The communication of benign biopsy results in the National Health Service Breast Screening Programme

Siân Zena Williamson, MSc, BSc

A thesis submitted in partial fulfilment of the requirements for the degree of Doctor of Philosophy in the Health Sciences

The University of Warwick, Warwick Medical School, Division of Health Sciences

September 2019
Dedicated to Lewis.

*It’s kind of fun to do the impossible*

Walt Disney
CHAPTER 1: Introduction - Putting the research into context .................................................................25

1. Chapter Introduction .......................................................................................................................26
2. Overview of thesis ...........................................................................................................................27
   2.1 Purpose of study ........................................................................................................................27
   2.2 Structure of thesis .......................................................................................................................27
3. Putting the research into context ....................................................................................................28
   3.1 Breast cancer and screening ....................................................................................................28
   3.2 The NHS Breast Screening Programme ................................................................................29
   3.3 What happens during screening in the NHSBSP? .................................................................29
      3.3.1 The screening appointment ...............................................................................................31
      3.3.2 Mammography results ....................................................................................................31
      3.3.3 Follow-up tests: biopsy ....................................................................................................31
      3.3.4 Biopsy results: multidisciplinary team meeting .............................................................32
      3.3.5 Delivering the result .........................................................................................................33
      3.3.6 After receiving the result ................................................................................................34
   3.4 How many women are told they have a benign result? .........................................................34
   3.5 Anxiety – state and trait ............................................................................................................34
3.6 False-positive anxiety, the healthy identity and uncertainty .......... 35
3.7 Receiving the result and continued anxiety ........................................... 38
3.8 Measuring anxiety .................................................................................. 38
3.9 Factors associated with false-positive anxiety ........................................ 39
3.10 Policy vs. practice .................................................................................. 40
   3.10.1 NHSBSP Communication Guidelines: 2015-16 ......................... 40
   3.10.2 Breast Care Nurses meeting .......................................................... 41
   3.10.3 Survey of communication practice (2014-15) .............................. 41
   3.10.4 Discord between policy and practice ............................................. 42
   3.10.5 NHSBSP Communication Guidelines: 2017-18 ......................... 43
3.11 Summary ............................................................................................... 44
4. Background: communication in healthcare ............................................. 45
   4.1 What is communication in healthcare? ................................................ 45
   4.2 Communication methods used in healthcare ....................................... 46
   4.3 Cost and efficiency of communication methods .................................. 49
   4.4 Anxiety and communication methods ................................................ 49
      4.4.1 Speed of receiving results and the anxious wait .......................... 50
   4.5 Privacy, errors & data security ............................................................ 51
   4.6 Understanding ...................................................................................... 52
      4.6.1 Non-verbal cues and understanding ............................................. 53
   4.7 Convenience of communication .......................................................... 54
   4.8 Satisfaction, preferences and attitudes ............................................... 54
      4.8.1 Preferences for in-person results .................................................. 55
      4.8.2 Preferences for telephone results ............................................... 56
      4.8.3 Preferences for written results ..................................................... 57
   4.9 Measurement issues ............................................................................ 57
      4.9.1 The issue of satisfaction .............................................................. 57
      4.9.2 The wrong population .................................................................. 58
5. Conclusions and contribution of the thesis .............................................. 59
6. Chapter summary ..................................................................................... 61
CHAPTER 2: Rationale, development, methodology, aims and objectives

1. Chapter introduction

2. Rationale
   2.1 Thesis aim

3. Philosophical assumptions

4. Models for effective communication
   4.1 Effective communication and impact on health outcomes
   4.2 Information-processing model of medical consultation
   4.3 Thesis model
   4.4 Bridging the gap

5. Development of questions and objectives

6. Research question, objectives and approach
   6.1 Phase 1: systematic review
   6.2 Phase 2: centre survey of current practice
      6.2.1 Survey design
      6.2.2 Piloting
   6.3. Phase 3: cluster randomised crossover trial
      6.3.1 Method selection
      6.3.2 Measurement of anxiety
      6.3.3 Trial
      6.3.4 Crossover
      6.3.5 Considerations of cluster randomised crossover trial designs
      6.3.6 Number of centres and feasibility
   6.4 Phase 4: communication preferences: surveys and interviews
   6.5 Phase 5: Integration
   6.6 Summary of the mixed methods approach

7. Contribution to knowledge

8. Research governance and funding statement
CHAPTER 3 - Communication of cancer screening results by letter, telephone or in person: A mixed methods systematic review of the effect on attendee anxiety, understanding and preferences

1. Chapter introduction ................................................................. 100
   1.1 Research questions ............................................................. 101
2. Abstract .................................................................................. 102
3. Introduction ............................................................................ 103
4. Methods .................................................................................. 105
   4.1 Search strategy ................................................................. 105
   4.2 Eligibility criteria ................................................................. 105
   4.3 Data extraction ................................................................. 106
   4.4 Data synthesis ................................................................. 107
   4.5 Quality assessment ............................................................. 108
5. Results .................................................................................. 110
   5.1 Included studies ................................................................. 110
   5.2 Quality assessment ............................................................. 111
   5.3 Synthesis findings ............................................................ 111
     5.3.1 Anxiety ..................................................................... 112
     5.3.2 Understanding ............................................................ 114
     5.3.3 Preferences ................................................................. 116
6. Discussion ............................................................................ 118
   6.1 Strengths and limitations ..................................................... 119
7. Conclusions ........................................................................... 121
8. Chapter summary ................................................................... 122
CHAPTER 4: Current practice in English breast screening centres and staff perspectives of telephoning results ......123

1. Chapter introduction ........................................................................................................... 124
   1.1 Research question and objectives .................................................................................. 124
2. Abstract ............................................................................................................................. 125
3. Background ....................................................................................................................... 127
4. Methods ............................................................................................................................ 129
   4.1 Participants .................................................................................................................... 129
   4.2 Survey piloting and instrument ..................................................................................... 129
   4.3 Data analysis ................................................................................................................ 130
5. Results ................................................................................................................................ 132
   5.1 Respondents .................................................................................................................. 132
   5.2 Quantitative findings ..................................................................................................... 134
      5.2.1 Frequency of results by telephone ......................................................................... 134
      5.2.2 Regional differences – frequency of telephone results ........................................... 135
      5.2.3 Time difference – telephone results vs. in-person results ....................................... 135
   5.3 Qualitative findings ....................................................................................................... 137
      5.3.1 Summary of non-cancer content analysis ................................................................. 139
      5.3.2 Summary of cancer content analysis ...................................................................... 142
6. Discussion .......................................................................................................................... 143
   6.1 Strengths ....................................................................................................................... 145
   6.2 Limitations ..................................................................................................................... 145
7. Conclusion .......................................................................................................................... 147
   7.1 Research and practice implications .............................................................................. 147
8. Chapter summary .............................................................................................................. 148
CHAPTER 5A: Communicating benign biopsy results by telephone in the NHS Breast Screening Programme - a protocol for a cluster randomised crossover trial ............149

1. Chapter introduction ........................................................................................................................................... 150
   1.1 Research question and objectives .................................................................................................................. 150
2. Abstract .............................................................................................................................................................. 151
3. Introduction ....................................................................................................................................................... 153
   3.1 Aim of the study ............................................................................................................................................. 155
4. Methods and analysis ......................................................................................................................................... 155
   4.1 Study design .................................................................................................................................................. 155
   4.2 Participants and settings ................................................................................................................................. 156
   4.3 Measuring anxiety ......................................................................................................................................... 158
   4.4 Randomisation and blinding ......................................................................................................................... 159
   4.5 Allocation of communication method ........................................................................................................... 160
   4.6 Data collection ............................................................................................................................................. 161
   4.7 Qualitative telephone interviews ................................................................................................................. 163
   4.8 Mixed methods integration ............................................................................................................................ 163
   4.9 Sample size considerations ........................................................................................................................... 164
   4.10 Planning, designing and monitoring to increase recruitment...................................................................... 167
   4.11 Outcomes and study measures (primary outcome, secondary outcomes)................................................. 168
      4.11.1 Primary outcome .................................................................................................................................. 168
      4.11.2 Secondary outcomes ............................................................................................................................. 168
5. Analysis ............................................................................................................................................................. 169
   5.1 Quantitative data - Statistical analysis ......................................................................................................... 169
      5.1.1 Primary outcome .................................................................................................................................... 169
      5.1.2 Secondary outcomes ............................................................................................................................. 170
   5.2 Qualitative data analysis ............................................................................................................................... 170
CHAPTER 5B: TRIAL RESULTS – THE IMPACT OF COMMUNICATION METHODS ON ANXIETY AND UNDERSTANDING

1. Chapter introduction ........................................................................... 175
   1.1 Research questions and objectives .............................................. 175
2. Results ................................................................................................. 176
   2.1 Centre characteristics .................................................................. 176
   2.2 Sample description – Time 1 ....................................................... 178
   2.3 Sample description – Time point 2 onwards .................................. 181
     2.3.1 Age of responders and non-responders ............................... 183
   2.4 Missing data ................................................................................ 184
3. Results ................................................................................................. 184
   3.1 Planned analysis .......................................................................... 184
   3.2 Mean anxiety scores and long-term anxiety .................................. 184
   3.3 Patients own understanding of their results ............................... 185
   3.4 Objective understanding of results ............................................. 185
     3.4.1 Distance travelled ................................................................. 186
   3.5 Low sample size/issues in recruitment ....................................... 186
     3.5.1 The overall experience of the study and delivering results ..... 187
     3.5.2 Recruitment challenges ....................................................... 187
     3.5.3 Opinions on the use of telephone results services in the future 189
     3.5.4 Suggestions for future research ........................................... 189
4. Discussion ............................................................................................. 191
   4.1 Suggestions for future research ................................................... 193
CHAPTER 6: Communication preferences for benign biopsy results – Frequencies, free-text comments and telephone interviews

