more 'automatic' decision making process is often heavily influenced by additional factors, such as heuristics, biases, emotion and the environment in which decisions are made. Heuristics are predictable mental shortcuts or rules of thumb that we often use to aid decision-making.(78) Cognitive biases are systematic and predictable flaws that can influence decision-making.(77, 78) Two recent papers acknowledge the importance these factors in the decision-making process following an offer to participate in cancer screening. *Barnes et al.* (51) and *Purnell et al*. (79) both describe a number of commonly known biases and heuristics and how these might directly affect the decision to be screened. However, other factors such as the degree of cognitive load

(i.e. the amount mental effort required in working memory) has been shown to adversely affect decision-making.(80) It may therefore be possible, that by taking into consideration cognitive load when addressing behavioural biases and heuristics in intervention designs targeted at changing screening behaviour, we may provide a promising method to reduce inequalities in cancer screening rates and therefore in cancer outcomes.

Summary of key BE factors that affect the decision-making process specific to cancer screening participation.

A number of well-known heuristics, cognitive biases and behavioural factors are likely to play a role in an individual's decision to be screened for cancer. This section discusses these key factors in more detail and outlines how they may affect screening behaviour.

Loss aversion: In general, people place more value on avoiding losses than potentially gaining something of the equivalent value.(81) In terms of cancer screening small friction costs of attending screening such as the cost of transportation, childcare and time off work (or in other health systems the monetary cost of screening) may act as disproportionately large deterrents to cancer screening.(82)

Present time bias / Future discounting: Loss aversion in the context of cancer screening is somewhat related to the present time bias. This bias outlines that humans tend to place more value on events that occur in the present time and are more likely to discount events that might happen in the future.(83) In the context of cancer screening this might explain a degree of procrastination or 'not getting around to' participating in screening that is frequently reported (18, 19), because individuals might put more weight on the immediate challenge of having a screening test (such as arranging an appointment, getting time off work, arranging and paying for transport and childcare, the anticipation of anxiety or pain of the test and possible result) and discount the long-term benefit of potentially avoiding or mitigating the effects of a cancer diagnosis (including expensive healthcare bills or having to take prolonged time off work).(51, 83)

Optimism bias: When asked about the likelihood of a positive or negative future event occurring to them, most people are overly optimistic in their judgement.

In terms of a positive event occurring they are more likely to overestimate the frequency, whereas for a negative event people are more likely to underestimate the likelihood.(84-86) This is likely to also apply in the case of cancer screening, where much evidence suggests a significant proportion of eligible individuals have unrealistically low perceived personal risk of developing cancer in the future. (17-20, 42, 79, 87) As a result these individuals may be less likely to place importance and value on attending cancer screening.

Social desirability bias: As highlighted in section 0 social support can affect the likelihood of attending screening. Evidence suggests that individuals are heavily influenced both by what others do and by what they think others believe they should do.(88) This bias may play a role in cancer screening whereby some people may be more likely to attend screening if they think most of their peers also attend screening. Social norms is a term used to explain that individuals are heavily influenced by the behaviours, actions and opinions of others around them. The term is used in both HP and BE and can be used as a behaviour change technique, to encourage a target audience to conform to the behaviours, actions or opinions of those around them, by informing them of the frequency of these. Descriptive social norms describe how other people behave. These might be people in the participant's social group or who are relevant to the participant. For example 9 out of 10 people in your neighbourhood pay their taxes on time.(89, 90) Injunctive social norms describe what people relevant to the participant would expect the participant to do.(90) An example would be 'Your close family and friends whose opinion you value expect you to have regular cervical screening'.

Status quo bias: This bias describes the tendency for individuals to 'do nothing' and avoid change from their current situation or from the decision outcome they previously made.(48) This bias may play a variety of roles in cancer screening participation. For example, it may contribute to the explanation of why previous screening behaviour often predicts future screening behaviour, in that previous attenders are more likely to attend in the future, whereas previous non-attenders are less likely.(40, 41, 46, 47) Evidence also shows that when individuals are offered screening but asked to actively make an appointment for e.g. a mammogram or to 'opt-in' to receive a bowel cancer screening home test kit they are less likely take the action required to take part.(91-95) By changing the default option to remove the friction cost of needing to make an effort e.g. by default mailing bowel screening

home test kits to all eligible individuals rather than asking them to request a kit if they would like to be screened or sending everyone a timed appointment for a screening mammogram, providers can alter the environment in which the participation decision is made, to make participation easier and therefor more likely.(48, 91, 93, 94)

Availability heuristic: The availability heuristic refers to a tendency to estimate the likelihood of a future event occurring by how easily it is to recall a similar event or imagine such an event occurring, in this case a cancer diagnosis.(79, 96) This can therefore affect individuals in different ways. A woman who knows someone who died of breast cancer might estimate her own personal risk of dying from breast cancer as much higher. Equally, someone who is surrounded by young and healthy people, who she identifies with might find it more difficult to imagine being diagnosed with cancer and so may estimate their risk as lower.(51, 79) There is a crossover with other biases and heuristics here, in that such an individual may also have an optimism bias, which might further contribute to low risk perception.

Affect: The emotional state at the time of receiving the invite to screen can have a strong effect on an individual's decision to take part in screening.(79, 97) This effect may be two-fold. On one hand, thinking about having the test might cause anxiety and distress about possible pain, embarrassment or fear of a cancer diagnosis.(16, 18, 19, 21, 46, 65, 67, 73) This might have communalities with the availability heuristic discussed above, in that the memory of previous screening experiences might be associated with emotions in the form of the relief of a negative test, the anxiety in remembering the pain and embarrassment of the test itself or the anxiety around waiting for a test result. Such emotions may contribute to the decision of whether or not to be tested again. On the other hand, personal experience with a friend or family member who has suffered from a cancer might invoke positive thoughts towards participation, in the hope of picking up a cancer early or being relieved at a negative screening result.

Cognitive load: The definition of a cognitive bias as a systematic flaw in our decision making process might in this context be extended to include the concept of cognitive load. The ability to weigh up the potential outcomes in terms of benefits and risks of a certain behaviour relies on cognitive function. However, it also relies on the current level of cognitive load experienced by the individual making the decision. A number of factors can affect cognitive burden, thereby reducing capacity to accept new information and assess the potential consequences. Such factors can include food

insecurities or financial and health burdens and therefore may be more prevalent in groups that are more deprived and of lower socioeconomic status.(80, 98) In the context of cancer screening, individuals from lower SES groups, who are more likely to be effected by financial or health burdens, may therefore be more likely to make poorer decisions regarding their health and preventative health opportunities. It is well recognised that the rates of cancer screening participation are significantly lower in more deprived groups (43, 99-101), which in turn contributes to the fact that individuals from more deprived groups are more likely to present with advanced disease and have poorer cancer outcomes overall.(43, 102, 103) It is therefore important to be cognisant of cognitive burden when designing health communication to ensure that these reduce rather than increase the cognitive burden. Cognitive burden can be reduced in communications through clear language and easily comprehensible health information, so as not to further disadvantage individuals from more deprived groups in society terms of their decision-making.

Decision environment

The factors described above can all contribute to the environment in which an individual makes decisions. Furthermore, how information is delivered by healthcare providers further shapes the environment in which the public makes decisions. The way in which information is portrayed in health communications, whether thoughtfully planned or not can therefore affect how decisions are made. Thoughtful application of behavioural science theory is therefore paramount to enable the public and patients to choose the healthier option more easily, whilst not removing other options. Key components to consider in the design process include the content, format and channel of health communications to ensure effective message content and delivery.

The field of behavioural economics has been criticised in the past for 'nudging' people to behave in ways that they would otherwise not behave. For example, much work has shown that organ donor registration and donation rates improve when the national default option is auto-enrolment or opt-out. (104, 105) However, *Malanowski et al.* highlighted that in Poland, a country where auto-enrolment is in place, the 'central objection registration office had registered 29,013 objections over the prior 18 years accounting for a 0.075% of the national population. Despite the small

percentage of objections, this indicates that the surviving relatives of some of those who were auto-enrolled might feel that this was against the wishes of the deceased. However, Richard Thaler, the Nobel laureate and co-author of Nudge(77) recently said: 'If anything you do influences the way people choose, then you are a choice architect'.(106) Therefore, the existing communication processes and materials sent from screening services (invitations, reminders, follow up letters, results), including the choice of content, format and communication channel are in themselves a form of choice architecture (i.e. shape the environment in which decisions are made) whether intended or not. The format of such information, in terms of length, presentation, ease of reading can contribute to the degree of cognitive burden caused by reading the document.(107-109) Furthermore, although the information and statistics presented may satisfy the need to provide full and balanced information, how such information is portrayed and framed can differentially affect the likelihood of the recipient participating in screening. The choice of communication channel such as letters, leaflets, posters, health campaigns, mobile text message or phone reminders may also differentially change behaviour. For example, an exceedingly long and generic document sent by the screening hub that provides comprehensive information on the benefits and harms may in fact result in lower engagement and participation rates in screening as recipients may be less likely to read the document.(107-109) Therefore, using HP and BE theory to redesign how existing information is provided may improve the salience of information to the recipient, thereby improving participation.

1.5.1. Intervention design using the MINDSPACE framework

As previously outlined, key biases and heuristics may contribute to screening participation behaviour and provide an exciting target for behaviour change intervention in cancer screening. The MINDSPACE framework published in 2010 by the UK Cabinet Office condenses a number of behavioural economic theories and tools to create a pragmatic and practical guide to intervention design targeting behaviour change.(32) The MINDSPACE framework provided the most comprehensive and detailed guide to BE theory informed techniques to change

behaviour and has previously been successfully used to change behaviour elsewhere in clinical practice.(110) The nine elements of the framework are represented by the acronym MINDSPACE, which stands for **m**essenger, **i**ncentives, **n**orms, **d**efaults, **s**alience, **p**riming, **a**ffect, **c**ommitment and **e**go. The framework does not specifically target the healthcare setting but more broadly provides techniques for behaviour change that are intended to be applied across different public policy fields. This section will outline the nine elements of the MINDSPACE framework, and explore existing evidence of the use of these techniques in cancer screening. In addition, the framework will be used to highlight potential novel intervention opportunities to target cervical cancer screening participation, which formed the basis for the intervention design for two trials reported in chapters 2 and 3 that aimed to improve participation in cervical screening. Limitations identified during these trials led to the intervention for the final trial reported in chapter 5, being created by instead using the Theoretical Domains Framework, which will be discussed in more detail in chapter 4.(111, 112)

1.5.2. The Messenger tool

The *messenger* tool highlights that when processing information we are heavily influenced by who communicates the information. The messenger effect may work in different ways, including being affected by the authority we perceive the messenger to have and how we might relate to the messenger both demographically(113) and socially(32, 114). The *social desirability bias* contributes towards the impact of the *messenger* effect as we are heavily influenced by what we think others expect of us as discussed above (see Section 0). This may be in terms of our family and friends but also social leader figures such as religious leaders or clinicians such as one's General Practitioner (GP).

Examples of the *Messenger* tool

The messenger tool is relevant, particularly in healthcare, as much evidence has shown that in addition to the impact of behaviour and views of one's social network, a physician endorsement, in particular from one's GP, can change behaviour. Much of the evidence using GP endorsements in cancer screening has come from bowel screening and showcases improved participation rates compared to when information

is provided by the screening services or the local authorities responsible for running the programmes.(115-119) *Hewitson et al.* showed an absolute increase of twelve percentage points using a GP-endorsed letter coupled with a procedural information leaflet. *Zajac et al.*(115) and *Cole et al.(118)* both showed an absolute increase of around 9% in uptake using GP-endorsement letters. *Wardle et al.*(119) showed a more modest one percentage point increase in the participation rates using GP endorsement. The impact of this latter study may have been smaller than the other studies for two reasons. Firstly, the authors used a banner within a letter that still clearly originated from the bowel screening programme. Secondly, the banner stated 'Your GP practice [GP practice name] supports the Bowel Cancer Screening Programme', and therefore did not use the physicians name itself. *Barthe et al.*(117) found no significant difference in uptake, however the authors suggest a number of reasons for this, including; cultural differences in France in terms of the lack of a norm for receiving letter communications from one's GP; the 'endorsement' consisted only of a signature at the very bottom of the letter, furthermore both intervention and control letters were sent out by the screening service and contained a number of screening service related logos.(117)

Within breast screening programmes, *Giorgi et al.* found between a 2 and 4 percentage point increase in participation when comparing a GP-endorsed invitation letter compared to a screening centre letter.(120). *Bell et al.*(64) also found an impressive 18% point increase in uptake, however, the intervention here was multimodal including a GP endorsement, translated screening literature and language support. It was therefore not possible to isolate the effect of the GP-endorsement alone in this trial.

Two Dutch studies testing GP-endorsement letters in cervical screening observed similar findings, with reported absolute increases in participation rates of 7-15%.(121, 122) Of these studies, *De Nooijer et al.*(121) also found that the increase in participation was more marked in population subgroups, which traditionally have lower uptake, including groups of lower socioeconomic status, ethnic minority groups and populations living in urban areas.(121) These findings support the hypothesis proposed in section 0 that BE informed interventions may have a disproportionately larger effect on individuals with higher levels of cognitive burden who are likely to be from more deprived backgrounds.

There is therefore strong evidence for the use GP endorsements from all three screening programmes, which should be considered as a component of intervention design in future research.

Messenger	we are heavily influenced by who communicates information
Incentives	our responses to incentives are shaped by predictable mental shortcuts such as strongly avoiding losses
Norms	we are strongly influenced by what others do
Defaults	we "go with the flow" of pre-set options
Salience	our attention is drawn to what is novel and seems relevant to us
Priming	our acts are often influenced by sub-conscious cues
Affect	our emotional associations can powerfully shape our actions
Commitments	we seek to be consistent with our public promises, and reciprocate acts
Ego	we act in ways that make us feel better about ourselves

Table 1.5.1 MINDSPACE framework components

1.5.3. Using Incentives

Incentives can be utilised to offset potential imminent 'losses' or 'risks' that may otherwise deter the preferred behaviour.(32) Incentives can therefore be used to overcome both the *loss aversion* and the *present time bias* (see section 0 for definitions). In the case of screening, incentives may be used to overcome potential barriers, such as the cost of time off work or transportation being weighted more heavily than the potential to avoid dying from cancer in the future.

Examples of *Incentives*

In the context of the NHS, public- and patient-facing financial incentives are not commonplace as a tool to change behaviour, especially compared to the United States where providers have been known to offer incentives in form of gift cards, lotteries, payroll checks or credit toward deductibles.(123, 124) However, the evidence to support incentives is mixed and may be dose dependant. *Merrick et al.* found no difference in mammography rates between a control group and groups receiving either a $15 gift card, a $250 lottery or the offer to choose between the gift card and

the lottery. (124) *Adler et al.* also found no effect in the use of small financial incentives to improve bowel cancer screening.(125) Whereas *Mehta et al.* showed that a slightly larger financial incentive of $100 resulted in a small but significant increase in bowel screening of just over 2% points.(126)

Not all incentives are monetary. *Bell et al.* used a multimodal approach in an attempt to improve mammographic screening, one element of which included free transport to the screening facility. However, the authors found that the resource was underutilised and inefficient.(64)

Despite its widespread use in the U.S., the adoption of incentives within the NHS is unlikely for several reasons. Firstly, providing incentives would be expensive in an already and increasingly cash-strapped health service. Secondly, there are ethical considerations that should be evaluated when offering members of the public financial incentives in exchange for participating in cancer screening, particularly as screening is not without risk.(123) Thirdly, potential unintended effects such as; the offer of money to take part in screening may imply to some members of the public that there is a risk to attending screening; and the use of financial incentives might remove the inherent drive to take part in screening, thus leading to decreases in uptake should the incentives not be sustainable. Finally, as outlined above, the evidence does not always support the use of incentives and emerging evidence may suggest that larger financial incentives may have only a small effect.(126) For these reasons, as well as a lack of available funding and because financial incentives would be unlikely to be adopted in cancer screening programmes, financial incentives were not considered as an intervention for the planned trials.

Although incentives can also be provider-facing, a recent review evaluating the effectiveness of provider assessment, feedback and incentives found that although there was evidence for assessing providers and giving feedback on performance, the evidence around provider-incentives was not very strong.(127) Furthermore, this thesis focused on public-facing interventions and therefore provider-facing interventions are not further evaluated here.

1.5.4. Social *Norms*

MINDSPACE's *Norms* refers to social norms, which takes advantage of the *social desirability bias* i.e. as humans we are heavily influenced by the actions of others (descriptive norms) and what we think others expect of us (injunctive norms). Evidence shows that providing the target audience with information on actual frequencies of the desired behaviour can change behaviour.(128-130) This tool has some crossover with the *Messenger* tool, as this too utilises the *social desirability bias* in that we are influenced by the characteristics of the source of the information and our relationship to the source. As discussed above, social networks also play a role in what women might perceive is the social norm. Evidence shows that women who think their husbands might disapprove of them having a smear test may be less likely to participate.(67) Likewise, some evidence has shown that women who are members of religious groups may be less likely to attend.(18) This is likely to be because of the link between the sexually transmitted human papilloma virus (HPV) and cervical cancer, leading to the implication that participation in cancer screening might imply sexual activity or multiple sexual partners. On the other hand, one study found that the support of one's social group in terms of friends and family increased the intention to attend mammographic screening.(131)

Examples of *Social norms*

A number of sources have highlighted the prevalence of social norms in cancer screening behaviour. A Korean survey study on barriers to cervical screening reported that subjective social norms were the strongest predictor of intention to attend cervical screening in the future and highlighted this as a potential method to improve participation.(132) Three further surveys and interview studies in breast and cervical screening also identified that study participants reported social norms as a key facilitator of mammographic screening.(73, 133, 134) However, a German randomised controlled trial investigating the role of social norms in colorectal screening found that both providing true 'low' descriptive norm information (18% participation within the past year) and true 'high' descriptive norms information (65% participation lifetime participation) resulted in lower intention attend than the control of not providing any social norms information.(130) This highlights a number of issues with social norms. There is little doubt that 18% participation represents a 'low' social norm rate of participation. However, it is possible that this study showed

that the participation rate in the 'high' descriptive norms group was not sufficiently high to change behaviour in the direction of increasing the intention to be screened. In fact, it may have resulted in individuals feeling justified to not take part in screening. The thought leader on social norms, Robert Cialdini, recognised this in a paper published in 2003, in which he highlighted that by emphasising higher rates of poor behaviour one can make it more acceptable.(135) However, when using social norms by providing the target audience with the frequency of the desired behaviour, it is important to reflect truthful figures. There has not yet been a good example of the effective use of social norms in cervical cancer screening, which have been seen elsewhere such as in rates of anti-microbial prescribing by GPs and in public tax collections.(89, 128) This makes social norms a potentially interesting contender for novel interventions in cervical screening.

Evidence from breast screening has shown that social networks including the support from friends and family for screening can have a subtle but significant influence on breast screening participation.(131) Interestingly however, evidence from cervical screening showed how social networks that may disapprove of screening may have a detrimental effect on participation rates.(67)

1.5.5. Using Defaults

Defaults utilise the *status quo bias,* which highlights the human tendency to do nothing or more generally to avoid change. As a result, when faced with decisions with uncertain consequences, we often choose what we selected last time.(32) Evidence shows that changing the default to opt-out rather than opt-in can result in behaviour change.(95, 105, 136) Evidence from screening has shown that an individual's previous screening behaviour, either attendance or non-attendance strongly predicts future screening behaviour i.e. previous attenders are more likely to attend than previous non-attenders.(40, 41, 46, 47, 131) This highlights the importance of enabling first-time invitees who intend to take part to actually attend, as this in itself will predict future attendance. Moreover, it underpins the difficulties in changing the behaviour of persistent non-attenders.

Examples of *Defaults*

A number of examples have shown that by changing the default to opt-out, thereby reducing the friction in terms of effort required to participate, and making the desired behaviour easier, can improve the participation in cancer screening programmes. Within bowel screening three trials have shown that by directly mailing the faecal occult blood (FOB) home test kit to individuals due for screening, participations rates were raised by 6, 10.5 and 24.6 percentage points, compared to sending letters asking them to opt-in to receive the kit.(91, 92, 95). Within breast screening, two trials showed that offering women a default timed and dated appointment to attend, thereby reducing the need to contact the service to schedule an appointment, improved participation by 6 and 10 percentage points.(93, 94) A further study also showed a 3.6 percentage point increase through offering timed appointments for cervical screening.(137) In the same study, sending women home sampling kit for cervical screening as a default resulted in a 5.1 percentage point increase in uptake.(137)

1.5.6. Using Salience

Salience utilises that fact that our attention is drawn to things that are novel and relevant to us.(32) This tool can address a number of biases and cognitive factors. Firstly, health messages might be made more salient through message framing which may target the *loss aversion bias*. Loss aversion bias hypothesises that when individuals are faced with risk, they are generally less willing to tolerate a potential loss, because there is a stronger tendency to avoid losses, than there is a tendency to achieve a potential gain (see section 0).(138)

Secondly, salience might be used to address the *availability bias*. Section 0 highlighted how the cognitive factor of low perceived risk might be influenced by one being unable to recall anyone like them having suffered from for example cervical cancer. Therefore, by finding ways to evoke more realistic risk perceptions one may be able to make the behaviour such as cancer screening more salient.

Thirdly, thoughtfully designing the format of any communication to reduce cognitive burden, by using simple language and shortening information provided, or highlighting important information in bold or in a text box, might increase the likelihood of the information being read to completion and key points being acknowledged, which in turn may change behaviour.

Fourthly, a key cognitive factor highlighted in section 0 was forgetfulness. The use of simple reminder tools that bring to attention an outstanding screening opportunity or remind of an upcoming screening appointment may improve participation.

Examples of *Salience*

Message Framing: It is generally accepted that gain framing is more effective in preventative health behaviours and loss framing in disease detecting behaviours.(139-142) For example in the context of encouraging beach-goers to use sunscreen, gain framing was more effective than loss.(143) Whereas in the context of breast self examination to detect cancerous lumps loss framed messaging has been shown to be more effective.(144) A number of reviews have highlighted the effect of using framing in breast cancer screening.(145-147) *O'Keefe et al.* reviewed 53 trials investigating the use of framing in preventative health behaviours including various cancer screening programmes.(145) The authors found that in the case of breast cancer screening, there was evidence that loss framing could have a small but significant effect on improving participation rates. A subsequent review by *Gallagher et al.* supported these findings.(147) However, one particular study, investigating framing in mammography found that loss framing was only effective in women with average or high risk perception of susceptibility to breast cancer. No effect was found for gain or loss framing in women with low risk perception.(148)

Interestingly, there were only two studies that investigated the effect of framing in cervical screening. The first was a small trial (n=116) investigating the use of framing in cervical screening which, which did not identify any significant effect. (146) However, this is likely to have been due to the small sample size as well as the fact that the intervention targeted women who had attended the initial screening round and had received an abnormal result and were therefore being recalled for follow up. Therefore, they may have been expected to have strong motivation to attend given the previous abnormal screening result, and this is likely to have been a key factor affecting the null findings from the intervention.(149) The second, describes a trial using a 2x2 factorial design that assessed the rate of screening attendance of women randomised to either receive a gain or loss framed message which was then presented in the context of being either a preventative or diagnostic behaviour. The results were consistent with other framing evidence in that women who were presented with gain-framed messages in the context of prevention and women who were presented with loss-framed messages in the context of diagnosis were more likely to attend cancer

screening at 6 months.(139) As a smear test can both prevent and detect cervical cancer, making use of gain framing is of particular interest in this setting. Unfortunately, the communication channel for this intervention design was a 10-minute educational video, making its application difficult to scale. More scope therefore exists to investigate the role of message framing in the context of cervical screening, using a method of dissemination that can more easily be scaled.

As highlighted in the above study, the impact of tools such as message framing may be undermined by factors such as low risk perception. Low risk perception may lead to women assigning less value to screening and therefore not prioritising such activities. Research to address low risk perception has shown that encouraging realistic perceptions by tailoring information to an individual's risk, can improve participation rates in cancer screening.(150) One study targeting female first-degree relatives of breast cancer patients showed that targeted personalised risk information resulted in an absolute increase in perceived risk of 10% compared to the control arm.(151) A further study that tested personalised letters that targeted specific barriers and included personalised risk information, which were informed by a telephone interview with the recipient showed an increased uptake in women from lower socioeconomic groups and black women.(152) However, the challenge of improving realistic risk perceptions involves the need to collect, process and feedback data on personally held risk perceptions at an individual level. This inherently makes the intervention difficult to scale, particularly within the limits of the current screening programmes. A scalable and standardised intervention to raise risk perceptions would inadvertently risk inappropriately raising anxiety amongst women with pre-existing high risk perceptions.

Salience can be applied not only to information content, but also format. Evidence from outside the health arena from the field of marketing has demonstrated the importance of shorter sentences, and letter content in reducing the burden on the reader and in turn likely reading completion.(108)
Thoughtful design of the format of health communications by reducing the length, making information more easily comprehensible and by drawing attention to important points through for example a bold or bigger font, could further improve the salience of the information provided. There has been little work conducted which

specifically considers the format of communications in screening. Despite this, the Public Health England Screening department has recognised its importance and developed supportive guidance which was published by Public Health England outlining the 'Core principles for development of public information' that highlights the importance of format, highlighting the need to make information easy to understand and read.(27)

As outlined in section 0, forgetfulness may account for a large proportion of non-attendance at screening. The effectiveness of reminders has been shown extensively, which studies mostly focussing on letter and phone reminders, although this can be expensive and difficult to scale.(153-155) More recently, studies have demonstrated the ability of text message reminders (SMS) to improve participation rates in screening.(156-158) *Arcas et al*., *Vidal et al.* and *Kerrison et al.* showed a 5.8%, 10% and 12% absolute increase in attendance respectively at breast screening when using SMS.(156-158) However, a trial comparing the use of SMS to letter and phone call invitations in cervical screening in Malaysia showed a letter was more likely to actually be received by women than an SMS or a phone call, however the response rate if a woman was reached in each method was significantly higher in the SMS and phone call groups.(159)

Outside of cancer screening, two large systematic reviews have shown that SMS provide a low cost, effective way to improve attendance at outpatient appointments.(160, 161) One trial in particular showed that manipulating the content of SMS can further affect attendance at screening. *Hallsworth et al.* tested different SMS content and found that informing patients of the monetary value of the appointment and cost to the health service (estimated £160 per appointment provided) of the appointment and cost to the health service significantly reduced the 'did not attend' rate compared to other SMS content including a simple control, an SMS containing the clinic phone number to cancel the appointment and a social norm SMS.(162) Only one trial has tested the content of differently worded SMS reminders in cancer screening. *Lakkis et al.* tested a simple SMS against a series of three informative SMSs sent at several week intervals after the initial invitation SMS describing the benefits of breast screening.(163) No significant difference was found between trial arms, however the interpretation of this result is difficult as the sample

size of 385 is likely to mean the study is underpowered. Furthermore, the authors do not disclose the content of the intervention SMS which further limits the interpretation. *Hallsworth et al.*'s trial is therefore of particular interest as it demonstrates that SMSs can be used as a communication channel by which different behaviour techniques can be delivered and tested in addition to providing a simple reminder in the form of the SMS itself. Moreover, text message reminders provide a low cost intervention that is easy to disseminate and scale. Little work has been done in cancer screening looking at the content of SMS. Therefore the mode of delivery using SMS was chosen for two of the trials reported in this thesis (chapter 3 and 5).

1.5.7. Using Priming

Priming often relates to olfactory or visual prompts such as the use of lemon scented detergent smell to improve hand hygiene(164) or small tableware to reduce portion size.(165) This tool may not be applicable to pragmatic intervention design within the cancer screening programmes.

1.5.8. Using Affect

Affect as discussed above, is the emotional state in which decisions are made or the emotions evoked when faced with a decision, which can have an impact on the decision subsequently made. Interventions to address affect might focus on countering negative affects such as anxiety about a potential cancer diagnosis, likely to arise as a result of thinking about participating in the desired behaviour. In the context of screening this might be in form of interventions that highlight a positive affect related to taking part, such as the relief and reassurance of a negative test result and being proud to have put one's health first.(79)

Examples of *Affect*

A number of emotional barriers exist to cancer screening. It may be possible to change screening behaviour though addressing the emotions, which may be elicited when people consider taking part in screening. Anxiety about pain and embarrassment during the test itself are often cited as key barriers to breast and cervical screening.

Evidence shows that for some women, mailed self-sampling HPV test kits can improve participation by allowing the test to be completed in the privacy of their own home.(16) In the case of bowel cancer screening, the traditional home testing kit (FOBT) requires two samples to be taken from three different stool samples. This understandably creates a strong *affect* barrier due to the disgust at the thought of completing the test, and storing it between taking samples. *Chubak et al.* showed that by changing the test to a single sample test, participation rates rose by 8% points.(166) As a result the new single test kit will be introduced as standard practice across the NHS in 2019.

The *affect* at the point of being offered screening or the change in *affect* as a result of the screening offer will vary between individuals. For example some women may feel anxious at the thought of screening because they worry about pain or embarrassment, whereas others may not. Therefore, addressing *affect* factors in health communications may require tailoring to the beliefs held by different individuals. Otherwise, a broad population approach may risk inducing negative affect in women who do not already have such negative feelings towards screening, and as result make them less likely to attend. The aim of the intervention design for trials within this thesis was to develop interventions that could be deployed on a large scale, and be easily adopted by screening programmes. Given the constraints of the current cancer screening infrastructure, in that it is not currently able to tailor health communications based on individual or subgroup characteristics, it was not feasible to select *affect* as a potential intervention arm.

1.5.9. Commitment tools

The '*commitment*' tool seeks to take advantage of the tendency to want to be consistent with commitments made to others or in public. Evidence shows that commitment devices such as making a public commitment to a friends or colleague can be powerful a behaviour change tool, particularly when coupled with a monetary commitment.(167)

Using *Commitment* devices

An example using a commitment device comes from a trial in bowel cancer screening, which found that providing individuals with fridge magnets that reminded

them and their family to complete the three stools samples required and return their bowel screening test kit led to an absolute increase in completion rate of 10%.(168) This shows how an intervention can utilise multiple behavioural tools, as the magnet also brings the individual's bowel screening invitation into the family domain by it being placed on the fridge thereby making it more visible and social to members of the household. It is possible therefore that support from family and friends encouraged participants to complete the test. Although, the recipients of the fridge magnet were handed them by their GP, thereby utilising the messenger effect, this does make the interpretation of effect of the commitment device more challenging as part of the improvement in participation may have resulted from the messenger effect. Work by the Behavioural Insights team (a social purpose company that runs randomised controlled trials to test behavioural economic theory informed interventions), published in their online blogs, tested a commitment slip that doubled as a planning device, which was printed on the bottom of an invitation letter for breast screening and prompted recipients to make an appointment and write down the time and date.(169) The intervention was tested in a study in which around 7,700 individuals were randomised and found a 2.4 percentage point increase in participation.(169) Therefore, commitment and planning devices may serve as a useful tool in the intervention design.

1.5.10. Using *Ego*

The *ego* tool seeks to highlight that drivers of our behaviour are often shaped by how certain behaviours align with how we see ourselves and what makes us feel good.(32) MINDSPACE outlines that if our beliefs and our behaviour are at odds - also known as cognitive dissonance - then we are more likely to change our beliefs than our behaviour to make ourselves (ego) feel better about our actions.(32) A common example used is smoking behaviour. Given knowledge that smoking is dangerous, an individual is more likely to adjust beliefs about their personal risk (*optimism bias*), than to quit smoking.(32) Therefore, it may be helpful for interventions targeting ego to also target risk perception. Similarities also exist with the *affect* tool, as designing interventions that target one's *ego* might emphasise positive feelings to be anticipated as a result of choosing the desired behaviour. In the case of screening this might be 'it

feels good to put my health first'. This tool is also somewhat related to the norms tool, in that an element of social norms is driven by our need to maintain relationships with others but also to maintain a favourable concept of one's self with respect to others.(170) Therefore, although *ego* was not considered as a discrete intervention for this thesis, it has elements that align with a number of other MINDSPACE tools with respect to cancer screening and will therefore be considered to be an adjunct.

MINDSPACE Framework limitations

Although MINDSPACE provides a pragmatic and useful tool to help develop potential behavioural interventions, it has some limitations. As highlighted above, the itemised tools in MINDSPACE do not always map cleanly and directly to a particular bias or heuristic. It is therefore possible that given a certain target behaviour, some of the tools may be targeting a number of different biases. This is not in itself problematic in terms of achieving behaviour change particularly given that the framework is targeted towards policy makers. However, from an academic standpoint, it is beneficial to be clear in the design phase, which tool and which behavioural factor one is seeking to manipulate. A lack of clarity on this point may make the interpretation of any resulting behaviour change more challenging.
Michie et al. (171) critique of the framework asserted that it does not provide a comprehensive list of important intervention types, and notes that the framework is comprised of a 'mixture of modes of delivery (*e.g.*, messenger), stimulus attributes (*e.g.*, salience), characteristics of the recipient (*e.g.*, ego), policy strategies (*e.g.*, defaults), mechanisms of action (*e.g.*, priming), and related psychological constructs (*e.g.*, affect)' resulting in a lack of coherency.(171) However, recognising that the authors of MINDSPACE intended for the framework to target a broader audience than just those in academia, this combination of intervention modes may have been intentional, as any or a combination of these modes might provide an effective method to change a target behaviours encountered in the different sectors.

A further criticism given, was that MINDSPACE only attempts to change behaviour by addressing predictable but irrational decision-making and not the dual process.(171) However, this criticism may be somewhat unjustified as the MINDSPACE framework did not set out to provide a comprehensive framework that

would also include more traditional behaviour change methods including the more deliberate, rule-based decision making and instead sought to fill a knowledge gap in the use of behavioural economic theory to change behaviour.(32)
The above criticism, justified or not, may not be entirely unbiased, as within the same paper the authors outline their own framework for behavioural intervention design.(171) *Michie et al*.'s validated Theoretical Domain's Framework (TDF) is a comprehensive theoretical framework, which draws on pre-existing behavioural theories and compiles a catalogue of 33 theoretical psychological barriers and drivers (domains) known to affect behaviour and decision-making, which are informed by components of both rational (e.g. knowledge, skills and behavioural regulation) and irrational (e.g. optimism, social influences and emotion) decision making theory.(111) It provides a tool to comprehensively catalogue psychological domains that can influence any target behaviour of either healthcare providers or health care users. In its original form the TDF items were grouped into 12 behavioural domains that measures behavioural concepts deemed to influence behaviour.(172) These were expanded to include 14 domains in a later validated iteration of the framework and can be used to structure qualitative research such as focus groups or interviews, but also to inform the design quantitative research such as surveys and questionnaires.(111) The application of the TDF is intended for both qualitative research as well as quantitative research through questionnaires. Insights gained from the TDF could then be used to inform intervention design. However, as the TDF has arisen from the field of HP, it does not attempt to address a comprehensive number of predictable irrational biases and heuristics, informed by the field of BE and addressed by the MINDSPACE framework.

Methodological approach taken in thesis

The methodology that informed the intervention design process in the trials reported in this thesis was an iterative and pragmatic process. It is clear that both the MINDSPACE and the TDF frameworks, have advantages and disadvantages. However, despite the above criticism of the MINDSPACE framework, it provides the most comprehensive guidance to intervention design using BE theory. Furthermore, the use of BE theory to inform behaviour change intervention design is novel in the context of cervical and breast cancer screening. As a result the MINDSPACE

framework was used to inform the intervention design for the trials described in chapters 2 and 3. However, the challenge of selecting the key behavioural factors to target to target became apparent during the intervention design process of these RCTs. Although the RCT reported in chapter 3 attempts to mitigate this by testing a larger number of intervention arms, it was decided that it would be beneficial to attempt to measure specific behavioural drivers and barriers to screening. Insights gained could then help guide the intervention design process to a specific behavioural target. Therefore, chapter 4 reports a population survey that applies this framework to measure the strength of a wide range of behavioural factors in predicting history of attendance in breast cancer screening.(111, 112) Chapter 5 reports an RCT which utilised the insights gained through this survey to inform trial intervention design and test interventions. The intervention design was also supplemented by elements from within the MINDSPACE framework. The methods for the statistical analysis for each study are discussed in the respective studies and were conducted by the author of this thesis.

Although the focus of work in this thesis is to utilise behavioural science theory to help shape the content of health communications in cancer screening, it is not intended that these revised communications replace the need to provide full and balanced information on the benefits and risks of taking part in cancer screening. In fact, BE informed approaches to behaviour change should be considered an adjunct or additional tool by which to enable non-attenders, who intend to attend cancer screening (26), to move from intention to action, whilst simultaneously not coercing any individual against their will and not attempting to change the minds of those who actively choose not to attend.

1.5.11. Hypotheses

There is a clear opportunity and need to optimise health communications within cancer screening programmes to enable those who intent to participate in cancer screening to be tested.

The hypothesis of this thesis is that the use of behavioural science informed intervention design informed by behavioural economic and health psychology frameworks (MINDSPACE and the TDF) can improve participation in cancer screening programmes. Both the target behaviours of cervical and breast cancer screening participation as well as the target location of London were selected pragmatically due to the suboptimal breast and cervical screening rates seen in London compared to other areas of England. Furthermore, regional screening hub buy-in and willingness to participate in research studies to help improve their participation rates was a further key factor in the trial setting.

2. An invitation letter content trial to improve cervical screening uptake; a randomised controlled trial

2.1. Summary

Background

Cervical screening saves 4500 lives each year nationally. However, national coverage fell from 75.7% in 2011 to 72.7% in 2016. How health information is communicated, can affect patient and public behaviour. Framing health information, in terms of potential gains (e.g., lives saved) versus losses (e.g., lives lost) through the taking part in screening, might affect uptake.

Methods

In a parallel RCT, women who were due for screening and lived in the trial area between 21/10/2015 – 16/12/2015, were randomly allocated to be sent a simplified gain or loss framed message, or the existing invitation letter (1:1:1). Participants were masked. The primary outcome was screening participation at 32 weeks.

Results

6223, 6223, and 6202 women were allocated to the control, gain framed, and loss framed groups, respectively. The mean age was 35.4 years (SD 9.9). Attendance at 32 weeks was 32.7% (2032) in the control compared with 32.3% (2011) in the gain framed group and 33.5% (2079) in the loss framed group. Adjusted binary logistic regression showed a significant increase in uptake in the loss frame group compared to the control group (adjusted odds ratio 1.1, 95% CI 1.0–1.21, p=0.04).

Conclusions

Using loss framing in invitation letters increased the uptake of cervical screening. This study demonstrates how information in invitation letters can be made more salient. Further research to explore these techniques is required.(173)

A conference abstract of this chapter was published in The Lancet. (173)

2.2. Introduction

Coverage rates of cervical screening have fallen in England from 75.7% in 2011 to 72.7% in 2016. (2, 3) However, over the same period, the coverage rates for cervical screening in London fell from 74.1% to 66.7%. (2, 3) Therefore, both the capital and national coverage rates fall below the national target of 80%. This is concerning, as it is estimated that cervical screening saves approximately 4,500 lives in England each year.(13) However, it is crucial to achieve high participation rates in the NHS cervical screening programme (NHSCSP), to effectively reduce cervical cancer morbidity and mortality. *Landy et al*. recently modelled that if 100% of women who were eligible for cervical screening, participated regularly, then 83% of cervical cancer deaths could be prevented, compared to the current estimates of avoided 70% of cervical cancer deaths.(11) Understandably, 100% regular participation is unrealistic as some women choose to not be screened. However, evidence suggests that over 90% of the public in the UK are in favour of taking part in cancer screening.(1) A further study from the Netherlands compared cancer screening non-participants to participants found that, only 12% of individuals not attending screening felt they had made an informed decision, compared to 81% in of individuals who were screened.(26) There is therefore an opportunity focus behaviour change interventions towards individuals who intend to attend screening but do not manage to be screened. Much evidence outlined in chapter 1 has shown that although a number of beliefs and attitudes may affect participation rates in cervical screening, many women also simply forget, or feel they are too busy to make time and therefore struggle to prioritise making an appointment to be screened.(16, 18, 19) This pragmatic trial used the MINDSPACE framework to identify potential intervention designs informed by behavioural economic theory to be tested within the letter that women receive when invited for cervical screening (CS).

2.3. Methods

2.3.1. Aims

The hypothesis is that women receiving a shortened CS invitation letter, which highlights a behavioural science informed message will have a higher rate of CS participation than women receiving the current control invitation letter. The aim of this pragmatic parallel RCT was to test the effectiveness of two intervention letters that were shortened compared to the standard invitation letter, and contained either a gain or loss framed messages within a salient communication box, which conveyed the potential benefits (i.e. lives saved) or potential risks (i.e. potential lives lost) by choosing whether or not to participate in cervical cancer screening.

2.3.2. Intervention design – Invitation letter

Previous letter content research

Previous research to investigate the optimal content of the CS invitation letters has focused on a number of different interventions including; GP-endorsements, and additional informative leaflets. *Segnan et al.* showed a 13% relative increase in participation in women receiving a letter from their GP rather than the screening service.(174) Two studies carried out in the Netherlands have shown a 7.9% and an 11%-15% absolute increase in participation in women who received a GP-endorsed letter rather than a CS service letter invitation.(121, 122)
Good evidence from the field of BE indicates that the content of health messages and how these are framed, can impact subsequent attendance behaviour. Such methods for behaviour change have not yet been tested within invitation letters and therefore provide a novel intervention design aimed at improving CS participation.

Intervention Content Methodology

The potential intervention designs informed by the MINDSPACE framework discussed in chapter 1 were assessed by an expert panel convened by the research

team. The panel included a behavioural economist from Imperial College London, a public health consultant from Public Health England (PHE) who specialises in cancer screening, an expert in behaviour change from the Department of Health's Behavioural Insight Team (DH BIT) and the author of this thesis. The expert panel assessed the intervention design options for appropriateness for testing within the setting of cervical screening and agreed a shortlist of potential trial arms. These included; the Messenger tool, a commitment slip, social norms and gain and loss framing. These were then discussed with key stakeholders at the Department of Health Behavioural Insights Team and then with the national screening board. A number of options were initially considered. However, the sample size calculation and constraints of the trial running time allowed for a maximum of three trial arms, including a control arm. Therefore, the trial contained two intervention arms, which were tested against a control arm.

Selection of intervention design

The messenger, social norms, gain and loss framing and commitment slips were considered as appropriate by the expert panel and put forward for feasibility and acceptability assessment by the Department of Health Behavioural Insights Team (DH BIT), which acted as a collaborator on this trial and NHS Shared Business Services (NHS SBS) a joint venture between the Department of Health and Sopra Steria, a computer services and consulting company, which was a provider of business support services to the NHS in England including the cervical screening call recall service in North East London, at the time when this trial was.(175)

The messenger design

Much evidence supports the effectiveness of the messenger design using a GP-endorsement in cervical screening.(121, 122, 174) However, after consideration by the stakeholders, the NHS SBS deemed it not possible to print the name of each recipient's General Practitioner on the invitation letter without significant change in practice and added expense. Furthermore, consent from each GP practice would be required for the name of the practice or GP to be printed within the letters prior to starting the trial. This was unachievable within the timeframe of the trial. Therefore, the messenger design was not selected.