1. Chapter introduction ................................................................................. 198
2. Research questions and objectives ....................................................... 199
3. Methods ................................................................................................. 200
  3.1 Design .................................................................................................. 200
  3.2 Participants .......................................................................................... 200
  3.3 Survey instruments .............................................................................. 200
  3.4 Interviews ............................................................................................. 201
  3.5 Procedure ............................................................................................. 201
  3.6 Ethical approval .................................................................................... 202
  3.7 Analysis ................................................................................................. 202
    3.7.1 Surveys ............................................................................................ 202
    3.7.2 Interviews ........................................................................................ 202
    3.7.3 Integration ......................................................................................... 204
4. Results ...................................................................................................... 205
  4.1 Communication preferences ............................................................... 205
  4.2 Qualitative results ............................................................................... 206
    4.2.1 Reasons for telephone preference .................................................. 206
    4.2.2 Reasons for in-person preference ................................................... 208
    4.2.3 Quantitative survey – other comments .......................................... 210
  4.3 Qualitative interviews .......................................................................... 211
  4.4 Qualitative interviews: Overall thematic findings .............................. 212
5. Strengths and limitations ......................................................... 243
  5.1 Strengths ........................................................................... 243
  5.2 Limitations ....................................................................... 244
6. Policy recommendations and future research ......................... 248
  6.1 Patient choice .................................................................... 249
  6.2 Email and Skype results ..................................................... 250
  6.3 Improving future audits of communication ......................... 250
7. Conclusions and contribution of the thesis ............................ 252
References ................................................................................ 254

Appendices................................................................................ 275
  Appendix 1 – Psychological consequences questionnaire (90) .... 275
  Appendix 2 – Timeline of ethical approval ............................... 276
  Appendix 3 – University of Warwick Sponsorship .................. 282
  Appendix 4 – Biomedical & Scientific Research Ethics Committee .... 284
  Appendix 5 - Public Health England Breast Screening Programme
    Research Advisory Committee .............................................. 286
  Appendix 6 - Health Research Authority (HRA) NHS West Midlands -
    Coventry & Warwickshire Research Ethics Committee ............ 288
  Appendix 7 – Search terms....................................................... 291
  Appendix 8 – Eligibility criteria .............................................. 292
  Appendix 9 – Characteristics of included studies .................... 293
  Appendix 10 – Meta-matrix ...................................................... 294
  Appendix 11 – Quality assessment for systematic review .......... 297
  Appendix 12 – Online centre survey ....................................... 301
  Appendix 13 – Time 1 PIS ......................................................... 306
  Appendix 14 – Time 1 consent ............................................... 310
  Appendix 15 – Time 1 survey .................................................. 312
LIST OF FIGURES

Figure 1: Diagram of patient-pathway through the NHSBSP screening process ................................................................. 30
Figure 2: Model of uncertainty in population-based screening programmes (adapted from Marteau, 1994) ................................................................. 37
Figure 3: Bar-chart showing the percentage of centres who deliver benign results by telephone (routinely, occasionally or never) from Margaret Casey study (2014-15) ........................................................................ 42
Figure 4: The Shannon-Weaver Model of Communication .................. 69
Figure 5: Schram’s Model of Communication (taken from Blythe, 2010) ..... 71
Figure 6: Pathways linking clinician–patient communication to health outcomes (adapted from Street, Makoul, Arora & Epstein, 2009) ............ 72
Figure 7: The information-processing model of medical consultation (Frederikson, 1993) ......................................................................................... 73
Figure 8: Theoretical model underpinning the thesis ......................... 75
Figure 9: The ‘bridge’ between uncertainty and certainty. A visual representation of how communication method ‘bridges’ the return to certainty and the healthy identity ..................................................... 76
Figure 10: Diagram of the research phases ........................................ 79
Figure 11: Diagram of how mixed methods were used ....................... 92
Figure 12: Flow chart of paper selection ........................................... 110
Figure 13: Flow of required sample size for the study (total sample size, not considering clusters/cluster size) with design effect applied ............ 165
Figure 15: Flowchart of the total sample recruited ............................. 178
Figure 16: Distribution of age for women recruited at Time point 1 ....... 179
Figure 17: Model of uncertainty in population-based screening programmes (adapted from Marteau, 1994) .................................................................. 223
Figure 18: The ‘bridge’ between uncertainty and certainty. A visual representation of how communication method ‘bridges’ the return to certainty and the healthy identity ..................................................... 233
Figure 19: How emotional and practical reasons for communication preferences may be influenced by uncertainty/certainty and anxiety/stability ........................................................................ 237
Figure 20: The 'bridge' between uncertainty and certainty. A visual representation of how preparation, support and follow-up facilitate the return to certainty .............................................................................................................. 242

Figure 21: Overall quality assessment and risk of bias for the qualitative studies included in the systematic review .............................................................................................................. 298

Figure 22: Overall quality assessment and risk of bias for the quantitative studies included in the systematic review ................................................................. 300
LIST OF TABLES

Table 1: Scoring system for triple-assessment in breast screening ........... 33
Table 2: Generic and disease-specific measures of anxiety .................. 39
Table 3: Advantages and disadvantages of different methods of
communication, adapted from Gurol-Urganci, de Jongh (134) .......... 48
Table 4: Time points of the study .................................................... 86
Table 5: Number of centres who responded to the online survey and
provided optional qualitative comments ...................................... 133
Table 6: Frequency and percentage of centres who routinely, occasionally or
never deliver results by telephone for non-cancer and cancer results (n=63)
.......................................................................................................... 134
Table 7: Frequency of who delivers results by telephone, for non-cancer and
cancer results (n=63) ........................................................................ 135
Table 8: Mean (SDs) number of days between assessment and delivery of
results for centres who routinely, occasionally and never benign (non-cancer)
telephone results ............................................................................... 136
Table 9: Time points for the study .................................................... 157
Table 10: Allocation of communication method by arm of the trial ......... 159
Table 11: Differences in recruitment process between research sites .... 177
Table 12: Baseline characteristics of women recruited at Time point 1,
presented as percentages ................................................................. 180
Table 13: Baseline characteristics for participants in Time point 2 ......... 182
Table 14: Mean PCQ anxiety score and SDs comparing telephone and in-
person groups ............................................................................... 185
Table 15: Objective understanding between telephone and in-person groups
.......................................................................................................... 186
Table 16: Women's preferences for results communication (all participants)
.......................................................................................................... 205
Table 17: Women's preferences for results communication (Women who
received a benign result only) ....................................................... 206
Table 18: Qualitative survey data - reasons for telephone preference (n=99)
.......................................................................................................... 207
Table 19: Qualitative survey data - reasons in-person preference ......... 209
Table 20: Sample characteristics of telephone interview participants ........ 211
Table 21: Quality assessment of qualitative studies included in the systematic review, assessed using the Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews – Checklist for Qualitative Research. ......................................................... 297
Table 22: Quality assessment of qualitative studies included in the systematic review, assessed using the Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews – Checklist for Analytical Cross Sectional Studies. ......................................................... 299
ACKNOWLEDGEMENTS

Firstly, I would like to thank my supervisors Dr. Sian Taylor-Phillips, Dr. Harbinder Sandhu, Dr Rebecca Johnson and Dr David Ellard for all their support and guidance over the last few years. Gratitude is also extended to the collaborators of the project Jacquie Jenkins, Olive Kearins and Margaret Casey. Thank you for your knowledge and also giving up your time to help support this PhD project.

For the systematic review of the thesis, I would like to acknowledge Samantha Johnson, Jacoby Patterson and Rebecca Crosby for their contribution.

I would like to thank all the breast screening centres who participated in the research. Everyone I met was incredibly friendly and could not do enough to help with the PhD. A thank you is also extended to all the women who participated in the research.

I would also like to thank my family, in particular my mum and dad, for their unconditional support and always facilitating me in pursuing my dreams.

A special mention to my PhD ‘family’ in the Farmhouse, Bex, Muna. Ariel, Becky, Zain and Farah. I would not have made it through this journey without you crazy bunch to make me smile, let me brainstorm on the whiteboard and put things into perspective when everything seemed to be going wrong! People say that doing a PhD can be incredibly isolating, but you have made my experience the exact opposite.

Finally, my amazing partner and fiancé Lewis Holt. I am eternally grateful for your compassion during my lowest moments, and for taking such an interest in everything I do. You came into my life when I needed you most. Thank you.
**FUNDING STATEMENT**

This PhD was fully funded by the Economic and Social Research Council, DTC Warwick, who provided the student stipend, PhD fees and expenses for conferences. Additional funding (£4,000) was provided by Public Health England for travel and stationary expenses during the research.

**DECLARATION**

This thesis is submitted to the University of Warwick in support of my application for the degree of Doctor of Philosophy. It has been composed by myself and has not been submitted for a degree at another university.

The work presented (including data generated and data analysis was carried out by myself, except in the cases outlined below:

- Jacoby Patterson: CHAPTER 3 systematic review (second author title and abstract screening authors M-Z, second author full-text review, second author data extraction, second author quality assessment, second author review of meta-matrix to ensure data matched findings)
- Rebecca Crosby: CHAPTER 3 systematic review (second author title and abstract screening authors A-L)
- Samantha Johnson: subject librarian at the University of Warwick. Gave feedback on the search terms for the review, designed by Sian Williamson (PhD author)
- Olive Kearins & Jacquie Jenkins: CHAPTER 4 centre survey (assisted with the dissemination of the survey to NHSBSP staff, by emailing links and reminder messages)
- Margaret Casey: CHAPTER 4 centre survey (provided access to the previous survey version including the design and results)
- Nick Parsons: CHAPTERS 5A/5B trial (advised on the statistical analysis plan)
Olive Kearins, Margaret Casey and Jacquie Jenkins were collaborators from the NHS Breast Screening Programme who provided support to the student throughout the PhD. This included advising on best practice for research within the breast screening setting, facilitating contact with other members of staff and reviewing drafts of papers.

Rebecca Johnson, Harbinder Sandhu, Sian Taylor-Phillips and David Ellard were the supervisors for the PhD project. They provided support and advice to the student throughout the PhD, including discussing best approaches to the research, discussing findings and reviewing drafts of papers/chapters.

From this research, the following collaborative articles have been published:


ABSTRACT

Introduction

Attending a breast biopsy and receiving the results can be an anxious process. The method of delivering biopsy results could affect women’s experience of screening and resultant anxiety. The NHS Breast screening programme (NHSBSP) guidelines state that telephone results ‘should not be routinely offered’. Despite this, most English Breast Screening centres now deliver benign results by telephone, believing they are reducing the amount of time women spend anxiously waiting. However, concerns remain about the potential ‘harm’ of telephoning women with results.

This thesis aimed to investigate the impact of communication methods (telephone versus in-person) on women receiving a benign biopsy result from the NHSBSP, exploring the outcomes of patient anxiety, understanding of results and preferences for communication. This will inform future updates to policy guidelines for the communication of breast screening results in the NHSBSP.

Methods

A mixed methods approach was used with the overall research designed in 5 phases: Phase 1) A mixed-methods systematic review of current communication methods used in cancer screening programmes and the impact on attendees; Phase 2) A cross-sectional survey to record how results are currently being delivered in the NHSBSP, including qualitative data on NHSBSP staff views on communication methods; Phase 3) A cluster randomised crossover trial comparing women who have received a benign result by telephone versus in-person to measure anxiety and understanding of results. Phase 4) Qualitative interviews with women who have received a benign result from screening to explore communication preferences and reasons for these preferences; Phase 5) Mixed methods synthesis of the quantitative and qualitative data on attendee communication preferences from Phase 3 and Phase 4.
Results

The systematic review in Phase 1 found a lack of available evidence regarding the impact of communication methods in cancer screening internationally. The survey of current communication practice in Phase 2 found that most breast screening centres routinely deliver benign results by telephone, with common (but not universal) practice being to give all women an in-person appointment to re-attend but then telephoning benign women unexpectedly ahead of this appointment. The cluster randomised crossover trial in Phase 3 faced recruitment challenges which revealed lessons to be learned when recruiting women attending the breast assessment clinic. Reasons for declining participation included patient anxiety, time, and preferences for in-person results communication. The mixed-methods synthesis of the findings from Phases 4 and 5, found that communication preferences differed between individuals and was related to anxiety, with a trend towards less anxious women preferring telephone results and more anxious women preferring in-person results. The reasons for communication preferences were either practical (e.g. travel and parking factors) or emotional (e.g. wanting to see a friendly face).

Conclusions

The experience of attending breast assessment and receiving a biopsy result is a journey of uncertainty and can be an anxious process. The communication method used to deliver a benign result acts as the ‘bridge’ between patient uncertainty and certainty, helping women to alleviate their concerns and return to a ‘healthy identity’. However, some women may misunderstand their result and experience ongoing uncertainty, being unable to ‘cross the bridge’.

Telephoning benign results is common practice in the NHSBSP. The experience and impact of different methods of communicating results has individual variability. However, unexpected telephone results are associated with additional anxiety for some women. Some women feel unprepared for an unexpected telephone result and may be left with lingering uncertainty.
Preparing women for results, providing support and giving opportunities for follow-up reassurance may mitigate the impact of the communication method used to deliver breast biopsy results. This may improve the experience of women receiving benign biopsy results by telephone.

**Recommendations**

- The NHSBSP should focus upon preparing women attending breast assessment to help them understand the screening and results process. The aim is to reassure women, reduce feelings of uncertainty and minimise anxiety. This may negate the negative impact of an unexpected telephone call.
- When telephone results are used to deliver results, support should be provided. This will allow women to ask questions over the telephone to clarify misunderstandings, resolve uncertainty and minimise anxiety.
- When telephoned, women should be offered the opportunity of a follow-up appointment to explain the results in-person if they wish. This follow-up appointment may be necessary for the subset of women who experience heightened anxiety and may facilitate the return to the healthy identity. Results should also be confirmed in writing. This may minimise any lingering uncertainty and anxiety, which may be experienced as a result of the unexpected telephone call.
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMJ</td>
<td>British Medical Journal</td>
</tr>
<tr>
<td>BSREC</td>
<td>Biomedical &amp; Scientific Research Ethics Committee</td>
</tr>
<tr>
<td>BSPRAC</td>
<td>Breast Screening Programme Research Advisory Committee</td>
</tr>
<tr>
<td>ESRC</td>
<td>Economic and Social Research Council</td>
</tr>
<tr>
<td>GCP</td>
<td>Good Clinical Practice</td>
</tr>
<tr>
<td>HRA</td>
<td>Health Research Authority</td>
</tr>
<tr>
<td>IBM SPSS</td>
<td>IBM Statistical Package for the Social Sciences</td>
</tr>
<tr>
<td>ICC</td>
<td>Intra-cluster correlation coefficient</td>
</tr>
<tr>
<td>ICPV</td>
<td>Independent Cancer Patient Voices</td>
</tr>
<tr>
<td>ID</td>
<td>Identifier</td>
</tr>
<tr>
<td>JBI</td>
<td>Joanna Briggs Institute</td>
</tr>
<tr>
<td>MDT</td>
<td>Multidisciplinary Team</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
</tr>
<tr>
<td>NHSBSP</td>
<td>National Health Service Breast Screening Programme</td>
</tr>
<tr>
<td>PCQ</td>
<td>Psychological consequences questionnaire</td>
</tr>
<tr>
<td>PID</td>
<td>Participant Identifier</td>
</tr>
<tr>
<td>PIS</td>
<td>Participant Information Sheet</td>
</tr>
<tr>
<td>PPI</td>
<td>Patient and Public Involvement</td>
</tr>
<tr>
<td>PRISMA</td>
<td>Preferred Reporting Items for Systematic Reviews and Meta-Analysis</td>
</tr>
<tr>
<td>PROSPERO</td>
<td>International Prospective Register of Systematic Reviews</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
</tr>
<tr>
<td>SAP</td>
<td>Statistical analysis plan</td>
</tr>
<tr>
<td>SD</td>
<td>Standard deviation</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>USA</td>
<td>United States of America</td>
</tr>
</tbody>
</table>
CHAPTER 1: Introduction - Putting the research into context
1. Chapter Introduction

In this section of the thesis, I will introduce the topic of my PhD project and I will outline the overall structure of my thesis.

Next, I will give an overview of the context in which the PhD exists, providing background on the following topics:

- Breast cancer
- Screening
- The National Health Service Breast Screening Programme (NHSBSP)
- The screening process
- False-positive results
- How false-positive results relate to anxiety

I will then explain the current state of communication policy guidelines in the National Health Service Breast Screening Programme (NHSBSP) and describe where my PhD project fits within this context.
2. Overview of thesis

2.1 Purpose of study
This PhD project began because of a request from policymakers. The National Health Service Breast Screening Programme (NHSBSP) asked for research to investigate the impact of communicating screening results by telephone rather than in-person.

2.2 Structure of thesis
There are five phases of research in this thesis: Phase 1) Systematic review; Phase 2) Centre survey; Phase 3) Cluster randomised crossover trial; Phase 4) Qualitative interviews and Phase 5) Mixed-methods integration. The thesis consists of eight chapters. In this chapter (Chapter 1) I will introduce the topic of the thesis, presenting the background literature and contextualising the research. In Chapter 2 I will describe my approach to the project and justify the methods used. In Chapter 3 I will describe and report the systematic review investigating the impact of results communication methods on patient anxiety, understanding and preferences in the context of cancer screening. In Chapter 4 I will describe and report the findings from my survey of the current communication practices in English breast screening centres. In Chapter 5a I will present the protocol of the cluster randomised crossover trial of telephone vs in-person delivery of benign results. In Chapter 5b I will present the findings from this trial. In Chapter 6 I will report the quantitative and qualitative findings relating to women’s communication preferences including a mixed-methods synthesis of the data. In Chapter 7, I will discuss the overall findings from the thesis, including the strengths and weaknesses. I will also explain the implications of the findings for future research and NHSBSP communication policy guidelines.
3. Putting the research into context

In this section, I will provide the general context for the research, breast cancer, screening and the NHSBSP. Next, I will highlight the issue of false-positive anxiety in breast screening. I will then explain the discordance between communication policy and best practice within the NHSBSP that led to a need for this research.