A commitment slip

As outlined in chapter 1 (see section 1.5.9) commitment devices can be an effective tool to change behaviour. By making a commitment to oneself or others, individuals are more likely to perform the planned behaviour. In the context of cancer screening, using a fridge magnet used in the communal space of a home to improve bowel cancer screening (168) or tear-off slips at the bottom of breast screening invitation letters (169) have shown to improve participation. The panel therefore also considered the use of a tear-off commitment slip. However the NHS SBS was unable to create a letter template that allowed the slip to be printed at the bottom of the invitation letter. The draft commitment slip interventions produced by the NHS SBS were not easily recognisable as a 'tear off' slip, which was intended to provide recipients with a space to fill in their appointment time and date, to use as a reminder. Therefore, the commitment slip was also not selected.

Descriptive social norms

The descriptive social norms design was also considered. However, previous work has shown that if the true rates of the desired behaviour are low, then the effect of highlighting this through descriptive social norms interventions may have a detrimental effect on behaviour. (129, 135) In the case of bowel cancer screening a German study showed that an inadequately 'high' social norm of participation in bowel cancer screening of 65% actually resulted in lower intention and participation than in the control where no social norm message was used.(130) Given the low rates of coverage in North East London, it was felt that a descriptive social norms message (for example, '6 out of 10 women had a cervical smear') would not be likely to have a strong positive effect, and may even be detrimental to uptake rates, as recipients of such an intervention may feel justified in not attending cervical screening. Given these concerns, the social norms intervention was not selected for this study.

***Message framing* effect**

By framing health information in different ways, it is possible to influence how an individual makes decisions. If the same information is framed positively; for example by indicating that 'there is a 90% chance of survival' it will have a different effect than the converse negatively framed information 'there is a 10% risk of death'. The use of 'gain' and 'loss' framing refers to communicating a message in terms of what can be gained by performing a certain behaviour, or what could be lost by not

performing a certain behaviour. The theory behind gain and loss framing is discussed in more detail in chapter. In practice it is generally accepted that when using message framing, that gain frame is more likely to be effective in preventative behaviour such as accepting vaccinations, taking exercise or applying sunscreen. Whereas, loss framing is more likely to be effective in disease detecting behaviour, such as having a mammogram or encouraging breast self-examination.(140-142) However, unlike some other cancer screening tests, a smear test can both prevent and detect cancer. This is because the test can pick up pre-cancerous as well as cancerous changes in the cervix. By intervening at the pre-cancerous stage, the progression to cancer can be prevented. However, as cervical screening targets asymptomatic women, if at the time of the smear test cancer has already developed, the cancer would be detected at an earlier stage when the individual is likely to have experienced no or only few symptoms. Therefore, the public belief of whether CS is considered preventative, diagnostic or both, may be an important factor in whether gain or loss framing is more effective. *Rothman et al.* highlights that even if subjects are aware that a behaviour is both, some individuals may feel similarly towards cancer screening as they do towards, for example dental check-ups in that regular attendance is considered health affirming.(140) As touched upon in Chapter 1 section 1.5.6, some previous work has investigated the role of message framing in cervical screening. *Lauver et al.* found no difference between the effect of using gain compared to loss framed messages on women who had already attended cervical screening and were being recalled for abnormal smear results.(149) However, the sample size of this study was small (n=116). Furthermore, rather than receiving the framed messages when invited for routine screening, these women received the intervention at the time in which they were recalled because of an abnormal result, having recently attended a routine smear test. It is therefore plausible that these women felt significantly at risk of disease and therefore the study had high participation rates anyway.(149) A further study using a 2x2 design, investigated the effect of presenting the potential benefits of participating compared to the losses incurred by not participating in cervical screening in terms of cervical cancer prevention or detection. Women were recruited from non-gynaecological outpatient waiting rooms and randomised to watch a 10-minute, educational video that either highlighted the potential benefits of participating in terms of prevention or diagnosis, or the potential risks of not participating in terms of prevention or diagnosis of cervical cancer. (139) At six months, women were

followed up and asked to self-report screening participation. Consistent with expectations, the trial found that if cervical screening was portrayed as a preventative measure, then gain frame was more effective at improving participation rates. However if it was portrayed as cancer detecting, then loss frame was more effective at improving intention to attend screening. Overall, the video portraying cervical screening as a cancer detection method using loss framed messages was the most effective.(139) However, this trial has a number of issues. Firstly, participants were identified in healthcare waiting rooms, indicating they might be a self-selecting group that are more likely to seek medical attention than the general population. The primary outcome measure was self-reported attendance at screening. Given that the women were aware they were in a women's health trial there is a chance that self-reporting was affected by a social desirability bias to please the researchers and may therefore have been inaccurate. Furthermore, the use of a 10-minute educational video is an intervention that is difficult to scale up to larger populations. This research however did support the previously accepted notion that gain-framed messages are more effective in prevention and loss-framed more effective in detection. This is of particular interest as some evidence has shown that more women believe CS is diagnostic than preventative.(176)

A further element to consider, when planning a message framing intervention is the desired frequency of the behaviour. Women are invited to cervical screening either every three or five years depending on their age. It is possible that women who have a smear and receive an abnormal result will be followed up more closely and therefore called back more frequently. However, for the purpose of this study we will assume that the majority of women are called back at the standard time intervals of three or five years. Evidence has suggested that for the one-off behaviour of a single dose HPV vaccine, the loss frame was more effective than the gain framed message, despite the behaviour being preventative.(177) This may suggest that the required frequency of the target behaviour may have an impact on how people respond to message framing.

As outlined above, previous evidence suggests message framing may have an impact on cervical screening participation behaviour and so is a strategy likely to deliver a change in behaviour. However it is still unknown whether gain or loss will be more

effective given the nature of CS as both preventative and detecting, whilst also being an infrequent behaviour. As was highlighted above (139) the contextual public belief of whether participating in CS is preventative or diagnostic may further mediate the effectiveness of this intervention. Testing message framing in this study will also allow further exploratory analysis to investigate how message framing affects different age groups and level of deprivation, in addition to exposure to cancer screening in terms of first time invitees compared to women who are routinely recalled. Furthermore, by using framing within the letter it is more easily disseminated compared to the video intervention described above.(149) In addition, the NHS SBS were able to accommodate message framing within their letter template. So testing message framing in the intervention arms provides an intervention that is practically possible, as well as theoretically interesting, novel, and likely to lead to change in behaviour.

Intervention Formatting Methodology

Aside from the message content, other tools have shown an impact on highlighting key messages to the target population. Examples might include using formatting to increase the salience of health messages and simplifying the communications by for example shortening the letter content to reduce the cognitive burden on the recipient.

Salience effect

How people make decisions is often influenced by the environmental context in which the decision is being made. Evidence shows that when making decisions our attention is often drawn to what seems relevant and novel to us.(32, 178) Therefore, salience tools can be used in the intervention design process. To ensure the intervention message content was attended to by the reader, a salient text box was included in the intervention arms. As seen in Figure 2.1, making the intervention text more visible and distinct from the rest of the invitation letter, ensures that the reader is more likely to read the text, which forms the content of the framing intervention.

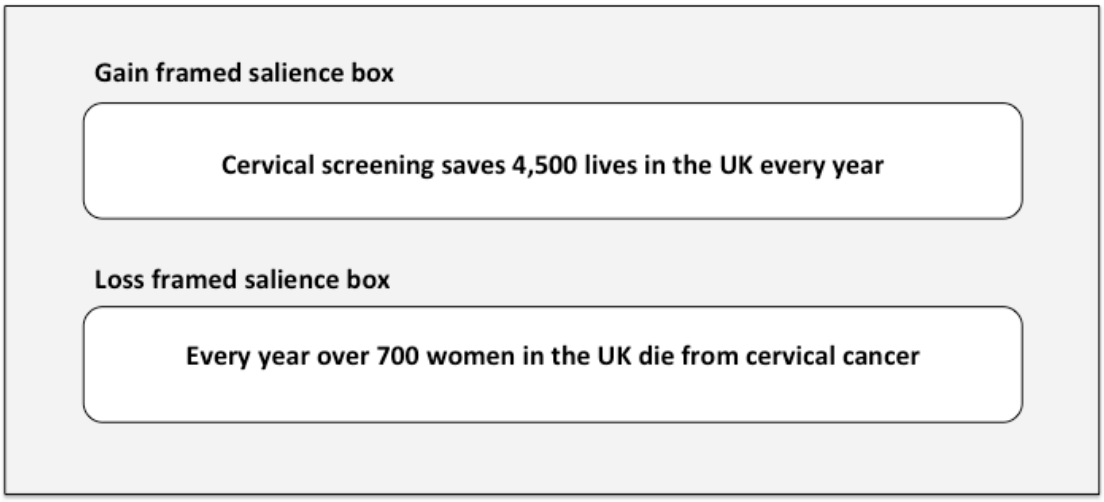


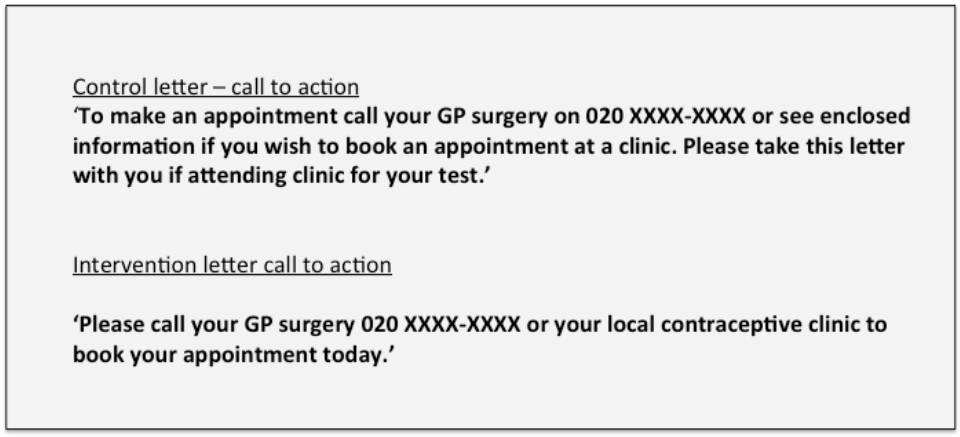
Figure 2.1 Gain and loss frame salience box

Letter simplification and abbreviation

Kitson et al. (108) noted that shorter sentences and words in advertising could improve sales by reducing the burden on the reader. It has been well recognised that reducing the cognitive burden is key to aiding behaviour change.(179) In the healthcare setting, portraying health messages more simply and in a more easily readable way, is now endorsed by national bodies including the CDC(109) and MHRA(107).

As a result, the research team, in collaboration with staff at the DH, examined the standard practice invitation letter that acted as the control in the trial, and where appropriate removed content for the intervention letter design. To enable women to make a screening appointment the existing 'call to action' phrase that was printed in bold in the control standard practice letter was maintained in bold and was also shortened. (See Figure 2.2)

Figure 2.2 'Call to action' wording for the control and intervention arms



Letter content that was deemed unnecessary, or that represented information that was duplicated from the NHS Cervical screening leaflet (which is included as standard in the screening invitation pack) was removed.(180) The wording was also simplified where possible to aid reading. (See Appendix A for trial arm letters.)

2.3.3. Trial design

This trial describes a three-armed parallel RCT, which compared two intervention cervical screening invitation letters with the current invitation letter (a standard-practice control), on their effect at increasing screening attendance in women due for cervical screening in North East London, which had a low baseline coverage rate.

Collaboration of Services

This trial was conceived through a cross-departmental and cross-professional collaboration, led by the author at Imperial College London in collaboration with the DH Behavioural Insights Team and the NHS SBS for North East London.

Study setting

The NHSCSP is provided by regional screening hubs that serve a number of surrounding boroughs or Primary Care Trusts (PCTs). Regional screening hubs have a call/recall team that is responsible for identifying and notifying women who are due for screening. At the time this trial was run, the NHS SBS was the service provider

for the Inner North East of London region of the NHSCSP, which provided the CS service to women in the boroughs of City and Hackney, Newham and Tower Hamlets. The NHS SBS utilised the same IT data system (Open Exeter) for all three boroughs. In 2014-15, when this trial was conceived, the age appropriate coverage for the Inner North East London PCTs was 68.4%, 66.6% and 64.7% for City and Hackney, Newham and Tower Hamlets respectively.(181) This was lower than the London-wide average for the same time interval of 68.8% and fell well below the national average for the same year of 73.5%.(181)

As a result the NHS SBS's Inner North East London region was pragmatically chosen as the target location for the trial, given its lower uptake, uniform IT system and single unit provider for the call/recall service through the NHS SBS.

Furthermore, the NHS SBS was able to facilitate changes to the invitation letter template for the purposes of the trial as well as randomise recipients to trial arms making them a suitable research partner.

Standard practice

In England, CS is offered to every three years to women aged 24-49 years and every 5 years to women aged 50. If women have an abnormal test they are referred for further tests or might be recalled for an earlier repeat smear or shorter interval surveillance. Each week the regional hubs that provide the service for the NHSCSP identified women who were due for screening. A list of these women is created and local GPs are requested to remove any individual who is temporarily or permanently ineligible for screening (e.g. pregnancy, on-going treatment or hysterectomy). This list is then passed back to the regional call/recall team who send invitation letters to women eligible for their smear test. The invitation letter asks women to make an appointment with their GP or family planning clinic for a smear test. If women have not attended after 18 weeks, a reminder letter is sent. At 32 weeks the screening round is closed and women who have not attended will be routinely recalled after three or five years depending on their age. Within this time interval women continue to be able to self-refer for CS by presenting to their local services. Women who have attended will be recalled according to the outcome of their smear test, either early for further tests if the result is abnormal, or in the vast majority of cases in three or five years for their routine interval screen, depending on their age. The call/recall team records

attendance status through collecting the date of the most recent smear test as reported by the laboratory assessing the tests.

Participants

Inclusion Criteria

Women who were due for cervical screening by age (24-64 years) and who lived in the trial area of Inner North East London (City and Hackney, Newham and Tower Hamlets) during the trial intervention period of October 2015 to December 2015 were eligible to take part.

Exclusion Criteria

Women who were not eligible for screening, for example, due to pregnancy, on-going health or cancer treatment that prevented participation temporarily or those who had previously undergone a total hysterectomy thereby becoming permanently ineligible, were excluded as per standard practice. In these cases their GP practice would remove them from the list of eligible women due for screening sent by the NHS SBS for 'cleansing' prior to participants being invited from screening and therefore prior to being included in the trial by NHS SBS.

Withdrawal Criteria

As women were being routinely invited for screening by letter and only the content was to be changed, women were not offered to opt out of the trial. Women who choose to not take part in cervical screening, could either disregard their invitation letter or were able to opt out of screening through the usual pathway by contacting their GP or the screening service.

Recruitment

All women who lived within the designated trial area of Newham, City and Hackney, and Tower Hamlets who were eligible and due for cervical screening during the trial intervention period (between October and December 2015) were recruited to the trial. As per standard practice, each week the NHS SBS identified women who were due

for screening and these women were randomised to receive one of the three invitation letter trial arms.

Consent

This was a pragmatic trial with the purpose of establishing if there is a more effective letter content to encourage women to make an appointment for cervical screening. Women were randomised to receive either the standard practice letter or an intervention letter. By explicitly asking these women for consent the trial results would have been biased as those choosing to consent would have likely been women who see value in cervical screening, thereby creating a selection bias. Therefore, the trial did not seek consent of participants and ethical approval was granted without requiring participation consent.

Ethical approval and trial registration

Approval for the project was given by the National Screening Programme Board and ethical approval was received from the National Research Ethics Committee REC reference number 15/EE0375. The trial was registered on ISRCTN 93653543.

Primary and Secondary Outcome

Primary outcome

The primary outcome was participation rate by intervention arm compared to the control arm at 32 weeks from the time the letter was sent. The 32-week time point was selected as it marks the closure of the screening round by the screening programme.

Secondary outcome

Secondary outcomes included exploratory subgroup analysis to assess the uptake by trial arms in different age groups, levels of deprivation and by previous exposure to cervical screening.

Sample Size

The sample size was calculated to detect a 2 percentage point increase in uptake with a 5% margin for type I error and a 20% margin for type II error to allow for a 2 sided test. A 2% point increase in uptake is in line with the outcomes from a similar trial and represents a meaningful increase in uptake. (153, 182) Thus the sample size was calculated at 8843 participants by trial arm, resulting in a total sample size of 26,529.(183, 184) This sample size was also deemed achievable in terms of recruitment during the 3-month trial period set out by the DH.

Randomisation

Women are called to cervical screening on a weekly basis through the NHS SBS. Therefore, the NHS SBS randomised a set of women each week into the three trial arms. The NHS SBS used a computerised random number generator to generate numbers between 0 and 9. The data list was then sorted by the random number. The list was then split into 3 equal groups. Each week roughly 3000 women were invited in the geographical region. As a result, the first third of women on the list were allocated to the control arm (Letter A), the second third were allocated to intervention arm 1 (Letter B) and the final third were allocated to intervention arm 2 (Letter C). This resulted in approximately 1000 women each week being allocated to each of the three trial arms. The randomisation process was overseen by collaborators within the Department of Health. The researcher did not have access to this data. A senior team leader at NHS SBS then processed the mail merge for each list with the corresponding trial arm letter i.e. letter A, B or C. A manual visual inspection was carried out by the NHS SBS team on a small sample of letters to ensure that the women allocated to receive each trial arm were sent the correct letter.

Trial Running Time

In total, approximately 3000 women are invited weekly for cervical screening from all three boroughs. To reach the target sample size of 27,000 participants, the trial arms were sent out for nine consecutive weeks. Therefore, the process was repeated each week for nine weeks. The screening round for each person invited closes 32 weeks

after the initial invitation letter is mailed, at which point the final attendance status is recorded. Therefore, the screening status data point was collected at 32 weeks after the invitation letter was sent out.

2.3.4. Data collection and analysis

The NHS SBS routinely records NHSCSP data on CS participation, including the status and date of the smear test result of women who are invited in each screening round every week. At 32 weeks from the initial invitation letter being sent, the screening round is considered closed. Further information routinely collected by NHS SBS and therefore collected in the dataset included; the date the invitation letter was sent, participant age at the time the letter was sent, participant postcode, GP practice code, CCG allocation, previous invitation history (the number of times each woman had previously been invited for cervical screening), and attendance history (the previous dates on which a cervical test result was entered on the database, up to a maximum of 8). This data was anonymised and passed to the author for analysis. The researcher was not blinded to the intervention arms. The postcodes were converted into the corresponding index of multiple deprivation (IMD) rank and decile, by uploading a file containing only postcodes and a unique identifying number to the 'Postcode Lookup' function on the English indices of deprivation 2015 webpage of the Department For Communities and Local Government website, after which the postcodes were deleted.(185) This website uses information from the 2011 Census and the information output includes the Lower-layer Super Output Area (LSOA) that the postcode falls within and the corresponding deprivation data for that LSOA.(185) The data was then cleaned and where appropriate dummy variables were created.

Continuous covariates

Continuous covariates included in the analysis were: age, the total number of previous tests attended, the total number of previous invites to screening, and the number of months since last test attended. However, evidence suggests that previous attendance at screening predicts future attendance.(40, 41) Therefore, the more recently women have attended, the more likely it is that they will attend again. However, the 'number of months since last attended' variable described above included a number of women

who had never attended who were assigned a score of 0 in this category, as well as women who had attended several years ago with very high scores for this category. These extremes however are likely to represent two different types of women. Therefore, a dichotomous dummy variable 'never attended' was created to represent all women who had never attended screening in the past to account for this in the analysis.

Categorical covariates

The categorical covariate 'invitation action code' was also included which describes the nature of the outcome of the previous invitation round. The options for this variable are: 'routine recall', 'non-responder', 'early recall', 'suspension' and 'private'. The 'routine recall' group refers to women who on their last screening test had a normal result and are being called up again routinely. If this invitation round represents a woman's first invitation to screening in this region (by age or because they moved to the area since the last invitation round, they were included in the routine recall group. The 'non-responder' group represents women who did not attend during the last screening round. The 'early recall' group represents women who recently had an abnormal or inadequate smear and are therefore being invited for an early rescreen. The 'suspension' category represents women who had an abnormal smear and were referred for further tests and now have re-entered the screening programme following investigation and if necessary, treatment. The 'private' category represents women who informed the screening programme during the last screening round that their smear was carried out privately previously.
For the purposes of the covariate formatting to reduce the number of categories within this variable the 'early recall' category was combined with the 'suspension' category. This was justified because women who have recently attended and been recalled due to an inadequate or abnormal smear and women who have recently attended and been recalled due to an abnormal smear requiring referral are very likely to have similar behaviours in terms of recent attendance and similar concerns due to being recalled.

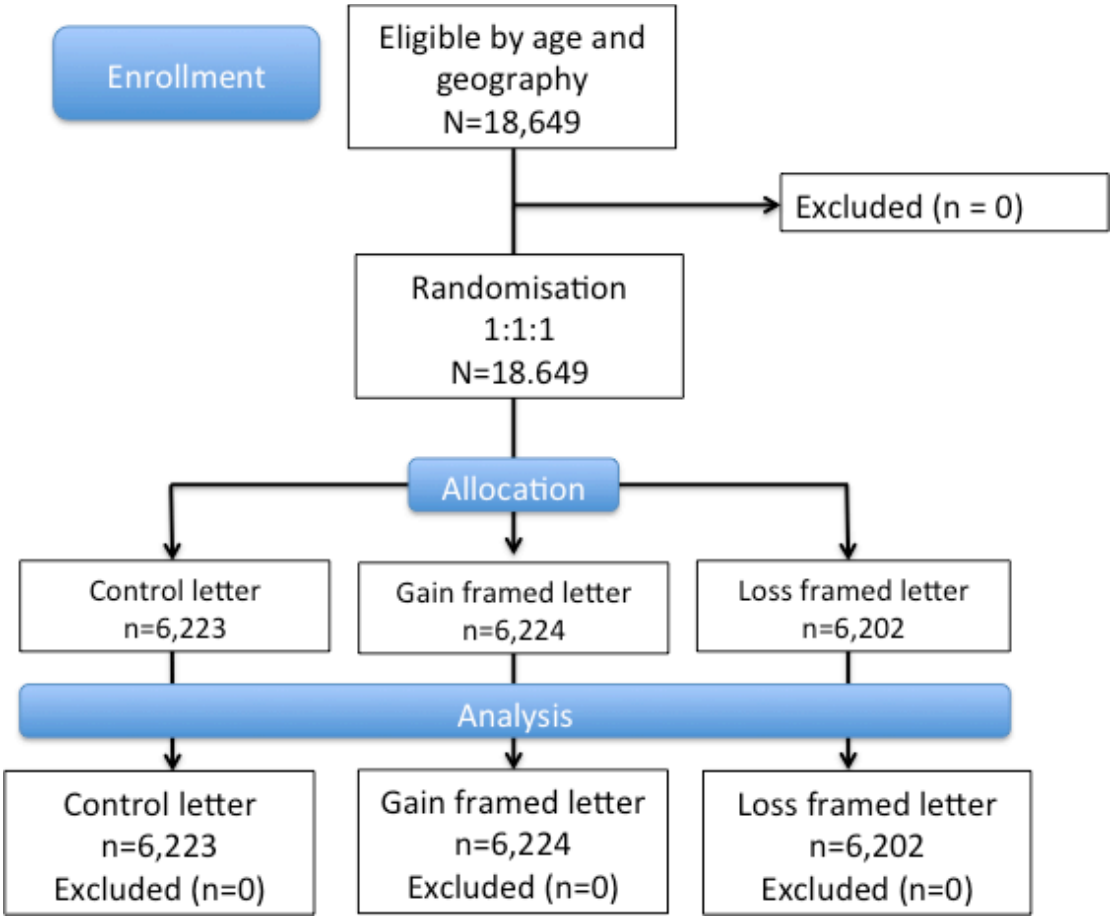
Data analysis

Data analysis was performed using IBM SPSS Statistics (Version 22.0/23.0).(186) One-way ANOVA tests were performed to assess adequate randomisation in terms of age, deprivation, invitation type, PCT area, previous invitation and attendance history. A chi-squared test was used to assess main effects of the intervention by trial arm. Tests of normality were performed. Logistic regression was performed to investigate the primary outcome of attendance, adjusting for the covariates of; trial arm, age, IMD decile, invitation type, number of invites, previous number of tests attended and months since the last test attended. Results were deemed to be statistically significant if the p-value was less than 0.05. Exploratory subgroup analysis was performed to assess uptake by previous exposure to CS, previous attendance history and IMD decile.

2.4. Results

The trial recruited 18,649 women in total of the 26,529 participants planned in the sample size calculation. The trial arms were allocated 6223, 6224 and 6202 women to the control, intervention 1 (gain-framed) and intervention 2 (loss-framed) trial arms respectively. This is 2620, 2619 and 2641 fewer than planned in the control, intervention 1 and 2 arms respectively. Unfortunately, at the trial design stage, the NHS SBS team estimated that approximately 3000 women are recruited weekly for screening in the trial region. However, this number represented both women being invited at the beginning of the screening round as well as women who had not attended within 18 weeks of receiving the first invite and were due to be send a reminder letter. As a result, only approximately 2,000 women were invited per week during the trial intervention period. As the contract with NHS SBS was due to terminate at the end of the trial period as a new provider for the service had been commissioned, we were unable to extend the length of the trial to reach the desired sample size.

Figure 2.3 CONSORT Flow diagram



2.4.1. Demographic and descriptive statistics

The median age of women in the trial was 33 years (mean age 35.4 years, SD 9.89), the median IMD decile was 3 (mean 2.78, SD 1.45), the median number of invites was 4 (mean 4.93, SD 3.92) and the median number of tests attended was 1, (mean 2.17, SD 2.5) The one-way ANOVA for demographic differences between trial arms was not significant for age ($F(2, 18646)=0.904$, $p=0.405$), IMD ($F(2, 18646)=1.754$, $p=0.173$), number of previous invites age ($F(2, 18646)=0.882$, $p=0.414$) or previous screening attendances age ($F(2, 18646)=1.461$, $p=0.232$) (see Table 2.4.1), indicating adequate randomisation.

Table 2.4.1 Demographic data by trial arm

	Control	Gain Frame	Loss Frame	p - value
Age in years				
Mean Median Standard Deviation (SD)	35 33 SD±10	35 33 SD±10	36 33 SD±10	0.405
IMD decile				
Mean Median Standard Deviation (SD)	2.76 3 SD±1.42	2.76 3 SD±1.43	2.8 3 SD±1.48	0.173
Invitation type				
Normal recall Non responders Early recall Suspended 12 months Private test	2290 (33.6%) 2251 (32.7%) 768 (35.0%) 176 (32.1%) 38 (34.8%)	2982(33.5%) 2333 (33.5%) 693 (31.6%) 185 (33.7%) 31 (28.4%)	2936 (33.0%) 2304 (33.4%) 734 (33.4%) 288 (34.2%) 40 (36.7%)	0.480
Number of Invites	4 (SD±3.9)	4(SD±3.9)	4 (SD±4.0)	0.414
Previous number of tests attended	2 (SD±2.7)	1 (SD±2.6)	1(SD±2.7))	0.232

Linearity and Collinearity tests

Linearity tests were performed to assess the relationship of continuous covariates with the outcome variable of attendance at 32 weeks.(187) The covariates ‘age’, ‘IMD decile’ and ‘months since last test’ were linearly distributed as per the Box-Tidwell test. The covariates ‘Number of invites’ and ‘Total tests attended’ failed the Box-Tidwell test even after transformation. However, statistical advice was sought and the continuous covariates were deemed to be acceptably linearly distributed to continue to regression without transformation. Collinearity statistics were assessed to ensure that covariates were not in a collinear relationship. A variance inflation factor (VIF) of <2.5 was accepted as representing no problematic collinearity between covariates.(188) No evidence of collinearity was found between continuous variables.

2.4.2. Primary outcome - Attendance at 32 weeks

At 32 weeks the overall uptake was 32.8%. Participation rates by trial arm were 32.7% (2,032), 32.2% (2,011) and 33.5% (2,079) in the control group, gain frame and loss framed letters respectively. A two-sided chi-squared test did not show a significant main effect (X^2 (2) = 2.195, p=0.334). These rates of participation are much lower than those reported in the national screening programme data, due to the fact that they reflect the uptake within an 18 week window since receiving an invitation to be screened. Whereas, the nationally reported data reflects the rate of coverage, i.e. the percentage of women who had a cervical screening test regardless of whether they were called up for screening through the programme or due to self-referral in the previous 3.5 or 5.5 years depending on their age.

Table 2.4.2 shows the results from the multivariate logistic regression adjusted for age, IMD decile, previous screening outcome, number of previous invitations, total tests attended and months since last test. The B coefficient (B) represents the change in the log odds for a one-unit change in an independent variable when all other independent variables are kept constant. An indication of how each variable predicts attendance can be found in the odds ratios (OR), which show the change in likelihood of attending screening associated with a 1 standard deviation (SD) change in the variable score. The loss frame trial arm was significantly more effective at improving attendance compared to the control arm with an adjusted odds ratio (OR) of 1.1 (CI 1.00-1.21, p = 0.045). The gain frame arm was not significantly different to the control arm with an odds ratio of 1.02 (CI 0.93-1.12, p = 0.65). Age did not significantly affect participation. With ann increasing IMD decile (i.e. as women become less deprived) there was a small but significant reduction in attendance (OR 0.95, CI 0.92-0.98, p < 0.001). There was no significant difference between previous non-responders and women being invited for an early recall compared to those being invited for routine smear tests. However, women who previously had attended a private CS were less likely to attend screening (OR 0.48, CI 0.30-0.78, p = 0.003). It is possible that these women elected to be screened privately again and were therefore not counted. Women who received a higher number of invites were less likely to have attended (OR 0.86, CI 0.85-0.87, p < 0.001), whereas women who had a higher number of previous CS attendances were more likely to attend (OR 1.25, CI 1.22-

1.28, p < 0.001). Women who had an increased number of months since their last attendance were slightly less likely to attend screening (OR 0.99, CI 0.99-1.0, p <0.001).

Table 2.4.2 Adjusted multivariate logistic regression for attendance at 32 weeks.

	B	S.E.	p-value	OR	95% CI	
Trial arm			0.110			
Control						
Gain frame	0.02	0.05	0.650	1.02	0.93	1.12
Loss frame	0.10	0.05	0.045	1.10	1.00	1.21
Age	0.00	0.00	0.464	1.00	0.99	1.00
IMD decile	-0.05	0.01	0.000	0.95	0.92	0.98
Previous outcome			0.032			
Routine recall						
Non-responders	21.53	1141.63	0.985	$2.3x10^9$	0.00	.
Early Recall	-0.02	0.06	0.713	0.98	0.88	1.09
Private test	-0.73	0.25	0.003	0.48	0.30	0.78
Number of invites	-0.15	0.01	0.000	0.86	0.85	0.87
Total tests attended	0.22	0.01	0.000	1.25	1.22	1.28
Months since last test	-0.01	0.00	0.000	0.99	0.99	1.00
Never attended	-25.10	1141.63	0.982	0.00	0.00	.
Constant	0.21	0.10	0.033	1.24		

2.4.3. Exploratory subgroup analysis

Subgroup analysis by previous screening exposure

Amongst women of all ages receiving their first invite from this screening hub, uptake was 69.2% (n = 369), 75.2% (n = 380) and 72.5% (n = 291) for the control, gain and loss frame trial arms respectively, which was not statistically significant, X^2 (2) = 4.712, p = 0.095.

The logistic regression of women receiving their first screening invitation was controlled for age and IMD decile. Other covariates were not included here, as they do not apply given that this subgroup reflects women being invited for their first screen. The regression showed a significant increase in uptake for women receiving the gain framed letter (OR 1.35, CI 1.03-1.78, p = 0.03), but no significant difference

for the loss framed letter compared to the control (OR 1.19, CI 0.913 – 1.55, p = 0.20), see Table 2.4.3.

Table 2.4.3 Adjusted multivariate logistic regression at 32 weeks for women receiving their first invitation to screen.

	B	S.E.	p-value	OR	95% CI	
Trial arm			0.092			
Control						
Gain frame	0.30	0.14	0.030	1.35	1.03	1.78
Loss frame	0.17	0.14	0.198	1.19	0.91	1.55
Age	0.03	0.01	0.000	1.03	1.01	1.04
IMD decile	-0.02	0.04	0.563	0.98	0.91	1.05
Constant	-0.02	0.27	0.934	0.98		

Women of all ages receiving their second screening invitation or more had an uptake of 29.2% (n = 1,663), 28.5% (n = 1,631) and 29.8% (n = 1,688) in the control, gain and loss frame trial arms respectively, indicating no significant difference in uptake, X^2 (2) = 2.312, p = 0.32. The adjusted logistic regression showed that women receiving the loss frame letter were significantly more likely to attend with an odds ratio of 1.1 (CI 1.00-1.21, p = 0.05), with no difference found in women receiving the gain frame letter, OR 1.03, CI 0.93 – 1.31, p = 0.57, (see Table 2.4.4).

Table 2.4.4 Adjusted multivariate logistic regression for attendance at 32 weeks in women receiving their second invitation or more.

	B	S.E.	p-value	OR	95% CI	
Trial arm			0.132			
Control						
Gain frame	0.03	0.05	0.572	1.03	0.93	1.13
Loss frame	0.1	0.05	0.050	1.10	1.00	1.21
Age	0	0	0.281	1.00	0.99	1.00
IMD decile	-0.03	0.01	0.038	0.97	0.94	1.00
Previous outcome			0.000			
Routine recall						
Non-responders	21.58	1562.76	0.989	$2.4x10^9$	0.00	0.00
Early Recall	-0.54	0.05	0.000	0.58	0.53	0.65
Private test	-0.74	0.24	0.002	0.48	0.30	0.77
Total tests attended	0.17	0.01	0.000	1.19	1.17	1.22
Months since last test	-0.01	0	0.000	0.99	0.99	0.99
Never attended	-25.13	1562.76	0.987	0.00	0.00	0.00
Constant	-0.26	0.1	0.014	0.78		

Previous attendance history

In the subgroup of women who had attended the last CS round and had a normal test outcome the uptake by trial arm was 41.3%, 41.4% and 43.1% for the control, gain and loss frame letters respectively (X^2 (2) = 2.556, p = 0.279), see Table 2.4.5.

Table 2.4.5 Uptake by trial arm at 32 weeks for women who attended in the previous round

	Control arm	**Gain Frame**	**Loss Frame**	X^2	**p-value**
Routine recall % Attendance (n)	41.3% 1235	41.4% 1234	43.1% 1266	2.556	0.279
Non-attender % Attendance (n)	19.6% 442	18.8% 438	19.2% 442	0.549	0.760
Early Recall % Attendance (n)	36.8% 347	37.8% 332	39.3% 362	1.251	0.535
Private test % Attendance (n)	21.1% 8	22.6% 7	22.5% 9	0.032	0.984

Amongst women who did not attend their CS in the previous round, uptake rates were 19.6% (442), 18.8% (438) and 19.2% (442), in the control, gain and loss framed arms respectively (X^2 (2) = 0.549, p = 0.76). In women who were recalled early from the previous screening round had an uptake of 36.8% (347), 37.8% (332) and 39.3% (362), in the control, gain and loss frame trial arms, (X^2 (2) = 1.251, p = 0.2). In women who declared that they were tested privately in the previous screening round had an uptake of 21.1%, 22.6% and 22.5% respectively, (X^2 (2) = 0.032, p = 0.984). Logistic regression did not identify any significant difference in uptake by trial arms for these subgroups.

2.4.3.1. Level of deprivation

The IMD ranks allocated to each patient were grouped into three subcategories. The top third represents participants who are the most deprived, the intermediate third represents women with an IMD rank in the middle third of IMD ranks nationally and the lowest third represents participants who are in the least deprived third nationally. There were 15,213, 3,020 and 416 women in the most deprived, intermediate deprivation and least deprived groups, respectively, indicating that the sample population in this trial is more deprived than the population nationally, which is in keeping with the trial location of North East London.

In the most deprived third, uptake was 33.4%, 32.4% and 34.2% in the control, gain and loss framed arms, (X^2 (2) = 3.776, p = 0.15). Uptake in the intermediate deprivation subgroup was 29.0%, 31.1% and 30.9% uptake (X^2 (2) = 1.316, p = 0.518) in the control, gain and loss framed arms respectively. In the least deprived subgroup uptake was 31.6%, 37.9% and 28.1% in the control, gain and loss framed arms respectively, (X^2 (2) = 3.226, p = 0.199), see Table 2.4.6.

Table 2.4.6 Uptake by trial arm in IMD rank subgroups.

	Control arm	**Gain Frame**	**Loss Frame**	X^2	**p-value**
Most deprived % Attendance (n)	33.4% 1,696	32.4% 1,655	34.2% 1,721	3.776	0.151
Intermediate deprivation % Attendance (n)	29.0% 299	31.1% 306	30.9% 311	1.316	0.518
Least deprived % Attendance (n)	31.6% 37	37.9% 50	28.1% 47	3.226	0.199

In the most deprived subgroup, the adjusted multivariate logistic regression showed that the loss frame arm was associated with a significant improvement in uptake compared to the control arm, with an OR of 1.1 (CI 1.00 – 1.23, p=0.047), see Table 2.4.7, however, there was no significant difference between the gain frame and control arms. In the intermediate deprivation and least deprived subgroups the

multivariate logistic regression did not show any statistically significant difference in uptake between the intervention arms.

Table 2.4.7 Adjusted multivariate logistic regression for attendance at 32 weeks in the most deprived subgroup.

	B	S.E.	p-value	OR	95% CI	
Trial arm			0.048			
Control						
Gain frame	-0.02	0.05	0.774	0.99	0.89	1.09
Loss frame	0.10	0.05	0.047	1.11	1.00	1.23
Age	0.00	0.00	0.551	1.00	0.99	1.00
Previous outcome			0.288			
Routine recall						
Non-responders	21.54	1264.95	0.986	$2.2x10^9$	0.00	.
Early Recall	0.00	0.06	0.998	1.00	0.89	1.13
Private test	-0.63	0.33	0.052	0.53	0.28	1.01
Number of invites	-0.15	0.01	0.000	0.86	0.85	0.87
Total tests attended	0.22	0.01	0.000	1.24	1.21	1.27
Months since last test	-0.01	0.00	0.000	0.99	0.99	1.00
Never attended	-25.08	1264.95	0.984	0.00	0.00	.
Constant	0.08	0.10	0.412	1.09		

2.5. Discussion

2.5.1. Uptake by trial arms

Overall there was a 0.8% increase in participation in women receiving the loss framed invitation letter. When controlling for covariates there was an overall small but significant increase in uptake in women who received the loss framed message compared to the control message of 1.1 adjusted OR. There was no significant difference between the gain framed message and the control. This is of interest, as outlined in Section 0 above, it is generally accepted that loss framing is more effective in engaging people in a diagnostic behaviour, whereas gain framing more effective in preventative behaviours. (140-142) Evidence suggests that this is also the case in cervical screening. (139) This trial sought to establish the effect of framing on CS

participation in the absence of highlighting this distinction to the trial participants. The results might therefore be interpreted in the context of previous research to suggest that the general public may primarily perceive CS to be diagnostic rather than preventative. It may therefore have been of interest to investigate if the study subjects primarily thought of CS as a preventative or diagnostic tool to help guide future intervention design.

The subgroup analysis showed that a number of women with different characteristics appear to respond differently to the gain and loss framed messages. Women receiving their first invitation seem to be more likely to attend if they received the gain framed letter (OR 1.35) compared to women who were being invited for the second or more time, who were more responsive to the loss framed letter (OR 1.1). It is challenging to interpret the reason for this difference by screening exposure. However, some previous research has shown that women with higher perceived risk of breast cancer were more likely to attend breast screening if they received a loss framed message compared to a gain framed message.(148) In the context of the present study, it is possible that increasing exposure to the screening programme may contribute to an individual's awareness, thus leading to increases in perceived personal risk of the disease. It is also possible that women who are CS naïve, who are likely to be predominantly younger women, do not expect to be faced with a possible cancer diagnosis and therefore are more likely to associated CS as a preventative or health affirming activity, which might support why in this cohort, the gain framed message was the most effective.

Women who were categorised as being in the most deprived third nationally, were more likely to attend if they received the loss framed letter. However, the deprivation of women in the trial area was positively skewed to the more deprived and 15,213 (81.6%) of the total number of participants recruited (18,649) for the trial were in the third most deprived group according to national IMD ranking. It is therefore, possible that if women who are more deprived are more likely to attend after receiving a loss framed letter but less deprived women respond better to either of the other trial arms, that the overall effect found in this trial is being heavily affected by the overall level of deprivation within this trial sample. This is further supported by the similar ORs of 1.1 and 1.11 for attendance in the loss frame trial arm for the overall effect and the top

third most deprived respectively. However, the sample sizes in the intermediate and least deprived groups were much smaller and therefore it is not possible to draw a strong conclusion as to whether women of different levels of deprivation differ in their responses to gain or loss framed messaging in the invitation letter compared to the control.

2.5.2. Impact sizes

The impact of the interventions overall and within the subgroups is small (0.8 % absolute increase in the loss framed compared to the control). However, the intervention was focused on changing existing invitation letters rather that introducing a new reminder or other channel of communication. It is therefore not unexpected to find a small impact on participation. Similar trials that have tested modified letters compared to standard invitation letters have found similar effect sizes to the present study.(153) Evidence suggests that introducing further reminder letters or other channels of communication such as text message reminders or phone calls may be able to achieve larger effect sizes. (153, 157, 182)

Using behavioural levers such as message framing takes advantage of the human tendency to discount potential future benefits compared to the immediate pay off or cost of a behaviour today. It is possible however, that in populations with high levels of deprivation, such populations experience higher levels of life stress and therefore may be more likely to focus on the immediate behaviour and its costs or gains, even after exposure to a message framed intervention that highlights the future potential gains and losses. It is therefore possible that the small impact seen was in part affected by the high proportion of deprivation amongst the sample group. On the other hand, identifying interventions that can effectively overcome temporal discounting of future benefits of screening, such as cervical cancer prevention, then such tools might disproportionately benefit those who are more deprived.

2.5.2.1. Limitations

Due to the need to integrate within the screening programme and not cause significant disruption, whilst ensuring the correct trial arm allocation, the researcher was not

blinded in this trial. Participants were unable to be truly blinded as the intervention was information based. However, women were not aware of other treatment arms available and therefore were not aware of whether or not they were in the intervention arm. In addition, as women were not invited to take part and not consented to the change in content to the letter, the Hawthorn effect can be expected to be minimal.

As discussed in the methods section of this chapter, the sample size was not reached for two reasons. Firstly, the NHS SBS overestimated how many women are routinely invited for screening on a weekly basis as they included the initial invite and reminder invite of non-attenders at 18 weeks. As a result approximately 2,000 instead of 3,000 women were sent the initial invitation letter each week. When the lower invitation rate was noticed, the research team sought to lengthen the trial period to include further weekly screening rounds. However, this was not possible as the NHS SBS was due to end their service contract for the cervical screening programme in the region as this service had been taken over by another firm. Therefore, the trial was terminated as planned after 9 weeks, so the target sample size could not be reached. As a result, the study is underpowered.

One of the challenges of using a letter as the mode of communication, is that researchers have no way of knowing who definitely received, opened and read their invitation letter. However, given that this intervention tests the communication channels currently used by the screening programme, this potential barrier to receiving the communication is a realistic challenge that will also affect the standard practice invitation letter routinely mailed. As a result, however it is possible that message framing may be more effective when using another vector of communication, where the mode of delivery can be more easily monitored, for example using a text message reminder. Certainly, being able to measure the percentage of messages successfully delivered would allow for a per protocol analysis that might show a stronger effect size. Nonetheless, this may overestimate the effect in the ‘real world’ setting where postal address accuracy, letter opening and reading rates will continue to affect the effectiveness of such health communications.