3.1 Breast cancer and screening

Breast cancer is the most prevalent form of cancer for women worldwide and breast cancer incidence is steadily increasing over time (1). Worldwide, an estimated 570,000 women died in 2015 from breast cancer (2) and, in England in 2014, 44,540 women were diagnosed with breast cancer (3). In UK females, breast cancer is the 2nd most common cause of cancer-related mortality (4). The early detection of cancer can result in early intervention and an ultimately improved prognosis (4-8). Therefore, population-based cancer screening programmes have been implemented to minimise cancer mortality.

A screening programme is defined as a system targeted towards healthy individuals to reduce the risk of future disease and potential mortality, through early detection (9). A screening programme should be ethically designed to provide a benefit whilst minimising potential physical and psychological harm (9-12). The National Health Service Breast Screening Programme (NHSBSP) is classed as a screening programme, and therefore should adhere to these principles.
3.2 The NHS Breast Screening Programme
The NHSBSP began inviting women to attend in 1988, aiming to detect, diagnose and treat breast cancer at an earlier stage in the UK (4). The service systematically screens an asymptomatic population to identify clinical abnormalities that are indicative of early signs of breast cancer (4, 13). In the case of the NHSBSP, women between the ages of 50-70 are invited to be screened on a rolling triennial basis (4, 14-17). However, it should be noted that there is a current age extension trial in the NHSBSP, increasing the age range and inviting women between 47-73 years of age (18).

At the time of this thesis (2018-19), data from the Quality Assurance lead for the NHSBSP recorded that there were 79 breast screening centres in England. In 2018-19, 2,555,694 women were invited to be screened, with 1,816,676 women actually attending (71% uptake) (19). The programme determines an acceptable level of update across the population to be 70% (20).

3.3 What happens during screening in the NHSBSP?
To highlight the issues that exist in communication within the NHSBSP, I will now describe what happens to a ‘typical’ woman attending asymptomatic breast screening. This process may vary based upon individual-level factors (such as family history of cancer) or based upon differences in process within each breast screening centre.

For an overview of the process, see Figure 1.
Figure 1: Diagram of patient-pathway through the NHSBSP screening process
3.3.1 The screening appointment
When a woman reaches the age of eligibility for breast screening, she will be sent an invitation letter to attend her local breast screening service. At the initial screening appointment, a mammogram (x-ray) will be performed on each breast to screen for any abnormalities (14). In the UK, two views of each breast are taken (mediolateral oblique and cranio-caudal) (14).

3.3.2 Mammography results
The results of the mammogram take a maximum of two weeks to be delivered, as recommended by NHSBSP guidelines (21). During this time, a clinician specialising in the reading of mammograms will review the images for each woman, assessing whether any clinical abnormalities can be seen and whether the woman needs to be recalled for further tests. If an abnormality is found on the image, the woman is sent an invitation letter to return to an assessment clinic (13, 22). At this assessment clinic, women will have follow-up tests. Initial tests can include a clinical examination, a further diagnostic mammogram and/or ultrasound (14, 16, 21, 23). Around half of the women attending the assessment clinic will have results suggesting no cancer at this stage and will be sent home after these initial tests. However, some women will require a further test, called a biopsy.

3.3.3 Follow-up tests: biopsy
A biopsy is the definitive test to confirm if the clinical abnormalities found during screening are cancer. A core needle biopsy involves the removal of sections of tissue from the suspicious breast region, with multiple passes of the needle allowing different angles and areas to be sampled (14, 24). Once the tissue has been extracted, it can be sent for cytological examination. The procedure of breast biopsy is designed to be as minimally invasive as possible, leaving only minor bruising. However, some women can find this experience painful and distressing (23-27)
Once a woman has completed her follow-up tests at the assessment clinic, she can return home to await her results. These results can take up to a week be processed, with clinical guidelines recommending that all biopsy results should be delivered to the woman within this one week waiting period (28). Some screening centres may give women a follow-up appointment before they leave the assessment clinic to ensure they are seen again in-person within the one-week turn around period.

### 3.3.4 Biopsy results: multidisciplinary team meeting

Results of diagnostic tests, including core biopsy, are discussed on a case-by-case basis at a multidisciplinary team (MDT) meeting within the breast screening service. A woman’s result is confirmed using a triple-assessment (14, 29), which includes the following tests:

- **Clinical examination** – where a clinician palpates the breasts to see if any abnormalities can be felt.
- **Imaging** – where technology is used to view within the breast. This may include repeat mammography or ultrasound.
- **Biopsy**

During the MDT, healthcare professionals with expertise in each of these areas will contribute their clinical opinion on the outcomes of testing for each woman.

Results are scored on a scale of 1-5 for the outcome of each diagnostic test, with 1 indicating normal clinical features and 5 indicating signs of malignancy (29) (see *Table 1*). Each score is prefixed with a letter indicating which diagnostic test found the result. Clinical examinations are prefixed with a P (standing for palpation), mammography results are prefixed with an R (for radiology) and biopsy results are prefixed with a B. For example, the clinician responsible for interpreting the biopsy result for a woman may assign a score of B2. This would mean that the pathological outcome for the biopsy is benign. If all three tests results are positive, the certainty of a cancer diagnosis is 98-99% (30). If a clinical decision cannot be made based on the
results of the MDT, the woman will be recalled to attend an additional assessment clinic for further follow-up tests.

Table 1: Scoring system for triple-assessment in breast screening

<table>
<thead>
<tr>
<th>Outcome of diagnostic test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Normal</td>
</tr>
<tr>
<td>2 Benign</td>
</tr>
<tr>
<td>3 Uncertain</td>
</tr>
<tr>
<td>4 Suspicious</td>
</tr>
<tr>
<td>5 Malignant</td>
</tr>
</tbody>
</table>

3.3.5 Delivering the result

Once the woman’s result has been confirmed at the MDT, the result can then be discussed with the woman. In the UK, the actual mode of delivering results varies at each centre and may change based upon the outcome of the test. For example, some centres may telephone women with benign results but invite women with cancer results to be seen by a clinician in-person.

International cancer screening services also vary in how results are communicated. This is reflected different policy guidelines for quality assurance globally (31). There is an opportunity to learn from how other countries deliver breast screening results. However, currently there is no research that brings together the international evidence for the communication of cancer screening results. Furthermore, there is no clear evidence for why results communication methods vary, both nationally and internationally.
3.3.6 After receiving the result
Women who are identified as having cancer will be referred onto the relevant care pathway. Women who receive a normal or benign result will have no further follow-up. These women will be referred back into the population-level programme and will be sent an invitation to attend screening again in three years.

3.4 How many women are told they have a benign result?
A benign result is when a woman has been identified at the screening mammogram phase as potentially having cancer but the follow-up tests at the assessment clinic have revealed no abnormalities. This is also called a false-positive result, as the woman was falsely identified as having a potential cancer (4, 32-34).

Receiving a benign result from screening is very common, with the majority of women who are recalled ultimately given a false-positive result (8, 35-38). In 2016-17, 2,199,342 women in England were screened by the NHSBSP. 89,104 (4%) of these women were referred for assessment and 40,255 women had a core biopsy (1.8%). Of the women that have a biopsy, 18,402 are found to have cancer (0.8%). Therefore, a total of 21,853 (1%) women have a false-positive (or benign) result each year, following a biopsy (39). Therefore, calculated from this data (39), of women who are recalled and have a biopsy (n = 40,255), 46% are found to have cancer and 54% of women have a benign result.

3.5 Anxiety – state and trait
Screening programmes should provide a benefit that outweighs both physical and psychological harm (40). However, there is much debate about whether the benefits of breast screening outweigh these harms (4, 6, 7, 32). One of the main harms from breast screening is the unintentional anxiety caused by false positive results, which has been discussed extensively within the research literature (4, 17, 41-45). Anxiety is a negative subjective
experience, encountered when a person perceives a ‘threat’ (46). In the literature it may be referred to in different ways such as worry, fear or psychological distress (47).

Although anxiety is experienced by a lot of women receiving false-positive results, it is evident from the mixed research findings that some women cope better with this anxiety than others (8, 48-50). Some women will be extremely anxious, whilst others remain calm (43, 51). This may be due to differences in personality, with some people tending to be more anxious than others (52). Anxiety can be categorised into trait anxiety and state anxiety. People with high trait anxiety tend to be anxious across many situations, and could be considered to have an ‘anxious personality’. State anxiety tends to occur when an individual feels anxious about a specific situation or event, rather than being generally anxious (53).

Research suggests that both trait and state anxiety may play a role in the distress women feel during screening (54, 55). One paper investigated the differences in psychological distress for patients, prior to a breast cancer diagnosis (56). Individuals with higher levels of trait anxiety tended to have higher levels psychological distress prior to diagnosis. However, a large number of women may also experience state anxiety when attending screening recall (57). In this thesis, I have approached anxiety from the state perspective, focusing on the specific anxiety women might experience when recalled from screening. The reason for this decision is that trait anxiety is not an easily modifiable factor in minimising negative outcomes for screening attendees. However, I acknowledge differences in anxiety that may be based upon trait-anxiety and personality differences by exploring individual experiences and also controlling for baseline (or trait) anxiety.

### 3.6 False-positive anxiety, the healthy identity and uncertainty

Some researchers suggest that, when a woman enters the screening programme, she will identify as a ‘healthy’ individual. This ‘healthy identity’ is then disrupted when the mammogram finds a suspicious result (24, 26, 38, 39).
This identity change for some women may feel synonymous with a cancer diagnosis, and some women compare themselves to cancer patients when they know they have been recalled (22, 38, 51). This change in identity, may be most likely for women who attend screening asymptptomatically and are not anticipating a cancer diagnosis. There may be some exceptions for some women (e.g. women who attend screening when prompted by symptoms, women who know close friends/family with breast cancer, women who have other co-morbidities and health issues). For these women, this change in identity and subsequent anxiety may manifest differently compared to women who attend asymptomatically or who have no personal experiences of breast cancer. For the purposes of this thesis, I define the change in the ‘healthy identity’ as women who attend breast screening who perceive themselves to be in good health, attend with no knowledge of symptoms, and are not expecting a cancer diagnosis. This healthy identity is then followed by uncertainty following recall.

For some women, the biopsy result is seen as the ‘critical’ link to their future (26). Until the result is confirmed, these women ‘imagine the worst’, feeling as though a cancer diagnosis is imminent (38, 42, 51, 60, 61). This distressing period of time is often referred to as ‘the anxious wait’ (38, 42, 43, 51, 62-65). During this time, most women report disruptions to activities of daily living, with some women only managing to cope by attempting to ‘not worry’ (63). Women may contemplate the emotional, physical and social implications of ‘being a cancer patient’, mentally preparing themselves for a potential life with cancer (61). Other women may reflect upon their own mortality (26). Some women even identify themselves with friends or relatives who have died from breast cancer (42).

There is a psychological shift during this waiting period, from certainty to uncertainty, which may be linked to the change in identity from healthy to a potential cancer patient (38, 43, 58). Liao and colleagues suggest that there is a link between heightened uncertainty and increased anxiety in breast screening (66). Uncertain test results are often appraised as more worrying than clearly positive or even negative results (58, 67, 68). Wirsching and
colleagues suggested that women with a cancer diagnosis might feel more emotional stability than women with benign breast disease, due to the clearer certainty and expectations associated with their diagnosis (69).

Aside from the rapid change in identity the patient navigates during this period of uncertainty, there might be other reasons why false-positive results are associated with higher levels of anxiety. The communication of false-positive results may cause uncertainty and unnecessary distress, due to the potential ambiguity of a false-positive result (67, 70). In the case of a false-positive result, although the woman might be receiving ‘good news’, this may also be interpreted as confusing news (71). Girgis and colleagues suggest that abnormal results in healthcare are frequently misunderstood (72). This may be due to discordance between what qualifies as ‘bad news’, with healthcare professionals often misjudging how patients perceive their own results (73, 74).

![Figure 2: Model of uncertainty in population-based screening programmes (adapted from Marteau, 1994)](image-url)
3.7 Receiving the result and continued anxiety

For some women, receiving their result confirming the absence of cancer leads to a decline in anxiety (8, 35, 75-78). Associated feelings of relief are often experienced, with some women easily returning to their ‘healthy’ identity (38, 43). However, some women experience continuing uncertainty and it is not known what the causes of this may be (43, 49, 51, 79-81). Meechan et al. (49), who conducted a study in New Zealand, found that 33% (n = 103) of women were not reassured following a benign breast biopsy, experiencing ongoing uncertainty and continued anxiety. Continued anxiety is most often seen in women who had an ‘invasive procedure’ (such as breast biopsy) as part of their clinical assessment (4, 34, 82). A reason for this is that invasive investigation may cause patients to perceive their situation as more serious, and therefore anticipate that the outcome will be more severe (15). If this perception is not addressed when results are delivered, the lack of clear communication and unresolved uncertainty might impact upon anxiety (see Figure 2). Anxiety can remain elevated for long periods of time and may last up to three years after receiving a false-positive result (15, 33, 35, 75, 83, 84).

Receiving a false-positive result may be associated with a reduction in future re-attendance at screening (11, 33, 34, 67, 85, 86). For a woman who is recalled from mammogram for further tests and biopsy, only to be told that no cancer has been found may lead to feelings of distrust towards the programme itself and the accuracy of the tests used (15, 34, 36, 85, 87). However, the opposite may also be true, with false-positive results associated with an increased fear of breast cancer leading to increased screening behaviour (34, 38, 85).

3.8 Measuring anxiety

Differences in levels of continued anxiety post-results could be due to the differences in how research has attempted to measure anxiety (88). Anxiety is a difficult concept to measure because it is based upon the subjective experiences of the individual. Existing anxiety measures can be broken down
into two types: generic measures and disease-specific measures, which focus upon fear and anxiety of breast cancer itself (21, 89), see Table 2. Studies that use generic measures find lower levels of anxiety post-results (76). Conversely, research using disease-specific measures (such as the Psychological Consequences Questionnaire (90)) find a long-term impact of false-positive results on anxiety, lasting up to three years post-results (84). This suggests that generic measures lack the validity necessary to assess the anxiety caused by screening, which is a view supported by Salz and colleagues (91). Furthermore, the majority of research relating to false-positive results measures anxiety retrospectively and therefore may be subject to recall bias (92).

Table 2: Generic and disease-specific measures of anxiety

<table>
<thead>
<tr>
<th>Generic measures</th>
<th>Disease-specific measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The Hospital Anxiety and Depression Scale HADS (93)</td>
<td>• Psychological Consequences Questionnaire PCQ (90)</td>
</tr>
<tr>
<td>• General Health Questionnaire GHQ (94)</td>
<td>• Consequences of Screening in Breast Cancer COS-B (89)</td>
</tr>
<tr>
<td>• State-Trait Anxiety Instrument STAI (95)</td>
<td></td>
</tr>
<tr>
<td>• Profile of Moods Scale POMS (96)</td>
<td></td>
</tr>
</tbody>
</table>

3.9 Factors associated with false-positive anxiety

Some of the factors that are associated with anxiety include history of a previous false-positive mammogram, family history of breast cancer, lower levels of education, a younger age, living in an urban location, individual differences in personality/baseline anxiety, risk perception and lack of social support (21, 22, 50, 54, 56, 58, 97-101). Negative screening outcomes may also be associated with pre-screening interactions with friends, family and the media, influencing how women might perceive breast screening and cancer itself (102). These factors are difficult to modify and tend to be focused at the level of the individual, which makes the minimisation of
screening anxiety a challenge (10). However, it is possible that there are modifiable changes that can be made at the organisational level of screening that may minimise anxiety (10, 58). Examples of modifiable changes include communication about the screening programme, reducing the wait time to receive results and how results are communicated (11, 21, 58, 86). Research by Brett & Austoker (15) found that ‘the two aspects of a woman’s past screening experience that [are] found to be consistently associated with adverse psychological consequences… were communication and information needs.’ (pg.298). Systematic review evidence suggests that women associate a lack of clear communication of screening results with an increase in anxiety (61).

3.10 Policy vs. practice
The importance of false-positive anxiety in breast screening can be clearly seen in previous research. Therefore, it is important to consider how results are communicated, in order to minimise this anxiety. This is important due to recent changes in NHSBSP communication policy guidelines, which I shall now describe.

3.10.1 NHSBSP Communication Guidelines: 2015-16
In 2015-16, the NHSBSP service specification stated that all results, including false-positive results, should be given in-person:

“In accordance with NHSBSP standards and protocols, the provider should notify women and their GPs of the outcome of assessment. Results should be reported to the women in person, with a member of the clinical team present.” (Section 2.3).

This version of the service specification does not refer to delivering results by telephone. Other guidelines from the same time period do not mention communication methods used to deliver results (29).
3.10.2 Breast Care Nurses meeting

Despite the service specification guidelines, at national meetings Breast Care Nurses and clinicians noticed that the communication methods used differed between their services, with some centres delivering false-positive results by telephone. However, at that point in time best practice guidelines recommended that all results should be delivered in-person.

As part of their job role, Breast Care Nurses aim to minimize and manage the anxiety experienced by women during breast screening. To do this, Breast Care Nurses aim to work to a standard of care built on evidence-based research. However, in this case this was not possible as there was a clear difference between policy recommendations and methods of communicating results in practice, with little evidence to support either approach. Breast Care Nurses were therefore concerned that telephone results may impact negatively upon screened women, particularly with regards to how anxious women might feel. However, they also recognised that telephone results had the potential to reduce the amount of time spent anxiously waiting for results.

Other guidelines for quality assurance for radiographers in 2011 (103) stated:

“Ideally women should be informed of any results in person; where results are given by telephone, they should be confirmed in writing.”

Again, there is very little evidence to support this process of results communication. This warranted further investigation within the NHSBSP.

3.10.3 Survey of communication practice (2014-15)

Margaret Casey, a Clinical Nurse Specialist in Breast Care, conducted a survey to record the differences in how results are communicated across all services in England. The results of this study were not published but revealed a clear difference between the policy recommendations and how results were communicated in practice.
From 81 English Breast Screening services surveyed, 41% routinely delivered benign biopsy results over the telephone. 42% of centres occasionally delivered benign biopsy results over the telephone, with the remaining 17% never delivering any results over the telephone (see Figure 3). Overall, 83% of breast screening services were delivering at least some results over the telephone, despite communication guidelines suggesting that delivering results in-person was best practice.