Any intervention required the assessment and sign-off of the DH R&D committee. The original gain and loss framed messages put forward were:

> **'Attending cervical screening saves 4,500 lives in the UK every year'**

and

> '**Not attending cervical screening could lead to 4,500 avoidable cancer deaths in the UK every year'.**

In terms of gain and loss framing this represents a true reflection of the same information portrayed in gain and loss terms. The R&D committee however, requested the wording for the gain framed message to be changed to '**Cervical screening saves 4,500 lives in the UK every year'.** The loss frame intervention was altered to reflect the number of actual deaths that occur each year. '**Every year over 700 women in the UK die from cervical cancer'.** Therefore, although this is a loss message, it is not a true loss frame that reflects same information portrayed in the gain frame message. However, to work within the constraints of the health systems and its regulatory authorities this change was accepted.

This study was conducted in an area of London with high levels of deprivation. It is possible that other geographical areas with different socio-economic and demographic characteristics may react differently to these interventions. It would therefore be beneficial to test these interventions in other areas to see if similar effects are found. Further work could also be done to establish whether gain and loss framing is more effectively delivered through another communication channel, such as text messages. To assess the effect of these interventions on subgroups that might react differently to gain and loss framing it would be beneficial to run larger studies or subgroup targeted studies that are adequately powered to detect such differences.

The interventions were informed by the MINDSPACE framework, designed by an expert panel and then pragmatically selected based on what could be tested within the screening programme. It is possible that some of the other intervention options considered might have been more effective than message framing, but could not

feasibly be tested in this trial setting. Therefore, rigorous evaluation of other interventions suggested by the expert panel would be beneficial, as it may be possible that other screening hubs might be able to accommodate these more easily into the screening programme. For example, it may be possible to test a tear-off commitment device in a hub that can produce a letter, which makes this both salient and recognisable as a planning tool by recipients of the invitation letter. Efforts to involve public and lay individuals in the intervention design may have also strengthened the intervention tools tested and should be considered in future trials.

Data on trial participant ethnicity was not available from the screening hub, however this represents an important piece of the puzzle in terms of participation rates, as these are known to vary by ethnicity. Hackney, Tower Hamlets and Newham represent ethnically diverse populations, which have seen a large shift in their populations. Hackney for example has seen an increase in its population size by over 20% between the 2001 and 2011 census, (189) and currently just under 20% of its population is aged between 20-29 years.(190) Such changes in the population in terms of size and makeup are likely to affect screening rates as well as the effectiveness of different interventions in changing screening behaviour. Future trials should therefore make every effort to record and collect ethnicity data, to enable us to study the effect of interventions in different ethnic groups.

2.6. Conclusion

The format and word content of cervical screening invitation letters can affect participation in cervical screening. Using message framing in invitation letters can have a small but significant impact on the uptake of cervical screening at little or no extra cost. Overall, loss framing resulted in a small but significant increase in uptake. Women who were invited for their first CS test were more likely to respond to a gain framed message, whereas women being recalled for their second or more test or who were more deprived were more likely to respond to a loss framed invitation letter. Further research to explore these techniques in a more deprivation diverse group may be beneficial. How such changes to the content of health communications might affect uptake is often hard to predict. However, as the trial sample arose from an urban

geographical area with higher average levels of deprivation, further trials in diverse populations would be beneficial to measure the effect of new intervention designs on different population cohorts.

3. Behavioural text message reminders to improve cervical screening participation: a randomised controlled trial

3.1. Summary

Background

Coverage of cervical screening (CS) in London (66.7% in 2016) has been consistently lower than the rest of England (72.7% in 2016). Simple text-message reminders (SMS) have successfully improved breast screening and cervical screening rates. However, the content of such SMS reminders has not been examined. We measured the effect of modifying the content of text message reminders on cervical screening rates in a low-coverage London borough.

Methods

Screening eligible women were segmented into two groups prior to randomization based on their age. Women aged >30 years, who were due for screening from 16/2/15-5/10/15, were randomised (ratio 1:1:1:1:1:1:1) to no SMS or one of six SMSs: a simple SMS, general practice (GP) message, total and proportional social norm (SN) message (communicating screening rates of peers), and gain and loss-framed messages (lives saved or lost through CS participation). Women aged 25–29 years were randomised to no SMS or a GP-endorsed SMS. The primary outcome was CS participation at 18 weeks. (191)

Results

1568, 1522, 1493, 1514, 1488, 1560 and 1507 women aged 30-64 were allocated ‘no SMS’, neutral SMS, GP-message, proportional SN, total SN, gain frame or loss frame trial arms, respectively. In the intention to treat (ITT) analysis the GP-message (38.4%) resulted in the biggest difference in uptake compared to ‘no SMS’ control (34.4%). The neutral SMS, proportionate SN, total SN, gain and loss framed SMS resulted in an uptake of 38.1%, 34.7%, 34.8%, 37.1 and 37.0% respectively. An adjusted logistic regression showed that the GP message and the neutral SMS only, resulted in a significant increase in participation compared to the control with an OR of 1.19 (95% CI 1.02-1.37, $p<0.05$) and 0.18 (95% CI 1.02 – 1.37) respectively.

1453 and 1482 women aged 24-29 were allocated ‘no SMS’ control or the GP-endorsed SMS trial arm, respectively. Uptake was 26.4% and 31.4% in the control and intervention arms, respectively ((OR 1.28 (95% CI 1.09-1.5, $p<0.05$)).

Conclusion

SMS improve the participation in cervical screening. Their content, in terms of choice of behaviour change strategy used, can maximise the effect of the SMS reminder on participation rates.

An abstract of this chapter was published in The Lancet.(192)

3.2. Introduction

As discussed in chapter 1, cervical screening is estimated to save over 4,500 lives each year in England.(13) However, high screening participation rates are necessary to reach the at-risk population. Evidence suggests that over 90% of the British public thinks that cancer screening is a good idea.(1) Despite this, the national coverage rates for cervical screening have fallen steadily over the past five years are consistently below the national average. (3) As outlined in chapter 1 evidence from behavioural sciences can to some extent explaining the gap between intention to attend and actual attendance,(193) particularly when examining specific barriers and enablers to cancer screening. Alongside commonly referenced beliefs and attitudes towards screening that may act as barriers to participation, cognitive factors - such as forgetfulness - are commonly reported barriers to screening attendance.(16, 18, 19) Two English studies found that 21% of non-responders in England and 28% of non-responding Black women in London stated they 'did not get around to' having a smear test.(18, 19)

A Dutch study found that as many as 32% of non-responders stated that they forgot to have a smear.(16) And evidence has shown that simple reminders can have an impact by prompting people to make an appointment. These reminders have frequently been in the form of letter or phone call reminders.(153, 182) *Eaker et al.* in particular found that the use of letter and telephone reminders improved participation rates by 10 and 31 percentage points respectively.(153) As discussed in chapter 1, there is evidence that SMS reminders can improve health behaviours, in particular attendance at routine healthcare appointments.(160, 161) SMS has also been successfully used in breast and cervical cancer screening to improve participation rates.(156-158, 194) Although SMS reminders are already frequently used within the NHS, little attention is paid to the message content.(161) However, several studies have shown that the content of health communications using channels other than SMS can affect participation rates, particularly in cancer screening.(121, 139, 146, 151, 195) Considering the effect of message content on health behaviours and the known effectiveness of text messages in improving attendance, a large trial (n=9,848) recently studied the effect of wording within SMS reminders on attendance rates for routine hospital outpatient appointments.(162) This trial found that stating the cost of a missed appointment to the health system along with the phone number to cancel the appointment, was the

most effective SMS compared to other SMS content (a simple reminder SMS, a reminder with the phone number to cancel, or a social norms message with the phone number to cancel) and reduced 'do not attend' rates by 2.9%. However, as outlined in chapter 1, a trial testing the message content of SMS reminders in breast screening that compared a simple SMS reminder to a more informative SMS reminder, did not find any difference in participation between trial arms.(163) However, the sample size of this trial was small (n=385) and the word content of the SMS reminders was not reported. For this reason, interpretation of the results is difficult as the lack of difference noted might reflect the SMS content chosen or the small sample size. There is therefore no evidence on whether SMS reminder message content might improve cervical screening participation rates.

This chapter describes a randomised controlled trial that tests the effect of six different intervention strategies within SMS reminders against a 'no SMS' control, on the participation rates of cervical cancer screening amongst women eligible for screening in an inner-city area of London with low baseline uptake rates. The intervention techniques and their word content within the SMS were informed by behavioural science theory.

3.3. Methods

3.3.1. Aims

The aim of this RCT is to test whether SMS reminders based on different techniques from behavioural sciences can improve CS screening uptake. The hypothesis is that an intervention SMS that reminds women that they are due for a cervical smear but also contains a further behaviourally informed message will be more effective than the 'no SMS' control arm.

3.3.2. Trial design

Cervical screening invitation - Usual Care

Women in England, aged between 24 and 49, who are registered with a GP, are invited for CS every three years. Women between the ages of 50 and 64 are invited every five years. The invitation to screen is sent in the form of a letter and is delivered with a booklet on CS by the individuals local CS Hub. The letter invites women to make an appointment with a local service (i.e. their own GP practice or a family planning clinic) for a cervical screen. Invited women are given eighteen weeks to make an appointment and have a test. Anyone who does not have a CS result recorded on the regional hub NHS Cervical Screening Programme (CSP) IT system at 18 weeks is then sent a reminder letter.

Study setting and procedure

The study was conducted in the London Borough of Hillingdon, where coverage of CS in 2014 (the time of study conception) was 73.6%, which is below the London average, (75.2%) the national average, (77.8%).(181) Since then, national data indicates that coverage has fallen further with the Hillingdon's coverage in 2016 only reaching 66.1%, falling just below London's coverage of 66.7% and well below England's coverage of 72.7% in the same year.(3) Although a proportion of this drop is due to a revised definition of age-appropriate coverage[1], there has been fall in coverage nationally of 1.5% points.(3) All 48 GP practices located within the Hillingdon Clinical Commissioning Group (CCG) were invited to take part in the study and consenting practices were asked to sign a letter of consent. On a weekly

[1] The figures stated at a regional level for 'coverage' are higher in 2014 than in 2016 as the Health and Social Care Information Centre (HSCIC) (now NHS digital) changed its definition of 'coverage' in this time interval. In 2014, national and regional coverage was reported as the percentage of eligible women who had been screened within 5 years regardless of age. Since then the updated 'coverage' refers to 'age-appropriate coverage' meaning women aged 24-49 who have had a smear test within the previous 3.5 years and women aged 50-64 who have had a smear test within the previous 5.5 years. This resulted in a drop in reported coverage rates in subsequent annual reports, such that under the new definition the coverage for England in 2014 was published as 74.2% in later annual reports instead of 77.8% as was reported in the 2014 annual report. The new age-appropriate coverage for England in 2016 was 72.7%, which still indicates an overall drop in national coverage over the two year period. The regional coverage rates including those of London and Hillingdon for 2014 using the new definition were not re-published.

basis, the Hillingdon regional NHS CSP call recall team (the administrative team within the region screening hub that is responsible for coordinating the invitation (call) and routine recall of individuals due for screening) identified a list of women who were due for screening. This list containing the NHS hospital number for each woman was sent via secure email to the research team. At this point the research team removed any individuals who's GP chose not to participate in the trial. Participants who had opted out individually (please see 'Consent from participants' section below) were also removed. The list was then segmented by age into Group 1 (aged 29 and under) and Group 2 (aged 30 and over) and randomised to trial arms. The randomised list was then uploaded to the iPLATO platform. iPLATO Patient Care Messaging (PCM) is a communication platform developed specifically for health services, which can enable healthcare providers to send reminder SMS to patients for routine appointments. iPLATO has existing contracts within the NHS and complies with NHS data security levels.(196) iPLATO then sent the allocated SMS to participants for whom a mobile phone number record was available at a chosen time.
Women who were randomised to receive a text message, were sent an SMS in the third week after their invitation letter was posted. To reduce confounding, where possible SMS were sent at the same time of day and day of the week. The time of 2pm GMT was chosen pragmatically as an acceptable time to receive a reminder SMS, and Wednesday was chosen to avoid any bank holidays during the trial period. At 18 weeks, the call recall team provided the research team with a list of unique identifier numbers that corresponded to participants who had not yet attended a smear in the preceding time period since the invitation letter. To reach the sample size, a cohort of women was invited according to the trial procedure every week for 33 weeks. A study participant's final attendance status was recorded 18 weeks after their invitation letter was sent. The study data collection closed 18 weeks after the last invitation letter was sent and when the research team received the final attendance status report.

Consent from General Practitioners and key stakeholders

The research team aimed to recruit approximately 80% of Hillingdon GPs; similar rates have been achieved in previous SMS studies conducted in this area.(157) Written consent was obtained from each participating GP to allow installation and use of iPLATO PCM and enable access to the relevant patient data required for the trial

(i.e. participant unique identifier number, date of birth, first 3 postcode digits and GP practice code), and to allow the GP practice name to be used in one of the trial arms as a GP message.

Consent from participants

Women who were eligible for CS in Hillingdon during the trial period received an information leaflet regarding the SMS trial along with their screening invitation letter and booklet. The information leaflet provided information regarding the aims of the trial as well as routes to opt-out of receiving a SMS, which included e-mail, text-message, and return of a letter and a telephone number to call.

Age Groups

Eligible women were stratified by age into two groups to reflect women being invited for their first CS and women who have previously been invited for CS. Evidence shows that uptake is poorer amongst younger women,(3) and particularly in breast screening women who have attended once are more likely to attend in the future.(40, 41) As a result the trial investigated these women separately.

Group 1 included women aged ≤ 29 years, and acts as a proxy for women invited for their first CS also known as the prevalence group. It was acknowledged during the planning phase that this group would also include some women being invited for the second screen. However, from the data provided by the local call/recall team it was not possible to preselect women who were being invited for their first smear test accurately, within Hillingdon. Secondly, national coverage data is reported annually based on 5-year age groups including 20-24 and 25-29. Therefore, using the age of 29 years as the upper limit for this group would provide a group that is reflected in nationally reported data. Group 2 included women aged ≥ 30 years and acts as a proxy for the 'incidence' group i.e. women who have previously been invited for CS. Due to the smaller age range in Group 1 fewer women were expected to be recruited over the same time period compared to in Group 2. Therefore Group 1 tested two trial arms: a control arm (no SMS reminder) and an intervention arm (of GP message), in order to be able to reach the sample size required in each trial arm over the trial period. Group 2 tested seven trial arms, including a control arm (no SMS), a neutral

SMS reminder, and five intervention SMS reminders. The neutral SMS contained the core message that was included in each of the interventions messages.

Participants

Inclusion Criteria

Women aged between 24 and 65 who are due for CS as identified by the local screening hub during the trial period and were registered with a consenting GP were eligible to participate.

Exclusion Criteria

Women who had previously undergone a hysterectomy or had already opted out of the screening programme for other reasons were excluded by GPs and the call recall team.

Withdrawal and Opt-out

Women who chose to not take part in the trial and opted out prior to randomisation and the SMS sending date were removed from the trial.

Primary and secondary outcomes

The primary outcome of this study was the proportion of invited individuals who attended screening within eighteen weeks of the delivery of the invitation letter, comparing those allocated to not receive an SMS with those allocated to receive an SMS, as well as by allocated trial arm (intention-to-treat).

The secondary outcomes include attendance rates by trial arm in women of different levels of deprivation and age groups.

Sample size calculation

The sample size was calculated to detect a 5% difference in uptake between groups with a 5% margin for type I and a 20% margin for type II error. This expected improvement of uptake between the control and intervention arms, was based on the results of similar studies examining the impact of SMS reminders on attendance rates at other health appointments.(197) Furthermore, a trial using SMS in breast screening, where a 5% point difference was deemed to be a statistically and operationally

significant improvement to the service and was achieved, indicates that this level of increase in uptake would be achievable through SMS reminders.(197) Using the annual baseline uptake in 2013 of prevalence (≤ 29 years) and incidence (≥ 30 years) groups of 35.32% and 51.19% respectively(198) we calculated the minimum sample size for each trial arm in the respective groups to be 1,500 and 1,600 participants, in order to detect a 5% increase in uptake, giving a total sample size of 14,200 participants.

Randomisation & Blinding

Randomisation

The research team randomised participants using simple computerised allocation methods using the Microsoft Excel 'randbetween' function. Women in group 1 (aged 24-29 years) were randomised in a 1:1 ratio to each of the two study arms (See Table 3.3.1) while women in Group 2 (aged 30 - 65 years) were randomised in a 1:1:1:1:1:1:1 ratio to each of the 7 trial arms. Participants in group 1 were allocated either to Arm 1 or Arm 2. Participants in group 2 were randomly allocated to Arm 1, 2, 3, 4, 5, 6 or 7. (see Figure 3.1)

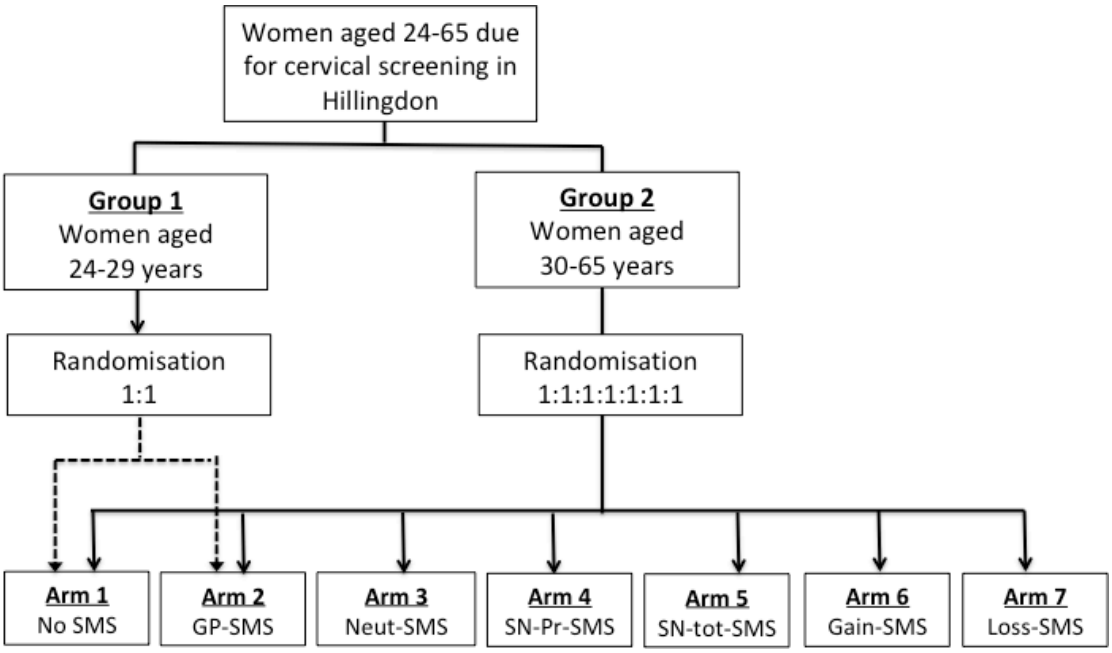


Figure 3.1 Flow diagram of age group segmentation, randomisation and trial arm allocation

Blinding

Participants were blinded in terms of knowing what trial arms were available. However, as the intervention is the content of a health message, participants were aware of whether or not they received an SMS, as well as being aware of the content of their own message. The research team that analysed the data was not blinded to the interventions received by participants.

Trial registration, ethics and funding

The trial was registered at ClinicalTrials.gov where the full protocol is also available. The registration number is NCT02363088. Ethical approval was sought from the NRES Committee South East Coast – Brighton & Sussex (REC Ref: 14/LO/1390). Funding was sought from the Patient Safety and Translational Research Centre at Imperial College London, Public Health England and the Imperial Health Charity.

3.3.3. Intervention design – SMS message content

The wording of the SMS content was guided by the MINDSPACE framework outlined in the introduction to this thesis. The final content was selected by an expert panel, which consisted of a Public Health England consultant, two behavioural economists, a health psychologist and the research team, which included two academic clinicians and the clinical lead for cervical screening of West London. SMS word content was carefully considered for all trial arms to ensure messages were ethically acceptable, and to ensure the benefits of screening were accurately represented and not overstated. The data used within the SMSs was based on the most up-to-date information available from the NHSCSP(199) and Health and Social Care Information Centre (HSCIC) as well as evidence used in the cervical screening information leaflet provided routinely with the invitation letter.(13, 198)

The five intervention arms each contained additional wording to the core text used in the neutral SMS reminder (Neut-SMS). The five manipulated reminders include: 1) a GP-endorsed SMS (GP-SMS); 2) a proportional social norms message SMS (SN-Pr-SMS); 3) a total number social norms message SMS (SN-To-SMS), 4) a gain frame SMS (GAIN-SMS) and; 5) a loss frame SMS (LOSS-SMS). (See Table 3.3.1)

Neutral SMS

A neutral SMS reminder (Neut-SMS), which simply stated that the recipient is due for CS and asked the recipient to book an appointment, was designed to act as a second control. This allowed for testing of behavioural content in the following five intervention arms against this simple reminder SMS. This neutral SMS also acted as the core message and was embedded within each of the following SMS reminders. The phone number of each participant's GP practice was also included in this SMS reminder and therefore included in all SMS messages sent out. This aimed to reduce the barrier of participants needing to look up their GP's phone number when receiving the reminder SMS.

GP endorsement

As discussed in chapter 1 previous studies have identified that GP-endorsements for routine CS can improve uptake. (121, 174, 200, 201) There is also evidence that higher risk groups including younger women and lower socioeconomic groups respond better to GP-endorsed invitation than older women and women of higher socio-economic groups.(121) Therefore the GP-SMS was designed to test the effect of a GP-message in both Groups 1 and 2, respectively. iPLATO ensured that the name of each participant's GP practice would appear within the text message.

Social Norms

Descriptive social norms (SNs) are the behaviours people expect from the social groups or society around them and, more importantly, people are prone to conform with the behaviours they feel are acceptable and expected.(32) However, individuals often over- or under-estimate the frequency with which behaviours are exhibited by their peers. Evidence suggests that after informing people about the actual frequency of a certain behaviour (if the actual frequency of the desired behaviour is high), individuals are more likely to perform that behaviour themselves. A number of examples have showcased this effect such as; informing young adults of actual drink driving rates to reduce alcohol consumption(202), informing university students of the healthy food choices to increase salad consumption on campus(203) or informing general practitioner's with high antibiotic prescription rates of how their rates compare to their peers. (128)

A number of interview and survey studies have shown that women report social norms as being a key factor in attending cancer screening.(73, 132-134) SN messages can be presented in a number of ways, and it is not yet clear if SN interventions represented in the form of a proportion of the population or total number are more effective at changing behaviour. However, although a SN intervention to improve the uptake of CS has not been tested, evidence has highlighted the importance of selecting truthful social norms that represent a high proportion of the desired behaviour.(135) As the baseline coverage in Hillingdon was 73.6%, this was deemed an acceptable rate to test SNs informed messages. However, it is possible that the proportional representation of '7 out of 10' is not a strong enough proportion to shift behaviour. Another method of using SNs is to inform the recipient of how a large number of individuals, just like them are behaving in total numbers rather than represented in proportion. Therefore, two descriptive norm messages were tested to investigate whether informing women of the 'total number' (SN-To-SMS) or the 'proportion' (SN-Pr-SMS) of women who attend screening locally can increase uptake.

Gain and Loss Frame

Framing health messages in terms of the potential benefits (gains) or costs (losses) of a certain behaviour can influence the message effect on the target population.(139-142, 144-147) It is generally accepted that gain framed messages are more effective at altering preventative health behaviours and loss framed messages more effective at altering illness-detecting behaviours.(142) However, the opposite may also be true in the case of low frequency heath behaviours such as HPV vaccinations, which although it is a preventative behaviour is more susceptible to loss framed messaging.(177) In the context of breast screening, evidence has shown that loss framed messages can be more effecting at improving participation, which is generally considered to be a predominantly 'disease detection' test rather than a preventative test. (145) CS both prevents and detects cervical cancer, and the frequency at three to five years is low. Therefore, it is difficult to predict whether a gain or loss framed messages would be more effective at changing screening behaviour. As discussed in Chapter 1, some evidence using educational videos has shown that when presenting cervical screening as a disease detection test, loss frame is more effective. Whereas,

presenting CS as a preventative test results in higher participation rates after a gain framed message.(139) Therefore, both a gain framed (Gain-SMS) and a loss framed message (Loss-SMS) were included in this trial.

Table 3.3.1 - SMS intervention by trial arm, (group 1 – aged 29 and younger, group 2 – aged 30 and older)

Trial arm	SMS type	SMS content
Arm 1 Group 1 & 2	Control / No SMS	No text message reminder
Arm 2 Group 1 & 2	GP-SMS	**"<GP NAME>:** Your cervical smear test is due. To book please call <GP phone number>"
Arm 3 Group 2	Neut-SMS	"Your cervical smear test is due. To book please call <GP phone number>."
Arm 4 Group 2	SN- To-SMS	**"Last year 12000 women in Hillingdon took part in cervical screening.** Your cervical smear test is due. To book please call <GP phone number>**"**
Arm 5 Group 2	SN-Pr-SMS	**"Last year in Hillingdon 7 out of 10 women took part in cervical screening.** Your cervical smear test is due. To book please call <GP phone number>"
Arm 6 Group 2	Gain-SMS	**"Cervical cancer screening saves 4500 lives in England every year.** Your cervical smear test is due. To book please call <GP phone number>"
Arm 7 Group 2	Loss-SMS	**"Failing to attend cervical screening could lead to 4500 avoidable deaths in England each year.** Your cervical smear test is due. To book please call <GP phone number>"

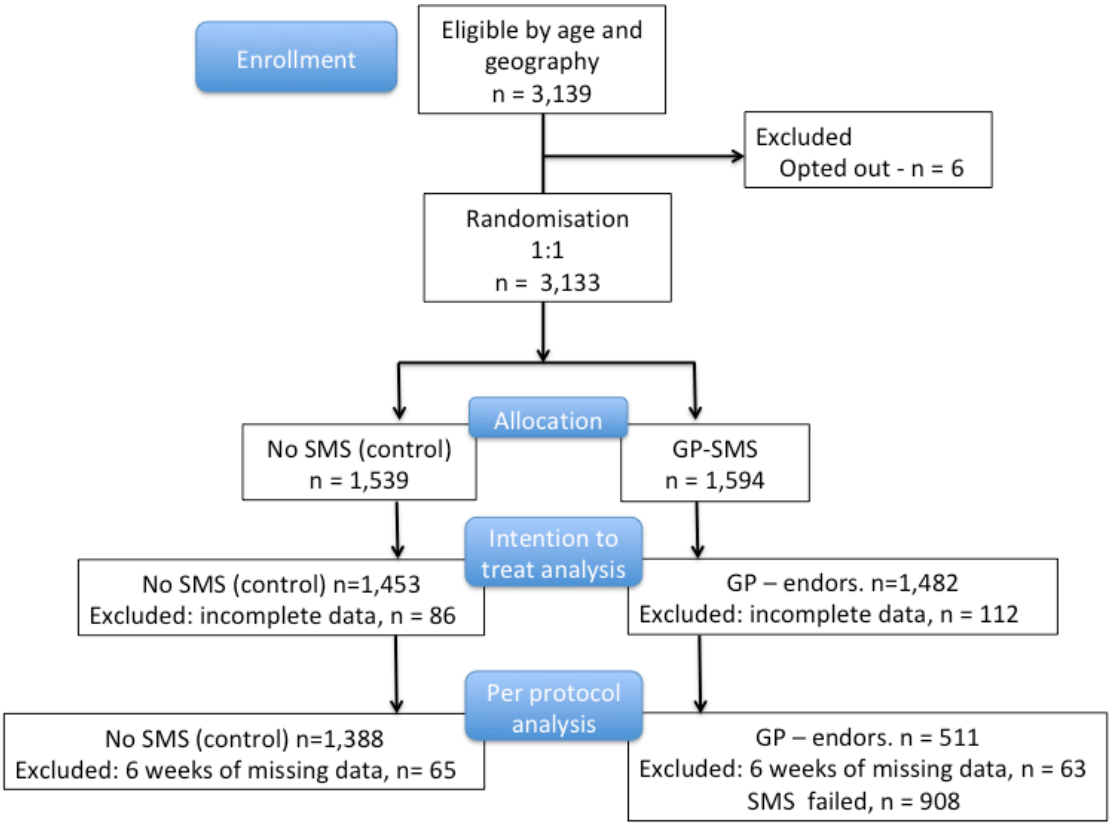
3.3.4. Data analysis

The data was analysed using the statistical analysis software package: '*IBM SPSS Statistics 22'*. Primary and secondary outcomes were evaluated using Chi-squared tests and regression analysis, with the trial arms as the exposure and the 'attendance status' as the outcome variable. Where there were significant differences, multivariate analyses were performed to provide odds ratios and 95% confidence intervals after adjusting for age and area-level deprivation (determined using census derived indicators of deprivation for individual postcode sectors). Subgroup analysis according to age groups, and different levels of deprivation was conducted.

3.4. Results

Of 48 GP practices within Hillingdon, 40 practices gave written consent to take part, giving a participation rate of 83%. In total 14,597 women were eligible to take part during the trial intervention period of March to October 2015. Of these 3,139 were aged ≤ 29 and were allocated to group 1 and 11,458 were aged > 30 years and were allocated to group 2. Results for group 1 and group 2 are discussed separately below.

Figure 3.2 - Group 1 - CONSORT flow diagram



3.4.1. Group 1 - Descriptive statistics

During the trial intervention period of March to October 2015, 3,139 women aged 24-29 were eligible to participate. Six women opted out and were excluded. Women were randomised to the control arm control (n=1,539) and the GP-SMS arm (n=1,594), respectively. The intervention SMS were sent between the 5th of March and 22nd of October 2015. Attendance data was collected until the 23rd of February 2016. The trial

was closed when the sample size was collected. Outcome data, i.e. attendance status at 18 weeks was not available from the call-recall team due to a technical error in data collection for 198 patients in group 1 across both trial arms. This was as a result of a blank file being sent by the call recall team to the research team, for which the data was not able to be retrieved at the time of data analysis. Therefore these participants were excluded from the analysis. The final number of participants analysed included 1,453 and 1,482 women in the control and GP-SMS arms respectively.

Table 3.4.1 - Group 1 - Demographic data by trial arm

	Control (n=1,453)	**GP-SMS (n=1,482)**	**Independent t-test p - value**
Age in years			
- Mean	26.1	26.1	0.88
- Median	26.0	26.0	
- Standard Deviation (SD)	SD±1.87	SD±1.89	
- Interquartile range (IQR)	4.0	4.0	
IMD decile			
- Mean	5.7	5.6	0.407
- Median	5.0	5.0	
- Standard Deviation (SD)	SD±2.44	SD±2.36	
- Interquartile range (IQR)	5.0	5.0	

The mean age in the control and GP-message arm was 26.1 (SD±1.87) and 26.1 (SD±1.89) respectively, with no significant difference between trial arms (p = 0.88). The mean IMD decile for the control and GP-message arms was 5.7 (SD±2.44) and 5.6 (SD±2.36) respectively, with no significant difference between trial arms (p=0.407).

The covariate for age failed the Box-Tidwell test for a linear relationship with the outcome variable of attendance.(187) As a result, the ages were grouped into three age groups; age-group 1 (ages 24 and 25), age-group 2 (ages 26 and 27) and age-group 3 (ages 28 and 29). This grouped age variable passed the Box-Tidwell test for linearity and was therefore used in the regression analysis.(187) The IMD decile variable passed assumption tests for normality and linearity.

3.4.2. Group 1 - Primary outcome results

Attendance in the control arm was 26.4% (n = 384), and 5% higher in the GP-message arm at 31.4% (n = 466). This was a significant increase in uptake (X^2 (1) = 8.972, p = 0.003), representing a 18.9% relative increase in participation.
A multivariate logistic regression was performed and showed that when controlling for age group and IMD decile, women receiving a GP-endorsed SMS reminder were significantly more likely to attend (OR 1.3, 95% CI 1.09 – 1.51, p = 0.002). Women in their late twenties or who were less deprived were significantly more likely to participate (OR 1.19, 95% CI 1.09 – 1.31, p < 0.001) and (OR 1.04, CI 1.01 – 1.08, p = 0.018), respectively.

Table 3.4.2 - Group 1 – Intention to treat (ITT) analysis – Multivariate logistic regression analysis

	B	S.E.	p-value	OR	95% CI
GP-endorsed SMS	0.25	0.08	0.002	1.29	1.09 - 1.51
Age grouped	0.18	0.05	<0.001	1.19	1.09 - 1.31
IMD decile	0.04	0.02	0.018	1.04	1.01 - 1.08
Constant	-1.59	0.15	<0.001	0.20	

3.4.3. Group 1 - Secondary outcome results

An intention to treat subgroup analysis was performed to investigate the effect of the GP-SMS on uptake amongst women who were in the most deprived third, intermediate deprived third and least deprived third of the national population, according to their IMD rank. Women were segmented by their IMD rank into groups corresponding to national IMD rank thirds, quartiles and quintiles and assessed for even distribution in terms of frequency by subgroup to enable subgroup analysis with sufficient numbers per group to allow for analysis of women who have different levels of deprivation. IMD ranks were most evenly distributed in terms of frequency by segmentation group when segmented into thirds. The top third corresponds to women allocated to an IMD rank within the third most deprived nationally (N=548). The intermediate deprivation level corresponds to women allocated to an IMD rank

within the middle third level of deprivation nationally, (N=698) and lowest third contains women allocated to an IMD rank within the third least deprived ranks nationally (N-653).

Percentage of attendance by trial arm at different levels of deprivation

This subgroup analysis shows that women in the most deprived third have a lower uptake in the control arm (22.7%) compared to women who are in the intermediate or least deprived groups (28.7% and 27.0% respectively) and this difference was not statistically significant (X^2 (2) = 4.933, p = 0.085).

Table 3.4.3 - Group 1 - ITT - Uptake by trial arm deprivation subgroups

	No SMS	GP- SMS	X^2	p-value
Most deprived third				
% attendance	22.7%	30.2%	6.261	0.012
(n)	(97)	(129)		
Intermediate deprived third				
% attendance	28.9%	30.3%	0.235	0.628
(n)	(154)	(172)		
Least deprived third				
% attendance	27.0%	33.9%	5.517	0.019
(n)	(133)	(165)		

Women who are in the most deprived third show a significant improvement in uptake reaching 30.2% when allocated to the GP-SMS arm, p=0.012, which corresponds to a 33% relative rise in uptake. Women in the middle third deprivation group have an uptake in the control arm of 28.7% and this improves to 30.3% in the intervention arm, however this is a non-significant difference (p = 0.628). Women in the least deprived third have a baseline uptake of 27% in the control and 33.9% uptake in the intervention arm, p=0.019, which represents a 25.6% relative increase in uptake. Of note there was no significant difference in the uptake rates in the intervention arms when comparing participation by level of deprivation, (X^2 (2) 1.999, p = 0.368). As women in the most deprived third had the lowest participation rates in the control arm, this may indicate that the intervention may reduce the difference in participation rates between women of different levels of deprivation.

Table 3.4.4 - Group 1 - ITT – Multivariate logistic regression analysis by deprivation subgroup

Multivariate regression by Subgroup	B	S.E.	p-value	OR	95% CI
Most deprived third					
GP-endorsed SMS	0.39	0.16	0.013	1.48	1.09-2.01
Age grouped	0.20	0.09	0.034	1.22	1.02-1.46
Constant	-1.61	0.219	<0.001		
Intermediate deprived					
GP-endorsed SMS	0.06	0.13	0.67	1.06	0.82-1.37
Age grouped	0.25	0.08	0.001	1.29	1.10-1.50
Constant	-1.38	0.12	<0.001	0.25	
Least deprived third					
GP-endorsed SMS	0.34	0.14	0.02	1.40	1.06-1.83
Age grouped	0.09	0.08	0.30	1.09	0.93-1.28
Constant	-1.148	0.18	<0.001	0.32	

Table 3.4.4 shows the multivariate logistic regression (MLR) repeated for each deprivation subgroup. The MLR controlled for age group shows that the GP-endorsed SMS reminder is most effective at improving uptake in women who are the most deprived with an OR of 1.48 (95% CI 1.09-2.01, p = 0.01). Women who are the least deprived also appear to be more likely to attend after receiving a GP-endorsed SMS (OR 1.4, 95% CI 1.06 -1.83, p = 0.02). Women in the intermediate level of deprivation showed a non-significant increase in uptake of screening (OR 1.06, 0.82-1.37, p = 0.67). In the most deprived and intermediate deprived subgroups, uptake is also affected by the age group (OR 1.22, 95% CI 1.02-1.46, p = 0.03) and (OR 1.29, 95% CI 1.1-1.5, p < 0.00) respectively, indicating that women who are in older age groups are more likely to attend than women in the younger age groups. However, in the subgroup containing women who are in the least deprived third, age does not appear to affect uptake (OR 1.09, 95% CI 0.93-1.28, p = 0.3).

Group 1 - Mobile phone number recording accuracy in electronic health records

GP practice level data of participant mobile phone number accuracy was available for the first 28 weeks of the trial. In group 1, the mean percentage of correctly recorded mobile phone data, incorrectly recorded mobile phone number and no mobile phone data recorded by practice was 36.4% (SD ± 16.4%), 11.2% (SD ± 7.2%) and 52.6%

(SD ± 17.3%), respectively. There was a large variation in correctly recorded data by practice with accurate mobile phone number records ranging from 0% to 66.7% in group 1.

3.4.3.1. Per Protocol Analysis

Using the SMS delivery status data available for the first 28 weeks of the trial, a per protocol analysis (PPA) was performed, which compared the attendance in the control arm and the intervention arm in women who actually received an SMS, given data on phone number availability and SMS delivery status. However, as only 36.4% of patients in the intervention arm actually received the SMS, this resulted in an almost two-thirds attrition in sample size for the intervention arm between the intention to treat and per protocol analysis.

It must be noted as no SMS was sent women in the control arm, no mobile phone data was able to be collected, with regard to who would have been sent an SMS, had they been allocated to an intervention arm. Therefore, these two groups may have subtle differences in make up as women whose phone number is recorded on their GP practices electronic health record might be characteristically different from women whose number is not recorded.

As data on phone number availability and SMS delivery status was only recorded for the first 28 weeks the per protocol analysis only takes into account this time period and therefore the remaining 6 weeks were excluded from this analysis.

Table 3.4.5 - Group 1 – Per Protocol Analysis (PPA) – Uptake by trial arm.

	No SMS	**GP- SMS**	X^2	**p-value**
% Attended (n)	26.4% (366)	40.9% (209)	37.359	<0.001

In the PPA, the uptake in the control arm was 26.4%, whereas the uptake in the GP-message arm was 14.5% higher at 40.9%, which was statistically significant and provided a 55% relative higher uptake in women receiving the GP-endorsed SMS. (Table 3.4.5)

Table 3.4.6 - PPA – Multivariate logistic regression analysis

	B	S.E.	p-value	OR	95% CI
GP-SMS	0.64	0.11	<0.001	1.90	1.53 - 2.35
Age grouped	0.18	0.06	0.003	1.20	1.07 - 1.35
IMD Decile	0.05	0.02	0.028	1.05	1.005 - 1.09
Constant	-1.63	0.18	0.000	0.20	

The multivariate logistic regression controls for age and IMD decile and indicates that women who received a GP endorsed SMS reminder were 1.9 times more likely to attend than those not receiving an SMS reminder (95% CI 1.53-2.23, p <0.001). As in the ITT analysis above, as age and IMD decile increase (less deprived women) there was an increase in participation rates: OR 1.2, 95% CI 1.07-1.35, p = 0.003, and OR 1.05, 95% CI 1.005-1.09, p = 0.028 respectively.

Table 3.4.7 Group 1 - PPA - Uptake by trial arm in deprivation subgroups

	No SMS	**GP- SMS**	X^2	**p-value**
Most deprived third				
% attendance	21.4%	41.9%	22.196	<0.001
(n)	(88)	(57)		
Intermediate deprivation				
% attendance	29.4%	39.1%	5.906	0.015
(n)	(149)	(75)		
Least deprived third				
% attendance	27.4%	42.1%	13.054	<0.001
(n)	(129)	(77)		

The subgroup analysis by level of deprivation subgroups was repeated for the PPA and found a significant increase in participation in all three deprivation subgroups including the intermediate level of deprivation subgroup. In the most deprived group, uptake was 41.9% in the intervention group compared to 21.4% in the control group (X^2 (1) = 22.196, p < 0.001). In the intermediate deprivation group the uptake in the intervention arm was 39.1% compared to 29.4% in the control, X^2 (1) = 5.906, p = 0.015. In the least deprived subgroup the uptake was 42.1% in the intervention arm compared to 27.4% in the control, X^2 (1) = 13.054, p < 0.001.

Table 3.4.8 Group 1 - PPA – MLA analysis by deprivation subgroup

Multivariate regression by Subgroup	B	S.E.	p-value	OR	95% CI
Most deprived third					
GP-endorsed SMS	0.95	0.21	<0.001	2.58	1.70 - 3.91
Age grouped	0.20	0.12	0.098	1.22	0.96 - 1.54
Constant	-1.69	0.265	<0.001	0.185	
Intermediate deprived					
GP-endorsed SMS	0.49	0.18	0.027	1.49	1.05 - 2.11
Age grouped	0.31	0.02	0.001	1.36	1.13 - 1.65
Constant	-1.48	0.22	<0.001	0.29	
Least deprived third					
GP-endorsed SMS	0.65	0.18	0.000	1.92	1.34 - 2.74
Age grouped	0.02	0.1	0.813	1.02	0.84 - 1.25
Constant	-1.01	0.20	<0.001	0.36	

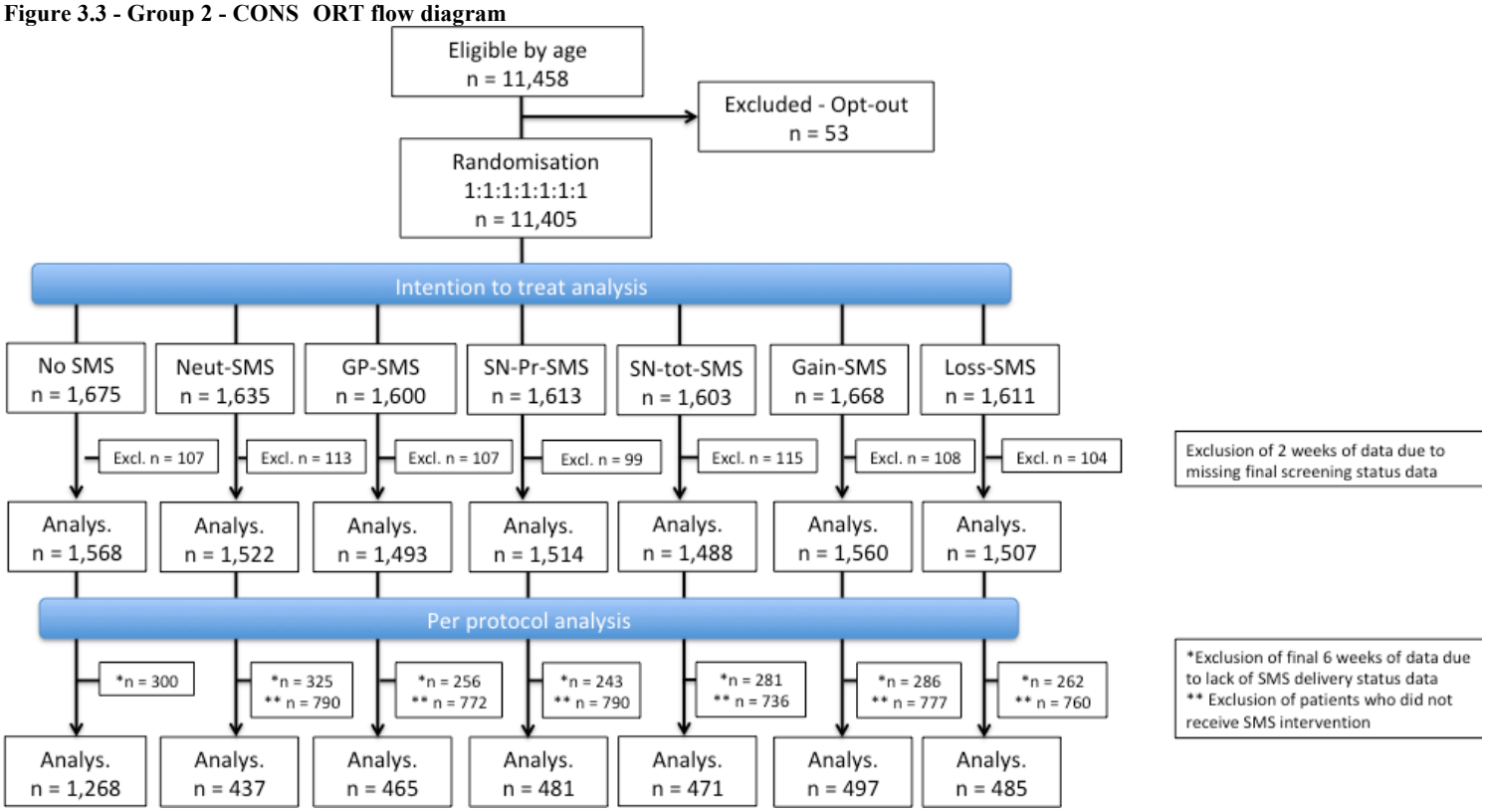
Multivariate logistic regression for deprivation subgroups is described in Table 3.4.8. In the PPA multivariate logistic regression for women in the most deprived third, receiving the GP-message reminder were more than two and a half times more likely to attend than women not receiving an SMS reminder (OR 2.58, 95% CI 1.70-3.91, $p < 0.001$). In the intermediate deprivation subgroup, women receiving the intervention were one and a half times more likely to participate (OR 1.48, 95% CI 1.05 – 2.11, $p = 0.027$). In the least deprived third, women receiving the intervention were almost twice as likely to attend (OR 1.92, 95%CI 1.34-2.74, $p < 0.001$).

3.4.4. Group 2 – Descriptive statistics

During the enrolment phase of March to October 2015, 11,458 women aged between 30-64 years were eligible for screening and therefore segmented into group 2. Fifty-three women opted out of the trial and were excluded. Women were randomised into 7 trial arms at a 1:1:1:1:1:1:1 ratio. The intervention SMS were sent between the 5th of March 2015 and the 22nd of October 2015. Attendance data was collected until the 23rd of February 2016. The trial was closed when the sample size was collected. Two weeks of data were excluded from the trial due to a data handling error. The first week was excluded due to incomplete attendance data being provided by the local

screening call/recall team (empty excel spread sheets). The second week was excluded due to an SMS deployment failure as a result of a faulty upload file, which resulted in the trial participants not receiving their allocated intervention. Therefore, 753 participants were excluded from the analysis across the trial arms in Group 2. The final number of participants included in the analysis was 1568, 1522, 1493, 1514, 1488, 1560 and 1507 in the 'no SMS' control, Neut-SMS, GP-SMS, SN-Pr-SMS, SN-To-SMS, Gain-SMS and Loss-SMS trial arms respectively.

Figure 3.3 - Group 2 - CONS ORT flow diagram



In the group 2 analysis, the overall mean age was 42.8 years and mean IMD decile was 5.9. There was no significant difference in age ($p = 0.853$) or IMD decile ($p = 0.498$) across trial arms. Both covariates (age and IMD decile) passed normality, linearity and collinearity tests.

Table 3.4.9 Group 2 - Demographic data by trial arm

	No SMS n=1,568	Neut-SMS n=1,522	GP-SMS n=1,493	SN-pr-SMS n=1,514	SM-tot-SMS n=1,488	GAIN-SMS n=1,560	LOSS-SMS n=1,507	p-value
Age in years								
Mean	42.9	42.8	42.7	42.7	42.5	42.9	42.9	.853
Median	41.5	42.0	41.0	41.0	41.0	42.0	42.0	
Standard Deviation (SD)	±9.32	±9.30	±9.23	±9.24	±9.19	±9.34	±9.34	
Interquartile range (IQR)	35-50	35-49	35-49	35-49	35-49	35-50	35-50	
IMD decile								
Mean	5.97	5.91	5.96	5.99	5.95	5.80	5.94	.498
Median	6.0	5.0	6.0	6.0	6.0	5.0	5.0	
Standard Deviation (SD)	±2.52	± 2.5	± 2.57	± 2.56	± 2.55	± 2.54	± 2.55	
Interquartile range (IQR)	3-8	3-8	3-8	4-8	3-8	3-8	3-8	

3.4.5. Group 2 - Primary outcome results

The uptake of cervical screening by women allocated to the 'no SMS' control trial arm was 34.4% compared to 36.7% uptake by women allocated to any of the SMS intervention arms combined, which was approaching significance on a two-sided chi-squared test (X^2 (1) = 2.931, p = 0.087). Uptake by intervention arm was 38.1%, 38.4%, 34.7%, 34.8%, 37.1% and 37.0% for the Neut-SMS, GP-SMS, SN-Pr-SMS, SN-To-SMS, Gain-SMS and Loss-SMS arms respectively which approaches significance, (X^2 (6) = 11.014, p = 0.088), see Table 3.4.10)

Table 3.4.10 - Group 2 - ITT - Uptake by trial arm.

	No SMS	Neut-SMS	GP-SMS	SN-Pr-SMS	SN-tot-SMS	Gain-SMS	Loss-SMS	X^2	p-value
% Attendance (n)	34.4% (540)	38.1% (580)	38.4% (575)	34.7% (526)	34.8% (518)	37.1% (579)	37.0% (557)	11.014	0.088

Multivariate logistic regression showed that the GP-SMS reminder and the Neut-SMS significantly improved the uptake of screening compared to the reference point of the no SMS control, OR 1.19, 95% CI 1.02-1.38, p = 0.02 and OR 1.18, 95% CI 1.02-1.37, p = 0.03, respectively. No other SMS interventions were significantly better than the control in the multivariate logistic regression. As age and IMD decile increased (i.e. deprivation decreases) the uptake also increased, OR 1.02, 95% CI 1.01-1.02, p < 0.001 and OR 1.03, 95% CI 1.02-1.05, p < 0.001, respectively.

Table 3.4.11 - Group 2 - ITT - MLR analysis

	B	S.E.	p-value	OR	95% C.I.
Intervention arm			0.83		
No SMS					
Neut-SMS	0.17	0.08	0.029	1.18	1.02 – 1.37
GP-SMS	0.18	0.08	0.020	1.19	1.03 – 1.38
SN-pr-SMS	0.02	0.08	0.823	1.02	0.88 – 1.18
SN-tot-SMS	0.03	0.08	0.740	1.03	0.88 – 1.19
Gain-SMS	0.12	0.08	0.101	1.13	0.98 – 1.31
Loss-SMS	0.11	0.08	0.139	1.12	0.96 – 1.30
IMD decile	0.03	0.01	<0.001	1.03	1.02 – 1.05
Age	0.02	0.00	<0.001	1.02	1.01 – 1.02
Constant	-1.48	0.12	<0.001	0.23	

3.4.6. Group 2 - Secondary outcome analysis

Exploratory subgroup analysis was performed to investigate the effect of different trial arms on women of different age groups and levels of deprivation.

Subgroup analysis of age groups

A subgroup analysis by age group was performed. Women were pragmatically split into two 10-year age groups of 30-39 years and 40-49 years. These groups represent women who are routinely invited on a 3-yearly basis. A further 15-year group was analysed to in further investigate women aged 50-65 years, which represents women who are invited every 5 years. In the 30-39 year, 40-49 year and 50-65 year groups there were 4,643, 3,362 and 2,648 participants respectively.

The uptake in the control arms differed significantly by age groups with participation rates of 29.2%, 36.6% and 40.5% for women aged 30-39 years, 40-49 years and 50-65 years respectively (X^2 1(2) = 15.697, p < 0.001). In the age group 30-39 years there was a significant difference in participation rates between women who were allocated to the control (29.2%) and women allocated to receive any SMS intervention arm (33.6%), X^2 (1) = 4.913, p = 0.03), see Table 3.4.12. There was no significant difference between the control arms and women allocated to receive an SMS in the older age groups.

Table 3.4.12 Uptake by age-subgroup, control versus any SMS

	No SMS	Any SMS	X^2	p-value
Subgroup age 30-39 % Attendance, (n)	29.2% (197)	33.6% (1332)	4.913	0.027
Subgroup age 40-49 % Attendance, (n)	36.6% (179)	37.5% (1007)	0.139	0.709
Subgroup 50-65 % Attendance, (n)	40.5% (164)	41.2% (2243)	0.07	0.792

When considering each trial arm separately within the youngest age group (30-39 years) the Neut-SMS, the GP-SMS and the Loss-SMS had the highest participation rates at 35.3%, 35.6% and 35.0% uptake respectively compared to the control of 29.2%, with the chi-squared test approaching significance (p = 0.094), see Table 3.4.13. In the age group 40-49 the Neut-SMS reminder produced the highest observed uptake rate of 39.3% compared to the control at 36.6%. However, there was no significant difference across trial arms in the 40-49 year age group. In the age group 50-65 years the GP-SMS and the Gain-SMS message had the highest observed participation rates at 44.9% and 44.8% compared to the control of 40.5%, however these were not significant, see Table 3.4.13.

Across all age groups the social norms messages show little improvement compared to the 'no SMS' control. In the age group 50-65 there is an absolute decrease in the uptake in the SN-To-SMS trial arm of 4.8%, though the group differences overall were not found to be significant.

Table 3.4.13 Group 2 - Uptake by age-subgroup

	No SMS	Neut-SMS	GP-SMS	SN-Pr-SMS	SN-tot-SMS	Gain-SMS	Loss-SMS	X^2	p-value
Subgroup 30-39yrs % Attendance, (n)	29.2% (197)	35.3% (231)	35.6% (232)	30.7% (204)	32.7% (220)	32.2% (215)	35.0% (230)	10.814	0.094
Subgroup age 40-49 % Attendance, (n)	36.6% (179)	39.3% (198)	37.4% (184)	35.6% (169)	37.1% (169)	37.6% (184)	37.9% (175)	1.632	0.950
Subgroup 50-65 % Attendance, (n)	40.5% (164)	41.5% (151)	44.9% (159)	40.8% (153)	35.7% (129)	44.8% (180)	39.3% (152)	9.296	0.158

Multivariate logistic regression controlling for IMD decile was performed for each age group, see Table 3.4.14. In the age group 30-39, women who received a neutral, GP-endorsed or Loss-framed SMS reminder were significantly more likely to attend compared to the control, OR 1.33, 95% CI 1.06-1.68, p = 0.02, OR 1.35, 95% CI

1.07-1.70, p = 0.01 and OR 1.31, 95% CI 1.04-1.65, p = 0.02 respectively. In women aged 40-49 and 50-64 there was no significant difference by trial arm in the logistic regression.

Table 3.4.14 - Group 2 - ITT – Multivariate logistic regression analysis by age-subgroup

	B	S.E.	p-value	OR	95% C.I.
Subgroup age 30-39					
Intervention arm			0.089		
No SMS					
Neut-SMS	0.28	0.12	0.016	1.33	1.06 – 1.67
GP-SMS	0.3	0.12	0.012	1.34	1.07 – 1.69
SN-pr-SMS	0.08	0.12	0.527	1.08	0.85 – 1.36
SN-tot-SMS	0.17	0.12	0.15	1.19	0.94 – 1.50
Gain-SMS	0.15	0.12	0.222	1.16	0.92 – 1.46
Loss-SMS	0.27	0.12	0.023	1.31	1.04 – 1.65
IMD	0.01	0.01	0.459	1.01	0.99 – 1.03
Constant	-0.94	0.11	<0.001	0.39	
Subgroup age 40-49					
Intervention arm			0.94		
No SMS					
Neut-SMS	0.11	0.13	0.395	1.12	0.87 – 1.45
GP-SMS	0.04	0.13	0.783	1.04	0.80 – 1.35
SN-pr-SMS	-0.05	0.13	0.688	0.95	0.73 – 1.23
SN-tot-SMS	0.02	0.14	0.876	1.02	0.78 – 1.33
Gain-SMS	0.05	0.13	0.735	1.05	0.81 – 1.36
Loss-SMS	0.05	0.13	0.688	1.06	0.81 – 1.37
IMD	0.03	0.01	0.018	1.03	1.01 – 1.06
Constant	-0.75	0.13	<0.001	0.474	
Subgroup 50-65					
Intervention arm			0.171		
No SMS					
Neut-SMS	0.04	0.15	0.765	1.05	0.78 – 1.40
GP-SMS	0.16	0.15	0.267	1.18	0.88 – 1.57
SN-pr-SMS	0.01	0.15	0.939	1.01	0.76 – 1.35
SN-tot-SMS	-0.2	0.15	0.174	0.82	0.61 – 1.09
Gain-SMS	0.17	0.14	0.223	1.19	0.90 – 1.58
Loss-SMS	-0.07	0.15	0.645	0.94	0.70 – 1.25
IMD	0.06	0.02	<0.001	1.06	1.03 – 1.10
Constant	-0.769	0.114	<0.001	0.464	

Subgroup analysis of level of deprivation

As for group 1, women in group 2 were segmented by their IMD rank into groups corresponding to national IMD rank thirds, quartiles and quintiles which were assessed for even distribution in terms of frequency by subgroup to enable subgroup

analysis with sufficient n-numbers to allow for analysis of women who have different levels of deprivation. IMD ranks were most evenly distributed in terms of frequency by segmentation group when segmented into thirds. The top third corresponds to women allocated to an IMD rank within the top third most deprived nationally (N=2,814). The intermediate third corresponds to women allocated to an IMD rank within the middle third level of deprivation nationally, (N=4,084) and lowest third contains women allocated to an IMD rank within the third least deprived ranks nationally (N=3,753).

Uptake in the control arm was 31.6%, 34.2% and 36.7% for the most deprived, intermediate deprived and least deprived thirds, respectively (X^2 (2) = 2.7, p = 0.259) reflecting a non-significant increase in uptake as deprivation decreases. There was no significant difference between the control arm and the combined SMS interventions by deprivation subgroup thirds (see Table 3.4.15)

Table 3.4.15 Uptake by deprivation subgroup, no SMS versus any SMS

	No SMS	Any SMS	X^2	p-value
Most deprived third % Attendance, (n)	31.6% (127)	33.6% (810)	0.614	0.433
Intermediate deprivation % Attendance, (n)	34.2% (207)	36.5% (1270)	1.242	0.265
Least deprived third % Attendance, (n)	36.7 (205)	39.2 (1253)	1.310	0.252

In the most deprived third, the neutral SMS intervention resulted in the highest observed participation rate of 39.2% compared to the control, which delivered a 7.6% point increase in uptake, however there was no significant difference across trial arms, (see Table 3.4.16). In the intermediate deprived third, the two messages with the highest attendance rates were the GP-message (40.3%) and the Loss framed message (40.1%), compared to the control of 34.2%, with a significant difference across trial arms of (X^2 (6) = 17,985, p = 0.006). In the least deprived third, all intervention arms produced a very similar 2-3% point increase in uptake from the control at 36.7%. Here, the most effective intervention arm was the GP-endorsed SMS reminder resulted in the highest observed participation rate at 40.0%, however no significant difference was found across trial arms in this subgroup.

Table 3.4.16 - Group 2 - ITT - Uptake by trial arm in deprivation subgroups

	No SMS	Neut-SMS	GP-SMS	SN-Pr-SMS	SN-tot-SMS	Gain-SMS	Loss-SMS	X^2	p-value
Most deprived third % Attendance, (n)	31.6% (127)	39.2% (164)	34.3% (135)	33.4% (129)	30.6% (118)	32.6% (142)	30.8% (122)	10.407	0.109
Intermediate deprivation % Attendance, (n)	34.2% (207)	35.2% (198)	40.3% (226)	30.8% (180)	34.7% (202)	37.9% (228)	40.1% (236)	17.985	0.006
Least deprived third % Attendance, (n)	36.7% (205)	40.0% (218)	39.4% (212)	39.9% (217)	38.1% (198)	39.9% (209)	38% (199)	2.245	0.896

The multivariate logistic regression by deprivation third showed that in the most deprived third, women receiving the neutral reminder were 1.43 times more likely to attend (95% CI 1.07 – 1.91, p = 0.02), see Table 3.4.17. For the intermediate level of deprivation subgroup, the GP endorsed and loss framed SMS resulted in an OR of 1.30 (95% CI 1.02 – 1.65, p = 0.03) and 1.28 (95% CI 1.01 – 1.62, p = 0.04), respectively for the GP endorsed and loss framed SMS, when compared to the control. In this subgroup, the proportionate Social Norms SMS was resulted in a reduced likelihood of attendance, however this was not statistically significant, (OR 0.86, 95% CI 0.67 – 1.09, p = 0.212). In the least deprived third subgroup, no significant intervention group differences were identified in the multiple logistic regression.

Table 3.4.17 - Group 2 - ITT – Multivariate logistic regression by deprivation subgroups

	B	S.E.	p-value	OR	95% C.I.
Most deprived third					
Intervention arm			0.114		
No SMS					
Neut-SMS	0.36	0.15	0.015	1.43	1.07 – 1.91
GP-SMS	0.14	0.15	0.369	1.15	0.85 – 1.54
SN-pr-SMS	0.1	0.15	0.523	1.10	0.82 – 1.49
SN-tot-SMS	-0.03	0.15	0.824	0.97	0.71 – 1.31
Gain-SMS	0.06	0.15	0.686	1.06	0.79 – 1.42
Loss-SMS	-0.02	0.15	0.922	0.99	0.73 – 1.33
Age	0.01	0.00	0.029	1.01	1.00 – 1.02
Constant	-1.19	0.22	<0.001	0.31	
Intermediate deprivation					
Intervention arm			0.008		
No SMS					
Neut-SMS	0.04	0.12	0.722	1.05	0.82 – 1.33
GP-SMS	0.26	0.12	0.032	1.3	1.02 – 1.65
SN-pr-SMS	-0.16	0.12	0.212	0.86	0.67 – 1.09
SN-tot-SMS	0.02	0.12	0.845	1.02	0.81 – 1.30
Gain-SMS	0.15	0.12	0.199	1.17	0.92 – 1.48
Loss-SMS	0.25	0.12	0.04	1.28	1.01 – 1.62
Age	0.01	0.00	<0.001	1.01	1.00 – 1.02
Constant	-1.13	0.17	<0.001	0.32	
Least deprived third					
Intervention arm			0.889		
No SMS					
Neut-SMS	0.14	0.13	0.257	1.15	0.90 – 1.47
GP-SMS	0.11	0.13	0.368	1.12	0.88 – 1.43
SN-pr-SMS	0.13	0.13	0.283	1.14	0.90 – 1.46
SN-tot-SMS	0.06	0.13	0.613	1.07	0.83 – 1.37
Gain-SMS	0.14	0.13	0.283	1.15	0.89 – 1.47
Loss-SMS	0.04	0.13	0.739	1.04	0.81 – 1.34
Age	0.02	0.00	<0.001	1.02	1.02 – 1.03
Constant	-1.55	0.18	<0.001	0.21	

Group 2 - Mobile phone number recording accuracy in electronic health records

As for group 1, GP practice level data of participant mobile phone number accuracy was available for the first 28 weeks of the trial. In Group 2, the mean percentage of correctly recorded mobile phone data, incorrectly recorded mobile phone number or no mobile phone data recorded by practice was 37.9% (SD ± 12.1%), 11.2% (SD ±

4.8%) and 51.1% (SD ± 13.9%), respectively. There was a large variation in correctly recorded data by practice with accurate mobile phone number records ranging from 0.9% – 61.8% in Group 2.

Per protocol analysis

A per protocol analysis (PPA) was performed using the first 28 weeks of trial data for which the SMS delivery status was available As for the PPA performed in group 1, no message was sent to the control group and thus no mobile phone data was available. Therefore all women allocated to this group were included in the per protocol analysis. By trial arm, 1,268, 437, 465, 481, 471, 497 and 485 women were analysed in the No SMS, Neut-SMS, GP-SMS, SN-Pr-SMS, SN-To-SMS, Gain-SMS and Loss-SMS respectively.

SMS delivery rates were compared between trial intervention arms in Table 3.4.18 using a chi-squared test, which revealed, no statistically significant difference between trial arms X^2 (5) = 6.733, p=0.462, although the gain and loss frame SMS arms did have non-significantly higher delivery rates of over 3% points compared to the neutral SMS. It is unclear as to why this may have been and may have been due to chance.

Table 3.4.18 - Group 2 - PPA - SMS delivery by trial arm.

	Neut-SMS	GP-SMS	SN-Pr-SMS	SN-tot-SMS	Gain-SMS	Loss-SMS	X^2	p-value
% SMS Delivered (n)	35.6% (437)	37.6% (465)	37.8% (481)	39.0% (471)	39.0% (497)	39.0% (485)	6.733	0.46

The uptake in the control arm was 34.1% (n = 432) compared to the uptake of 42.4% (n = 1203) in the intervention arms combined, X^2 (1) = 25.487, p < 0.001. There was a statistically significant difference between trial arms (X^2 (6) = 32.580, p < 0.001), with the highest observed participation rate of 47.4% seen in the loss framed SMS compared to 32.1% in the control, (See Table 3.4.19).

Table 3.4.19 - Group 2 - PPA - Uptake by trial arm

	No SMS	Neut-SMS	GP-SMS	SN-Pr-SMS	SN-tot-SMS	Gain-SMS	Loss-SMS	X^2	p-value
% Attendance (n)	34.1% (432)	42.8% (187)	42.2% (196)	40.7% (196)	39.9% (188)	41.4% (206)	47.4% (230)	32.580	<0.001

The multivariate logistic regression analysis (Table 3.4.20) shows that women who received any of the SMS reminder arms were significantly more likely to attend than women in the control arm. Here, the loss framed SMS resulted in a 1.76 fold increase in the likelihood of attendance (95% CI 1.42 - 2.18, p<0.001).
The total number SNs SMS appeared to be the least effective, yet still significantly higher attendance rates than the control arm (OR 1.32, 95% CI 1.06-1.65, p = 0.013). As age and IMD decile increased (i.e. as deprivation decreased) there was a small but significant increase in uptake with an OR 1.04, 95% CI 1.01 - 1.07, p = 0.003 and an OR 1.02, 1.01-1.02, p<0.001, respectively. The PPA therefore differs from the ITT analysis in that in the PPA the loss framed SMS resulted in the highest participation rate, whereas in the ITT the GP endorsed SMS had the highest participation.
Although, in the PPA the GP endorsed SMS also resulted in a significant increase in participation (OR 1.42, 95% CI 1.14 – 1.17, p = 0.002), both the neutral and loss framed SMS had higher ORs with respect to the No SMS control.

Table 3.4.20 - Group 2 - PPA - MLR analysis.

	B	S.E.	p-value	OR	95% CI
Intervention arm			<0.001		
No SMS					
Neut-SMS	0.39	0.11	0.001	1.48	1.18 - 1.85
GP-SMS	0.35	0.11	0.002	1.42	1.14 - 1.77
SN-pr-SMS	0.30	0.11	0.007	1.35	1.09 - 1.67
SN-tot-SMS	0.28	0.11	0.013	1.32	1.06 - 1.65
Gain-SMS	0.33	0.11	0.003	1.39	1.12 - 1.72
Loss-SMS	0.57	0.11	<0.001	1.76	1.42 - 2.18
IMD decile	0.02	0.00	<0.001	1.02	1.01 - 1.02
Age	0.04	0.01	0.003	1.04	1.01 - 1.07
Constant	-1.57	0.18	<0.001	0.21	

Further analysis was conducted to assess the impact of the different SMS interventions within the age and deprivation subgroups. To assess the exposure to the interventions in each subgroup a chi-squared test was performed on rate of SMS delivery by age group. There was a significant difference in SMS delivery rates

between age-subgroups, X^2 (2) = 48.344, p < 0.001. Only 31.5% of SMS were delivered in the 50-65 years subgroup compared to 41.2% and 38.7% in the 30-39 year and 40-49 year subgroups respectively, see Table 3.4.21.

Table 3.4.21 - Group 2 - SMS delivery rate by age-subgroup

	30-39 years	40-49 years	40-65 years	X^2	p-value
% SMS delivered (n)	41.2% (3266)	38.7% (2351)	31.5% (1844)	48.344	<0.001

There was also a significant difference in delivery of SMS by IMD subgroups, with the rate of delivery of 33.1%, 38.5% and 41.1% by most, intermediate and least deprived thirds respectively X^2(2) = 31.399, p<0.001.

Table 3.4.22 Group 2 - SMS delivery rate by deprivation subgroup

	Most deprived third	Intermediate deprivation	Least deprived third	X^2	p-value
% SMS delivered (n)	33.10% 1967	38.50% 2879	41.10% 2615	31.399	<0.001

PPA Age-group subgroups analysis

In the 30-39 year subgroup the there was a significant difference between trial arms with the loss framed message reaching the highest uptake at 46.5% compared to the control of 28.1%, X^2 (6) = 28.101, p < 0.001. In the 40-49 year and 50-64 year subgroups there was no significant difference between trial arms on the chi-squared test (X^2 (6) = 9.600 p < 0.143) and (X^2 (6) = 3.327 p = 0.767) respectively, see Table 3.4.23.

Table 3.4.23 Group 2 - PPA - Uptake by age-group subgroup

	No SMS	Neut-SMS	GP-SMS	SN-Pr-SMS	SN-tot-SMS	Gain-SMS	Loss-SMS	X^2	p-value
30 – 39 years % Attendance, (n)	28.1% (154)	39.4% (86)	38.8% (81)	38.1% (86)	36.9% (92)	37.9% (86)	46.5% (101)	28.101	<0.001
40 – 49 years % Attendance, (n)	35.4% (137)	45.8% (66)	42.0% (68)	40.3%% (60)	39.4% (54)	41.6% (67)	47.8% (75)	9.600	0.143
50 – 65 years % Attendance, (n)	42.5% (141)	46.7% (35)	50.0% (47)	47.2% (50)	49.4% (42)	48.6% (53)	48.6% (54)	3.327	0.767

Multivariate logistic regression shown in Table 3.4.24, shows that in the 30-39 year subgroup all intervention arms were significantly more effective than the control ($p<0.05$). However, the loss framed message had the highest uptake rates, corresponding to a 2.2 fold increase in the likelihood of attending screening compared to the control (95% CI 1.61-3.09, $p < 0.001$). Comparing the PPA here, to the ITT analysis above, shows that there is a discrepancy between the interventions arms with the highest participation rates. In the ITT analysis, the GP endorsed SMS had the highest observed OR of 1.34 (95% CI 1.07 – 1.69, $p = 0.12$) closely followed by the neutral SMS (OR 1.33, 95% CI 1.06 – 1.67, $p = 0.016$).

In the PPA, the loss frame also produced the highest participation rates in the 40-49 year subgroup (OR 1.67, 95% CI 1.15-2.43, $p = 0.008$), where the neutral SMS was the second strongest SMS (OR 1.54, 95% CI 1.04-2.27, $p = 0.03$), see Table 3.4.24. In the ITT analysis for the same age subgroup however, there was no statistical difference found in the regression analysis.

Table 3.4.24 Group 2 - PPA – Multivariate logistic regression by age-group subgroup

	B	S.E.	p-value	Exp(B)	95% C.I.
Subgroup 30-39 years			<0.001		
No SMS					
Neut-SMS	0.51	0.17	0.002	1.67	1.20 - 2.32
GP-SMS	0.48	0.17	0.005	1.62	1.16 - 2.26
SN-pr-SMS	0.45	0.17	0.007	1.57	1.14 - 2.18
SN-tot-SMS	0.41	0.16	0.012	1.50	1.09 - 2.06
Gain-SMS	0.45	0.17	0.007	1.56	1.13 - 2.17
Loss-SMS	0.80	0.17	<0.001	2.23	1.61 - 3.09
IMD decile	0.01	0.02	0.679	1.01	0.97 - 1.05
Constant	-0.99	0.15	<0.001	0.37	
Subgroup 40-49 years			0.150		
No SMS					
Neut-SMS	0.43	0.20	0.030	1.54	1.04 - 2.27
GP-SMS	0.27	0.19	0.161	1.31	0.90 - 1.9
SN-pr-SMS	0.20	0.20	0.324	1.22	0.83 - 1.79
SN-tot-SMS	0.16	0.21	0.423	1.18	0.79 - 1.76
Gain-SMS	0.25	0.19	0.186	1.29	0.88 - 1.88
Loss-SMS	0.51	0.19	0.008	1.67	1.15 -2.43
IMD decile	0.04	0.02	0.082	1.04	0.99 - 1.09
Constant	-0.84	0.17	<0.001	0.43	
Subgroup 50-65 years			0.865		
No SMS					
Neut-SMS	0.11	0.26	0.659	1.12	0.68 - 2.27
GP-SMS	0.26	0.24	0.278	1.29	0.81 - 1.91
SN-pr-SMS	0.16	0.23	0.483	1.17	0.75 - 1.79
SN-tot-SMS	0.23	0.25	0.352	1.26	0.78 - 1.76
Gain-SMS	0.25	0.22	0.266	1.28	0.83 - 1.88
Loss-SMS	0.22	0.22	0.327	1.24	0.81 - 2.43
IMD decile	0.09	0.03	<0.001	1.10	1.04 - 1.09
Constant	-0.89	0.20	<0.001	0.41	

In the 50-65 year subgroup the regression analysis did not show any intervention arm to be significantly more effective than the control arm, which was consistent with the findings of the ITT analysis.

PPA of the deprivation subgroups

The PPA of participation rates by deprivation subgroup is reported in Table 3.4.25. In the most deprived third, the chi-squared test showed no significant difference between trial arms, although the neutral SMS had the highest uptake at 46.9% compared to

32.6% in the control arm, (X^2 (6) = 10.176, p = 0.117). The lack of significance here, may reflect a small sample size as the trial was not powered to for this subgroup analysis.

In the intermediate deprivation subgroup the chi-squared test showed a significant difference between arms, with the loss framed and GP endorsed SMS reminders resulting in the highest observed participation rates of 51.0% and 47.7% respectively, compared to 32.6% in the control arm (X^2(6) = 28.799, p<0.001).

In the least deprived subgroup, the loss framed SMS resulted in the second highest attendance rate of 47.7%. Here, the SMS with the highest observed participation rate was the proportionate SNs SMS, with an uptake of 48%, (X^2 (6) = 11.165, p = 0.083) which is surprising as it had the lowest participation rate of the intervention arms in the intermediate deprivation subgroup at 36.2%.

Table 3.4.25 - Group 2 - PPA - Uptake by trial arm by deprivation subgroups

	No SMS	Neut-SMS	GP-SMS	SN-Pr-SMS	SN-tot-SMS	Gain-SMS	Loss-SMS	X^2	p-value
Most deprived third % Attendance (n)	32.6% (104)	46.9% (46)	34.9% (37)	37.4% (37)	30.9% (34)	31.7% (39)	40.9% (47)	10.176	0.117
Intermediate deprivation % Attendance (n)	32.2% (155)	40.7% (66)	47.7% (82)	36.2% (75)	40.3% (73)	44.0% (84)	51.0% (100)	28.799	<0.001
Least deprived third % Attendance (n)	37.0% (173)	42.4% (75)	41.2% (77)	48.0% (84)	45.0% (81)	45.4% (83)	47.7% (83)	11.165	0.083

The multivariate logistic regression by the deprivation subgroups is presented in Table 3.4.26. In the most deprived subgroup the neutral SMS resulted in an almost two-fold increase in participation, which was statistically significant (OR 1.91, 95% CI 1.12-3.03, p = 0.006). No significant difference was noted between other intervention arms and the control. This is consistent with the findings from the ITT analysis.

In the intermediate deprivation subgroup the loss-framed SMS showed 2.2 fold increase in the likelihood of participation (OR 2.2, 95%CI 1.56-3.08, p<0.001), with the GP endorsed SMS resulting in a 1.9 fold increase, (OR1.92, 95% CI 1.35 – 2.74, p < 0.001). However, in this subgroup all SMS interventions resulted in a statistically significant increase, except the proportionate SNs SMS.

Table 3.4.26 - Group 2 - PPA – Multivariate logistic regression analysis by deprivation subgroup

	B	S.E.	p-value	Exp(B)	95% C.I.
Most deprived third			0.096		
No SMS					
Neut-SMS	0.65	0.24	0.006	1.91	1.12 - 3.03
GP-SMS	0.14	0.24	0.569	1.15	0.72 - 1.82
SN-pr-SMS	0.24	0.24	0.319	1.27	0.79 - 2.04
SN-tot-SMS	-0.03	0.24	0.888	0.97	0.60 - 1.55
Gain-SMS	-0.02	0.23	0.941	0.98	0.63 - 1.54
Loss-SMS	0.39	0.23	0.084	1.48	0.95 - 2.30
Age	0.01	0.01	0.105	1.01	0.99 - 1.03
Constant	-1.27	0.36	<0.001	0.28	
Intermediate deprivation			<0.001		
No SMS					
Neut-SMS	0.37	0.19	0.048	1.45	1.00 - 2.09
GP-SMS	0.65	0.18	<0.001	1.92	1.35 - 2.74
SN-pr-SMS	0.18	0.18	0.300	1.20	0.85 - 1.69
SN-tot-SMS	0.36	0.18	0.047	1.43	1.01 - 2.04
Gain-SMS	0.50	0.18	0.004	1.65	1.17 - 2.33
Loss-SMS	0.79	0.17	<0.001	2.20	1.56 - 3.08
Age	0.00	0.01	0.553	1.00	0.99 - 1.02
Constant	-0.89	0.26	0.001	0.41	
Least deprived third			0.066		
No SMS					
Neut-SMS	0.28	0.18	0.129	1.32	0.92 - 1.88
GP-SMS	0.19	0.18	0.292	1.21	0.85 - 1.71
SN-pr-SMS	0.46	0.18	0.010	1.59	1.12 - 2.27
SN-tot-SMS	0.37	0.18	0.037	1.45	1.02 - 2.07
Gain-SMS	0.40	0.18	0.026	1.49	1.05 - 2.11
Loss-SMS	0.43	0.18	0.017	1.54	1.08 - 2.20
Age	0.03	0.01	<0.001	1.03	1.02 - 1.04
Constant	-1.87	0.27	<0.001	0.15	

In the least deprived subgroup the regression analysis showed a 1.59 fold increase in the proportionate SNs SMS (OR1.59, 95% CI 1.12 - 2.27, p = 0.01), closely followed the loss framed SMS (OR 1.54, 95% CI 1.08 - 2.20, p = 0.017). However, the gain-framed SMS and the total number SNs SMS also showed significant increases in uptake (OR 1.49, 95% CI 1.05 - 2.11, p = 0.026) and (OR 1.45, 95% CI 1.02 - 2.07, p = 0.037), respectively.

3.5. Discussion

To my knowledge, this is the first trial that investigates the impact of adding different behavioural science informed message content to SMS reminders in cervical screening. In particular, it is the first trial that measures the effect of a simple SMS reminder, GP-message, social norms and message framing within SMS reminders on participation rates for cervical screening.

3.5.1. Main findings

Overall ITT and PPA

The uptake in the control arm for both the younger and older age groups were comparable to those identified for an individual screening round in Hillingdon in 2013.(198). Intention to treat analysis shows that by sending women aged 24-29 years and 30-64 years an SMS reminder for cervical screening, an absolute increase in participation rates of 5% and 4% respectively can be achieved. The regression analysis in both groups shows that younger women and those who are more deprived are less likely to participate in screening than older and more affluent women. This is consistent with national data.(3) In younger women aged 24-29 years, there was an absolute increase in participation of over 14% in women who actually received an SMS. Whereas in older women (aged 30 years and older), there was an absolute increase of 8.3% between women not allocated to receive an SMS and those women who actually received any SMS.

In the older age group, the most effective SMS was the GP SMS, however this was closely followed by the neutral SMS. Although the impact of the GP message is in keeping with evidence for GP endorsements in cervical screening (121, 174, 200, 201), it is important to note that the word content of the SMS intervention tested (see Table 3.3.1), was an implicit GP endorsement, which was from the GP practice rather than from an individual practitioner. This word content was deliberate, as firstly, given that GP practices frequently house more than one general practitioner, patients frequently do not see their named GP or the same GP repeatedly. It is therefore possible that sending an SMS with an endorsement from a ‘Dr X’ with whom the

patient may not have a relationship, may have a detrimental effect on participation. It was therefore deemed that the more suitable that endorsement would come from the GP practice, as most patients would recognise the practice name with at they were registered. An important consideration was also the need to present non-coercive information, and the implicit endorsement was deemed to be a clear endorsement by the panel involved in the message content design, whilst not overly imposing. It is possible however, that both of these accommodations may have resulted in a less persuasive message, thereby undermining the potential impact an explicit endorsement from a named GP might have had.

Overall, the gain and loss framed SMS shared vary similar rates of participation as did the social norms SMSs. However, in the ITT analysis the proportionate and total social norms messages (uptake of 34.7% and 34.8% respectively) did not improve participation much beyond the control arm of not receiving any SMS (uptake 34.4%). Consistent with the ITT analysis, in the PPA the SNs reminders also resulted in the lowest participation rates across the intervention arms. This is unexpected given the amount of evidence that supports social norms in other clinical settings and social.(89, 128, 204, 205) However, as described above (see section 3.3.3) much support for the role social norms play in enabling attendance at screening comes from qualitative research using interview and survey studies on beliefs and barriers.(73, 132-134) However, little evidence exists that has tested the use of social norms as an intervention tool to improve cervical screening participation in robustly designed RCTs. The low participation rates observed in the two SN trial arms, might have arisen for a number of reasons; Firstly, it may be that using the '7 out of 10' proportion and '12,000 women' total number, did not represent a high level participation rate to women considering attending and therefore does not provide a sufficient shift in their expectation of other women' s participation rate (i.e. the 7 out of 10 women is a participation rate that they would have expected). This has been recognised in the literature. *Cialdini et al*. highlighted that by providing evidence that more people than expected, behaved in a less desirable way (in this case 3 in 10 not taking part in cervical screening) may in fact result in individuals feeling justified in not participating.(135)

Equally, it is possible that social norms work better on more publically discussed or visual behaviours such as smoking or alcohol consumption, where people are more

likely to see a behavioural norm reinforced by visualising others taking part. As cervical screening is a very personal and intimate activity it is possible that social norms are not an effective way to change such a behaviour. Thirdly, it is possible that although SNs has proven a powerful tool in other settings, it is not as strong a tool to enable participation as other tools tested in this trial, such as loss frame or GP-messages.

The ITT analysis showed that there was little difference in the elevation of participation rates when comparing the gain and loss framed intervention SMS (2.7% and 2.6% points, respectively) to the control. In the context of message framing in breast screening, evidence outlined in section 3.3.3 highlights that loss framing would be expected to result in a slightly but significantly higher impact than gain framing, as breast screening is largely considered a diagnostic rather than preventative behaviour. (142, 145, 147) However, cervical screening is considered to be both preventative and diagnostic. Therefore, public perception of cervical screening in terms of being predominantly preventative or diagnostic may affect whether gain or loss framing will be more effective at improving participation rates.

Further evidence has outlined how other characteristics of behaviour such as frequency and personal risk perception may play a role in the effectiveness of message framing. Loss framed messages are expected to be more effective than gain framed messages in more infrequent behaviours, e.g. human papilloma virus vaccinations.(177) Whereas other evidence has shown that women with medium to high risk perceptions may be more susceptible to loss framing.(148) It is therefore possible that in terms of the ITT analysis the rates of attendance in the gain and loss framed interventions were very similar as other factors may be at play (the frequency of behaviour, personal risk perception and public perceptions of preventative versus diagnostic benefits of cervical screening) each suggest a different relative advantage of gain or loss, leading to no clear advantage of one over the other.

However, in the PPA the loss framed SMS was the most effective overall, showing a surprising difference in participation compared to the ITT analysis. As the accuracy of mobile phone numbers was not statistically different between trial arms, one would expect that any message in the ITT analysis would have a similar factor increase in terms of the magnitude of impact in the PPA. This was not the case, with other intervention arms showing a similar magnitude of increase to each other, in terms of

impact, which was not congruent with the increase seen in the loss framed SMS arm. It is possible that the true effect of the loss faming word content is such that it results in a much higher increase in participation overall, however one would expect for this to also be reflected in the ITT analysis. For this reason the results of PPA in this case should be treated with caution.

Participation by age and deprivation

The most effective SMS differed by degree of deprivation and by age. In the younger group (24-29 years), the analysis by deprivation subgroup showed in both the ITT and PPA that the biggest impact on attendance was seen in women in the most deprived third, (33% and 96% relative increase, respectively). In the younger group the uptake in the control arm, when segmented by level of deprivation, showed a trend toward lower participation in women who were more deprived, which approached statistical significance. This trend was mitigated in the intervention arms, which may indicate that SMS reminders could have a bigger impact on women who are more deprived and highlights that GP-endorsed SMS reminders may play a role in reducing the inequality gap in cervical screening participation. This is consistent with a previous finding; *de Noorijer et al*. reported a large study carried out in the Netherlands that also found that GP-endorsed interventions preferentially improved participation in younger women and those from lower socioeconomic groups as well as ethnic minorities. (121)

In the older group (30-64 years), the baseline participation rate in the control arm was statistically significantly lower in the lower age subgroup (30-39 years). Interestingly, this group (30-39 years) was also the only group that observed a significant increase in the combined intervention arms. Although this may be in part a reflection of the fact that the mobile phone number accuracy was significantly higher in this age group (41.2% in 30-39 year olds versus 38.7% in 40-49 year old and 31.5% in 40-65 year olds), the PPA also indicated that only in the 30-39 year old was there a significant difference between trial arms ($p<0.001$). This indicates that younger women may be more responsive to cervical screening SMS reminders than older women.

In the intention to treat analysis, younger women (30-39 years) seem to be most likely to attend after receiving a GP endorsed SMS, with none of the SMS intervention arms

being more effective than the control in the older age subgroups. However, in the PPA the loss framed message emerged as the most effective SMS in women aged 30-49 years. In women aged 50 – 65 years none of the intervention messages were significantly better than the control in either the ITT analysis or the PPA. In the ITT this may in part reflect the lower mobile phone number availability in this age subgroup, making it more difficult to detect a significant difference in uptake. However, the fact that no difference was observed in the PPA, also indicates that this age group may be less likely to respond to an SMS relating to cervical screening and may prefer a different channel of communication in terms of health messages. This possibility is supported by the observation that overall the percentage increases were smaller in this age group in the PPA.