**3.10.4 Discord between policy and practice**

There was clear discordance between the best practice approach outlined in the service specification for breast screening in 2014-15 and how false-positive results were communicated in practice. In screening, any communication that takes place must balance benefit versus harm for the patient involved (104). Very little is understood in this setting about the
interaction between anxiety and communication method, highlighting a gap in the research literature.

The NHSBSP specified the need for research to examine the impact of delivering false-positive results over the telephone. The results of this research could then be used to revise current guidance, clarify the position of the national office and ensure the service specification is based upon empirical evidence. This thesis fulfils this research need by examining the impact of the different methods of communicating results in the NHSBSP.

3.10.5 NHSBSP Communication Guidelines: 2017-18
Since this research began, the NHSBSP service specification has been revised.

The NHSBSP service specification (2018-19) now states that telephone results 'should not be routinely offered' but can be given if specifically requested by the woman. If there is a strong suspicion that no cancer is present, women may be offered results by clinic appointment or telephone.

This update occurred as a result of the number of centres already telephoning false-positive results. Various audits from individual centres have evaluated the communication of results by telephone. These audits survey women who have recently received their benign biopsy result by telephone, with results suggesting that women are satisfied with this experience. However, because these audits only measure satisfaction with the results received, this may not truly indicate women’s preferences for communication. Furthermore, these audits measure satisfaction retrospectively and findings may be subject to recall bias. Finally, although some audits allow free-text responses, this may not capture the full experience and opinions of women receiving benign biopsy results. Therefore, despite the findings from these audits, there is still a lack of empirical evidence at the national level measuring the objective impact of communication methods for women receiving false-positive results in the NHSBSP (105). This further emphasises the need for this research.
3.11 Summary
In this section of the thesis, I have described the process of breast screening and assessment in the NHSBSP. This included the uncertainty associated with false-positive results, how women may question their ‘healthy identity’ and how this may impact upon anxiety. I have also discussed the current issues in the measurement of anxiety in this context, including the differences between generic and cancer-specific measures. This was followed by a description of the current state of policy guidelines in the NHSBSP and how these contradict how results are communicated in practice by breast screening centres. Overall, this section provides context to the thesis and also the issues that this thesis intends to address.
4. **Background: communication in healthcare**

In this section, I will begin by giving a general introduction into communication in healthcare. This will include what communication is, why good communication is essential in healthcare and why results communication is important. I will then discuss different methods of communication and their use in healthcare. Following this, I will summarise key issues from the literature relating to communication methods used. This will highlight some of the advantages and disadvantages of different communication methods.

I will conclude this chapter by explaining how this background informs the current PhD project.

4.1 **What is communication in healthcare?**

“Communication promotes both health and illness in society, and makes the system run at optimal or marginal effectiveness” (106)

At a basic level, communication requires a sender, a message, a receiver and a channel of communication (107). Good communication is central in healthcare, and has been shown to have a positive influence on patient health outcomes, including enhancing understanding (108), minimising anxiety (109), maximising emotional health, resolving symptoms and reducing pain (110). Conversely, poor communication is associated with negative patient outcomes and is estimated to cause the healthcare system significant financial and psychological costs (111).

Good communication should be a goal in every healthcare context and at every stage of the patient pathway. A key point of communication along any patient pathway is the communication of a test result (112-114), which may have an impact on patient perceptions, expectations and future health behaviour (115). Test results should be delivered quickly, clearly and accurately, in order to minimise anxiety for patients and, where a disease has been diagnosed, refer them onto the appropriate care pathway (10, 42,
116, 117). Although there is extensive literature relating to how to deliver bad news in healthcare, there is less evidence relating to how to deliver ‘good news’. In the case of a benign breast screening result, this is a ‘good news’ result. However, the anxiety and uncertainty associated with the screening process complicates this news (see section 3.5).

4.2 Communication methods used in healthcare
Across different healthcare contexts, a variety of communication methods are used to deliver results, including face-to-face consultations, telephone, letters and email (99, 114, 117-122). Media theorist Marshall McLuhan coined the phrase ‘the medium is the message’ (123). McLuhan argues that the medium used to deliver a message cannot be separated from the message itself, with the medium influencing the perception of the message and the psychological consequences. In the health care context, this highlights the importance of understanding the communication methods (or mediums) used and the psychological impact on patients (124-126). The method of communication used to deliver test results is a potentially modifiable factor that may have a great impact on improving patient outcomes (86). It is easier to modify one element of a healthcare system or programme, than to modify the behaviour or anxiety of every individual attendee (58).

In medicine, results delivered in-person are often seen as the ‘gold standard’ of communication (119). However, as technology advances, fewer healthcare results are now delivered in-person. Liederman et al. (127) stated that ‘face-to-face contact is not necessary for effective communication’ (pg. 52). Most commonly, results delivery is moving towards telephone and telemedicine (128). For example, human immunodeficiency viruses (HIV), syphilis results and cervical screening results are often offered by telephone (129-132). Despite this, a Cochrane systematic review of research evidence suggests that we still do not know enough about the impact of telephone results services on healthcare outcomes (133). This is concerning due to the rapid changes in communication that may not have been adequately
evaluated. Communication by letter is another method commonly used in healthcare, particularly in delivering patient education leaflets or appointment reminders. Letters are sometimes used to deliver results, usually those that are less ‘severe’.

Each method of communication used in results delivery has different advantages, disadvantages and challenges in implementation (see Table 3). Although the literature directly addressing results communication in breast screening is limited, findings from other areas of healthcare can be examined. These findings can then help to inform our understanding of delivering results in breast screening via different modalities. Therefore, in this section of the thesis I will use literature from various areas of healthcare in order to describe the advantages and disadvantages of different communication methods. I will also include evidence from the communication of both bad news and good news results.
Table 3: Advantages and disadvantages of different methods of communication, adapted from Gurol-Urganci, de Jongh (134)

<table>
<thead>
<tr>
<th></th>
<th>In-person</th>
<th>Telephone</th>
<th>Letter</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Immediacy</strong></td>
<td>Slow: Requires a visit to provider</td>
<td>Immediate but return call may be needed if patient does not answer</td>
<td>Slow</td>
</tr>
<tr>
<td><strong>Privacy and confidentiality</strong></td>
<td>High</td>
<td>Potentially low</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Likelihood of misinterpretation</strong></td>
<td>Low</td>
<td>Low/moderate</td>
<td>High</td>
</tr>
<tr>
<td><strong>Ability to ask questions</strong></td>
<td>High</td>
<td>Moderate</td>
<td>Low – no ‘back and forth’ dynamic between patient and healthcare professional</td>
</tr>
<tr>
<td><strong>Cost</strong></td>
<td>High</td>
<td>Low</td>
<td>Moderate</td>
</tr>
</tbody>
</table>
4.3 Cost and efficiency of communication methods

Healthcare services are always evaluating and improving in order to maintain a high standard of care. As healthcare communication evolves, new opportunities to use different methods of communication may allow for services to become more efficient in the delivery of results. This efficiency often translates into wider cost savings, both in terms of monetary value and resources. These cost savings also allow for money to be reinvested in other areas of the service or to the NHS itself.

Various barriers exist in providing in-person consultations for all patients. These include provision of space, staff and training (31). Using telephone results clinics may be more efficient, minimising the impact on workflow of patients who do not attend and reducing the burden on staff (135). Furthermore, some research shows that when telephone services are implemented into healthcare, cost savings can be made (128, 136-139). Written results can also be less resource intensive and provide a cost saving (115). Postal results have the potential to save even more resources as these can be written and delivered by administrative staff or in an automated system, freeing up medical staff for other duties.

Research into the cost of telephone follow-up for patients with breast cancer found that the service was more cost-effective for patients but not for the provider, with telephone consultations taking longer than in-person consultations (140). A full economic evaluation is required to determine which methods of results communication are most cost-effective in different healthcare services and locations (141).

4.4 Anxiety and communication methods

The psychological impact of receiving a false-positive screening result can manifest in many different forms, including anxiety, worry, fear and stress (47). However, little is understood about the specific impact that communication methods may have upon anxiety (105).
Evidence from genetic testing and hospital follow-up communication has found very little difference in anxiety between patients who were given results by telephone versus those seen face-to-face (135, 142). However, Novack suggested that there is an association between being in the presence of a healthcare professional and lower levels of anxiety (143). For some patients, the hospital environment itself can be reassuring and reduce feelings of distress (144). This may indicate an association between minimised anxiety and attending in-person to receive results. However, some patients may experience the opposite and be fearful of the hospital environment, thus leading to heightened anxiety when attending in-person (145). Lindfors and colleagues found no association between stress and how results were communicated (146). It is clear that the evidence relating to anxiety and communication methods is mixed. This may relate to the difficulties in measuring anxiety, including variability within the measures used (see section 3.7 Receiving the result and continued anxiety) and the challenges in capturing the individual experience. This may also reflect the complex relationship between anxiety and communication.