In the deprivation subgroup analysis, the mobile phone coverage was lowest in women in the most deprived group (33.1% in the most deprived third, 38.5% in the intermediate deprivation level, and 41.1% in the least deprived third). Yet in the PPA this group saw the biggest absolute increase in participation (18.4%), compared to 13.4% and 7.5% in the intermediate and least deprived thirds, respectively. This may indicate that if women in the most deprived groups actually receive an SMS, they are more likely to attend than women who are less deprived.

Furthermore, the content of the SMS mattered in terms of deprivation. Women who are more deprived were most likely to attend if they receive the simple neutral SMS reminder both in the ITT and per PPA. Whereas women of intermediate deprivation were most likely to attend if they received a GP-endorsed or loss framed SMS in the ITT analysis. In the PPA both the GP-endorsed and loss framed messages remained the most effective, with the loss framed SMS taking the lead.

Women who were in the least deprived third did not show any significant improvement in participation if randomised to an intervention arm compared to the control in the ITT analysis, however in the PPA both the proportional social norms SMS and the loss framed SMS were the most effective. As described above, the PPA does reveal some inconsistency in terms of the impact of different SMS reminders on participation compared to their impact in the ITT. Furthermore, as will be highlighted below, the particularly low rate of mobile phone coverage in this trial highlights the lack of mobile phone data held by GP practice IT systems. Therefore, the impact size seen in the PPA analysis may well be difficult to reproduce in the real world without

first addressing mobile phone number accuracy and availability on GP patient electronic health records. For this reason the ITT analysis is considered more reliable, particularly in terms of potential anticipated impact that might be seen, should such interventions be adopted into local practice.

3.5.2. Mobile phone number accuracy

It is important to note that the rates of mobile phone number accuracy differed significantly between age-subgroup and deprivation subgroups. Women who were younger, or who were less deprived were more likely to have an accurate phone number recorded on their GP's IT system. These women were therefore more likely to actually receive the SMS they were sent. This may explain in part why older women do not respond as well to SMS interventions as younger women. However, it is encouraging to note that despite women in the most deprived subgroup having the lowest percentage of phone number accuracy, when younger women (aged 24-29 years) were allocated to an intervention arm there was no significant difference in participation compared to women who were less deprived and also allocated to an intervention arm. This indicates that SMS reminders may have a role in reducing inequalities in terms of communication delivery that reminds women to take part in screening.

The results however, also indicate that many GP practices may not be routinely recording, checking and updating mobile phone number data of their patients. The availability of accurate mobile phone data means that the impact seen in the above results may be underestimating the potential impact of SMS interventions, as a large proportion of women allocated to an intervention arm did not receive an SMS. Statistics published by Ofcom indicate that 93% of the public in the UK uses a mobile phone and SMS messaging is almost ubiquitous amongst mobile phone users.(206) It is likely that a small proportion of the patients whose mobile phone number was not recorded represent those who have chosen to not share their mobile phone number with their GP or requested it not be used by a third party. Patients maintain the right to not give their mobile number to their GP or request that it is not passed on to third party companies. However, it is also likely that GP practices are not putting an

emphasis on collecting mobile phone data. Another important issue is that mobile phone numbers that are already recorded, may not be routinely checked by GP administration staff. This is highlighted in the rate of inaccurate phone numbers recorded ranging from 0% to 28%. However, it is plausible that such mobile phone numbers are correct in terms of numerical accuracy, such that they can be read by practice staff, but have been recorded with hyphens, brackets or accidental additional letters or punctuations such that computer software cannot read them. Nonetheless, using SMS reminders through companies like iPLATO, which have the capability to measure message delivery, allows researchers and healthcare providers to monitor the delivery of communications to the target audience. This is less easy when communicating through letters, as although it would be possible to track the correct address and receipt of a letter through for example 'signed for' letters, such an approach would be expensive and labour intensive, and therefore difficult to scale. Mobile phone SMS therefore, provides a promising channel of communication for communicating healthcare information. It is therefore important that as much emphasis is put on recording mobile phone numbers as on postal addresses of patients, if SMS communications are to be effective in healthcare going forward.

3.5.3. Limitations

The behavioural techniques used for the SMS interventions and their content were selected and informed by an expert panel. It is possible therefore that particular barriers or enablers unique to this population may not have been considered when designing the text message content. A more effective word content or behaviour change technique might therefore be available. It is important to consider how best to assess barriers, enablers and behavioural biases to a target behaviour within a population and how then to transform and incorporate such insights into the design process of interventions for such a trial.

Due to the sample size requirement and time constraints it was not possible to test more than one message in group 1. It would be useful to test subgroups such as women aged 24-29 year, with other SMS reminder content to assess how other behaviourally informed messages affect uptake within this age group. The call/recall

team was unable to identify which participants were being invited for their first screen and therefore we created group 1 as a proxy for the first invitation as women would become eligible for screening based on their age. It is possible that some women in this group were being invited for their second or subsequent smear. However, to enable an adequate sample size to be achieved within the time-limits the age range of 24-29 was selected. This is also the same age group that is reported in the NHS CSP national audit data annually and therefore, provides an easy reference group to whom the interventions would be directly relevant.

SMS reminders were sent out in the third week following the invitation letter to allow enough time for women to receive and act upon the information leaflet containing information on how to opt out of the trial. Unfortunately, it was not possible to identify women who had already made an appointment and had their smear test prior to receiving the SMS reminder. While this is a potential source of noise in the data, it would be expected that the proportion of women making their smear test prior to receiving the SMS would not differ by trial arm, and this should therefore not have had an impact on the results of the study.

Consideration of the best channel of communication is key. It is possible that the same message content tested in other channels, such as email or letter might have a different impact in different subpopulations of women, such as those in different age groups. It is possible for example that older women may prefer letter communications or be more likely to open letter mail, whereas younger women might prefer SMS or email communications.

3.5.4. Future research

It is clear from the results of this study, that demographics and socioeconomic factors affect how women respond to different SMS content. National screening coverage data also highlights that uptake varies considerably by geographical region.(3) It is well recognised that barriers and enablers to cervical screening vary by demographic, geography and personal beliefs.(3, 16-20, 45, 47, 65, 67, 73) Future research may choose to incorporate geographically and socioeconomically assessed factors

affecting screening when designing interventions. It would be of interest to test such an intervention against the most successful SMS reminder content in this trial.

Furthermore, it would be of interest to consider testing a 'kitchen sink' approach by combining the content of the two most effective SMS reminders (GP message and loss frame) to assess their combined power to improve uptake and compare this to their individual impact. However, the 160 character limit of SMS reminders may make the content drafting challenging.

In the longer term, screening services should strive to consider individual patient preference in terms of selecting the communication channel. Such services exist outside the healthcare sector, in other industries such as personal banking or online shopping, where the consumer can select their preferred communication channel going forward, e.g. phone, email, and text message. However, the service provision infrastructure does not yet have the capability to provide individualised communication channel preferences, and so it may take some time before such preferences can be measured and utilised by the NHS.

3.5.5. Generalisability

This trial had a large sample size, however low levels of accurate mobile phone numbers may mean the study was underpowered. As this study was run in an area of London of relative affluence (median IMD decile was 5.9 compared to 3 in the trial reported in chapter 2), it would therefore be informative to repeat such a trial within a geographically and socio-economically diverse population. While the results may be likely to be generalisable, further studies are recommended to ensure results are reproducible in other geographically and socioeconomically diverse area.

3.6. Conclusions

SMS reminders can significantly improve cervical screening participation rates. However, the content of such reminders matters. Overall, the most effective message content was a GP-message. Women of different demographic and socio-economic

characteristics appear to react differently to the SMS content. Women of higher levels of deprivation were more likely to attend after a neutral reminder, whereas women of intermediate deprivation responded better to a GP-endorsed or loss framed SMS. Women under the age of 39 were more likely to respond to a GP-message. This indicates that to maximise effectiveness, consideration of such factors is important when choosing the content. Currently, screening programmes provide a one-size-fits-all approach to invitations and reminders, however this research suggests that a more targeted approach based on subpopulation characteristics may be effective at improving uptake to screening. Lack of phone number availability is likely to undermine the efficacy of such SMS reminders. Therefore, considering measures to improve availability and accuracy of mobile phone number data will be key to maximising the benefits of SMS reminders. As trends suggest that the public continue to shift their routine communication channels from letters to mobile phone and digital media, the healthcare system must strive to keep up and consider ways to capitalise on this change. A first step might be efforts to increase the emphasis on having mobile phone numbers and email addresses as part of essential patient information, alongside postal addresses.

4. Predictors of breast screening participation; an online survey

4.1. Summary

Background

Breast cancer affects 1 in 8 women in the UK, accounting for 31% of all cancers and 15% of cancer deaths in women. In 2014, breast screening coverage for London was only 63%, falling below the national average (73%). This survey aims to measure psychological and behavioural factors influencing attendance at breast screening.

Methods

A survey containing 98 items corresponding to 15 behavioural domains was designed, based upon the Theoretical Domains Framework,(111) to investigate behavioural factors affecting breast screening participation. The online survey was distributed to women who were eligible for breast screening and aged 47-73 years in London, South East and West England. The pilot and full surveys were assessed for internal validity. The impact of the behavioural domains were assessed using logistic regression to predict self-reported history of attendance and intention to attend future screening opportunities, which are known predictors of future attendance.

Results

78 and 922 women returned the pilot and full survey, respectively. Of the 922 women, 88.6% (817) reported intending to attend in the future. Of the women who had previously been screened (822), 88.1% (722) reported having attended screening regularly. 'Behavioural regulation' was the strongest predictor of previous screening attendance (OR 1.92, 95% CI 1.46-2.53, $p<0.001$) as well as of intention to attend (OR 1.56 95% CI 1.16-2.10, $p=0.003$). The emotional consequences domain was the strongest predictor of not intending to attend screening (OR 0.68, 95% CI 0.53-0.88, $p=0.003$), followed by Environmental context (OR 0.66, 95% CI 0.53-0.82, $p<0.001$).

Conclusion

This survey comprehensively categorises behavioural factors affecting screening participation and measures their predictive strength for previous participation and

intention to attend future screening. The results informed the design of behavioural interventions aimed at improving participation rates.

4.2. Introduction

4.2.1. Breast screening participation trends

In the UK breast cancer is the most common female cancer, affecting 1 in 8 women, accounting for 31% of all cancers and 15% of cancer deaths in women.(207) Mammographic breast screening is offered every three years to women aged 50-70 years, to aid early detection of breast cancer at a time when treatment is more likely to be curative.(6) An age-extension programme that also invites women aged 47-49 and 71-73 years is currently being rolled out regionally and will become national practice in the near future.

In 2015, when this study was conceived, the national breast screening coverage was 75.4% for women in England. In the same year, coverage for London was only 69.3%, falling below both the national average and the national target uptake of 70%.(208) Over the past five years, coverage rates both nationally and in the capital have shown a continuing downward trend.(209) (see Figure 4.1)

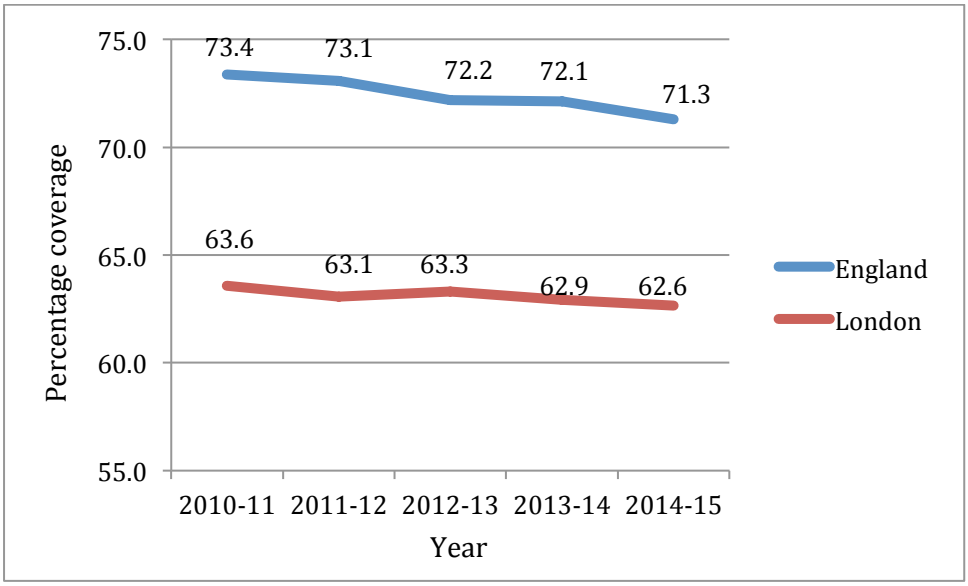


Figure 4.1 Five-year trend in breast screening coverage in England (209)

As discussed in chapter 1, the success of any screening programme relies amongst other factors on the participation of the screening programme by the asymptomatic but 'at risk' target population.(14)

4.2.2. Previous work to improve uptake

Across the three cancer screening programmes (breast, bowel and cervical cancer), there has been considerable previous work to investigate the barriers and enablers to participation, and to test interventions to improve engagement. (19, 22, 26, 45, 47, 210) Past research has highlighted logistical, cognitive and emotional barriers that can impede attendance at mammographic screening.(45) Several trials have used behavioural interventions to try and increase participation rates. These have focused on health communication content, (e.g. endorsement letters, message framing(64, 120, 211)) channel of communication (e.g. reminder letters, text messages and phone calls(154, 157, 158, 212) and efforts to reduce the burden on women intending to attend (e.g. providing timed appointments(93, 94, 137)). These interventions have demonstrated varying degrees of effectiveness (see chapter 1). The intervention design process for such trials was often informed by selecting a single factor (e.g. reminders) from previously barriers reported in the literature (e.g. forgetfulness)(157) to inform the behavioural target, or focused on non-psychological factors influencing screening such as language and ethnicity(64). Often these studies did not state how their interventions were informed.(154, 212) The intervention design that informed the behaviour change tools deployed in the trials described in chapters 2 and 3 also did not attempt to measure behavioural barriers, enablers and biases to cervical screening as they were informed by the MINDSPACE framework. *Michie et al*. recognised that efforts to design behaviour change interventions are often led from the individual researcher or institution, and are often not based on theories of behaviour change or a thorough understanding of the breadth of measured intrinsic and extrinsic barriers and enablers of such behaviour.(112) It is possible that a more important behavioural target that might result in effective behaviour change, might not be selected as a trial intervention.

As a result, the methodology used to select the target behavioural factors, which informed the intervention design for both previous RCTs reported in this thesis might be criticised. While a literature review informed the intervention design targets in terms of potential behavioural barriers and enablers, there was no attempt to examine the prevalence or strength of these behavioural factors in the target population for whom these interventions were designed. Furthermore, no single comprehensive effort was made to catalogue and measure all possible behavioural factors that might influence the decision to attend. Instead, they were selected by an expert panel. As *Michie et al.* highlights, it is therefore possible that key behavioural barriers or facilitators to attending cervical cancer screening were not considered while designing the intervention, or that behavioural constructs were included in the intervention design which are not relevant, or only weakly related to, cervical screening.(111) Therefore, despite much pre-existing evidence to highlight different barriers and enablers to breast screening, this chapter describes an online survey informed by the Theoretical Domains Framework (TDF). The survey measures the predictive strength of different behavioural factors of two outcome variables of history of attendance and intention to attend screening in the future. Both of these variables are known predictors of future attendance.(40, 41, 131, 213)

Michie et al.'s validated Theoretical Domain's Framework (TDF) is a comprehensive theoretical framework, which consolidates domains from 33 psychological theories.(111) It provides a tool to comprehensively catalogue psychological domains that can influence any target behaviour of either healthcare providers or health care users. In its original form the TDF items were grouped into 12 behavioural domains that measures behavioural concepts deemed to influence behaviour.(172) These were expanded to include 14 domains in a later validated iteration of the framework and can be used to structure qualitative research such as focus groups or interviews, but also to inform the design quantitative research such as surveys and questionnaires.(111) This framework was therefore applied to design a survey to measure and catalogue behavioural barriers and enablers into psychological domains that influence to breast cancer screening participation. The insights gained through the survey were then used to identify specific behavioural domains that were deemed to be strong predictors of attendance at screening in the target population, which informed the intervention design and were then tested in an RCT (see chapter 5).

The application of the TDF is intended for both qualitative research as well as quantitative research through questionnaires.(111) Although public opinion regarding cancer screening including mammographic screening is generally very positive (1), there has been much public and academic debate on the risk-benefit ratio of breast screening, which in turn has generated some strong and polarised viewpoints. (6, 10, 36) Therefore, to avoid research participants being subject to social desirability bias (i.e. the tendency to provider answers that they feel are socially desirable rather than those that their reflect true feelings or opinions), the delivery method chosen was an online survey, rather than focus groups facilitated by healthcare professionals or researchers.(88) This method also allowed for the selection of screening eligible women in a broader geographical area that included the location where the future intervention study would take place.

4.3. Methods

4.3.1. Aim

The aim of this study was to develop and test a comprehensive questionnaire to measure barriers and facilitators of breast screening uptake, as well as to use this questionnaire to investigate the factors that predict screening intention and past screening attendance.

4.3.2. Study design

The survey constructs (also referred to as domains) were informed using the TDF.(111) Where appropriate the choice of survey items used to measure a construct was informed by a literature review of existing barriers to mammographic screening. This ensured comprehensive coverage of possible factors affecting screening uptake. Socio-economic and demographic characteristics collected included age group, region, level of education, employment, ethnicity, household income and marital status.

The survey was piloted on a smaller number of recipients with a target sample size of 75 respondents. Initial analysis using Cronbach's alpha was performed to ensure that items were appropriately placed within behavioural domains, that these domains had sufficiently high internal validity and to identify items that were unnecessary and could be removed in order to reduce the survey length and therefore participant burden.

The final survey was then sent to further respondents to reach a total sample size of 1000 women. The survey was distributed online by a social marketing company; Bilendi, which hosts an online survey platform and which invited eligible women to participate via email.(214) Participants were reimbursed for their time through online tokens. Data analysis was performed to measure the survey validity and to assess how domains predicted two outcome variables: self-reported history of attendance and intention to attend.

Survey domain measures

The pilot survey contained 98 items of which 54 items assessed constructs from the TDF, two items assessed outcome measures (see section 0 below) and seven items assess socio-economic and demographic characteristics. Nine items were open-ended questions that could be answered with free-text, and sought to establish that other items included in the survey were not missing key behavioural barriers or enablers to screening. For example, these were to establish that the items included in the social norms domain asked about relevant 'other people' who might influence their decision. Such as: 'Are there people or types of people who would approve/disapprove of you attending a screening mammogram? Please specify.' The answers to these questions were examined and were not found to have potential factors that were not already assessed elsewhere in the survey. The questions were removed from the full survey. Twenty-six further questions were included in the pilot and full survey but not included in this analysis. These included; items on screening habits such as the number of previous mammograms attended, participation in other cancer screening programmes and the use of private mammograms, items on personal risk factors such as family history or previously abnormal mammograms, items assessing the number of adolescent or adult dependants within the individual's household and items assessing the frequency in which individuals change their address, mobile phone

number or general practitioner. Fourteen domains selected for the survey, were informed by the TDF and deemed relevant to breast screening behaviour. The fifty-four survey items that were allocated to the 14 conceptual theoretical domains were designed to test each domain. They were designed and allocated by two researchers including the author of this thesis and a behavioural psychologist. Any disagreement over an item placement within a domain was resolved through discussion. The only domain in the TDF, which was not included as a psychological domain (as an independent variable) in this study was the 'Intention' domain. This is because the 'Intention' domain was used as one of two outcome variables alongside 'History of attendance'. After a review of the literature it was decided that a fourteenth domain on 'Dread' would also be included. The domains were: Knowledge, Skills, Social role and identity, Beliefs about capabilities, Beliefs about consequences, Optimism, Reinforcement, Goals, Memory and Attention, Environmental context, Social influences, Emotion, Behavioural regulation and Dread. Response options were based on a seven point Likert scale where possible.(215) Where a Likert scale was not possible or appropriate a multiple choice option was used. Negatively framed questions were included to encourage evaluation of each question individually.(216) These were reverse coded before proceeding with data analysis.

Outcome measures

The outcome measures were self reported previous attendance at screening and intention to attend future screening rounds. Previous attendance was measured with an item that asked: 'In the past I have attended a screening mammogram whenever I have been invited'. The item was assessed with three possible answers: 'Yes, always', 'Yes, sometimes' and 'No, never'. The 'Yes, sometimes' and 'No, never' answers were grouped to create a binary variable containing an 'infrequent or non-attenders' group, compared to the 'Regular attenders' group (those who responded 'Yes, always'). Intention to attend future breast screening rounds was assessed with one item that asked: 'If/When I am invited for a screening mammogram I will definitely attend. The item was assessed with three possible answers: 'Yes', 'No', 'I don't know'. The 'No' and 'I don't know' answers were grouped to create a binary variable containing an 'non-intenders' group, compared to the 'Intenders' group (those who responded 'Yes').

Participants and setting

Inclusion Criteria

Women of screening age (47-73 years) in the London, South West and South East England area were invited to participate in the survey through Bilendi.(214)

Exclusion Criteria

Men were not invited to complete the survey. Women who declined to participate in the survey or did not consent to their answers being included in the research were excluded prior to the survey commencing. Women who were not eligible for breast screening (e.g. women who had undergone a bilateral mastectomy) were excluded from the study.

Withdrawal Criteria

Women were able to withdraw from the survey at any point whilst completing the survey until it is submitted, by abandoning the survey. Incomplete surveys were treated as withdrawals and therefore not included in the analysis.

Consent

A participant information page was presented to respondents at the beginning of the survey. This informed participants that the results would be used as part of a research study and stated that any incomplete surveys would not be included in the research. The information page also asked respondents to tick a consent box to be included in the research. Any participants who did not tick the box were unable to continue to the survey and were therefore excluded.

Ethical approval

Ethical approval was sought from the Imperial College Research Ethics Committee. ICREC reference number: 15IC2710.

Sample size calculation

The sample size for the total survey (pilot and full survey) has been calculated at 1000 respondents, based on the number of survey items of 98, and the general requirement of approximately 10 survey responses per question for Principle Component Analysis (PCA) to be feasible.(217)

4.3.3. Data analysis

The survey results were analysed using *IBM SPSS Statistics 22* using Cronbach's Alpha (CA), PCA and a backwards stepwise logistic regression (BSLR) analysis.

Cronbach's Alpha

Cronbach's alpha was used to assess the internal consistency of different items within each domain, to ensure that items within a domain are testing the same or similar construct. A target CA value of 0.7 or above was deemed acceptable.(218, 219) Where this was not achieved in the pilot or where an item did not substantially improve the CA, constructs were removed, in order to reduce the number of items and therefore the participant burden. Where a construct was consistently below the 0.7-threshold new questions were developed to test in the full survey. CA analysis was repeated on responses in the final survey.

Principle Component Analysis

A parallel analysis is a method used to determine the number of factors or domains to extract during the subsequent Principle Component analysis.(220) It has the advantage over inspection of the Scree plot, because it does not rely on visual inspection of the Scree plot and allows a calculation to determine the statistically significant number of domains to extract. PCA is a data reduction technique, which was then performed to confirm the item content of each domain, by extracting the fixed number of domains identified by the parallel analysis.

Logistic backward stepwise logistic regression

Once the domain content was finalised, a new variable was created to represent the mean responses to the items within each theoretical domain. This was calculated by adding the scores of each item within a given domain and then dividing by the number of items within that domain.

Alongside the survey constructs that contribute to the theoretical domains, questionnaire recipients were also asked about their history of attendance (self-reported) and intention to attend future screening opportunities, as well as demographics and socio-economic variables. These included: age, geographical region, level of education, employment characteristics, ethnicity, household income and marital status, which may also affect participation in screening.(209, 221, 222)

Tests of normality including Box-Tidwell and multicollinearity tests were performed for all continuous variables to be included in the regression, in order to ensure assumptions of the test were met. Two logistic regressions were then performed using the backward stepwise function using the mean scores of the psychological constructs to predict each of the two dependant variables; 'history of attendance' and 'intention to attend'. The analyses were then repeated and adjusted for demographic and socio-economic variables. In the 'history of attendance' analysis women who reported that they had not previously been invited to breast screening were removed from the analysis.

4.4. Results

4.4.1. Sample

The questionnaire was distributed to women who were eligible by age and lived in the geographical areas of London, South and East England, (see Section 0). Seventy-eight women returned to the pilot survey and 922 women returned the full survey. The survey item, which assessed age, asked women to select the five-year age interval to which they currently belonged. Within the full survey the mean age group was 55-59 years and 183, 437 and 302 women lived in London, South East and South West England respectively (see Table 4.4.1).A university degree or additional postgraduate degree was held by 46.3%. Over 90% described themselves as White British, with 5.1% made up of ethnic minority groups. Over 55% of women lived in households with a joint annual income of less that £34,999 before tax. The majority (64.8%) of women were married. English was the first spoken language for 96% of the population. Only 5.1% reported having had a private mammogram in the past. Within the full survey, 88.6% (817) reported intending to attend future breast screening opportunities. Of those women who reported having previously been invited to breast screening (820), 88.1% (722) reported having previously attended breast screening regularly.

Table 4.4.1 Demographic and socio-economic variables

Variable	Value	n	%
Age group	47-49	120	13.0
	50-54	201	21.8
	55-59	191	20.7
	60-64	184	20.0
	65-69	166	18.0
	70-73	60	6.5
Region	London	183	19.8
	South East	437	47.4
	South West	302	32.8
Level of education	O-level / GCSE	281	30.5
	A-level / Secondary school Graduate	153	16.6
	Trade/Technical/Vocational Qualification	176	19.1
	Bachelor's degree	180	19.5
	Masters degree or postgraduate degree	71	7.7
	Doctorate degree	10	1.1
Employment characteristics	Professional or higher technical work	146	15.8
	Manager or Senior Administrator	159	17.2
	Junior Manager	80	8.7
	Non-managerial, non-manual work	129	14.0
	Foreman or Supervisor of Other Workers	30	3.3
	Skilled Manual Work	113	12.3
	Semi-Skilled or Unskilled Manual Work	96	10.4
	Other	163	17.7
	Have never worked	6	0.7
Ethnicity	White British	835	90.6
	White other	28	3.0
	Black British	11	1.2
	Black other	9	1.0
	Asian British	13	1.4
	Asian other	4	0.4
	Mixed British	10	1.1
	Did not disclose	12	1.3
Household income before tax	Less than £24,999	343	37.2
	£25,000 to £34,999	172	18.7
	£35,000 to £49,999	134	14.5
	£50,000 to £74,999	88	9.5
	£75,000 to £99,999	25	2.7
	£100,000 to £149,999	10	1.1
	£150,000 or more	2	0.2
	Refuse/Don't know	148	16.1
Marital Status	Single, never married	91	9.9
	Married, or domestic partnership	597	64.8
	Separated	19	2.1
	Divorced	161	17.5
	Widowed	54	5.9
Private mammograms	Yes	47	5.1
English as first language	Yes	885	96.0

4.4.2. Pilot survey assessment

Fifty-four items from the pilot survey were subject to CA. Where the CA identified items that, if removed from a domain, would increase that domains CA value, the items were removed. Where a CA did not reach a CA of 0.7, items were added to the domain for analysis in the full survey, in order to try and improve the CA. Of the 14 domains, eight domains reached a CA of more than 0.7 after removal of 16 items in total. On review of the domains not reaching an acceptable CA the 'Social influences' domain was split into two domains and retested. The items in the first of these domains described how the survey respondent's family and friends would behave in terms of screening participation when invited. Whereas items in the second domain described how the respondent's friends, family and general practitioner would expect the respondent to behave when she was invited for breast screening. Both domains had CA scores of above 0.7 and so were retained and renamed 'Social Norms – Descriptive' and 'Social Norms – Injunctive'. Therefore, in total there were ten domains with CA values of more than 0.7. This included three domains with a CA of more than 0.8 and one domain with a CA of more than 0.9. Of the four domains that did not reach a CA of 0.7 or more (Beliefs about capability, Reinforcement, Memory, Behavioural regulation) four new items (one to each domain) were added in total. These new items were tested within their domains in the full survey to assess if the additional items improved the domain's CA. On review of the domain labelled 'Skills', which had a suboptimal CA score, both researchers agreed that a physical skill was not a useful domain in the context of screening, as no practical skill that can be learnt is required to have a mammogram. Therefore, this domain was not included in the full survey. As a result of the change in item content in each of the domains, the names of each domain were reassessed to ensure they were representative of the survey items and what was being measured (see Table 4.4.2).

Table 4.4.2 Domains of the pilot survey and Cronbach's alpha scores.

Domains informed by TDF for pilot survey	Domain name after CA and item review	Cronbach's Alpha
1. Knowledge	Knowledge	0.731
2. Skills	nil	0.188
3. Social role and identity	Value	0.855
4. Beliefs about capabilities	Controllability	0.555
5. Beliefs about consequences	Belief about test effectiveness	0.727
6. Optimism	Perceived Risk	0.897
7. Reinforcement	Reinforcement	0.579
8. Goals	Priority	0.985
9. Memory and Attention	Memory	0.648
10. Environmental context	Environmental context	0.865
11. Social influences	Social norms descriptive	0.730
	Social norms injunctive	0.764
12. Emotion	Emotional Consequences	0.778
13. Behavioural regulation	Behavioural regulation	0.505
14. Dread	Dread	0.715

4.4.3. Full survey assessment

Cronbach's alpha

A CA analysis was performed on the domains, based on the items stipulated by the research team. Each domain contained between two and four items. All domains showed a high level of internal consistency with CA coefficient of > 0.7, except for four domains which had suboptimal CA coefficients. These included controllability (CA = 0.607), beliefs of test effectiveness (CA = 0.666), reinforcement (CA = 0.624) and dread (CA = 0.546). (See Table 4.4.3)

Parallel and Principle Component Analysis

Following the CA analysis, the 43 items were then subject to PCA. First, a parallel analysis was performed, which determined that the number of factors (or domains) to extract for the PCA was 15.(220, 223, 224) The 15 factors aligned closely with the number of domains anticipated as informed by the TDF (14 domains), and accounted for 64.1% of the total variance.

Table 4.4.3 Cronbach's alpha analysis of theoretical domains of full survey

Theoretical Domain	Number of items	Cronbach's alpha
1. Knowledge	3	0.796
2. Controllability	3	0.607
3. Value	4	0.910
4. Perceived risk	4	0.880
5. Belief of test effectiveness	4	0.666
6. Reinforcement	3	0.624
7. Priority	2	0.871
8. Memory	3	0.717
9. Environmental Context	3	0.863
10. Social Norms - Injunctive	4	0.838
11. Social Norms – Descriptive	2	0.815
12. Emotional Consequences	4	0.727
13. Behavioural Regulation	2	0.837
14. Dread	2	0.546

Assumption tests

Bartlett's Test of Sphericity tests the null hypothesis that within the dataset tested there is no scope for reduction of the number of dimensions within the correlation matrix and therefore a PCA would be an appropriate analysis. An overall level of significance of the correlations within the correlation matrix of >0.05, indicates that a PCA is not appropriate and should not be performed. Bartlett's test was significant X^2 (903) = 23006.11, p < 0.001), indicating it is appropriate to use the PCA. The Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMO) provides an indication of weather a dataset has a sufficiently adequate sample for a PCA to be an appropriate and meaningful test. The KMO was high (KMO=0.939), indicating that the sampling was adequate (>0.8) for the purpose of using PCA. (225) Therefore, it was accepted to proceed with the analysis. It was expected that some of the items would be correlated, therefore an Oblimin rotation was performed. This rotation is appropriate when the factors included in the PCA are correlated. The resulting pattern matrix is displayed in

Table 4.4.4. Items with factor loadings of more than 0.25 were accepted. Table 4.4.5 shows the 15 factors and the 43 items with high loadings (>0.25 or <-0.25). Labels for each of the final factors were assessed and adjusted where appropriate.

Reallocation of items to new factors

The PCA placed the items in the same domain as the research team in following domains: Priority, Memory, Environmental context, Social norms – descriptive, Behavioural regulation and Dread. The domain 'Social norms – injunctive' was split into two components reflecting the source of the injunctive social norm, i.e. the participant's social groups' opinion and their General Practitioner (GP)'s opinion of the participant's screening behaviour. The resulting CA coefficients for both new domains were acceptable (0.72 and 0.78 for the injunctive social group and the GP respectively). Both researchers agreed that the allocation of items into the two new domains was appropriate. The PCA dismantled the 'Reinforcement' domain by firstly reallocating item Q21 to the 'Knowledge' construct, which resulted in this construct also covering reassurance. The resulting CA coefficient was 0.83 and therefore the domain name was changed to reflect this to 'Knowledge and 'Reassurance'. Item Q17 was also removed from 'Reinforcement' and placed in 'Emotional Consequence'. This was deemed an appropriate fit, based on review of the other items within this domain and the resulting CA coefficient of 0.82. Item Q62.1 was removed from the 'Controllability' domain and also placed in the 'Emotional Consequences' domain. However, although this improved the Cronbach's Alpha co-efficient in the 'Emotional Consequences' domain from 0.786 to 0.824, it did not conceptually fit with the other items. Therefore, it was not included in the final domains used for analysis.
The final item reallocated from the dismantled 'Reinforcement' domain (Q56) was combined with Q61 and together these formed the Reciprocity and Future risk domain, which resulted in a weak CA coefficient of 0.6. The PCA allocated the construct Q29 most closely to the domain 'Perceived Risk'. However, the factor loading remained borderline acceptable (0.25) and the CA coefficient was also higher without Q29 (0.88 vs. 0.87). Therefore Q29 was not included in the final 'Perceived Risk' domain. The item Q27 was also most closely aligned to 'Beliefs of test effectiveness', albeit with a low factor loading (0.26). A CA analysis showed that the domain was stronger without this construct (0.63 vs. 0.62). Furthermore Q27 relates

to anxiety about a potential cancer diagnosis, which was felt to not conceptually fit in the domain and so it was not included in the final analysis. Item Q61 was moved from the domain 'Value' and combined with Q56, which was originally in the dismantled 'Reinforcement' domain. The resulting factor loadings and CA (0.6) make this a weak domain to include in the final analysis. However, the two constructs were retained and the domain was relabelled 'Reciprocity & Future risk'. The final items allocated to each domain as well as the removed items are shown in Table 4.4.5.

A mean score for each domain was then calculated and used in the regression analysis.

Domain	1 Social norms - descriptive	2 Dread	3 Behavioural regulation	4 Priority	5 Value	6 Social norms -Inj. - social groups	7 Environmental context	8 Perceived risk	9 Controllability	10 Beliefs of test effectiveness	11 Emotional consequences	12 Social norms - Inj. - medical authority	13 Knowledge & Reassurance	14 Memory	15 Reciprocity & FuturerRisk
Q78	1.05	-0.01	-0.05	0.00	-0.01	-0.03	-0.07	0.00	0.02	0.01	0.01	0.01	-0.01	-0.02	-0.05
Q77	0.62	0.03	0.09	0.01	0.02	0.10	0.07	-0.05	-0.02	0.02	-0.04	-0.02	0.04	0.03	0.05
Q38	-0.01	-1.01	0.01	-0.02	0.00	0.02	-0.05	0.00	-0.02	0.03	-0.07	0.04	0.04	-0.02	-0.02
Q43	0.05	-0.30	0.02	0.13	0.05	-0.02	0.18	-0.01	0.08	-0.07	0.19	-0.08	-0.06	0.03	0.05
Q80	0.03	-0.02	0.93	0.07	-0.04	0.05	-0.01	-0.02	0.00	-0.03	0.02	-0.02	-0.01	-0.01	-0.02
Q82.1	0.05	-0.05	0.52	-0.02	-0.07	-0.06	0.07	-0.06	0.05	0.02	0.07	0.07	0.03	0.05	0.05
Q73	0.02	0.00	0.05	0.98	0.00	0.01	-0.03	0.03	0.02	0.01	-0.02	0.02	0.03	-0.03	0.00
Q74	0.00	-0.07	-0.01	0.54	-0.05	0.02	0.05	-0.18	-0.02	-0.02	0.01	0.05	0.03	0.12	-0.01
Q10	-0.01	0.00	0.04	0.01	-0.86	0.01	-0.01	-0.04	0.02	0.02	0.00	0.03	0.06	0.03	0.00
Q12	0.03	-0.01	0.03	0.01	-0.80	0.05	0.01	-0.01	0.01	-0.01	-0.02	0.01	0.13	-0.03	0.01
Q18	0.05	-0.02	0.10	0.07	-0.69	0.04	0.06	-0.08	-0.04	0.02	-0.04	0.04	0.01	0.01	0.04
Q35	0.02	0.00	0.03	0.01	-0.06	0.82	-0.01	-0.03	0.06	-0.02	0.07	0.05	0.02	0.02	-0.06
Q34	0.09	-0.05	-0.01	0.03	-0.02	0.71	0.05	0.04	0.00	-0.08	-0.03	0.11	-0.01	0.00	0.07
Q44	0.02	0.02	0.00	-0.04	0.00	0.00	0.87	-0.02	0.03	-0.03	-0.01	-0.02	-0.01	-0.03	0.02
Q41	-0.02	-0.01	0.02	0.01	-0.01	0.05	0.80	-0.03	0.01	0.02	0.05	0.03	0.04	0.00	-0.05
Q45	0.01	-0.02	0.07	0.13	-0.04	-0.02	0.59	-0.08	0.01	-0.04	0.06	0.03	-0.04	0.03	0.08
Q51	0.04	-0.03	0.05	-0.02	-0.02	-0.01	0.01	-0.83	0.02	-0.01	0.02	-0.01	0.04	0.02	0.04
Q52	0.03	-0.04	0.02	0.02	-0.09	0.04	0.05	-0.77	0.01	-0.03	0.05	0.03	0.01	-0.01	0.00
Q53	0.03	0.02	0.00	0.07	0.00	-0.02	0.03	-0.64	0.01	-0.01	-0.02	0.04	0.05	0.00	-0.01
Q29	0.04	0.03	0.10	0.23	-0.14	0.04	0.01	-0.25	0.02	-0.11	0.11	0.04	0.07	0.00	0.15
Q33	-0.04	0.03	-0.01	0.00	-0.09	0.00	-0.05	0.03	0.94	-0.04	0.05	0.06	-0.07	-0.04	0.01
Q39	0.05	-0.02	0.01	0.00	0.08	0.02	0.07	-0.04	0.48	0.04	-0.06	-0.04	0.07	0.05	-0.01
Q23	0.02	0.01	0.00	-0.06	0.09	-0.11	0.02	0.00	-0.02	0.79	0.02	0.05	-0.02	-0.02	-0.07
Q22	-0.01	-0.02	-0.02	0.02	-0.05	0.02	-0.05	-0.06	-0.01	0.59	0.02	-0.04	-0.11	0.02	-0.02
Q26	0.02	0.01	0.00	0.00	-0.01	-0.01	-0.01	0.09	0.01	0.47	0.02	-0.01	0.03	-0.01	0.04
Q57	0.01	-0.04	0.01	-0.02	-0.03	0.08	0.05	-0.05	-0.01	0.04	0.72	-0.01	0.07	0.00	-0.03
Q32	0.05	0.09	0.05	0.07	0.02	-0.03	0.07	-0.01	0.02	0.01	0.63	0.05	0.07	0.00	0.07
Q59	-0.02	-0.03	0.10	0.08	0.08	-0.02	0.07	-0.07	0.04	0.01	0.59	0.02	0.05	0.07	-0.06
Q62.1	0.05	-0.08	0.19	0.02	-0.03	0.06	0.10	0.03	0.03	0.05	0.42	0.06	0.04	0.06	0.35
Q17	0.10	-0.09	-0.05	0.05	-0.25	0.06	0.00	-0.04	0.07	-0.06	0.35	-0.02	0.08	0.00	0.18
Q27	-0.05	0.01	0.02	0.00	0.04	0.10	0.02	0.01	0.02	0.26	-0.27	0.01	0.10	0.03	0.04
Q37	0.00	-0.03	0.00	0.05	-0.06	-0.01	0.01	-0.01	0.00	-0.02	0.03	0.83	0.04	0.03	0.03
Q36	0.04	-0.03	0.04	0.00	0.06	0.26	0.00	-0.07	0.07	0.01	0.00	0.55	0.00	-0.01	-0.03
Q19	0.03	-0.01	0.03	-0.02	-0.02	0.00	-0.01	-0.05	0.02	-0.09	0.03	0.04	0.77	-0.04	0.01
Q20	0.00	-0.05	0.00	0.03	-0.05	-0.03	0.00	-0.04	0.02	-0.01	0.03	0.01	0.68	0.07	-0.04
Q24	0.07	-0.01	-0.01	0.09	-0.07	0.08	0.00	-0.07	0.00	0.08	0.07	0.02	0.50	-0.01	0.08
Q21	0.06	0.00	0.06	0.04	-0.18	0.07	0.02	0.02	-0.06	-0.08	0.05	0.01	0.47	-0.01	0.07
Q75	0.09	-0.06	0.06	0.02	-0.08	-0.09	0.15	0.11	0.01	-0.01	0.00	0.14	0.00	0.62	-0.02
Q76	-0.02	0.03	-0.09	0.16	0.00	0.07	0.14	-0.12	0.03	0.00	0.08	-0.07	-0.01	0.52	-0.09
Q46.1	-0.01	-0.01	0.04	-0.02	0.03	0.04	-0.12	-0.04	0.03	0.01	0.00	-0.01	0.03	0.47	0.05
Q82.2	0.07	-0.02	0.29	0.09	-0.06	-0.01	0.06	0.05	0.00	-0.01	-0.05	0.06	0.02	0.46	0.05
Q61	0.04	-0.07	0.16	0.11	-0.08	0.01	0.01	-0.20	-0.02	-0.01	-0.01	0.12	0.08	0.07	0.42
Q56	0.03	-0.04	0.01	0.01	-0.19	0.03	0.01	-0.07	0.00	-0.05	-0.12	0.12	0.05	0.02	0.25
Percentage variance	20.98	2.55	3.27	11.23	5.72	3.73	3.35	1.89	1.82	2.68	2.09	1.15	1.61	1.39	0.69
Eigenvalue	9.02	1.10	1.41	4.83	2.46	1.60	1.44	0.81	0.78	1.15	0.90	0.49	0.69	0.60	0.30
Cronbach's Alpha	0.83	0.53	0.84	0.87	0.94	0.72	0.86	0.88	0.63	0.63	0.82	0.78	0.83	0.71	0.60

Table 4.4.4 Principle Component Analysis - Pattern Matrix

Table 4.4.5 Final domains and their item content. The items were assessed on a 7-point Likert scale. Where items were negatively phrased, their scales were reversed prior to analysis.