### 4.4.1 Speed of receiving results and the anxious wait

Waiting to hear results or a diagnosis may be the hardest part of any medical experience, and can often be a time of heightened stress and anxiety (23, 63, 115). Campbell and colleagues suggest that the main advantage of communicating results by telephone is that it is ‘quicker’ (145). In a systematic review by Gurol-Urganci and colleagues which investigated mobile phone communication, anxiety levels were found to be lower when results were delivered by telephone, because the results were delivered sooner (134). Some patients also prefer to receive results more quickly, even if this means they miss an in-person interaction with a healthcare professional (62, 117-119, 147, 148). Therefore, if a method of communication can reduce the amount of time anxiously waiting and is preferred by patients, this could be beneficial (26, 149). Telephone results
may be the quickest method of communication, however, written results may also offer a potential speed advantage (150).

Timely results are not consistently associated with a reduction in negative psychological outcomes. Heleno et al. (64) found no difference in longitudinal anxiety in relation to length of time waiting for results. The authors noted the possible influence of type II error. However, this may be due to differences in patient perceptions of the severity of the result based upon the speed of delivery. Not all patients perceive quicker results as a positive sign, with speed of results delivery perceived as an indicator of a more serious issue (51). Likewise, some patients perceive a longer wait for results to mean that the outcome is non-urgent (23, 42, 51, 115). The relationship between speed of results and patient perceptions might be more complicated than originally assumed.

Elder and colleagues found that some patients are willing to wait longer for their results in order to be seen in-person, whilst others would rather be told a serious result (such as a cancer diagnosis) by telephone rather than have to wait (118). This shows the individual differences that exist in patient’s communication preferences and how preferences may vary depending on the outcome of the rest (see section 4.8 Satisfaction, preferences and attitudes).

4.5 Privacy, errors & data security
A key issue relating to communication is privacy. Patients who receive results in private locations, may be able to absorb information more clearly, may feel less anxious and also feel more valued (147, 151). Guidelines for breaking bad news in cancer place high importance on the setting in which a diagnosis is received (72, 152-154). In this instance, in-person results may offer more privacy than other methods, with results often delivered in a private room (120). However, disturbances to privacy can still happen in this setting such as interruptions from other staff members. In the context of
breaking bad news, a comfortable, private and ‘safe’ setting is used in order to minimise the anxiety associated with diagnosis.

Telephone communication via a landline may also offer privacy, but in a different way. By allowing the patient to receive results in the comfort of their own home, this may make patients feel safe and reassured. Mobile phone results may offer the same privacy if the patient is at home when answering. However, if the patient is busy (for example, doing the food shopping or at work) these locations may not be private enough to receive results (118, 155). Therefore, an important element of any telephone consultation is to establish that the patient is comfortable with the conversation taking place at that time and in that location (156).

Errors in results communication are a big risk in healthcare organisations and can cause serious adverse consequences for patients, including increased anxiety and uncertainty (157, 158). When communicating results by telephone, the potential risk of errors occurring increases, such as contacting the wrong person or audio issues with the technology leading to a lack of clarity (158). Similar errors may occur with written information which may be sent to the wrong address or to the wrong person. Attending in-person to receive results involves a lower chance of error, in comparison to other methods of communication (158).

4.6 Understanding
A higher level of understanding is associated with lower levels of anxiety (109, 159-161). When delivering a healthcare result, the message should be clear in order to ensure patient understanding, as patients often ‘read between the lines’ when interpreting healthcare information (42, 109). The understanding of test results may vary from patient to patient, based on factors such as lower income, lower literacy, not having English as a first language etc. (108, 109, 151, 162-164). It is therefore important to consider the individual differences that may have an influence on understanding beyond the method of communication used.
The role of written communication in healthcare, and how this may impact upon understanding, has been extensively explored. In some circumstances, written information may be advantageous as it provides a record of communication that makes details easier to remember (114, 116, 117). Car and colleagues suggest that written communication offers the possibly of sharing medical information with a family member or partner (165). Sharing information in this way, and seeking social support, can help patients better understand their result and make them feel more at ease.

However, written test results can be misinterpreted by patients, which then leads to negative emotional consequences (115, 151, 166, 167). One reason for the misinterpretation of written information is that patients may not understand the specialised medical terminology used (74, 115, 151, 168). Another reason for misinterpretation is the one-way communication provided by written information. In-person and telephone results are dyadic, with the ‘back-and-forth’ nature of the conversation allowing the patient to ask questions and for the healthcare professional to adapt the consultation to suit patient needs (31, 147). In written communication, this opportunity is lost and many people who do not fully understand the information provided may not contact a healthcare professional for further follow-up advice to alleviate any concerns (31, 74, 114, 169). Therefore, written results may only be suited in situations where the result is easily understood or requires no further follow-up. Written information may also be used to confirm results that have been delivered in-person or by telephone.

4.6.1 Non-verbal cues and understanding
The inclusion of non-verbal cues is an area where in-person results have an advantage over results delivered by telephone or letter where key non-verbal cues are eliminated (128). Knapp and Hall suggest that over 50% of the meaning we convey in conversation is imparted through nonverbal cues, such as body language and facial expression (170). In the doctor-patient relationship, an association has been found between use of nonverbal cues and patient satisfaction with care (171). A potential explanation for this is
that nonverbal cues can help to add meaning to language, which is particularly helpful in explaining the specialised terminology used in medical consultations (109). By adding meaning to the message, this may make the overall content clearer and easier to understand. Research also suggests that patients who understand their healthcare message (a result, information about treatment etc.) tend to have lower levels of anxiety (159-161). However, non-verbal cues involve being in the presence of a healthcare professional which may also have an impact on patient anxiety and understanding (see section 4.4 Anxiety). Therefore, due to the complex nature of communication, it is difficult to investigate which factors are most associated with anxiety and understanding in the context of communication methods.

4.7 Convenience of communication
Telephone and written communication may have a geographical advantage over in-person communication (141, 172, 173). The provision of telephone or written results may remove the need to travel to a hospital or other healthcare setting to receive a result (128, 141, 151, 174, 175). For some patients, this may also be more convenient, meaning that they do not have to take time off work or make alternative arrangements for any care dependents (141, 151, 174, 176). Telephone or written results eliminate the potential costs of traveling to the hospital either by car or public transport, especially for patients who cannot travel easily due to health or social issues (128, 135, 155, 174, 175, 177). Telephone and written results also eliminate the amount of time patients sit waiting at the clinic (128, 147, 151).

4.8 Satisfaction, preferences and attitudes
Various studies have surveyed patient populations regarding how satisfied they were with the communication of their results and how they would prefer to be contacted. Patient satisfaction is associated with effective results communication (178, 179). Dolan and colleagues found several factors that
are associated with dissatisfaction with communication, including an inconvenient method of results disclosure, a long wait time to receive results, results lacking clarity, not feeling able to ask questions and increased anxiety (178). Despite this, patient preferences for communication methods are mixed (114) because preferences tend to be dependent on the individual (119, 128). Generally, patients prefer verbal methods of communication (in-person or telephone) over written methods (by letter) (163). Patients also tend to prefer the method of communication that they have received in their past healthcare experiences (118, 142, 147).

Communication method preferences depend upon whether the patient is receiving good news or bad news (119, 128, 180). Patients prefer in-person communication when their result is abnormal, especially when receiving results which are perceived as more serious and emotionally charged such as cancer diagnoses (180). However, this is not always the case. Choudry and colleagues found that some people do not change their communication preferences based on the severity of the outcome (119).

A large number of patients never share their preferences for communication with healthcare professionals (147). Therefore, there is often a mismatch between the communication methods provided by services and the communication methods preferred by patients (117). This is important to consider when evaluating the communication methods used in healthcare because patient outcomes tend to be more favourable when patients are satisfied with communication (178, 179).

**4.8.1 Preferences for in-person results**

In medicine, in-person results are often seen as the ‘gold standard’ for patient care (103). Patrick-Miller and colleagues investigated the implementation of telephone communication for genetic results disclosure in breast cancer. Although telephone results were viewed favourably by the study population, many women refused to participate. The main reason for declining to participate was women not wanting to be contacted by
telephone, due to having a clear preference towards in-person communication (173). Patients with higher levels of anxiety tend to favour in-person communication (117).

In a gynaecologic oncology setting, Kuroki and colleagues found that women were more satisfied when results were communicated in-person (91%) versus over the telephone (72%) (120). Although other aspects of satisfaction were also measured, the exact reasons for higher satisfaction with in-person methods were not fully explored. One reason might be that some patients feel it is easier to ask questions in-person (145). A further exploration using qualitative methods could give insight into reasons for the differences in communication preferences.

4.8.2 Preferences for telephone results

Healthcare communication has changed over time and now some patients might prefer results to be delivered by telephone (117, 119, 128, 150). Some women receiving telephone results report high levels of satisfaction, with telephone results communication meeting patient needs (128, 135).

Brandon and colleagues investigated patient perceptions of care during and after breast biopsy and found that 90% of patients rated the use of telephone results as acceptable (25). However, this study had a low response rate (43%), which could mean that a different preference might have been expressed by those who did not participate. Furthermore, the study involved only one breast screening centre. Therefore, the overall satisfaction with telephone communication may just be an artefact of a particularly effective communication system at this centre and might not be generalizable to other services.

In a UK breast screening centre, Campbell and colleagues found that 93% of women receiving benign breast biopsy results by telephone were satisfied in comparison to 62% who received results in-person (145). Potential reasons for this were discussed, such as telephone results minimising wait time. However, patients themselves were not interviewed. This research was only
The issue of satisfaction. Furthermore, satisfaction may not be the best measure of preferences (see section 4.9.1 The issue of satisfaction).