		Domain mean	Factor loadings	Cronbach's alpha
Social norms - descriptive		5.42 (SD ±1.22)		0.83 (SD ± 2.67)
Q77	In my **group of friends** most women above the age of 50 have regular mammograms.		1.05	
Q78	In my **family** most women above the age of 50 have regular mammograms.		0.62	
Dread		4.95 (SD ± 1.41)		0.53 (SD ± 2.82)
Q38	If I dread doing something I do it as soon as possible to get it out of the way.		-1.01	
Q43	I tend to put things off that I am dreading doing.		-0.30	
Behavioural Regulation		5.91 (SD ± 1.32)		0.84 (SD ± 2.63)
Q80	I have a clear plan of how I will make time to attend my screening mammogram.		0.93	
Q82.1	If/when invited, I have a clear plan of how I will attend my mammogram appointment.		0.52	
Priority		5.58 (SD ±1.16)		0.87 (SD ± 2.81)
Q73	Generally, there is something more urgent that needs my attention than making time for a screening mammogram.		0.98	
Q74	Generally, there is something of a higher priority than making time for a screening mammogram.		0.54	
Value		6.29 (SD ± 1.16)		0.94 (SD ± 3.49)
Q10	Valuable - Worthless		-0.86	
Q12	Beneficial - Harmful		-0.80	
Q18	A priority - Not important		-0.69	
Social norms - Injunctive - social groups		5.98 (SD ± 1.25)		0.72 (SD ± 2.50)
Q34	Most people who are important to me think that I should attend breast screening when invited.		0.82	
Q35	The people in my life whose opinions I value would approve of my attending breast screening when invited.		0.71	
Environmental Context		5.16 (SD ± 1.66)		0.86 (SD ± 4.99)
Q41	The distance of the screening centre from my home will affect whether I attend.		0.87	
Q44	Availability of transport (public or personal) to the screening centre might affect me attending.		0.80	
Q45	If I am given an inconvenient appointment time, I might not attend.		0.59	
Perceived risk		5.86 (SD ± 1.18)		0.88 (SD ± 3.55)
Q51	If I have no breast symptoms, then attending breast cancer screening is *unlikely* to be beneficial.		-0.83	
Q52	If I examine my breasts regularly then there is *not* much benefit to me from attending breast screening.		-0.77	
Q53	A woman of my age is *unlikely* to develop breast cancer.		-0.64	
Controllability		6.28 (SD ± 0.92)		0.63 (SD ± 1.84)
Q33	I have complete control over whether I attend breast screening when invited?		0.94	
Q39	It is completely up to me whether or not I attend breast screening when invited.		0.48	
Beliefs of test reliability		4.81 (SD ± 1.07)		0.63 (SD ± 1.84)
Q22	A breast cancer might be missed (false negative).		0.79	
Q23	A breast cancer might be diagnosed when, really there is no cancer (false positive).		0.59	
Q26	A cancer may be diagnosed that might not need any treatment, or would not affect me in my lifetime.		0.47	
Emotional consequences		5.06 (SD ± 1.46)		0.79 (SD ± 5.76)
Q17	Upsetting - Reassuring		0.35	
Q32	I dread being invited for a screening mammogram.		0.63	
Q57	I am worried about pain and comfort during a mammogram.		0.72	
Q59	I expect to be very embarrassed during a screening mammogram.		0.59	
Social norms - Injunctive - Medical authority figure		5.56 (SD ± 1.34)		0.78 (SD ± 2.68)
Q36	My GP expects me to attend my screening mammogram appointment when invited.		0.83	
Q37	Generally speaking I intend to do what my GP expects of me?		0.55	
Knowledge & Reassurance		6.39 (SD ± 0.78)		0.83 (SD ± 3.11)
Q19	Breast screening can pick up cancer at an earlier stage.		0.77	
Q20	If a breast cancer is treated early, survival is more likely.		0.68	
Q21	Receiving a normal screening result will provide reassurance.		0.47	
Q24	Not attending screening may lead to a breast cancer growing undetected for longer.		0.50	
Memory		6.11 (SD ± 1.04)		0.71 (SD ± 4.15)
Q46.1	I have never accidently missed a mammogram appointment because I forgot - Please give your honest response to the statements below about breast screening:		0.47	
Q75	I never forget about routine health appointments.		0.62	
Q76	I have previously missed my mammogram because I forgot about the appointment.		0.52	
Q82.2	I always make a note of the time and date of any routine health appointments.		0.46	
Reciprocity and Future Risk		5.80 (SD ± 1.21)		0.60 (SD ± 2.41)
Q56	I would make an effort to attend breast screening if the result could inform me of my future risk of developing breast cancer.		0.42	
Q61	Attending screening mammograms is consistent with the importance I put on my personal health.		0.25	
Removed items				
Q29	I do not want to attend breast screening as I may end up having unnecessary treatment / tests, for an abnormal mammogram result that may not turn out to be cancer.			
Q62.1	62.1. For me personally, attending breast screening is very easy/very difficult.			
Q27	An abnormal result may make me anxious about a cancer diagnosis.			

4.4.4. Backward stepwise logistic regression

Tests of normality

The linearity of the continuous variables including age and all 15 domains with respect to the logit of the dependent variable of previous attendance was assessed via the Box-Tidwell procedure.(187) Based on this assessment, all continuous variables were linearly related to the logit of the dependent variable. The multi-collinearity tests indicated that there were a number of domains that had problematic multicollinearity with other domains. However, the purpose of multicollinearity tests is to assess the independent continuous variables to see if these might be measuring similar factors affecting the dependent variable in a regression analysis. The benefit of such tests is to highlight where collinearity may cause the standard errors to be inflated to such an extent that a beta-coefficient in a regression analysis is no longer statistically significant, when in fact it should be. However, a degree of multicollinearity would be expected between the domains identified as they share many common psychological concepts. For example people who score highly for 'Perceived risk' are also likely to score highly in the 'Priority' domain, as if they feel at risk of breast cancer they are likely to place higher priority on attending screening. The multicollinearity test indeed showed problematic collinearity for these two domains. As multicollinearity tests can explain why significance was not reached, it was decided to proceed to the regression analysis accepting the existing multicollinearity as this meant that any statistical significance of domains identified would be conservative estimates, and therefore reliable.

History of attendance

Respondents were asked if they had attended breast screening in the past. Of those who reported to have previously been invited to screening (n=820), there was a very high rate of self-reported previous attendance at screening; 88% (n=722) answered 'Yes, always', with 6.6% (n=54) answering 'Yes, sometimes' and 5.4% (n=44) answering 'No, never'. The 'Yes, sometimes' and 'No, never' answers were grouped to create a binary variable containing an 'infrequent or non-attenders' group, compared to the 'Regular attenders' group (those who responded 'Yes, always'). A

BSLR was completed using this binary 'previous attendance' variable as the outcome variable, and the 15 psychological domains as dependent variables. A second regression analysis was completed, which included the psychological domains from the first regression as well as demographic and socio-economic factors including: age, geographical region, level of education, employment characteristics, ethnicity, household income and marital status. The final step of the first and second regression analysis contained identical variables, which were all behavioural domains and did not contain any demographics or socio-economic variables. This indicates that the demographics and socio-economic factors did not play a significant role in predicting self-reported history of attendance when the psychological domains were controlled for demographic and socio-economic factors. Therefore the results for the second model are not reported here. Overall the remaining domains in this model explain 62.7% of the variance, after the domains for Dread, Social norms – Injunctive – social groups, Social norms – Injunctive – GP, Beliefs of the test reliability, Knowledge & Reassurance, Reciprocal Future were removed. The final model and the domains included can be seen in

Table 4.4.6. An indication of how each domain predicts past attendance can be found in the odds ratios (OR), which show the change in likelihood of previously having attended screening associated with a 1 standard deviation (SD) change in the domain score.

Table 4.4.6 Backward stepwise logistic regression model – final step for 'History of attendance'.

	OR	*p-value*	95% C.I.for OR	
			Lower	Upper
Domain				
Controllability	0.67	0.029	0.47	0.96
Behavioural Regulation	1.92	0.000	1.46	2.53
Priority	1.56	0.003	1.16	2.10
Value	1.51	0.002	1.16	1.97
Social norms - descriptive	1.36	0.022	1.05	1.76
Environmental context	0.66	0.000	0.53	0.82
Perceived risk	0.75	0.067	0.54	1.02
Emotional consequences	0.68	0.003	0.53	0.88
Memory	1.52	0.008	1.12	2.08
Constant	0.043	0.064		
Nagelkerke pseudo r^2	62.70%			
Hosmer and Lemeshow test	$X^2(8)=9.65$, p=0.265			

The domains; Behavioural regulation, Priority, Value, Social norms – descriptive and Memory have ORs of larger than 1 indicating that women who score highly in these domains are more likely to have regularly attended mammographic screening in the past. The two strongest 'enablers' to regular previous screening attendance were Behavioural regulation (OR 1.92, 95% CI 1.45-2.53, p<0.001) and Priority (OR 1.56, 95% CI 1.16-2.10, p=0.003). This means that women with a Behavioural regulation score of 1SD above the mean were almost twice as likely to have attended breast screening regularly in the past, and women with a Priority score of 1SD above the mean were almost 1.5 times as likely to have attended breast screening regularly in the past. Controllability, Environmental context, Perceived risk and Emotional consequences have ORs of less than 1, indicating that women who score highly in these domains are less likely to have attended breast screening regularly in the past, although Perceived risk is not statistically significant. The strongest predictors of non-attendance were 'Environmental Context' (OR 0.66, 95% CI 0.53-0.82, p<0.001), Controllability (OR 0.67, 95% CI 047-0.96, p=0.029) and 'Emotional consequences' (OR 0.68, 95% CI 0.53-0.88, p=0.003), indicating that women who score 1SD above the mean for any of these domains were approximately 1.5 times less likely to attend regularly.

Intention to attend future screening

Women who completed the final questionnaire were asked about their intention to attend future breast screening when offered. Of the respondents 88.6% (n=817) answered 'Yes', 11.4% (n=105) answered 'No' and 0% answered 'I don't know'. As in Section 0 a BSLR was completed to determine the relationship between the psychological domains representing barriers and enablers to breast screening and intention to attend future screening rounds (Model 1). Again, a second regression analysis was completed to include these domains as well as demographic and socio-economic factors including: age, geographical region, level of education, employment characteristics, ethnicity, household income and marital status (Model 2). The final step of both models is reported in

Table 4.4.7. The overall variance accounted for in the final step of Model 1 and 2 was 74.0% and 75.4%, respectively, after the following domains were removed; Social

norms – descriptive, Dread, Social norms – Injunctive – social groups, Environmental context, Perceived risk, Beliefs of test reliability, Knowledge & Reassurance, Memory.

In Model 1, Behavioural regulation, Priority, Value, Social norms – injunctive – Medical authority and Reciprocity & Future had ORs above 1 indicating they are enablers to screening. Whereas, Controllability and Emotional consequences had ORs below 1 indicating they are likely barriers to screening. Behavioural regulation (OR 2.48, 95%CI 1.81-3.40, p<0.001) and Value (OR 2.07, 95%CI 1.54-2.79, p<0.001) were the two strongest predictors of intention to attend, indicating that women who score 1SD above the mean of these domains were twice as likely to intend to participate in future breast screening. However, women who scored 1SD above the mean for Controllability (OR 0.66, 95%CI 46-0.95, p=0.024) or for Emotional consequences (OR 0.57, 95% CI 0.43-0.77, p<0.001) were 1.5 times and 1.75 times less likely to intend to attend future breast screening opportunities, respectively. When comparing the domains predicting intention and previous regular attendance, Behavioural regulation had the highest observed OR for both outcomes. Whereas, Emotional consequences had the lowest OR when predicting intention, but when predicting previous regular attendance, Emotional consequences has a similar low OR to Controllability and Environmental context.

Model 2 highlights that marital status significantly affected the intention to attend breast screening. Although the ORs did not shift considerably within the psychological domains, women who were widowed are almost 8 times more likely to attend breast screening compared to single women (OR 7.8, 95% CI 1.16-52.62, p=0.035).

Table 4.4.7 Backward stepwise logistic regression models for 'Intention to attend' future screening rounds.

	Model 1				Model 2			
	OR	*p-value*	95% C.I.for OR		OR	*p-value*	95% C.I.for OR	
			Lower	Upper			Lower	Upper
Domain								
Controllability	0.66	0.024	0.46	0.95	0.61	0.009	0.42	0.88
Behavioural Regulation	2.48	0.000	1.81	3.40	2.54	0.000	1.81	3.55
Priority	1.36	0.034	1.02	1.81	1.39	0.023	1.05	1.84
Value	2.07	0.000	1.54	2.79	2.12	0.000	1.56	2.87
Emotional consequences	0.57	0.000	0.43	0.77	0.56	0.000	0.41	0.75
Social norms - Inj. Med auth.	1.46	0.024	1.05	2.03	1.44	0.031	1.03	2.02
Reciprocity & Future	1.61	0.019	1.08	2.40	1.77	0.007	1.17	2.67
Marital Status						0.033		
Single	-							
Married, Civil partnership	-				1.32	0.617	0.45	3.88
Separated					69750881.68	0.998	0.00	.
Divorced	-				0.51	0.251	0.16	1.62
Widowed	-				7.80	0.035	1.16	52.62
Constant	0.00	0.000			0.00	0.000		
Nagelkerke pseudo r^2	74.0%				75.7%			
Hosmer and Lemeshow test	$X^2(8)=5.205$, p=0.735				$X^2(8)=6.976$, p=0.539			

4.5. Discussion

The aim of this study was to develop a comprehensive tool to measure the determinants of breast screening participation behaviour. The core elements of eleven of the 14 domains proposed in the original TDF, (111) were retained in the final domains used in this study although some where renamed to reflect the final items included. (1. Knowledge, 2. Social role and identity (renamed - Value), 3. Beliefs about capabilities (renamed - Controllability), 4. Beliefs about consequences (renamed - Beliefs about test effectiveness), 5. Optimism (renamed - Perceived risk), 6. Goals (renamed - Priority), 7. Memory, Attention and Decision Processes (renamed - Memory), 8. Environmental Context and Resources (renamed - Environmental context), 9. Social Influences (split into – Social norms – Descriptive, Social norms – Injunctive – GP, Social norms – Injunctive – social groups), 10. Emotion (renamed Emotional consequences), 11. Behavioural Regulation). Only the Reinforcement and Skills domains were not included in the final domains in this study, and the Intention domain was included but as a dependant variable. The close adherence of the final domains to the original validated and well-recognised TDF provides some reassurance that the survey created is indeed a comprehensive tool to measure self-reported barriers and enablers to screening.

Eighty-eight percent of respondents, who had previously been invited for mammographic screening, reported having previously attended regularly. Given the national coverage of 75.4% in 2015 recorded by the NHS breast screening

programme, this baseline rate of self-reported regular screening is particularly high. It is possible that survey respondents were therefore overly optimistic in terms of their memory of their previous attendance or were subject to a social desirability bias to report higher rates of screening given the topic of the survey. On the other hand, it is possible that the sample was not representative, in that women who have not attended screening in the past may be less likely to agree to answer a questionnaire about breast screening and thus there may be a selection bias as a result.

4.5.1. Enablers and Barriers to breast screening

Enablers

'Behavioural regulation' was identified as the strongest facilitator of both outcome variables (previous regular attendance and intention to attend future screening opportunities) with similar impacts in both. This supports the evidence that people who make clear plans to attend health appointments, in terms making time and planning how they will attend their screening appointment, are more likely to intend to attend both in the case of breast screening, and other preventative health appointments such as prenatal screening.(226-228) The importance of behavioural regulation and planning has also been observed in other health settings. For example, planning was found to be a key mediator in adoption of physical activity in cardiac patients.(229) The fact that the OR for 'Behavioural regulation' is higher in the model predicting intention to attend a future screening round than in the model predicting previous regular attendance, may reflect the fact that many people are optimistic when asked of their intentions of behaving in a certain way in the future, whereas they may be more likely to more accurately report their history of attendance at screening.(84) This is supported by the evidence from the literature, which also suggests previous behaviour is a more effective predictor of future behaviour than intention.(230, 231) The 'Behavioural regulation' domain was the strongest enabler for both outcome variables and is therefore a strong contender to be used as one of the targets for intervention design in the planned RCT.

The next strongest domain predicting previous regular attendance was 'Priority'. The domain comprised items that measured the importance placed on making time for breast screening in comparison to other things in life requiring attention. When relating these constructs to the TDF, the Goal domain most resembles this construct. However another construct within Goal domain is 'Action planning' which is shared with the original TDF's 'Behavioural Regulation' domain, indicating a degree of overlap between the broader concepts of prioritising behaviour and behavioural regulation.(111) Previous work has recognised that one's ability to prioritise a behaviour can be heavily affected by social support and stress. As a result an individual's degree of social support and stress might affect participation in cancer screening.(210) Furthermore, evidence has shown a relationship between stress and socio-economic status (SES), whereby individuals who are more deprived are more likely to experience higher levels of stress.(232) The ability to prioritise preventative behaviours such as cancer screening may not only be an inherent personality trait or personal choice, but also be affected by underlying level of stress and SES. Therefore, Priority is a key domain, not only in terms of its predictive strength of attendance at screening but also because of environmental factors, which may contribute to an individual's ability to prioritise screening. It is therefore possible that, an effective intervention targeting Priority, may differentially affect the more disadvantaged cohorts within the screening eligible population. Furthermore, much previous evidence has shown that many women report being 'too busy' as a barrier to attending screening.(17, 18, 23, 24, 27, 61) These women are likely to have lower 'Priority' scores and therefore the use of prioritisation as a behavioural intervention target may be promising. On the other hand, because these women experience higher levels of stress and possibly less social support or are of lower SES, it is quite possible that a simple 'Priority' intervention may not be able to overcome the stronger underlying social factors that determine their ability to prioritise a seemingly non-urgent behaviour. Therefore, a simple Priority targeted intervention might not have an impact on behaviour, as the determinants of the 'Priority' domain are not easily modified by an intervention asking women to prioritise their health or breast screening.

It is well recognised that simply forgetting about screening appointments can affect participation rates.(16-19, 23, 24, 61) Further supporting evidence comes from trials that have shown the effectiveness of simple reminders in the form of letters, telephone

and SMS message reminders in breast, cervical and bowel cancer screening.(154, 157, 158, 233) It is therefore unsurprising that the Memory domain is a key enabler to previous attendance. As will be discussed in chapter 5, the memory domain was chosen as the control arm as a 'Memory' text message reminder is already in use as the standard practice within the West of London Breast Screening Service.

Although individual domains were not directly compared to each other, the regression suggests that the descriptive social norms domain also predicted previous regular attendance, albeit more weakly. However, it did not seem to predict intention. This inconsistent support is in line with findings from other investigations into social norms and screening. Evidence from bowel cancer screening shows that social norms can play an important role in mediating both intention to attend and screening participation.(234) However, this study also highlighted the importance of the information portrayed in the social norm in affecting the direction of the effect. This study presented both a 'high' and 'low' true social norm to study participants and found that both resulted in lower intention to attend and participation rates than in those who received no social norm messages. This was likely due to even the 'high' norm not being sufficiently high (65%) to change behaviour.(135, 234) Social network research from within breast screening behaviour has evaluated the role of women's social environment on participation in breast screening and found that although encouragement of friends and family did have a modest impact on attendance at follow up, baseline attendance was a stronger predictor of attendance.(131)

Barriers

The strongest barriers to previous regular screening attendance were environmental factors, closely followed by the perceived ability to control behaviour and the emotional consequences of attending screening. The ORs of these domains were very similar. It is well recognised that environmental factors such as available transport (235); ability to get time off work or distance to the screening hub(22) can affect attendance at screening. It is therefore not surprising that women with higher environmental barrier scores are less likely to have attended screening. However, environmental barriers were not a domain retained in the final regression for intention

to participate. This is likely because women who do not intend to attend screening are likely to have made up their minds prior to being exposed to environmental barriers that might further affect their decision. Women who do not intend to participate are likely to be women who either object to screening, or do not feel that screening is valuable or are deterred by emotional factors when considering the invitation to screen. This is supported by the finding of the value domain being a predictor of intention to attend as well as the fact that women who scored highly on 'Emotional Consequences' were less likely to report both regularly participating in breast screening in the past, and intending to participate in future opportunities. This is in agreement with much existing evidence that has shown that anxiety about the test itself and fear of pain and embarrassment are well-recognised barriers to breast screening.(17, 21, 24, 25, 65, 75, 76, 236)

High scores in Controllability predicted previous non-regular attendance and not intending to attend in the future. There are two possible explanations for this. Firstly, this might be explained by the optimism bias, which indicates that humans have tendency to overestimate the frequency of positive events but also their own ability to change their behaviour.(85) An example from outside screening is that smokers frequently overestimate their own ability to stop smoking.(86, 237) In the context of breast screening, it is possible that women feel they have high levels of control over attending screening but in fact have not attended regularly in the past. Therefore, they score more highly in the controllability domain, but also report not previously attending regularly. However, this explanation becomes problematic, when considering that the Controllability domain also strongly predicted non-intention to attend. This means that women who score highly in 'Controllability' were less likely to intend to attend. In this case it is possible that women who feel in complete control and do not intend as they either object or are making a conscious decision not to attend screening. Future research might consider using a more qualitative or exploratory approach to explore and clarify the views of women who do not intend to attend screening and how this relates to their beliefs about control.

4.5.2. Importance of behavioural domains over SES

Evidence has previously linked the level of socioeconomic status to rates of preventative health behaviours(238, 239) including cancer screening.(240) Further work has sought to explain the differences in behaviour of people from different SES groups through the psychosocial model that indicates that experiencing higher levels of life-stress and lower levels of social support, as associated with lower SES groups, may contribute to lower rates of preventative health behaviours.(241) However, a large body of research has also highlighted the importance of physical, cognitive and emotional factors, such as the psychological domains examined in this survey, as mediators to participation in preventative health behaviours such as cancer screening (see chapter 1).(17, 19, 24, 25, 42, 67, 76) Further evidence also suggests that such factors vary significantly by SES.(210, 242-244) *Wardle et al*.(210) sought to investigate the relationship between SES, psychosocial variables and cognitive factors on the intention to take part in colorectal screening in the future. The authors found that although people in lower SES groups were more stressed and had less support, these psychosocial factors were not able to explain their intentions to participate in bowel screening. Instead they found that cognitive barriers such as worry and perceived risk and benefits were able to explain a large component of the levels of interest in screening, to such an extent that these mitigated the effect of the SES level within the model so that they became non-significant.(210) The results of the survey reported in this chapter further support these results by *Wardle et al.*, as the model for the dependent variable of 'history of regular attendance' was not altered by including variables that contribute to SES or demographics such as age, geographical region, level of education, employment characteristics, ethnicity, household income and marital status. Furthermore the ORs for the model predicting intention to attend were only minimally altered through the marital status variable and no other SES variables remained in the model. The overall variance was also only minimally improved from 74.0% in Model 1 (psychological domains alone) compared to 75.7% in Model 2 (psychological domains and demographics). This indicates that although much emphasis is put on SES, in fact psychological domains comprise the majority of the model predicting both dependent variables (previous attendance and intention to attend) measured in this survey. This is not to say that SES does not affect screening attendance or intention to attend. Instead it supports evidence that the psychological

domains in the model may be accounting for different SES factors represented in the different SES variables, which were included in the analysis but not present in the final step of the regression in Model 2 (age, geographical region, level of education, employment characteristics, ethnicity, household income and marital status).

4.5.3. Limitations

There is a possible selection bias in that we recruited respondents through an online market research company and the survey was in English only. This means that the women who responded were generally internet-literate, and were likely to have a high proficiency of the English language. This may have been somewhat mitigated by the fact that over 55% of respondents lived in households with an annual gross income of less than £34,999 and over 66% had a technical vocational degree or lower as their highest level of, indicating that they are likely to represent a lower SES. It is also possible that women who have previously attended screening are more likely and women who have not attended in the past are less likely to be willing to complete a survey on breast screening. This is therefore also a potential selection bias. An alternative method for survey selection might be to use paper-based surveys that uses GP-lists of screening eligible women. Although such an approach might reduce the selection bias, it is also more labour and time intensive, whilst also being more expensive. For this reason, an online survey was the method selected for this study.

The geographical area for the survey (London, South East and South West England) was bigger than the area that the planned trial would be run in (West of London). So behavioural factors identified through this work may represent the South of England more generally than the West of London specifically. It is therefore possible that factors that are more important to the population in the West of London were not highlighted through this work. It was however, not possible to reach a sufficiently large number of women who matched the eligibility criteria in West London alone and for this purpose the larger area was accepted.
Despite trialling and adjusting the constructs included in each domain in a pilot and full survey, four of the final domains (Dread, Controllability, Beliefs of test reliability, Reciprocity and Future risk) had suboptimal final Cronbach's Alpha

coefficients. The factor loadings were however deemed acceptable and the Eigenvalues of each domain were determined to be statistically significant and so they were included in the regression analysis. Nonetheless, future survey iterations could include further constructs to more clearly define these four domains. A repeat analysis would hopefully yield higher Cronbach's Alpha coefficients allowing more confidence in including and interpreting these domains in the model.

As discussed above, the rates of previous attendance reported by respondents were higher than would be expected for the geographical area in which the survey was conducted. However, because the survey was entirely anonymous, the geographical reach very large and the screening hub organisation broken down into a number of regions, it was not feasible to calibrate the self-reported outcome of history of regular attendance to actual recorded attendance by cross-checking NHS Cervical Screening Programme records. It was therefore accepted that, optimism bias and a degree of social-desirability bias may have contributed to women overestimating their attendance at breast screening in the past.

4.5.4. Future work

The purpose of this study was to inform the focus of behavioural design efforts for an RCT based on the results from this survey. It is well recognised that the strength of different barriers and enablers are likely to differ according to a number of different factors such as region, ethnicity, cultural beliefs, age and level of deprivation. Work from bowel cancer screening has used segmentation analysis to characterise discrete subgroups that hold similar patterns of particular barriers or enablers, allowing a more targeted approach to intervention design.(245) Further work might therefore consider the use of such an analysis to better understand these subgroups.

Similar survey work using the TDF could also be done to systematically quantify and describe theoretical domains that affect participation in cervical cancer screening. It would then be of great interest to test interventions informed by expert panels such as in chapter 3 and 4 against interventions informed by the TDF to establish the most effective method to inform intervention design.

4.6. Conclusion

This study has measured the strength of a comprehensive set of behavioural domains in predicting breast screening intention and previous screening behaviour whilst adjusting for demographic and SES factors. It has provided more evidence that psychological domains are likely to be stronger mediators in predicting cancer screening behaviour and intention than many demographic or SES factors. The literature recognises that previous behaviour is a stronger predictor of future behaviour than an intention to carry out that behaviour.(230, 231) Therefore the domains that predict previous regular breast screening attendance were selected to inform the intervention design for the RCT described in chapter 5. These were Behavioural regulation and Priority.

5. Behavioural text messages in breast screening; a randomised controlled trial.

5.1. Summary

Background

Text message reminders (SMS) can improve breast cancer screening rates. Evidence shows that the message content can further improve the impact of SMS reminders in other clinical settings. Evidence from chapter 3 also shows that SMS content can significantly increase cervical screening rates. This 3-armed parallel RCT tested differently worded SMS reminders on breast screening participation.

Methods

Women who were due for screening in the West of London Breast Screening Service (WoLBSS) catchment area and were aged 47-73 years between August 2016 and November 2016 and who had provided their mobile phone number, were eligible. Participants were randomised into one of three trial arms (1:1:1) including the current standard practice SMS reminder message or either of two SMS reminder interventions. The message content of the intervention SMS content was informed by a population survey and included a Planning and a Priority message. SMS messages were sent to women with a recorded mobile phone number 7 and 4 days prior to their timed appointment. The primary outcome was the difference in mammographic screening uptake between trial arms.

Results

2,696, 2,614 and 2,634 women were allocated to the Control, Planning and Priority arm, respectively. After exclusions for opt-outs, self-referrals, and SMS cross-contamination, 854, 883 and 860 women were included in the analysis for the Control, Planning and Priority arms, respectively. Mean age was 58.8 (range 47-74 years, SD ± 6.09). The participation rate was 82.8% (707), 84.4% (745) and 82.7% (711) by control, Planning and Priority SMS trial arms respectively, X^2 (2) = 1.131, p = 0.568.

Conclusion

No statistical difference between trial arms was noted. However, due to logistical issues encountered during the trial, the recruitment did not achieve the target sample size (11,496). Furthermore, due to information governance stipulations, only women who had provided their mobile phone number to screening centre directly could be sent and SMS. Therefore, the sample of this trial is likely to represent women who were highly motivated to attend, which is reflected in the high participation rate. This indicates that women who have not previously been in contact with the screening hub (first time invitees and non-attenders) could be disadvantaged by SMS interventions for breast screening. (191)

An abstract of this trial was published in The Lancet in November 2017. (191)

5.2. Introduction

As highlighted in previous chapters, the design of the message content is key to delivering behaviour change, alongside the channel of delivery (e.g. letter, telephone or SMS). The methodology described in chapters 2 and 3 utilised insights informed by the MINDSPACE framework. However, this approach may have limitations including; not providing a method for identifying and selecting the key factor contributing to the behaviour to target, and relying on an expert panel for the selection of interventions, which may in term not be the most robust method for selecting key behaviour change levers to be deployed. To this end, chapter 4 describes a large population survey that measured psychological domains that influence breast cancer screening participation, in order to identify the psychological domains that most strongly predict screening behaviour, which inform the intervention design in the trial described in this chapter.

This chapter describes an RCT that compared the effect of two intervention SMS reminder messages to the SMS reminder message content currently used in the West of London Breast Screening Service (WoLBSS) on breast screening uptake. The message content was informed by the population survey, which measured predictors of history of attendance and intention to attend, and was based on the Theoretical Domains Framework (TDF).(111) The strongest predictor of both attendance and intention was the 'Behavioural regulation' domain. The next strongest predictor of previous regular attendance was the 'Priority' domain, whereas the next strongest predictor of intention to attend was 'Value'. Evidence suggests that previous history of a behaviour is a stronger predictor of future behaviour than intention.(40, 41, 46, 230, 231) Therefore, the second domain selected to inform the message content of an intervention SMS was 'Priority'.

Behavioural regulation and Priority domains

The behavioural regulation domain refers to self-regulatory processes and include constructs such as self-monitoring, action planning and habit breaking.(111) The items contributing to this domain included survey questions that assessed an individual's plan of how they will attend and how they plan to make time to attend

screening, (see Figure 5.1 Items used to measure the two theoretical domains most strongly predictive of previous attendanceFigure 5.1).
The Priority domain described in chapter 4, corresponds to the Goal domain in the TDF and seeks to measure the priority an individual places on breast screening participation.(111) The survey items contributing to the Priority domain asked respondents to rate to what extent they place priority on breast screening compared to events that they might consider to be more or less urgent and important (see Figure 5.1).

Communication Channel

A number of trials have shown the efficacy of using simple SMS reminders at improving attendance and reducing 'did not attend' (DNA) rates for routine hospital appointments.(160, 161) Within breast screening, further trials have shown that SMS are effective at improving participation in breast screening.(156-158) As a result, SMS reminders are being used more frequently by NHS organisations, both for routine hospital appointments but also within breast screening. However, little consideration has been paid to their message content.(162) Acknowledging this, a recent trial by *Hallsworth et al.* tested the content of such SMSs in a large RCT aimed at reducing missed routine hospital appointments.(162) This trial found that the most effective message informed participants of the estimated cost incurred by the health service to provide the patient with their appointment, which resulted in an absolute reduction of 'Did not attend' (DNA) rates of 2.7%.(162) A smaller RCT carried by *Lakkis et al.,* which also tested the effect of message content on breast cancer screening rates, found no difference between trial arms. However, the small sample size in this trial (n = 385) may have contributed to the non-significant finding.(163) Evidence from chapter 3 as well as from *Hallsworth et al.* (162) indicates that the anticipated difference in attendance as a result of different message content within an SMS is likely to be approximately 2-3 percentage point increase and would therefore require a much larger sample size than was achieved in the study by *Lakkis et al*.(163) Therefore, further assessment of SMS in breast cancer screening is warranted to establish if editing the message content based on behavioural sciences can further improve participation rates.

5.3. Methods

5.3.1. Aims

This study aimed to test the effect of behavioural science informed content in form of a Behavioural regulation and Priority intervention message within an SMS reminder on the breast screening participation rate in West London.

5.3.2. Intervention Design - SMS message content

It was pragmatically decided to test two interventions against the control arm and this was supported by the power calculation, as the sample size was deemed achievable by the screening service team at WoLBSS, (see section 0). The two domains most strongly predicting previous attendance were the 'Behavioural regulation' domain, (i.e. making a plan to attend) and the 'Priority' domain (i.e. how much a woman feels that screening is a behaviour she prioritises), see Figure 5.1.

Behavioural regulation
Q80 I have a clear plan of how I will make time to attend my screening mammogram
Q82.1 If/when invited, I have a clear plan of how I will attend my mammogram appointment

Priority
Q73 Generally, there is something more urgent that needs my attention than making time for a screening mammogram
Q74 Generally, there is something of higher priority than making time for a screening mammogram

Figure 5.1 Items used to measure the two theoretical domains most strongly predictive of previous attendance

Therefore, the content of two SMS interventions was constructed around these domains, taking into consideration the questions that made up the domains. Both intervention SMSs were reviewed by the WoLBSS routine care team, the clinical lead for WoLBSS screening, a behavioural economics specialist and a Public Health consultant in cancer screening at NHS England. Feedback was incorporated and the final message content was decided and approved by all stakeholders (see Figure 5.2)

It has been recognised from survey studies that women who are planning to attend breast screening are more likely to actually attend.(227) Furthermore, a trial that asked women to plan their breast screening appointment in terms of how they will

change appointment times, negotiate time off work and arrange transportation, showed that women who engaged with the planning tool were significantly more likely to attend than those who did not.(226) Within bowel cancer screening a trial testing the use of fridge magnets to remind individuals to complete a home test kit and return the test also showed a significant improvement in participation rates.(168) In addition, examples from outside cancer screening have shown how action planning can make behaviour change more likely.(228, 229, 246) *Sniehotta et al.* found that cardiac rehabilitation patients who planned how they would adhere to a new exercise regime were much more likely to be compliant.(229) Furthermore, *Sniehotta et al*. (229) highlighted the importance of detailed action planning, such as planning specific elements of the behaviour, rather than having a generic plan to take part in the exercise. However, a trial testing behavioural regulation and planning in pregnant women to encourage antenatal screening participation showed no overall difference in screening participation in the intervention group compared to the control. Yet, within the intervention group, women who actually completed the planning tool of recording the date and time of an appointment were significantly more likely to be screened than those who did not.(228)

Given the variety of evidence from different settings on the effectiveness of planning tools, it was decided that the behavioural regulation intervention would be most successful through incorporating a specific tool to help plan the desired behaviour. Rather than asking individuals to 'make a plan' to attend, which might be less effective as it is somewhat vague, the SMS provided a prompt to plan to attend screening by suggesting to make a diary note of the appointment time and date (see Figure 5.2).

As discussed in chapter 4, the impact of socioeconomic status (SES) on prioritisation of preventative behaviours can be mediated by stress and social support.(210, 232) Extensive evidence has shown that many women report being 'too busy' as a barrier to screening, indicating that they place lower priority on the importance of breast screening compared to other activities of everyday life. (17, 18, 23, 24, 27, 61) Therefore, the importance of prioritisation highlighted through the survey is in agreement with evidence from the literature and was selected as the second intervention tool to inform SMS content design.

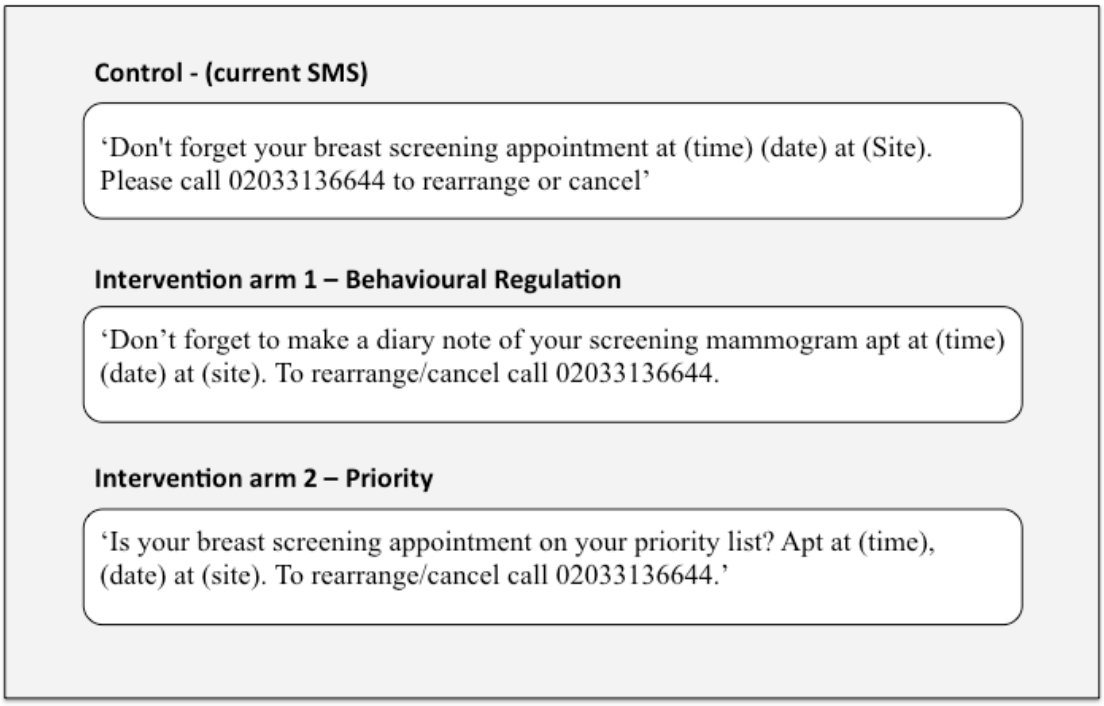


Figure 5.2 SMS message content by trial arm.

The message content for this intervention was designed to not assume that all women invited would intend to attend screening, and thus would not offend women who did not wish to attend. (This is despite the fact that only women who had given their mobile phone number to the service were included in the trial, which suggested that the majority had previously attended and therefore at some point had not objected to breast screening.) Given that a statement of prioritisation would imply a certain value attributed to breast screening which may be offensive to those who intend not to attend, the SMS was instead phrased as a question. The content was thus designed so that it would prompt women who intend to attend to prioritise the appointment, whilst not antagonising women wish not to attend.

The message content used in the control arm, which reflected the true current practice and was already in place as the routine SMS reminder within WoLBSS prior to the trial starting, reflects the 'Memory' domain, also tested in chapter 4. This domain was a statistically significant predictor of previous attendance. However, it did not predict attendance as strongly as the two domains selected for the intervention arms and therefore is a useful control both in terms of being the current practice as well as a less effective domain as measured by the survey. It is however possible that the

expected difference in participation rates between arms might therefore be reduced as it does not reflect a 'simple reminder' but still contains a behavioural element. On the other hand it could be argued that regardless of the message content, any SMS deployed that reminds women of a screening appointment, whether or not it states 'Don't forget your appointment' will act as a reminder and therefore was deemed an appropriate control.

5.3.3. Trial Design

Within WoLBSS, the current practice is for women to be sent an invitation letter approximately three weeks prior to their timed appointment. This is followed by an SMS reminder, which is deployed on the 7th and 4th day prior to their appointment. Therefore, the current message content and schedules were maintained within the control arm. Women allocated to either intervention arm were sent the same intervention SMS content on the 7th and 4th day prior to their scheduled appointment. As per usual practice, a daily list of women who were being called up for screening was generated through the WoLBSS IT system. Of these women, some will have provided WoLBSS with their mobile phone number, which is then recorded within their file on the IT system. These women have previously given their phone number directly to WoLBSS through prior contact, thereby consenting to receive SMS from WoLBSS. The full list was then uploaded to the iPLATO Patient Care Messaging Platform.(196) The iPLATO platform identifies participants who have a recorded mobile phone number allocated to their health record. The platform was programmed to then randomise these women into the three trial arms each time a list was uploaded, using a Mersenne twister algorithm. The SMS content was then generated for each person based on their trial arm allocation, the date, time and location of their appointment. The outcome measure of attendance status was recorded at three months from the invitation to screen, to allow for cancellation and rebooking of inconvenient appointments. Three months was deemed a reasonable and adequate time to record the final attendance status, in particular as women were offered timed appointment slots as per usual practice.

Study setting and data collection

This study was run in West London in collaboration with WoLBSS, which provided in addition to its routine screening service a routine SMS service which was implemented based on the results of the trial by *Kerrison et al*. discussed above, which was also run within WoLBSS.(157) Data including demographics, attendance status and screening outcome was collected by the WoLBSS IT system as per standard practice. The iPLATO platform collected data on accuracy of phone numbers and message delivery status. Anonymised data was retrieved from the WoLBSS and iPLATO IT systems, merged by a contracted third party who routinely carries out data synthesis for WoLBSS and given to the researcher. The variables in the final data set were: trial arm allocation, attendance status, age, invitation category (e.g. routine recall, first invite, high risk, self referral), availability of a mobile phone number, successful SMS delivery and any reason given for not attending (e.g. temporarily opted out, under treatment, deceased, moved away, recently screened).

Eligibility Criteria

Inclusion Criteria

Women who were eligible and due for breast screening in the WoLBSS catchment area during the trial period of August – November 2016 and had provided a mobile phone number to WoLBSS.

Exclusion Criteria

Women who were not eligible for breast screening, for example due to bilateral mastectomies, will have been opted out of mammographic screening as per standard practice. However if women contacted the service during the trial period and reported having undergone a bilateral mastectomy, they were opted out by the cancer screening routine care team and would not have been included in the trial. Women who did not have a mobile phone number recorded directly with WoLBSS (for example women who have provided their mobile phone number to their GP or the hospital but not directly to WoLBSS, or women who have not provided their mobile phone number to any health services) were excluded as it was assumed that these women have not

given their consent for WoLBSS to use their phone number for correspondence. This was a stipulation of the information governance department prior to running the trial.

Withdrawal Criteria

Women who have chosen not to participate in screening, and informed the screening centre or their GP of this decision, were removed from the list of eligible women due for screening by the routine care team as per routine practice.

Outcomes

The primary end point was the breast screening participation rate within three months of the invitation letter. The secondary outcomes are uptake according to age and previous invitation history.

Sample Size

The sample size was calculated to detect a 3% difference in uptake between groups with a 5% margin for type I and 20% margin for type II error. This expected improvement in uptake is deemed to be both realistic and operationally significant to the service. The uptake in West London in 2015 was 65.9%. Therefore a minimum sample size for each trial arm of 3,832 women was calculated, with a total sample size of 11,496.

Randomisation

As per usual practice, the WoLBSS IT system identified women who were eligible and due for screening on a daily basis during the trial period of August 10th to November 2nd 2016. A list of these women was then uploaded to iPLATO Patient Care Messaging platform with their allocated appointment date, time and location. The iPLATO platform was programmed to identify women whose mobile phone number was recorded within their health record held on the WoLBSS IT database. During the trial period, these women with a recorded mobile phone number were randomised into trial arms and allocated to receive one of the three SMS using the Mersenne Twister algorithm in a 1:1:1 ratio.(247) Each participant invited to breast

screening is allocated a unique identifying number by the screening centre (WoLBSS). This number differs from their NHS number. The iPLATO system then linked each patient's unique identifying number to their WoLBSS record to retrieve their mobile phone number. The corresponding trial arm SMS content was then generated, containing the patient's appointment date, time and screening facility and was programmed to be sent out at the allocated date and time prior to the appointment. Participants and the routine care team were blinded to the allocation. Although participants were able to see which SMS they received, they were unable to see other the content of the other SMS reminders and were not aware if they were in the control or intervention arm. The research team was not blinded.

Consent

The premise of the study is whether a change in an existing 'in-use' text message reminder can increase the number of patients attending their breast screening appointment. Consenting patients to change the message content of an existing service provided by WoLBSS would have resulted in a selection bias in that women who consented would have been aware they were taking part in a trial and would likely have changed their behaviour as a result of awareness of the trial. However, only women who had given their mobile phone number to WoLBSS directly and not via their GP or other secondary care hospital services were able to receive an SMS reminder. Therefore, they have previously given explicit consent to WoLBSS to receive a SMS by the service. No woman who had not previously given her mobile number to the service was able to be randomised or receive a SMS. As a result ethical approval was sought to not consent participants for the trial.

Ethics

Ethics was sought through the Yorkshire & The Humber – Leeds East Research Ethics Committee (Ref 16/YH/0276).

5.3.4. Data analysis

The null hypothesis is no difference in uptake between the trial arms. Women were excluded from the final analysis if they opted out, or had referred themselves and were not being routinely called up. Due to technical challenges of women who rescheduled their appointments being re-allocated to a trial arm, some women received more than two SMS reminders or SMS content from more than one trial arm. As a result these women were also excluded from the final analysis. An 'intention to treat' (ITT) analysis of the difference in uptake across trial arms was completed using a Chi-squared test. Logistic regression analysis was performed to further evaluate the effect of the trial arms when controlling for age and invitation category (e.g. routine, high risk, first invitation). Exploratory subgroup analysis was performed to investigate secondary trial outcomes, including participation by age and invitation type. A 'per protocol analysis' (PPA) evaluated the effect of the SMS content on participation in women who received the SMS that was sent, based on the delivery status provided by iPLATO data. However, unlike in the trial reported in chapter 3, this trial was only able to target women who had a mobile phone number recorded on the WoLBSS database. Therefore the per protocol analysis reflects women who actually received the SMS and excludes only those women who had a phone number recorded in their electronic health record but did not receive the SMS. This was either because the number was incorrect and therefore the SMS failed or because the number existed but was not in use (e.g. the phone was turned off during the 5 days following the SMS deployment).

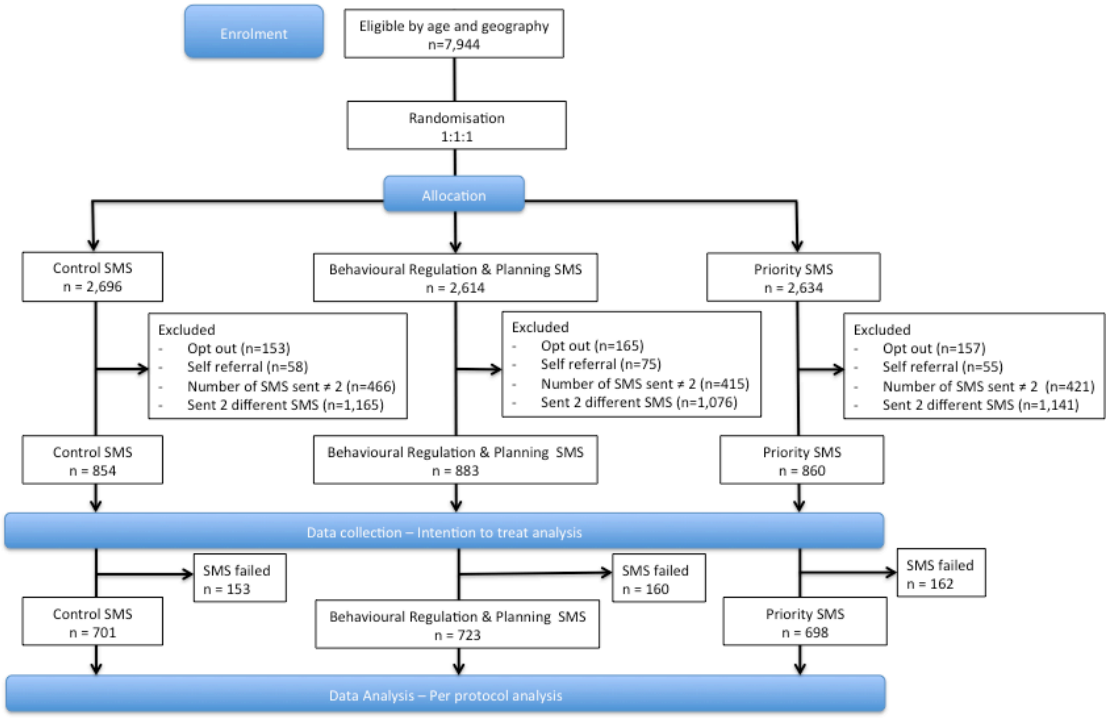
5.4. Results

5.4.1. Descriptive statistics

During the trial intervention period (10th of August to 2nd of November 2016), 27,810 women were eligible for breast screening in the WoLBSS catchment area. Of these 7,944 women (28.6%) had a mobile phone number recorded on the WoLBSS IT database. Of these 2,696, 2,614 and 2,634 women were allocated to the control, Behavioural regulation SMS and Priority SMS respectively. Unfortunately, due to a

regional reconfiguration of the screening service from regional London breast screening services to a single pan-London breast screening service in November 2016, the trial had to be terminated prior to the a priori determined sample size being reached. After the data was collected 153, 165 and 157 women in the control, Behavioural regulation and Priority trial arms respectively were excluded from the analysis due to contact with the screening service with a reason for non-attendance. These reasons recorded included; 'temporary opt out' (n=311), 'recently screened' (n=112), 'under medical care elsewhere' (n=33), 'moved away' (n=9), 'not known at the address' (n=5) or 'deceased since the last screening invitation' (n=5).

Figure 5.3 CONSORT Flow diagram breast screening SMS trial



In the control, Behavioural Regulation SMS and Priority SMS 58, 75 and 55 women self-referred (i.e. were not called up as per the routine call/recall central database, but contacted the screening hub requesting to be screened and are therefore highly like to attend their self-arranged screening test) and were therefore excluded from the analysis. A further 466, 415 and 421 women in the control, Behavioural Regulation and Priority arms respectively, received more or fewer than the two SMS reminders. A further 1,165, 1,076 and 1,141 women in the control, Behavioural Regulation and Priority arms were sent two or more different SMS content and therefore were also

excluded from the analysis. This was likely to be because women who were scheduled for an appointment that was inconvenient could contact WoLBSS and rebook their appointment. This in turn re-entered them into the trial, allowing them to receive further and different SMS reminders. This was difficult to avoid without significant disruption to the screening service and because the conditions of the ethical approval stipulated that the research team did not manage the randomisation process for this trial, as this would have resulted in access to identifiable data by the research team. It was also not acceptable to the screening hub to not send SMS reminders for rescheduled appointments to women who had received two SMS for their initial allocated appointment. Some women also were only allocated to receive one SMS. This is likely to have been as a result of the patient phone number being recorded on the database within 7 days of their appointment. In this case, the iPLATO platform was programmed to send a single SMS as per usual practice and so these participants were also excluded. Therefore, 854, 883 and 860 participants were included in the final analysis (total n = 2,597) in the control, Behavioural Regulation SMS and Priority arms respectively.

Age

The mean age of all participants included in the analysis was 58.8 years (SD ± 6.9). Mean age in the control, Behavioural regulation and Priority SMS trial arms was 58.8 years (SD ± 6.08), 58.9 years (SD ± 5.92) and 58.8 years (SD ± 6.03) respectively (F (2.259) = 0.185, p = 0.831), indicating no group differences in age of participants.

Uptake invitation type

There was a non-significant variation in attendance by invitation type with participation rates in the first invitation, routine recall invitation and high risk invitation groups of 78.4% (n = 98), 83.5% (n = 2,058) and 100% (n = 7) respectively (X^2 (2) = 3.622, p = 0.164).

5.4.2. Primary outcome – Attendance at mammogram appointment

The overall participation rate was 83.3%. The uptake in the control, Behavioural regulation & Planning and Priority SMS trial arms was 82.8%, 84.4% and 82.7% respectively. These uptake rates were not significantly different between groups, X^2 (2) = 1.131, p = 0.568.

The continuous dependent covariate for age was assessed using the Box-Tidwell procedure(187) with respect to the logit of the outcome variable of participation was found to be linearly related to attendance, and was therefore included in the regression without transformation.

A multivariate logistic regression, adjusted for age and invitation type, showed that there was no difference in uptake in women allocated to the intervention arms compared to the control.

Table 5.4.1 Adjusted multivariate logistic regression for breast screening attendance.

	B	S.E.	p-value	OR	95% CI
Trial arms			0.556		
Control					
Behavioural regulation	0.118	0.13	0.361	1.13	0.87 – 1.45
Priority	-0.007	0.128	0.958	0.99	0.77 – 1.28
Age	-0.009	0.009	0.336	0.99	0.97 – 1.01
Invite Type			0.241		
First invite					
High risk	1.965	$1.5x10^4$	0.999	$4.6x\ 10^8$	0.00 – 0.00
Routine	0.393	0.233	0.092	1.48	0.94 – 2.34
Constant	1.704	0.524	0.001	5.50	

Per protocol analysis

A per protocol analysis (PPA) was performed to assess the uptake by trial arm in women who actually received the SMS reminders. In this analysis 701, 723 and 698 women were analysed in the control, Behavioural regulation and priority SMS trial arms respectively.

Table 5.4.2 PPA - uptake by trial arm.

	Control SMS	Behav. Reg. SMS	Priority SMS	X^2	p-value
% Attended	87.7%	88.7%	88.4%	0.312	0.856
(n)	615	641	617		

In the control, Behavioural regulation and Priority SMS trial arms there was an uptake of 87.7%, 88.7% and 88.4% respectively, with no statistical difference found between arms X^2 (2) = 0.312, p = 0.856. An adjusted multivariate logistic regression analysis (see Table 5.4.3) also found no difference in uptake between trial arms and the control. However, here women who were being recalled for a routine mammogram were more than twice as likely to attend than women being invited for the first time (OR 2.16, 95% CI 1.33 – 3.53, p = 0.002).

Table 5.4.3 PPA – Multivariate logistic regression analysis for attendance

	B	S.E.	p-value	OR	95% CI
Trial arms			0.846		
Control					
Behavioural regulation	0.09	0.17	0.568	1.10	0.80 – 1.52
Priority	0.06	0.17	0.723	1.06	0.77 – 1.47
Age	0.00	0.01	0.840	1.00	0.98 – 1.02
Invite Type					
First invite			0.009		
High risk	1.99[1]	1.52[4]	0.999	4.47[8]	0.00 – 0.00
Routine	0.77	0.25	0.002	2.16	1.33 – 3.53
Constant	1.39	0.66	0.034	4.00	

5.4.3. Exploratory subgroup analysis

By age subgroup

Women were grouped into age subgroups of ≤54 years, 55-59 years, 60-64 years and 65 ≤ years, and uptake by trial arm was assessed in both an ITT and PPA analysis. In the ITT analysis, attendance by age group was 85.1% (n=619), 81.5% (n=644), 82.2% (n=466) and 84.6% (n=434) in women aged ≤54 years, 55-59 years, 60-65 years and ≥65 years respectively, X^2 (3) = 4.704, p = 0.195.

Table 5.4.4 Intention to treat analysis of uptake by trial arm in age subgroups.

	Control SMS	Behav. Reg. SMS	Priority SMS	X^2	p-value
Age ≤54 years					
% Attended	85.8%	85.0%	84.6%	0.140	0.932
(n)	217	199	203		
Age 55-59 years					
% Attended	80.3%	82.7%	81.4%	0.494	0.781
(n)	196	225	223		
Age 60-64					
% Attended	79.8%	83.4%	83.4%	1.146	0.567
(n)	154	161	151		
Age ≥65 years					
% Attended	85.4%	87.0%	81.2%	2.312	0.315
(n)	140	160	134		

In the ITT analysis, there was no significant difference in uptake by trial arm within the age subgroups (see Table 5.4.4. In age groups 55-59 years, 60-64 years and ≥65 years the Behavioural regulation SMS achieve the highest participation rate. However this was a non-significant absolute increase in uptake compared to the control arms of 2.4%, 3.6% and 1.6% respectively. In the 60-64 years age group both the Behavioural regulation and Priority SMS resulted in the same non-significant absolute increase in participation of 3.6%. In the oldest age group (≥65 years), the Priority SMS resulted in a non-significant reduction in participation of 4.2% compared to the control (see Table 5.4.4).

	Control SMS	Behav. Reg. SMS	Priority SMS	X^2	p-value
Age ≤54 years					
% Attended	89.3%	86.2%	88.1%	0.948	0.622
(n)	192	175	177		
Age 55-59 years					
% Attended	86.6%	89.9%	87.0%	1.328	0.515
(n)	174	196	194		
Age 60-64					
% Attended	86.0%	87.1%	90.2%	1.314	0.519
(n)	135	135	129		
Age ≥65 years					
% Attended	89.1%	91.8%	89.3%	0.745	0.689
(n)	114	147	131		

Table 5.4.5 Per protocol analysis for age subgroups

A PPA was performed (see Table 5.4.5) and showed that in the in youngest age group the control arm had the highest attendance rates. Whereas, in women aged 55-59 years and over 65 years the Behavioural regulation SMS resulted in the highest participation rate. In women aged 60-64 the Priority SMS resulted in the highest attendance rates. However, again none of these observations were statistically significant.

By invitation type

There were 125, 2465 and 7 women who were invited to their first mammography screen, routine recall and high-risk screen during the trial period, respectively. As there were only 7 women in the high-risk screening group and all women attended their screening appointment regardless of trial arm allocation the results are not shown here.

Table 5.4.6 ITT - uptake by trial arm in the 'invitation type' subgroups.

	Control SMS	Behav. Reg. SMS	Priority SMS	X^2	p-value
First screen					
% Attended	79.5%	72.1%	84.2%	1.802	0.406
(n)	35	31	32		
Routine recall					
% Attended	82.9%	85.0%	82.6%	2.031	0.362
(n)	668	712	678		

Again, there were no significant group differences in attendance rates. In women, who were receiving their first invitation to screen, the highest uptake was achieved in the trial arm receiving the Priority SMS with an uptake of 84.2% in the ITT analysis, (see Table 5.4.6). This was further confirmed on the PPA with a slightly higher participation rate of 85.3% (see Table 5.4.7). In the same group the Behavioural regulation SMS did much worse than the control at 72.1% compared to 79.5% in the ITT analysis. This was also confirmed in the PPA, however these were all non-significant findings and the sample size for this subgroup analysis was small.

Table 5.4.7 PPA- uptake by trial arm in the 'invitation type' subgroups.

	Control SMS	Behav. Reg. SMS	Priority SMS	X^2	p-value
First screen					
% Attended	80.5%	72.1%	85.3%	2.087	0.352
(n)	33	31	29		
Routine recall					
% Attended	88.1%	89.7%	88.5%	0.881	0.881
(n)	578	608	587		

In contrast, for women receiving a routine recall invitation to screening, the participation was highest in the behavioural regulation SMS arm at 85% compared to the control of 82.9% and the priority SMS of 82.6%. In the PPA, the Behavioural regulation SMS also produced the highest participation rate at 89.7% compared to the control at 88.1% and the Priority SMS at 88.5%. However, both of these are non-significant trends in uptake.

5.4.4. Mobile phone number availability

Of the women eligible for breast screening (n = 27,810) during the trial period, only 28.6% had a mobile phone number recorded within the WoLBSS IT database. Of those included in the trial, the overall rate of SMS delivery was 81.7% (n = 2122), with 9.0% (n=234) failing to deliver due to incorrect phone numbers and 9.3% (n=241) expiring after 5 days due to correct phone numbers that were not active during this time period (e.g. turned off or out of range). Delivery rates by trial arm were 82.1%, 81.9% and 81.2% for the control, Behavioural regulation and Priority trial arms respectively. There was no significant difference in SMS delivery, failure or expiry rates by trial arm, X^2 (4) = 3.909, p = 0.418 (See Table 5.4.8).

Table 5.4.8 SMS delivery, failure and expiry rates by trial arm.

	Control SMS	Behav. Reg. SMS	Priority SMS	X^2	p-value
Delivered				3.909	0.418
% Attended	82.1%	81.9%	81.2%		
(n)	701	723	698		
Failed					
% Attended	8.9%	9.9%	8.3%		
(n)	76	87	71		
Expired					
% Attended	9.0%	8.3%	10.6%		
(n)	77	73	91		

SMS delivery rates varied significantly by age group at 85.1%, 81.3%, 80.2% and 79.1% for women aged ≤54 years, 55-59 years, 60-64 years and ≥65 years, respectively. There was a lower delivery rate in older women, X^2 (6) = 12.993, p = 0.043. (See

Table 5.4.9)

Table 5.4.9 Delivery, failure and expiry rates by age-group subgroups.

	≤54 years	55-59 years	60-64 years	≥65 years	X^2	p-value
Delivered					12.993	0.043
% Attended	85.1%	81.3%	80.2%	79.1%		
(n)	619	642	455	406		
Failed						
% Attended	7.7%	8.0%	10.6%	10.7%		
(n)	56	63	60	55		
Expired						
% Attended	7.2%	10.8%	9.2%	10.1%		
(n)	52	85	52	52		

5.5. Discussion

5.5.1. Overall and subgroup effects

The overall uptake across screening arms of 83.3% was extremely high, and exceeded the expected coverage for the WoLBSS given the coverage of 65.9% in 2015. This is likely to reflect the selection bias of this particular group of women, who had provided their mobile phone number to the screening service. The study did not reach the a priori calculated sample size due to a regional reconfiguration of services curtailing the planned data collection period. Furthermore, the power of the trial was reduced by the need to exclude a large number of women as a result of cross-contamination of the SMS delivery. This should be considered when interpreting the results of this trial. Overall, there was no significant difference in participation noted between trial arms, although women allocated to the Behavioural regulation SMS showed a non-significant absolute increase in uptake of 1.6% overall compared to the control. When adjusted for age and type of invitation type, this results in an odds ratio of 1.13 increase in likelihood of attending when receiving the Behavioural regulation compared to the control SMS. However this was also not statistically significant. The Priority SMS did not appear to change the participation rate overall. The per protocol analysis showed very similar results to the intention to treat analysis, which reflects the high percentage of SMS delivered.

The exploratory analysis by age subgroups showed no difference in participation rates by age. However, non-significant trends indicated that in general women aged over 55 years receiving the Behavioural regulation message may have had a slightly higher participation rate than the control or the Priority SMS. In the oldest age group (65 years and over), the Priority SMS actually performed worse than the control resulting in an absolute reduction in participation of 4.2%, however this trend was again non-significant.

The subgroup analysis by invitation groups suggests that women being invited for their first breast screen, may have had higher participation rates if they received the Priority SMS compared to the control SMS, with an absolute increase of 4.7%, although this difference was not significant. However, in the same subgroup, women receiving the Behavioural regulation SMS showed an absolute reduction in

participation of 7.4% compared to the control, however this trend was again not significant, which may be due to the small sample size. In women who were being recalled routinely, those who received Priority SMS showed little difference in participation compared to the control, whereas the Behavioural regulation SMS trial arm showed a non-significant absolute increase of 2.1%.

Although no significant difference was found between trial arms there were a number of issues with the trial that resulted in lower than planned sample size, which meant that the study was under-powered. The observed non-significant differences in participation rates between different intervention arms are of a similar magnitude to those seen between intervention arms in the trials discussed in chapters 2 and 3, as well as a past study assessing the impact of SMS content on hospital outpatient appointment attendance.(162) In each of these trials the sample size reached by trial arm was much larger and the results were found to be statistically significant. It is therefore possible that a future adequately powered study using the same interventions might detect a significant effect on participation.

It is not possible to ascertain from the non-significant results of the subgroup analysis as to whether different types of message content have a different impact on women dependent on their characteristics (e.g. different age groups or invitation type). This however, would not be surprising as the trials described in chapters 2 and 3, did indeed show such differences within subgroups.

As discussed in section 5.3.2, there is evidence demonstrating the importance of behavioural regulation and planning in the context of other preventative behaviours such as breast and bowel cancer screening, antenatal screening and exercise. (168, 226-229, 246) These studies highlight how the use of planning tools can effectively change behaviour. These trials however, reiterate the importance of providing specific planning tools. The results of the current trial showed a non-significant weak positive trend in participation rates in those who received the Behavioural regulation or Planning SMS. Although the difference in participation rates observed, are of the magnitude expected for the intervention design chosen (the study was powered to detect an absolute difference of 3%, and found a difference of 2.2% between the control and the Behavioural regulation and Planning SMS), it is possible that the

message content could have been made more effective. For example, asking women to make a note in their diary may not have been the most effective 'planning' tool available. It is possible that asking women to plan how they might take time off work or arrange transport may have in fact resulted in a higher participation rate. Interestingly, these factors reflect the 'Environmental context' domain assessed in the population survey reported in chapter 4, which was measured as the strongest barrier to attendance. It is therefore possible that combining a behavioural regulation and planning tool with a specific environmental context target such as transportation may result in a potentially effective intervention to improve participation. However, such alternative planning interventions may not apply uniformly to all women, as for some women arranging time off work or transport may not be the major hurdle in their planning to attend. Therefore, it is harder to create an intervention that includes planning and the environmental context that would be expected to be uniformly relevant to women invited for screening and therefore effective.

As discussed in chapter 4 (section 2.5.1.1), a number of studies have shown that women often cite being 'too busy' as a reason for not attending screening.(17, 18, 23, 24, 27, 61) However, an individual's ability to prioritise preventative health behaviours may be heavily influenced by social stresses, such as a lack of social support, or being of lower SES.(210, 232) The complex behaviours and characteristics that give rise to the ability to prioritise may mean that a simple intervention that merely asks women if they are prioritising breast screening may not be sufficient to change a woman's likelihood of actually prioritising breast screening. These complex predictors of priority may have contributed to the finding of no difference in uptake between the priority arm and the control. It is particularly interesting that older women showed a non-significant yet lower attendance rate in the priority trial arm. Evidence shows that older women are more likely to have lower risk perceptions in terms of developing breast cancer than younger women.(20) Having a lower perception of risk and lower perceived importance of breast screening has also been associated with lower participation rates.(74) It therefore possible that older women may be less likely to change their behaviour as a result of a 'Priority" message, because they feel less at risk of breast cancer and thus may place less importance on attending. It could be hypothesised that such women may have been reassured by previous negative screening test results. This in turn may contribute to

an optimism bias of their personal risk of developing breast cancer. Conversely, women being invited for their first screen had non-significant yet higher participation rates if they received the Priority SMS compared to the other two trial arms. It is possible therefore that younger women may be more likely to respond to the Priority SMS as they feel at high risk and such a message may therefore be more salient to them.

5.5.2. Mobile phone number accuracy and availability

A mobile phone number was only recorded for 28.6% of women due for screening during the trial period. This is much lower that the rate of phone numbers recorded by GP practices seen in chapter 3 (47.4% in group 1 (24-29 years) - 48.9% in group 2 (30-64 years)). This is likely to be for two reasons, firstly patients are likely to have more frequent contact with their GP practice and therefore have more opportunity to offer their phone number. Secondly, the cohort of women being invited to breast screening is older than the cohort being invited to cervical screening. It is therefore possible that mobile phone use amongst older women is lower and may contribute to lower rates of recorded phone numbers within the breast screening services.
Of the women included in the trial, the accuracy of their mobile phone number as measured by the delivery status of the SMS reminder, was 81.7%. This means that 18.3% of recorded mobile phone numbers were either out of date or incorrectly recorded. The mobile phone numbers of older women were significantly less likely to be correctly recorded than those of younger women. This may reflect the amount of time that has passed since older women had provided their mobile phone number to the service as they are likely to have been invited to more than one screening round. As a result there may be an increased likelihood of a change in phone number over the time period, since they shared their mobile number. Given that the screening interval is three years this means that women are unlikely to have been in contact with the service in between mammogram appointments and therefore are unlikely to update their stored mobile phone number in this period. However, it highlights the importance of checking the mobile phone numbers for women each time they have contact with the service.

During the conception and setup of this trial, it was originally planned to send text message reminders to all women who were due for screening regardless of previous contact with the screening service. To achieve this, patient mobile phone numbers would need to be retrieved from their GP's IT system rather than the WoLBSS IT system, such as was done for the SMS trial in cervical screening described in chapter 3. However, the provision of breast cancer screening is considered a separate service in which a patient's GP does not part-take in the service provision, in contrast to cervical screening, where the GP practice provides the smear test. It is therefore not felt that women who have provided their phone number to their GP would have actively consented for their number to be shared with the screening service. For this reason the lead for information governance at the responsible trust did not give permission for the breast screening service to retrieve the phone numbers from the patients' GP databases. This means that only women who were due for screening, had previously interacted with WoLBSS and had given their mobile phone number, were able to be included in the trial. As a result there is a selection bias in this trial, which also persists throughout the routine care provided. The study participants included were likely to be highly motivated individuals, who may have had strong intentions to attend breast screening and may be more concerned about their health and in particular the risk of breast cancer, than the women who did not provide their mobile phone number and were therefore unable to be included. This is not only true of the study participants but also of the women who are routinely invited by WoLBSS for screening as the standard practice is for women who have provided their phone number to be sent an SMS reminder, whereas those who have not given their number will not be prompted to attend. Accepting that previous attendance predicts future attendance, (40, 41, 131) women who were included in the trial were highly likely to have attended in the past, and would therefore also have been more likely to attend in the future, regardless of an SMS reminder. This is reflected in the high baseline participation rate in the control arm of the trial. Furthermore, women who were being invited for their first screening mammogram and whose mobile phone number had been provided to the services in advance of their appointment were likely to represent individuals who had received the invitation letter and have contacted the screening service to provide their phone number or to rearrange their appointment at which point they may have given provided their phone number. Again, this is likely to indicate these women will be highly motivated to attend. As a result the sample is not

representative of all women who are eligible and routinely invited for breast screening in the catchment area of WoLBSS. It is therefore possible, that the women who might most benefit from SMS reminders, such as women who have lower motivation to attend or have not previously attended, are unlikely to have been reached in this trial or indeed through any SMS based intervention to improve participation including the current routine practice of sending SMS reminders.
Therefore, it could be argued that the 71.4% of women for whom no (correct) mobile phone number was available were disadvantaged in terms of receiving simple reminders to the service. This group may include women who engage with preventative health services less frequently in general, or are difficult to reach. However, those for whom no mobile phone number is available will also include a small minority who make a conscious and active choice to not be screened, but who have not been removed from the register.

The long time interval between screening invitations combined with the restriction that WoLBSS is not permitted access to patient mobile phone numbers held on GP practice databases, means that even women who have previously provided their phone number to WoLBSS but since have changed their phone number and updated this with their GP, will not receive an SMS reminder unless they have directly contacted the service to update their contact information with the screening centre. This no doubt further reduces the effectiveness of the SMS reminder service currently provided within the breast screening service.

Evidence suggests that mobile phones are used by over 93% of the British public.(248) Many hospitals and GP practices use patient mobile phone numbers to send SMS reminders for routine healthcare appointments. However, information governance experts currently determine that the GP does not take an active role in the service provision, as breast cancer screening is provided directly by the local screening service in terms of invitation to screening, the screen test itself and the subsequent follow-up. As a result it is deemed unacceptable to use information including mobile phone numbers given by a patient to their GP. Moreover, cancer screening provides a service that has not been initiated by the individuals being invited. Therefore it cannot be assumed that these women have given their consent for their phone numbers to be used for SMS reminders from the cancer screening service.

This differs from routine hospital appointments and GP appointments, as these have generally been initiated by the patient and usually arise due to a health complaint. This also differs somewhat from cervical screening as, although the patient again does not initiate the invitation to screening, smear tests are offered through the GP practice, which can hold the patient's mobile phone number. It is therefore acceptable in terms of information governance to use the patient mobile phone numbers held by the patients' GP practice to send SMS reminders for women due for cervical screening. As a result, this may mean that unless the policy on the use of phone numbers provided to GP practices were to change, the effectiveness of SMS reminders in general might be less effective in breast screening, than it could be in other settings such as in cervical screening. Furthermore, SMS interventions in breast cancer screening may increase health inequality through not targeting those who have previously not attended, who are also less likely to engage with preventative services in general, than those who have attended in the past or contacted the screening service and who are therefore more likely to attend in the future.

5.5.3. Is using a population survey the best way to establish the SMS content for breast screening reminders?

As described in chapter 4 a population survey was conducted to establish which behavioural domains to select to inform the message content for the interventions of this trial. It is possible however, that the insights gained from the survey may not translate directly into a change in behaviour when used in SMS reminders. This might be for several reasons. The first may relate to how the text message reminder content was phrased. As discussed above, the Behavioural regulation content may in fact be more effective if coupled with planning a particular element of attending screening such as what transportation to take. Secondly, it is possible that self-reported barriers and enablers to screening do not in fact represent the actual strength of barriers and enablers experienced. Instead, self-reported factors affecting screening may instead represent those that most readily come to mind. This may be explained by the availability bias, in that when thinking of previous experience, one might most vividly remember the embarrassment or pain of a smear or mammogram and therefore score

highly in this behavioural domain. Whereas, it is well recognised that a General Practitioner endorsement is a very effective method to improving uptake across all three cancer screening programmes.(115-119) Yet, the results of the population survey suggest that the injunctive social norm of the GP endorsement was not a strong predictor of attendance at screening. As a result future research might consider testing interventions based upon a number of different behavioural domains of different magnitudes of strength in terms of predicting attendance, to test the hypothesis that the TDF accurately predicts the behavioural domain that will most likely result in behaviour change given an intervention. Furthermore, although the TDF does attempt to measure both reflective and more automatic behavioural domains, it does not attempt to include behavioural economic principles in terms of measuring of behavioural biases and heuristics (rules of thumb) in behaviour change. Therefore, future research might consider comparing interventions informed by TDF domains of different strengths in predicting previous attendance as well as interventions identified through behavioural economic frameworks.

5.5.4. Limitations

There were significant logistical challenges throughout this trial, which resulted in the a priori sample size not being achieved. There are two reasons why this occurred. Firstly, due to logistical reasons the trial had to close approximately 3 months early. This was because the 'call recall' services within WoLBSS were relocated to the Royal Free hub, which now organises and provides the call recall service for all regional London breast screening hubs. Due to the transition period for the service, the new pan-London call recall team felt they could not support the continuation of the trial. Secondly, as with many trials that are integrated within the health service, this trial needed to cause minimum disruption to existing services and not increase the workload of the routine care-team. As a result the randomisation was performed through the iPLATO platform rather than by the routine care team. This however, meant that women who were allocated to a trial arm but then contacted the WoLBSS care team to rearrange their appointment, were re-entered into the list of women due for screening being offered an appointment and therefore, re-entered into the randomisation process. As a result there was a large amount of crossover between

trial arms with a large number of women receiving more than two SMS reminders (16%, or 1282 participants of 7944 recruited) as well as text message reminder content from more than one trial arm (43%, or 3382 of 7944 participants recruited). As this created noise in the data, these women were excluded from the final analysis. These necessary exclusions of participants further diminished the power of the trial. As a result the sample size was not reached.

Furthermore, when comparing the differences in participation rates in this trial to those of the cervical screening trial using SMS described in chapter (3), it must be highlighted that the breast screening SMS trial did not have a 'no SMS' control arm, nor a 'simple SMS' arm. It was not deemed ethically appropriate to include a no SMS control given that standard practice within WoLBSS was to send two SMS reminders. Due to previous research carried out within WoLBSS, that resulted in the current practice of an SMS with a 'memory' domain type message content,(157) this SMS acted as the control arm. Therefore, the control arm already contained a behaviourally informed message in form of a 'memory' domain message. Furthermore, the survey analysis in chapter 4 highlights that the memory domain remains a strong predictor of participation but was not as powerful at predicting participation in breast screening as the two domains chosen to inform the SMS content design. Therefore, the potential improvement in effect size was smaller and it could be argued that the sample size calculation was based on an ambitious estimated difference in uptake.
On the other hand, the memory domain was not directly compared to the Behavioural regulation or Priority domain in the survey analysis. It is therefore possible that there was no significant difference in their predictive strength of past behaviour and therefore, it might be expected that when translated into and SMS intervention they would not performed differently.

5.5.5. Future Research

A much larger trial to test these SMS reminders against the control in a larger geographical area would be of benefit. As discussed above it would also be worth considering an approach, which compares SMS content informed by different behavioural theories.

Furthermore, including a 'kitchen sink' approach, in terms of including more than one method within one SMS would be of interest. In particular, for example; a GP-endorsement, a Behavioural regulation SMS and an SMS that contained both. However, as discussed in previous chapters, it can be a challenge to create SMS content within the 160 character limit, whilst maintaining ease of comprehension. Future trial structure and management should be reassessed to devise processes to ensure that women allocated to one trial arm are not reallocated if they contact the screening service to change their appointment date or time.

5.6. Conclusions

Although no significant difference was found between the intervention arms and the control, non-significant trends suggest that overall the Behavioural regulation SMS may be marginally more effective than the current memory SMS used. Furthermore, women of different subgroups by age and type of invite (routine recall, high risk and first invitation) may respond differently to different SMS reminders. The lack of significant findings is likely to be due to under-powering of the study as a result of extensive logistical challenges, which limited the sample size. Given the limitations in terms of access and accuracy of mobile phone numbers of women eligible for breast screening, text message reminders may have limited impact in this setting. Furthermore, the use of SMS reminders may in fact be increasing the inequality in access to screening by only reaching those who provide their mobile phone number. Efforts should be made to ensure that screening staff regularly checks mobile phone numbers at the time of screening appointments as well as during any phone contact with the screening service. Further research and policy level debate is needed around the appropriateness of sharing the mobile phone numbers provided by individuals to their GPs with providers of preventative health services such as breast screening.

6. General Discussion

Each year the NHS spends £70 million on postal communications.(249) A large proportion of these represent communications with patients and the public. Such communications contain health messages that aim to inform patients and the public about their health and healthy behaviours, offer invitations and reminders for appointments, or inform of and invite to preventative health opportunities.
Much research has shown the importance of the content both in terms of the message and the format, as well as the communication channel, to increase the likelihood of the target audience reading, understanding and acting upon the information provided. There is also mounting evidence that text message reminders may provide an alternative, cost-effective communication channel for some health purposes, (160) such as the invitation and reminder to cancer screening. Evidence shows that more than 90% of the public think that cancer screening is a good idea, yet the participation rates for the programmes fall well below this. (1, 3, 5) The field of behavioural science has extensively investigated the factors affecting participation in cancer screening. Health psychologists have researched the barriers that individuals face when they intend to attend but do not actually attend and have provided techniques to measure these factors. Behavioural economists have focused on providing a theoretical basis for personally held biases and heuristics that may lead to irrational decision making, which also apply to cancer screening participation.(51, 79) This thesis sought to explore the effect of different message content within health communications on cancer screening participation, which were informed by behavioural science theory arising from elements of both health psychology and behavioural economics and their intersection.

6.1. Main findings

6.1.1. Message content in SMS and letter reminders

The study reported in chapters 2 highlights that changes to the format and content of cervical screening invitation letters, in the form of gain and loss framed messaging can improve smear test completion rates. Overall, loss framing had a small (OR 1.1) but significant impact on improving screening rates. These findings are consistent with evidence highlighted from breast screening, which indicates that loss framing may have a small but significant impact on participation.(140-142)

However, the trial also highlighted that women receiving their first invitation to cervical screening were significantly more likely to attend if they received the gain framed message (OR 1.35) compared to the control. Whereas, women receiving their second or more invitation were more likely to attend if they received the loss framed letter (OR 1.1). This is of interest as it is possible that women who are receiving their first invitation may potentially view cervical screening as preventative and therefore might respond better to a gain framed message.

The study reported in chapter 3 showed that sending a reminder text message in addition to the cervical screening routine invitation letter improved participation. In women who were aged less than 29 years, there was a significant absolute increase of 5% between the intervention arm (GP message) and the no SMS control in the intention to treat analysis. There was a significant absolute increase of 14.5% in the per protocol analysis. Although in this age group the only intervention SMS tested was a GP endorsed message, these finding are consistent with evidence from a Dutch trial, which indicated that younger women respond well to GP endorsed invitation letter compared to a letter from the screening service.(121) In women aged 30 years or older there was a 2.3% absolute increase from women allocated to the no SMS control to women who were sent any of the intervention arms, which was approaching significance ($p = 0.087$), and a significant 8.5% absolute increase in the per protocol analysis ($p < 0.001$). The biggest overall increase in the older age group was also between the GP endorsed SMS and the control resulting in an absolute increase of 4% in the intention to treat analysis, closely followed by the neutral SMS reminder with an absolute increase of 3.7%. Whereas, the social norms and message framed SMS

interventions were associated with participation rates that were higher than the no SMS control, these were not found to be significantly different to the control and observed lower participation rates that those in the GP message or neutral reminder arms. The impact of the GP message SMS is consistent with much previous evidence, which has shown the effectiveness of such endorsements over more generic invitations across the different screening programmes.(115-122) However, GP messages have not previously been compared side by side to other behaviourally informed message content in cervical screening.

The subgroup analysis also revealed that the impact of different messages varied according to levels of deprivation. For example, women who were more deprived had the highest observed participation rate if they received the neutral SMS reminder. Interestingly, a study by *Skinner et al.* found that women who were more deprived were more likely to have a mammogram if they received tailored GP-endorsed communications than a standard communication.(152)

Further subgroup analysis in chapter 3 indicated that women of intermediate levels of deprivation had the highest observed participation rate if they received the GP-endorsed or loss framed SMS. Whereas, women who were the least deprived did not appear to show any significant difference in participation if they received any of the SMS interventions or no SMS reminder. These findings are consistent with the prediction outlined by *Purnell et al.* that indicated that behavioural economic informed interventions may affect individuals from different levels of deprivation in different ways.(79)

Both trials described in chapters 2 and 3 indicate that women with differing characteristics such as belonging to a different age group, having a higher or lower level of deprivation, or having different exposures to the screening programme seem to respond differently to the message content tested. Currently, the cervical screening service provides a one-size-fits-all approach by sending a uniform invitation letter and reminder with the same format and message content to all women due for screening. However, the trials reported here, as well as evidence from the literature,(152) indicate that this uniform approach may not be the most effective method to engage individuals with different socioeconomic characteristics, to participate in cervical screening. In section 6.4 I will discuss potential future work, which considers a more targeted approach to health communications in cancer screening invitations and reminders.

The interventions for both of these trials were informed by the intervention design toolkit provided within the MINDSPACE framework. The final target behaviours were selected by an expert panel, which took into account the potential interventions that the local screening hubs could feasibly support and were judged to be most likely to have the biggest positive impact on participation. It is therefore possible that a more effective message content addressing a specific behavioural factor or bias, which is more central to changing screening behaviour, was not suggested through the MINDSPACE toolkit, or selected by the expert panel, or was not feasible to be tested by the screening hub.

In order to improve the robustness of the intervention design and selection strategy for the potential message content, the survey reported in chapter 4 sets out to measure how a large variety of psychological factors predict previous screening behaviour. These psychological factors also included target factors that were selected for the trial interventions in chapters 2 and 3; e.g. Injunctive social norms, such as the opinion of their GP or the descriptive social norms, such as the screening behaviours of other women in Hillingdon. However, the psychological factors also included a comprehensive list of other factors expected to affect breast screening participation. The validated Theoretical Domains Framework was used to guide the creation of a comprehensive population survey to aid the selection of key factors to target in future intervention design.(111) The survey identified two psychological domains that most strongly predict screening participation: 1) Behavioural regulation and planning to attend 2) a person's ability to prioritise screening. These domains then informed the intervention design for an RCT described in chapter 5, which compared two text message reminders against the current control SMS content. This trial did not identify any significant difference in uptake between trial arms. However, the trial was grossly underpowered due to a number of logistical obstacles encountered and may therefore be subject to a type II error.

6.1.2. Mobile phone availability

Both trials involving text message reminders were hindered by mobile phone number availability, for two different reasons. The results of the cervical screening trial discussed in chapter 3 highlighted that there is considerable variability in the accuracy of mobile phone number data held by GP practices, with only approximately 38% accuracy of mobile phone numbers, with the remainder either representing patients with no number recorded or an incorrect number recorded. This may indicate that GP practice administration staff are not routinely collecting and checking the accuracy of mobile phone number data or that these are not being recorded in the GP practice IT systems. The breast screening RCT encountered a different issue regarding access to mobile numbers. The mobile phone number is not currently considered part of a patient's core contact address. This means that it cannot be shared between the GP practice and the screening centres. This is an important distinction as information governance specialists argue that screening is a public health service that is offered to the public and was not initiated by the screening invitee. Therefore, women who have provided their mobile phone number to their GP for the purpose of their healthcare have not formally consented to it being used by the screening centre. In contrast to cervical screening, where GP practices offer smear tests, thereby providing the service of cervical screening, the GP does not take part in the service provision of breast screening. As a result, it is not currently permitted for breast screening services to access the mobile phone numbers stored on a patient's GP practice IT system, although it is in principle and technically possible. In the absence of the ability to access phone numbers held by GP practices, only women who have previously had contact with the screening centre, (i.e. have previously attended, or are due to attend and have made contact at which point they shared their mobile phone number) are able to be sent SMS reminders. This means that women who have never attended screening and have not otherwise made contact with the screening service where they might have provided their phone number, are unable to be contacted through this route. Therefore, the women who currently receive text message reminders are women who are already more likely to attend screening. This was reflected in the above average participation rate in all three trial arms (82.8-84.4%) compared to known overall participation rates for WoLBSS (68.3%). Furthermore, as women are only invited every three years unless they are deemed high risk, it is possible that the

patients who have updated their phone numbers with their GP practice since their last screening appointment, have not done so separately with their local breast screening hub. As a result, the current practice within some breast screening hubs of sending SMS reminders in advance of mammogram appointments may in fact be disadvantaging women who are first-time invitees or women who have been repeatedly invited and have persistently not attended due to personal barriers. However, the cohort which have not given their mobile number to the breast screening service will also include a small proportion of women who have made an informed decision to not take part in breast screening.

This issue raises questions about the public opinion of the acceptability of using text message reminders in breast cancer screening when women have not provided their phone number directly to the screening service. It raises further questions about the public's opinion of sharing a patient's mobile phone number, which was provided to GP practice with other secondary care organisations within the NHS as well as preventative services. One option might be to ask GP practices recording these numbers, to inform and consent patients for providing their mobile phone number to all NHS services, or selected services such as the GP practice, secondary care and preventative care (i.e. health promotion that was not initiated by the patient).

6.1.3. Intervention design – how to identify key behavioural factor and select the best intervention tool?

The intervention design approach for this thesis has been iterative and pragmatic and has taken into account system and provider restraints to enable trials to be run within the screening services. The use of the MINDSPACE framework focused the intervention design on behavioural economic theory, utilising specific tools such as the Messenger effect, Social norms and Message framing.(32) The use of behavioural economic theory applied to breast and cervical screening is a novel approach as it places more emphasis on the irrational behavioural biases that may contribute to non-attendance.

However, the MINDSPACE framework has some limitations. Although it provides a guide and tools for behaviour change, it does not aid the selection of the most

appropriate target behavioural factor (e.g. present time bias, or loss aversion bias) that might be contributing to non-attendance. Furthermore, it does not provide any guidance on the selection of the most appropriate MINDSPACE tool (e.g. the messenger tool or incentives). Therefore, any intervention design informed by the MINDSPACE framework relies on the researcher or an expert panel to make an educated judgement, as to which of the tools might be the most appropriate and most effective in evoking behaviour change.(32) In addition, although MINDSPACE includes an extensive list of BE informed behaviour change techniques, this list is not comprehensive and further tools such as; enhanced active choice, mental accounting, availability bias, the use of competition and gamification are not included.

The Theoretical Domains Framework provides a technique for identifying and measuring a comprehensive list of psychological domains that may act as barriers or enablers to any given behaviour.(111) For this reason the TDF was used to measure the strength of psychological domains in how they predict cancer screening participation. However, this approach also has inherent limitations, firstly as the TDF relies on self-reported beliefs about barriers and enablers. This can be problematic, as the self-reported factors may not correspond to the actual barriers experienced when contemplating or attempting to take part in cancer screening. For example in a survey, a woman's response to an item testing how they think their GP might feel about them attending cancer screening (Injunctive social norms) may not reflect or predict the strength of an intervention using GP message. GP endorsements have consistently been shown to be a powerful driver of screening attendance across the screening programmes (64, 115, 116, 120, 121, 152, 195, 200), an effect also observed in the trial reported in chapter 3.

The TDF is a result of the consolidation of 33 psychological theories, that bring together psychological domains from both rational, reflective decision making theory (behavioural regulation and planning, knowledge, skills) but also includes automatic drivers of behaviour and irrational decision making theory (optimism, social influences, memory, emotion).(111) Although, the TDF provides a technique to measure these domains, like the MINSPACE framework it does not attempt to measure the personal biases and heuristics informed by behavioural economic theory that influence behaviour. An example relevant to cancer screening is the present time

bias. Humans tend to place more value on events that occur in the present time and are more likely to discount events that might happen in the future.(83) In the context of cancer screening this might explain a degree of procrastination or 'not getting around to' participating in screening that is frequently reported (18, 19). This is because individuals might put more weight on the immediate challenge of having a screening test (such as arranging an appointment, getting time off work, the anticipation of anxiety or pain of the test and possible cancer diagnosis) than on the potential longer term benefits (such as preventing cancer or detecting a cancer early, when the treatment is more likely to provide a cure). It is however possible that some individuals experience different degrees of present time bias in general, which may then be altered to increase or decrease when faced with a specific behavioural choice such as cancer screening. Therefore, future work should consider how more holistic assessment tools and frameworks can be developed to comprehensively map out and measure not only the rational theory based domains, but also the more automatic, irrational domains, biases and heuristics that affect daily behaviour. It may be challenging to meaningfully measure biases, such as the present time bias through direct questioning in a survey for example. Therefore, novel ways to ascertain such behavioural factors, biases and heuristics should be pursued, ideally through direct observation of behaviour rather than self-reported perceived factors that affect the behaviour. Early work in this area, such as 'Behavioural phenotyping' is currently being pursued by a research team at the University of Pennsylvania's Centre for Health Incentives and Behavioural Economics (CHIBE). Here, researchers are using simulated and hypothetical scenarios in which individuals are asked to make decisions that measure such biases. Future research might focus on how individuals with stronger measurements of certain biases and heuristics respond to a present time bias targeted intervention, compared to those individuals with weaker measurements of the bias, in the context of cancer screening.

This research could then lead onto a behavioural intervention selection tool, which will aid the identification of the most effective technique to target such factors influencing behaviour change, and may be able to overcome the limitations of both the MINDSPACE and the TDF frameworks. However, measuring an individual's behavioural phenotype for any given bias and developing interventions to target these

may make any resulting intervention difficult to scale without adequate infrastructure within the screening services to allow for segmented intervention to be deployed.

The use of online pilots could also be used to test the final message content of such interventions. For example the priority intervention message described in chapter 5 could be tested online to see if it affects women's intention to be screened and their sense of wanting to prioritise screening. However, the limitation of such pilots is that they may not allow for accurate outcome measures of screening attendance, as they cannot be linked to the potential participation in screening. Furthermore self-reported screening attendance as a result of the pilot message content tested, is likely to be less reliable as it will be subject of reporting bias and social desirability bias.

6.2. Ethical considerations of behavioural science interventions in cancer screening.

Any intervention that is designed to change behaviour should be examined in terms of its ethical implications. Cancer screening is not without risks; all screening tests carry with them the risk of false positives resulting in unnecessary anxiety and over-investigation, and false negatives resulting in inappropriate reassurance. However breast and bowel cancer screening programmes also have specific risks. In the case of breast screening, there is a risk of over-diagnosis. This refers to women who screen positive for breast cancer and do indeed have a breast cancer diagnosis, but the combination of the characteristics of the tumour biology and the patient (e.g. age, frailty, co-morbidity), means that the individual will not die of their breast cancer but of something else. Therefore, it is considered an over-diagnosis, because if such women did not attend screening they may never have known they had breast cancer and may not have suffered any morbidity from unnecessary treatment or anxiety from the diagnosis. Although estimates of over-diagnosis are considered unreliable, it has been estimated that for every 10,000 women screened 129 women will be over-diagnosed and 43 deaths from breast cancer will be prevented.(6) In bowel cancer screening all individuals who have a positive faecal occult blood test (FOBT) result will be referred for a colonoscopy. However, only 11% of positive FOBT will result in a bowel cancer diagnosis.(250) Colonoscopy caries the risk of colonic perforation,

and although this is only estimated to be around 0.082%, the consequences for patients affected can be significant.(251) There is therefore a need to provide balanced information that addresses the risks and benefits of screening, to allow informed decision-making by those invited. Behaviour change theory, in particular that which addresses the irrational decision making process, has often come under scrutiny for coming close to the ethical line of coercion. Particularly in the case of breast screening where the risk to benefit ratio is not as convincing as compared to cervical or bowel screening, the use of behavioural economic techniques can be viewed as ethically problematic.(123) However, fundamentals of behavioural economics can also provide an explanation for why individuals may not take the opportunity to read and consider materials routinely provided by screening services that provide fully balanced and comprehensive information on the risks and benefits. Evidence suggests that the vast majority of the public think that cancer screening is a good idea, but significantly less actually participate regularly.(1) Therefore, interventions designed using behaviour change theory should strive to make it easier for those who intend to take part in cancer screening but do not regularly do so, to participate. Evidence also suggests that only 12% of those who do not attend feel they made a fully informed decision.(26) Interventions should therefore be provided in addition to and not in exchange for fully balanced information and guidance on the risks and benefits. Simultaneously, interventions should seek to respect the autonomy of individuals who have made a fully informed decision and wish not to participate.

6.3. Importance, strengths and limitations

Cancer screening saves lives through early detection of cancerous or pre-cancerous cells at a time when intervention is more likely to provide a cure and be less invasive. However, despite the majority of the public supporting cancer screening, participation rates across the screening programmes remain suboptimal. The research presented in this thesis investigated methods to provide salient information to screening-eligible individuals , which was informed by behavioural science theory. It highlights the importance of the content of invitations and reminders on improving screening participation. By providing information in a user-friendly format, such as the use of

shorter invitation letters, text boxes to draw attention to relevant information; SMS reminders that provide the participant's GP practice phone number and different SMS content, screening providers can further improve participation at cancer screening. Whilst much evidence supports the use for different behaviourally informed message content such as GP endorsements, social norms, message framing and behavioural regulation, the RCTs described in this thesis are the first to compare their observed effect on participation rate side by side in the context of breast and cervical screening.

A key strength of this research is its integration of the trials within the existing cancer screening hub infrastructures. The interventions have been designed to be easily adaptable and adopted by screening hubs, which might wish to implement successful interventions. As screening invitation letters are already routine practice across the country for all cancer screening programmes, changing the letter content of these, can often be achieved at no or little extra cost. Likewise, many GP practices and hospital trusts already subscribe to software that allows for automated SMS reminders to be deployed. Therefore, creating automated reminder messages or manipulating the content of existing SMS to optimise their effect can be a frugal way to change behaviour, which requires little effort on the part of the care providers and can be easily scaled. The research in this thesis however, informs the content of such messages.

However, a number of factors can affect the successful running and completion of an RCT within a health service as well as limit the intervention design opportunities. These can be practical restraints, such as designing interventions within the limits of the service provider or regulatory restraints such as the need to satisfy governing bodies. Integrating trials into well-established existing screening services, which have an existing service infrastructure and set operating processes can be challenging and can impact upon trial design. Ensuring interventions designed can be feasibly deployed and delivered by regional screening services is not only key for the successful running of the trial, but also of importance to ensure any successful intervention designed does not cause significant upheaval thereby potentially affecting its future adoption by and wider dissemination to other regional services. An example of this was highlighted in chapter 2, where the collaborating screening hub was unable to accommodate the potential intervention of a commitment slip printed at

the bottom of the invitation letter. The prototypes produced within the letter template were not easily interpreted as a commitment tool and were therefore not selected as an intervention to be tested.

However, the same trial described also was also required to gain approval from an internal research committee at the Department of Health. The research committee requested for the loss framed intervention message to be changed from reflecting how many deaths could be avoided through screening, to reflect the number of actually deaths attributed annually to cervical cancer. From the academic standpoint, the final 'loss framed' message content was not a true reflection of the same information portrayed in the gain framed message in the context of the potential loss experience through not taking part in cervical screening. However, this was accepted as a pragmatic compromise as the message still reflected the potential risk of death in the context of not being screened as it was delivered in the invitation letter for cervical screening, whilst it did not explicitly link the risk of death to screening behaviour.

A further hurdle to testing intervention design options was encountered in the RCT described in chapter 3. To include the GP phone number in the SMS reminder (and the GP practice name in the GP endorsed SMS) each participant's GP practice was approached and consented individually. Furthermore, participating GP practices were required to have SMS communication platform software installed on their IT system. Additionally, for SMS reminders to be able to be controlled and deployed centrally by the research team for the duration of the trial, participating GP practices within a screening hub catchment area were required to subscribe to a common SMS communication platform provider. This was not only a pragmatic and financial hurdle for the trial itself, but would be a factor when considering adoption of this intervention to other screening hubs, after the trial was complete. For the purpose of the trial, funding was sought from Public Health England to provide iPLATO licensing and software to each participating GP practice free of charge for the duration of the trial period.

As discussed in section 6.1.2, there was considerable variation in the accuracy rates of mobile phone numbers collected by GP practices. This further affects the potential impact SMS reminders will have, when deployed to change behaviours such cancer screening participation.

Although the Medical Research Council (MRC) framework (252) was not formally applied to the intervention design of the RCTs presented in this thesis, its core

principles of intervention development, evaluation of interventions, reporting and implementation were addressed in each of the trials as appropriate. However, the application of the MRC framework might have been beneficial to improve the piloting and feasibility of the design interventions. The use of public and patient engagement to pilot message content of text messages is likely to be of value in future trial designs. Furthermore, as showcased in chapter 5, issues around feasibility might have been identified earlier with a smaller pilot study.

The work presented in this thesis is likely to be generalisable across other geographical areas of the United Kingdom or other countries with organised cancer screening programmes, which provide their screening eligible population with systematically and population level screening outreach. It may also inform the programme design in countries considering implementing population level cancer screening as it highlights the importance for also considering communication infrastructures such as the ability to send letter and text message reminders. However, it is possible that in countries without universal coverage such as the United States, issues around access to healthcare particularly for more vulnerable members of society and concerns over financial contributions may still pose a strong barrier to screening that may reduce the efficacy of such interventions.

6.4. Future work

6.4.1. Testing techniques informed by different behaviour change theories

As discussed in section 6.1.3, it is not yet clear that intervention design informed by either MINDSPACE or the TDF is the most effective possible approach for changing screening behaviour. The trials described in this thesis tested interventions informed by either MINDSPACE or TDF. Future research might therefore include and compare the most effective interventions highlighted through both frameworks to establish their strength at behaviour change. In the context of cancer screening however, it is not yet clear that the TDF informed domains that most strongly predict previous attendance also correspond to or translate into the most effective intervention design to improve participation rates. It would therefore be of interest to run a larger trial that

uses all of the domains measured (both stronger and weaker domains) to inform intervention design and to test these against each other. This would allow for a more accurate assessment as to whether the domains identified through a survey using the TDF do in fact correspond to the strongest factors influencing behaviour change when implemented through intervention design.

Both trials that tested the message content in text message reminders used only one behavioural technique per intervention arm, such as; GP-message, message framing or social norms, prioritising or behavioural regulation and planning. It would however be of interest to test if a combination of two such techniques within one text message might be more or less effective than the techniques used in isolation. An example might be to test a GP-endorsement plus loss framed message against a GP-endorsement alone and a loss framed alone message content. Separately, it would be of interest to test a GP-endorsement plus TDF-informed message content against the effect of their individual elements of GP-message alone or TDF-informed message content alone. It would be important to run such a trial with a sample size sufficiently large to compare the effect on different levels of deprivation. This is because evidence from chapter 3 suggests that women who are more deprived might respond better to a simple SMS message content. Contrary to these findings, some evidence from literature suggests that women who are more deprived are more likely to attend if they receive a GP-endorsed message compared to a generic screening invitation.(152) It is important therefore to ensure a trial testing these techniques adequately powered to be able to measure the effects of such interventions on the participation rates in vulnerable groups. A further limiting factor for combining techniques within a single intervention, which uses text messages as the communication channel, is the challenge of creating a message content that fits within the 160 characters required for a single SMS.

The RCTs described in chapters 3 and 5 used a single text message and a repeated text message reminder, respectively. However, future work might also consider the use of sequential reminders using different message content to be sent in cascades to individuals who persistently do not attend.

Future studies might also consider the use of mobile phone applications and social media as a novel channel of communication to improve screening rates. However, some such channels might also result it a selection bias as particularly in the case of

mobile phone apps, these need to be downloaded before a message can be deployed through them. As a result this may add a friction cost and reduce access to such reminders.

6.4.2. Segmentation – subgroups respond differently.

Evidence both from the research literature and reported in the exploratory subgroup analysis of this thesis demonstrate that different subgroups of individuals with similar characteristics (e.g. women who are more deprived, or being invited for their first screening test) may behaviour differently when exposed to certain interventions.(121) The exploratory analysis carried out in this thesis was performed by intuitively selecting sub-groups based on demographics and running analysis to investigate if these groups have different participation behaviours in response to different trial arms. *Ishikawa et al.* however, used a different method in the context of individuals who had been recalled after an abnormal FOBT test for bowel cancer screening.(245) The authors used a classification tree analysis to identify common characteristics of existing discrete subgroups within the data based on the behaviour of these subgroups (e.g. a subgroup with high follow up rates, who are unemployed and fearful of screening compared to a subgroup with lower participation rates who are employed with a high degree of fear). This allowed the authors to identify naturally occurring subgroups within the dataset without pre-determining the subgroup characteristics. As a result information gained from this segmentation analysis could be used to help inform intervention design and target interventions based on specific behavioural factors and barriers depending on the characteristics of a particular subgroup. Geo-segmentation methods provide further potential opportunities for segmentation of population subgroups. These methods currently offered by private companies such as ACORN or EXPERION use a number of different data sources, including for example publicly available data, census data, commercial data and survey data. Using these sources, a wide variety of data points are used to create categorise population subgroups, which may share common lifestyles, attitudes and behaviours. These are mapped onto geographical areas, which in turn are currently used by other industries to inform targeted consumer campaigns. Such segmentation techniques could also be

used to further inform the intervention design and targeting of population subgroups to improve screening participation.

6.4.3. Accuracy of mobile phone number data held on patient records.

Although this thesis has focused on public facing interventions, it is worth considering provider-facing interventions to improve the effectiveness of the delivery of such interventions. Mobile phone data accuracy was shown to be poor and varied considerably across the different GP practices participating in the trial described in chapter 3. Therefore, future research could also focus on interventions to improve the accuracy and completeness of recording of mobile phone number data within the electronic health record held on the general practice IT systems. An example design might be an interrupted time series analysis of trends before and after an intervention. Such an intervention might use concepts from behavioural economics such as improving the transparency, providing feedback and utilising the effect of competition of the rates of accurate mobile phone numbers recorded across different practices. A possible intervention might be the introduction of a weekly league table that are shared across the GP practices within the clinical commissioning group (CCG), with weekly reward certificates to top performing and most improved practices.

6.4.4. Implementation of interventions in clinical practice

As a result of the trial described in chapter 2, I have been working closely with colleagues at Public Health England and NHS England to implement text message reminders across London for cervical cancer screening. As part of the steering group setup, I am continuing in an advisory capacity to support this rollout, which received preliminary approval to implement cervical screening text message reminders across the 32 London Clinical Commissioning Groups (CCG) commencing in August 2018.

6.5. Conclusions

Text message reminders improve the participation rates in cervical cancer screening. However, the message content of health communications including text message reminders and invitation letters can further improve the effect of these communications. Within cervical screening invitation letters, a shortened invitation letter with a loss framed message had a small but significant affect on participation. However, women being invited for their first screening responded better to a gain framed letter, whereas women being invited for their second or more smear test were more likely to attend after a loss framed letter. In SMS reminders, a GP endorsed message was the most effective overall; however in women who were more deprived the simple SMS message content was the most effective. Future work should focus on systematically evaluating and measuring behavioural factors including biases and heuristics and their prevalence in different discrete groups of individuals who are eligible for screening. This could then be used to inform both the intervention design of the message in terms of content, format and channel of communication, as well as a more targeted approach by deploying specific interventions to individual subgroups with common characteristics and demographics.

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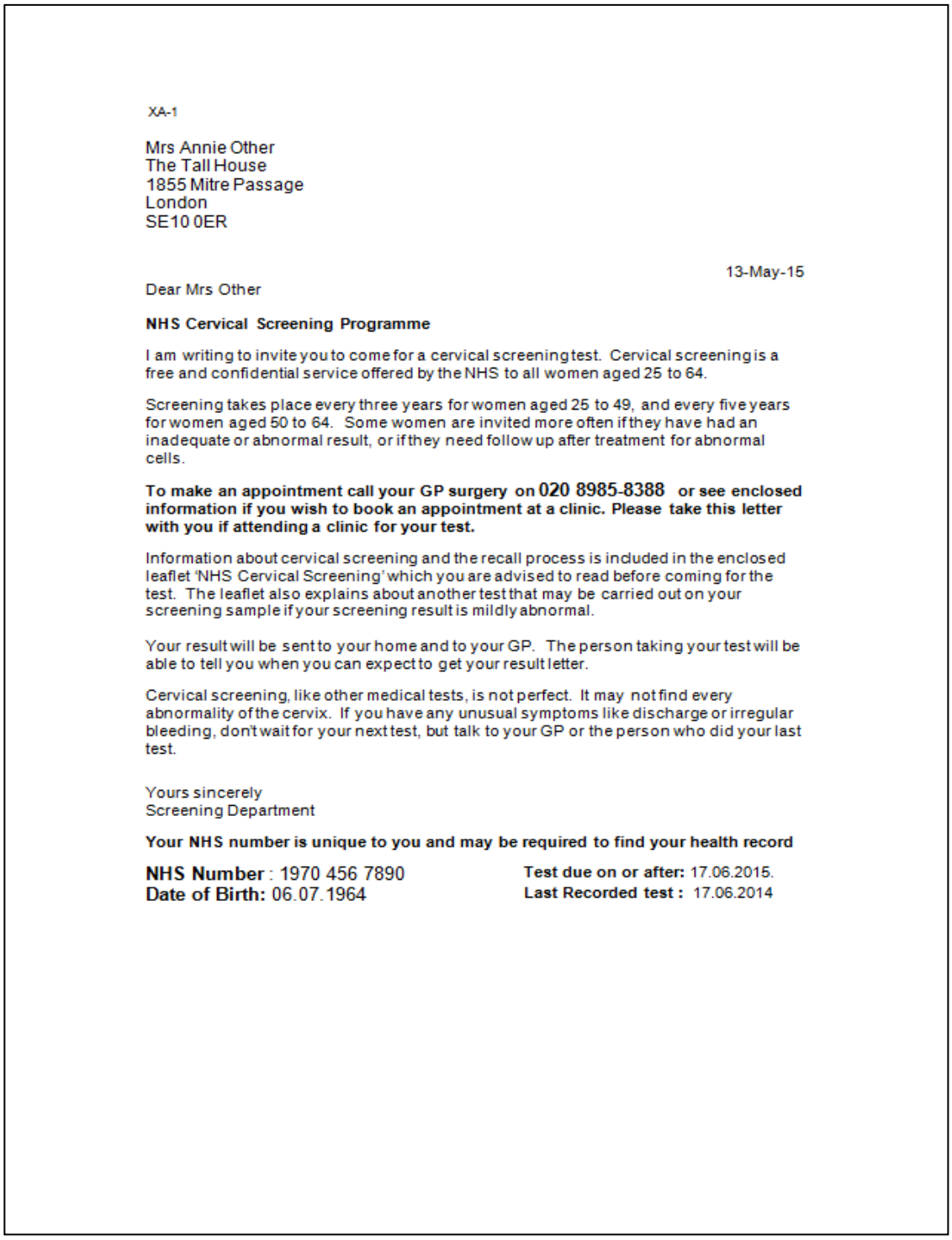
7. Appendices

7.1. Appendix - A

Chapter 2 - Trial arm letter designs



XA-1

Mrs Annie Other
The Tall House
1855 Mitre Passage
London
SE10 0ER

13-May-15

Dear Mrs Other

NHS Cervical Screening Programme

I am writing to invite you to come for a cervical screening test. Cervical screening is a free and confidential service offered by the NHS to all women aged 25 to 64.

Screening takes place every three years for women aged 25 to 49, and every five years for women aged 50 to 64. Some women are invited more often if they have had an inadequate or abnormal result, or if they need follow up after treatment for abnormal cells.

To make an appointment call your GP surgery on 020 8985-8388 or see enclosed information if you wish to book an appointment at a clinic. Please take this letter with you if attending a clinic for your test.

Information about cervical screening and the recall process is included in the enclosed leaflet 'NHS Cervical Screening' which you are advised to read before coming for the test. The leaflet also explains about another test that may be carried out on your screening sample if your screening result is mildly abnormal.

Your result will be sent to your home and to your GP. The person taking your test will be able to tell you when you can expect to get your result letter.

Cervical screening, like other medical tests, is not perfect. It may not find every abnormality of the cervix. If you have any unusual symptoms like discharge or irregular bleeding, don't wait for your next test, but talk to your GP or the person who did your last test.

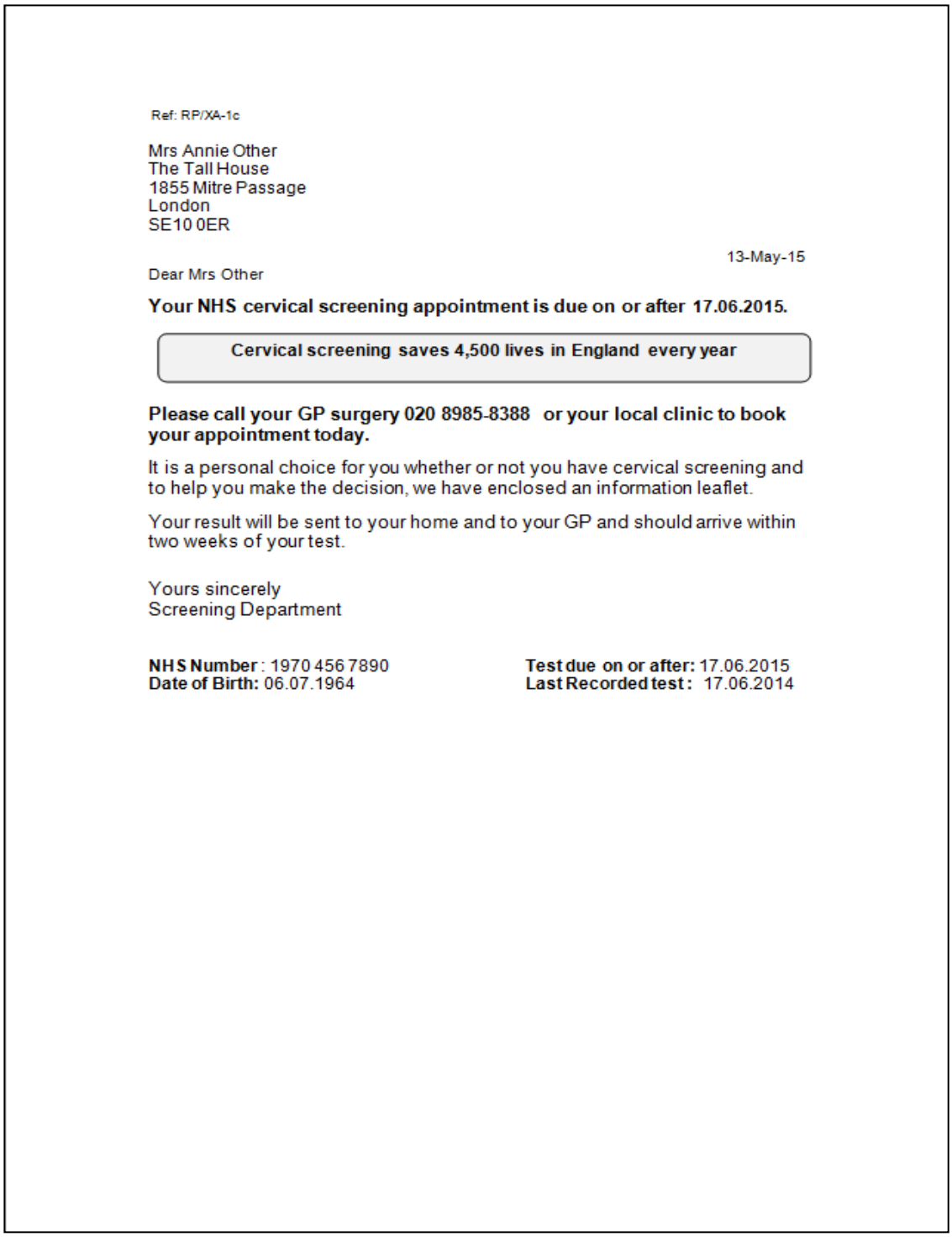
Yours sincerely
Screening Department

Your NHS number is unique to you and may be required to find your health record

NHS Number : 1970 456 7890
Date of Birth: 06.07.1964

Test due on or after: 17.06.2015.
Last Recorded test : 17.06.2014

Figure A1.1: Control letter – Routine care invitation



Ref: RP/XA-1c

Mrs Annie Other
The Tall House
1855 Mitre Passage
London
SE10 0ER

13-May-15

Dear Mrs Other

Your NHS cervical screening appointment is due on or after 17.06.2015.

Cervical screening saves 4,500 lives in England every year

Please call your GP surgery 020 8985-8388 or your local clinic to book your appointment today.

It is a personal choice for you whether or not you have cervical screening and to help you make the decision, we have enclosed an information leaflet.

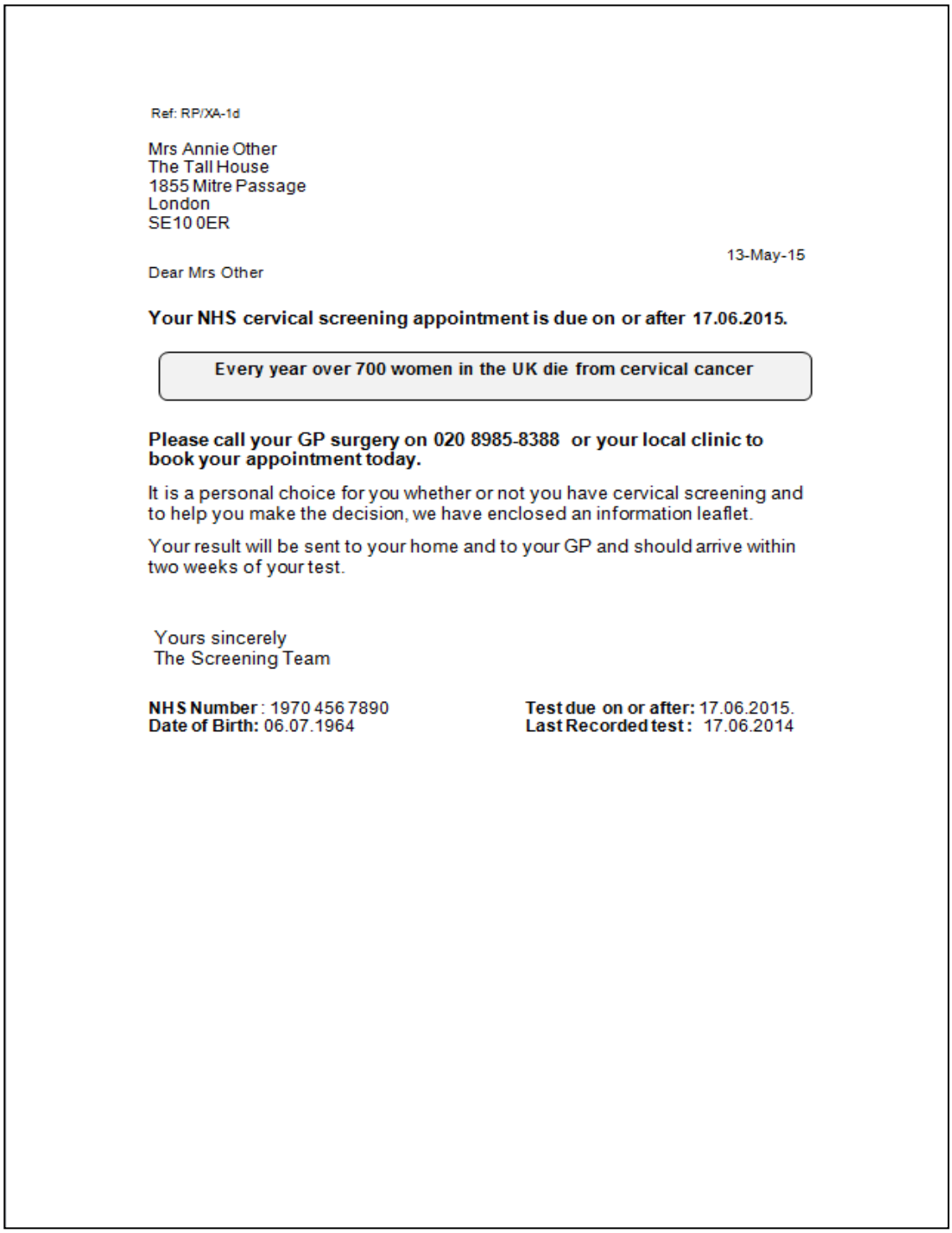
Your result will be sent to your home and to your GP and should arrive within two weeks of your test.

Yours sincerely
Screening Department

NHS Number: 1970 456 7890
Date of Birth: 06.07.1964

Test due on or after: 17.06.2015
Last Recorded test: 17.06.2014

Figure A1.2: Intervention Letter – Gain frame



Ref: RP/XA-1d

Mrs Annie Other
The Tall House
1855 Mitre Passage
London
SE10 0ER

13-May-15

Dear Mrs Other

Your NHS cervical screening appointment is due on or after 17.06.2015.

Every year over 700 women in the UK die from cervical cancer

Please call your GP surgery on 020 8985-8388 or your local clinic to book your appointment today.

It is a personal choice for you whether or not you have cervical screening and to help you make the decision, we have enclosed an information leaflet.

Your result will be sent to your home and to your GP and should arrive within two weeks of your test.

Yours sincerely
The Screening Team

NHS Number: 1970 456 7890
Date of Birth: 06.07.1964

Test due on or after: 17.06.2015.
Last Recorded test: 17.06.2014

Fig A1.3: Intervention letter – Loss Frame

7.2. Appendix – B

Chapter 4 – Pilot and full survey questions

		Pilot Survey	Full Survey
Elligibility questions			
S1	Are you a woman?	✓	✓
S2	Which age group are you in?	✓	✓
S3	S3: Where do you live?	✓	✓
S4	Which borough are you based	✓	✓
Survey Questions			
1	I have been invited for a screening mammogram before.	✓	✓
2	If/When I am invited for a screening mammogram I intend to attend.	✓	✓
2.2	If/When I am invited for a screening mammogram I will definitely attend?	x	✓
3	I attend private mammograms	✓	✓
4	In the past I have attended a screening mammogram whenever I have been invited.	✓	✓
5	How many times have you attended a screening mammogram?	✓	✓
6	In the past, I have attended/taken part in other types of cancer screening whenever I am invited (e.g. cervical screening/bowel cancer screening)	✓	✓
7	Do you believe that there are any advantages of attending breast screening when invited?	✓	x
8	Do you believe that there are any disadvantages of attending breast screening when invited?	✓	x
9	Is there anything else you associate with you attending breast screening?	✓	x
10	To me personally, breast cancer screening is: Valuable - Worthless	✓	✓
11	To me personally, breast cancer screening is: Unpleasant - Pleasant	✓	x
12	To me personally, breast cancer screening is: Beneficial - Useless	✓	✓
13	To me personally, breast cancer screening is: Tolerable - Intolerable	✓	x
14	To me personally, breast cancer screening is: Bad - good	✓	x
15	To me personally, breast cancer screening is: Convenient - inconvenient	✓	x
16	To me personally, breast cancer screening is: Irrelevant - relevant	✓	x
17	To me personally, breast cancer screening is: Upsetting - Reassuring	✓	✓
18	To me personally, breast cancer screening is: Top priorty - unimportant	✓	✓
19	Breast screening can pick up cancer at an earlier stage. - Below are some statements relating to women's beliefs about benefits and disadvantages of breast screening. Please read each statement below and answer according to how much you agre	✓	✓
20	If a breast cancer is treated early, survival is more likely. - Below are some statements relating to women's beliefs about benefits and disadvantages of breast screening. Please read each statement below and answer according to how much you a	✓	✓
21	Receiving a normal screening result will provide reassurance. - Below are some statements relating to women's beliefs about benefits and disadvantages of breast screening. Please read each statement below and answer according to how much you a	✓	✓
22	A breast cancer might be missed by screening. - Below are some statements relating to women's beliefs about benefits and disadvantages of breast screening. Please read each statement below and answer according to how much you agree or disagree	✓	✓
23	A breast cancer might be diagnosed from the screening, when really there is no cancer. - Below are some statements relating to women's beliefs about benefits and disadvantages of breast screening. Please read each statement below and answer ac	✓	✓
24	Not attending screening may lead to a breast cancer growing undetected for longer. - Below are some statements relating to women's beliefs about benefits and disadvantages of breast screening. Please read each statement below and answer accord	✓	✓
25	Mammograms involve a dose of radiation that might in itself cause harm or a cancer. - Below are some statements relating to women's beliefs about benefits and disadvantages of breast screening. Please read each statement below and answer acc	✓	x
26	A cancer may be diagnosed by screening that might not have needed any treatment, or would not affect me in my lifetime. - Below are some statements relating to women's beliefs about benefits and disadvantages of breast screening. Please read e	✓	✓
27	An abnormal screening result could make me anxious about a cancer diagnosis. - Below are some statements relating to women's beliefs about benefits and disadvantages of breast screening. Please read each statement below and answer according to	✓	✓
28	I do not want to attend breast screening as I may suffer unnecessary anxiety from an abnormal test result. - Please give your honest response to the statements below about breast screening:	✓	x
29	I do not want to attend breast screening as I may end up having unnecessary treatment / tests, for an abnormal mammogram result that may not turn out to be cancer. - Please give your honest response to the statements below about breast screening	✓	✓
30	My previous breast screening mammograms have been negative. I am therefore unlikely to develop breast cancer - Please give your honest response to the statements below about breast screening:	✓	✓
31	I am physically able to attend screening. - Please give your honest response to the statements below about breast screening:	✓	x
32	I dread being invited for a screening mammogram. - Please give your honest response to the statements below about breast screening:	✓	✓
33	I have complete control over whether I attend breast screening when invited. - Please give your honest response to the statements below about breast screening:	✓	✓

34	Most people who are important to me think that I should attend breast screening when invited. - Please give your honest response to the statements below about breast screening:	✓	✓
35	The people in my life whose opinions I value would approve of my attending breast screening when invited. - Please give your honest response to the statements below about breast screening:	✓	✓
36	My GP expects me to attend my screening mammogram appointment when invited. - Please give your honest response to the statements below about breast screening:	✓	✓
37	Generally speaking I intend to do what my GP expects of me. - Please give your honest response to the statements below about breast screening:	✓	✓
38	If I dread doing something I do it as soon as possible to get it out of the way. - Please give your honest response to the statements below about breast screening:	✓	✓
39	It is completely up to me whether or not I attend breast screening when invited. - Please give your honest response to the statements below about breast screening:	✓	✓
40	I think it would be difficult to attend breast screening due to high demands on my time from family or work. - Please give your honest response to the statements below about breast screening:	✓	x
41	The distance of the screening centre from my home will affect whether I attend. - Please give your honest response to the statements below about breast screening:	✓	✓
42	I plan to attend a mammogram in the future but not right now. - Please give your honest response to the statements below about breast screening:	✓	✓
43	I tend to put things off that I am dreading doing. - Please give your honest response to the statements below about breast screening:	✓	✓
44	Availability of transport (public or personal) to the screening centre might affect me attending. - Please give your honest response to the statements below about breast screening:	✓	✓
45	If I am given an inconvenient appointment time, I might not attend. - Please give your honest response to the statements below about breast screening:	✓	✓
46	I have never accidently missed a mammogram appointment because I forgot - Please give your honest response to the statements below about breast screening:	x	✓
46	If invited today, choose when you would prefer to attend screening:	✓	x
47	Are there people or types of people who would approve of you attending a screening mammogram?	✓	x
48	Are there people or types of people who would disapprove of you attending a screening mammogram?	✓	x
49	In my opinion breast cancer is generally very common. - Please indicate how much you agree with the statements below about the risk of breast cancer,	✓	✓
50	The likelihood of a woman like me developing breast cancer in my lifetime is low. - Please indicate how much you agree with the statements below about the risk of breast cancer,	✓	✓
51	If I have no breast symptoms, then attending breast cancer screening is unlikely to be beneficial. - Please indicate how much you agree with the statements below about the risk of breast cancer,	✓	✓
52	If I examine my breasts regularly then there is not much benefit to me from attending breast screening. - Please indicate how much you agree with the statements below about the risk of breast cancer,	✓	✓
53	A woman of my age is unlikely to develop breast cancer. - Please indicate how much you agree with the statements below about the risk of breast cancer,	✓	✓
54	A woman with my family's history of breast cancer is unlikely to develop breast cancer. - Please indicate how much you agree with the statements below about the risk of breast cancer,	✓	x
55	I would like to better understand my personal risk of getting breast cancer. - Please indicate how much you agree with the statements below about the risk of breast cancer,	✓	✓
56	I would make an effort to attend breast screening if the result could inform me of my future risk of developing breast cancer. - Please indicate how much you agree with the statements below about the risk of breast cancer,	✓	✓
57	I am worried about pain and discomfort during a mammogram. - Please indicate how much you agree with the statements below about the risk of breast cancer,	✓	✓
58	I am so worried about pain and discomfort that it might prevent me from attending. - Please indicate how much you agree with the statements below about the risk of breast cancer,	✓	x
59	I expect to be very embarrassed during a screening mammogram. - Please indicate how much you agree with the statements below about the risk of breast cancer,	✓	✓
60	I am so worried about being embarrassed, that it might prevent me from attending. - Please indicate how much you agree with the statements below about the risk of breast cancer,	✓	x
61	Attending screening mammograms is consistent with the importance I put on my personal health. - Please indicate how much you agree with the statements below about the risk of breast cancer,	✓	✓
62	For me personally, attending breast screening is very easy. - Please indicate how much you agree with the statements below about the risk of breast cancer,	x	✓
62	An average woman's chances of developing breast cancer in her lifetime is:	✓	
63	Do you know of any reasons why you might be less likely than the average woman to develop breast cancer?	✓	x
64	Do you know of any reasons why you might be more likely than the average woman to develop breast cancer?	✓	x
65	Has a blood relative close to you e.g. mother or sister ever had an abnormal screening mammogram?	✓	✓
66	Have you ever had an abnormal screening mammogram?	✓	✓
67	Has a blood relative close to you e.g. mother or sister ever been diagnosed with breast cancer?	✓	✓
68	Has a close friend ever been diagnosed with breast cancer?	✓	✓
70	Have you ever been diagnosed with breast cancer?	✓	✓
71	Have you ever been diagnosed with any other type of cancer?	✓	✓
73	Generally, there is something more urgent that needs my attention than making time for a screening mammogram. - Please indicate how much you agree with the statements below about the risk of breast cancer	✓	✓
74	Generally, there is something in my life of higher priority than making time for a screening mammogram. - Please indicate how much you agree with the statements below about the risk of breast cancer	✓	✓
75	I never forget about routine health appointments. - Please indicate how much you agree with the statements below about the risk of breast cancer	✓	✓

76	I have previously missed my mammogram because I forgot about the appointment. - Please indicate how much you agree with the statements below about the risk of breast cancer	✓	✓
77	In my group of friends most women above the age of 50 have regular mammograms. - Please indicate how much you agree with the statements below about the risk of breast cancer	✓	✓
78	In my family most women above the age of 50 have regular mammograms. - Please indicate how much you agree with the statements below about the risk of breast cancer	✓	✓
79	I keep track of my mammogram results. - Please indicate how much you agree with the statements below about the risk of breast cancer	✓	x
80	I have a clear plan of how I will make time to attend my screening mammogram. - Please indicate how much you agree with the statements below about the risk of breast cancer	✓	✓
81	Attending my mammogram is something I do without thinking. - Please indicate how much you agree with the statements below about the risk of breast cancer	✓	x
82	Receiving a text message to remind me of my breast screening appointment would be useful. - Please indicate how much you agree with the statements below about the risk of breast cancer	✓	✓
82	If/when invited, I have a clear plan of how I will attend my mammogram appointment. - Please indicate how much you agree with the statements below about attending breast screening and routine health appointments	x	✓
82	I always make a note of the time and date of any routine health appointments. - Please indicate how much you agree with the statements below about attending breast screening and routine health appointments	x	✓
85	What is the highest level of school/education you have obtained?	✓	✓
86	What is your marital status	✓	✓
87	Do any children aged 12 or under live in your household?	✓	✓
88	Do any adolescents (aged 13-17 years old) live in your household?	✓	✓
89	Are any members of your household aged 65 or over?	✓	✓
90	Are any members of your household disabled or have a physical handicap?	✓	✓
91	Is English your first language?	✓	✓
92	How would you describe your ethnicity	✓	✓
93	How many hours per week do you do paid employment?	✓	✓
94	What was your total household income before taxes in the last 12 months?	✓	✓
95	How often have you changed your address in the past 10 years?	✓	✓
96	How often have you changed your GP in the past 10 years?	✓	✓
97	How often have you changed your mobile phone number in the past 10 years?	✓	✓
98	Have you been invited for more frequent screening based on your family history or personal risk (normal screening is offered every 3 years)	✓	✓

7.3. Appendix – C

Abstract Publications

Huf S, King D, Honeywell S, Tseng F, Andresen I, Vlaev I, Darzi A. Massage framing in invitation letters for cervical screening: A randomised controlled trial. *Lancet* 2016;388(S57)

Huf S, King D, Kerrison R, Chadborn T, Richmond A, Cunningham D, Friedman E, Shukla H, Tseng F, Judah G, Darzi A. Behavioural text message reminders to improve participation in cervical screening: a randomised controlled trial. *Lancet.* 2017;390(S46)

Huf S, King D, Judah G, Fuller F, Vlaev I, Cunningham D, Darzi A. Behavioural text message reminders to improve participation in breast screening: a randomised controlled trial. *Lancet*. 2017;390(S45)

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Chapter 2

- National Institute for Health Research Imperial Patient Safety Translational Research Centre
- Department of Health

Chapter 3

- National Institute for Health Research Imperial Patient Safety Translational Research Centre
- Public Health England
- Imperial Health Charity

Chapter 4 & 5

- National Institute for Health Research Imperial Patient Safety Translational Research Centre
- Association of Breast Surgeons
- Prevent Breast Cancer (previously Breast Cancer Now)