4.8.3 Preferences for written results
Some patients prefer written results as a mode of communication, although this is less common than verbal methods (181). Some women find written results acceptable if they are communicated efficiently, however, others ‘dread’ waiting for a written test result to arrive in the post (182). Written results are perceived by some patients as an ‘insensitive’ way of communicating test results (169). Some patients prefer written communication as it provides a record that can act as a reminder and can be reread to understand in their own time (118, 169). Some patients also express a preference for the use of visual aids to help enhance communication.

However, most physicians prefer the use of direct, verbal methods of communication, believing that this reduces the possibility of negative psychological consequences and ensures higher quality communication (183).

4.9 Measurement issues
4.9.1 The issue of satisfaction
One of the main issues in the investigation of patient preferences is the use of satisfaction as a measure. Frequently, patients are surveyed asking how satisfied they were with their care, including the method by which they were communicated. However, satisfaction might not be a valid way to measure preferences. Patient satisfaction has been found to be highly correlated with simply receiving a result (114, 117, 184). This means that, regardless of the method used, patients would report high levels of satisfaction simply because they received their result. Furthermore, women who attend screening tend to be positive about their experience, giving high ratings of
satisfaction (26). Other researchers have noted the existence of a ceiling effect in the measurement of satisfaction (178). This will be discussed in more detail in Chapter 2 when discussing the measures which were chosen in the current research.

4.9.2 The wrong population
Another issue in the investigation of preferences is that studies use the ‘wrong population’ in their sample. Some studies use a healthy population who may not fit the eligibility for a specific test, who are then asked to rate how satisfied they would be receiving results in different hypothetical scenarios (119, 180). This is an unreliable way of measuring preferences because patients receiving a real healthcare result have more emotional involvement than a lay population. This will impact upon their preferences for communication. Other studies retrospectively measure satisfaction. This delay in satisfaction rating may lead to patients misremembering key events and rating their overall satisfaction differently to how they might have appraised this directly after receiving their result. This leads to recall bias (25).
5. Conclusions and contribution of the thesis

The experience of receiving a false-positive result from breast screening is associated with heightened uncertainty and anxiety, which the NHSBSP has a duty to minimise. A possible way to reduce anxiety at the screening population level is to evaluate how results are communicated. However, there is limited evidence investigating the impact of communication methods specifically in UK Breast Screening. Furthermore, there is a disparity between policy and practice for results communication. Therefore, there is a gap in the literature that needs to be addressed.

Results communication and its impact on patients has been investigated in other areas of healthcare. These studies have identified various advantages and disadvantages of different communication methods including the role of non-verbal cues, misinterpretation, privacy, errors, speed and patient preferences. These factors appear to be associated with the patient outcomes of anxiety and understanding of results.

Although the findings from the current literature may guide our approach, the background has shown several key issues that need to be addressed. These include the following:

- A lack of generalisability to the NHSBSP context – Firstly, most research has been conducted at only one study site and therefore, implications cannot be made for the wider population. Secondly, due to the potential confusion of a benign result and the fear associated with cancer, findings from other healthcare research might not reflect the patient experience in breast cancer screening.

- Issues in the measurement of anxiety – Firstly, research in breast screening uses different measures of anxiety (generic or breast-cancer specific). The use of generic measures of anxiety might not reflect cancer-specific worries and may only indicate personality-level differences. Secondly, most research measures anxiety retrospectively. This may not truly reflect the anxiety experienced during assessment and post-results.
• Using the wrong population – Most research in this area has used a lay population who are not the targeted group for the health condition. Therefore, the data provided by these participants may not reflect the experience of ‘true’ patients.

• Issues in the measurement of preferences – Most research has used satisfaction as a proxy for patient preferences which may cause bias.

• Too simplistic/one method only – A large amount of research has used survey methods which, when used in isolation, do not capture the complexity of communication in the breast screening context. Although some studies have used qualitative data to capture these experiences, this can be difficult to translate into policy recommendations due to the individual differences that exist. A multi-method approach combining quantitative and qualitative data may help to explain the impact of communication methods in breast cancer screening.

In this thesis, I aim to explore the impact of communication methods on women receiving a benign screening result in the NHSBSP. In doing so, I will directly answer questions raised by the NHSBSP, address the literature gap in this area and provide solutions to the methodological issues in previous research. This evidence can be used to inform policy guidelines and may have further implications for communication guidelines in international breast screening programmes. This thesis will also shed light on the complexity of the patient experience of receiving a result via different methods, and may prompt further consideration and discussion in other areas of healthcare communication.
6. Chapter summary

In this chapter, I have summarised the context in which the current PhD project exists. This included a background to the screening programme, the disparity between communication policy and practice in the NHSBSP and current healthcare research investigating different methods of results communication. I identified the gap in the literature (including current issues in the methods used) and how my thesis aims to fill this gap.

In the next chapter I describe my approach to the thesis, explaining how the methodology used answers my research question.
CHAPTER 2: Rationale, development, methodology, aims and objectives
1. Chapter introduction

In Chapter 1, I described the current context in which the thesis exists, including the background literature and differences between communication policy and practice in the NHSBSP. In this chapter, I will outline the rationale, development and methodology for the thesis. I will begin by summarising the rationale for the project and the overall aim. Following this, I will describe the philosophical assumptions that underpin this thesis. I will then highlight relevant communication models and present my theoretical models. Next, I will explain the development of the research question and objectives using stakeholder and patient and public involvement. Following this, I will outline the research question and objectives for the thesis. Then I will summarise my research approach and its phases, providing a justification for the methods chosen. I will then outline the contribution to knowledge that this thesis provides. Finally, I will present the funding statement and overview of the ethical approval for the thesis.
2. Rationale

In this thesis, I aim to explore the impact of communication methods on women receiving a benign biopsy result in the NHSBSP. There is a demonstrated need for this research for three reasons:

1) Receiving a false-positive result has been linked to increased anxiety, which has been demonstrated extensively within the research literature (21, 28, 41, 85). Screening programmes should provide a benefit, whilst minimizing potential harm. Therefore, research is needed to minimize the psychological harm associated with receiving a false-positive screening result. The method of communication for delivering results is a potentially modifiable factor.

2) Although there has been research in other areas of healthcare communication, there is a gap in our knowledge with regards to breast screening, and how the method of communication used to deliver the result may impact upon the women involved and what role this may play in false-positive anxiety.

3) There is clear discordance between how policy guidelines recommend results should be communicated and what is currently happening in the delivery of breast screening results in practice.

This thesis will be used to directly answer concerns raised by the NHSBSP about delivering benign results by telephone (see Chapter 1). This thesis will address the gap in research concerning the impact of communication methods on breast screening attendees whilst also addressing the methodological issues in the current literature (see Chapter 1). This evidence can be used to inform NHSBSP communication guidelines and may have further implications for guidelines in international breast screening programmes.
2.1 Thesis aim
The overall aim of this thesis was to investigate the impact of the communication method used to deliver results on patient anxiety, understanding of results and preferences for communication in the NHSBSP.
3. Philosophical assumptions

The aim that this thesis aimed to address was practical, spanning multiple disciplines including public health, psychology and communication. To capture the multidisciplinary nature of the topic, an approach to knowledge that attempted to consider multiple viewpoints was needed (185). This was the reason for selecting a multi-phase mixed methods approach to the thesis.

In research, the philosophical underpinning should always be stated. This is because, even when attempts are made to avoid this, the influence of the researchers own epistemology will still remain present (186). The underlying epistemological approach for this thesis was critical realism, which is an approach commonly used in mixed methods research (187). Mixed methods designs combine strengths from both quantitative and qualitative research and can minimise some of the weaknesses associated with single method approaches (188). In this thesis, critical realism is philosophically underpinned by pragmatism. Pragmatism takes a ‘use what works’ approach, allowing the use of diverse methods and procedures to choose a complementary approach best suited to answering the research questions, whilst valuing both subjective and objective knowledge (188-190). In this instance, epistemology is less about paradigms but more like tools in a toolkit (186). Critical realism is an alternative to positivism or empiricism (which tend to be favoured by quantitative researchers) and constructivism (which tends to be favoured by qualitative researchers).

Traditionally quantitative research focuses on the identification of objective truths (191), taking the positivist approach. A positivist approach was considered for this thesis, aiming to quantify the impact of communication methods on women attending breast screening. Quantifying the impact of communication methods would be beneficial, as findings would be limited in terms of bias and have generalisability to the NHSBSP as a whole. However, the literature and theory surrounding women’s experiences at breast screening suggest that psychological factors (such as anxiety and understanding) play a key role. From a positivist standpoint, these are concepts that are difficult to quantify, measure and generalise. Furthermore,
the literature also empathises the individual experiences of attending breast screening, with qualitative interview methods being commonly used.

On the other hand, qualitative research focuses on subjective and individual experiences (192), taking a constructivist approach. A constructivist approach was considered for this thesis, in order to address the potential flaws of positivism and to explore women’s subjective experiences. However, an entirely constructivist approach to this thesis would not yield findings which could help to inform future communication policy updates. The focus would be too subjective and too focused on the individual experience, with findings lacking generalisability.

In the case of the thesis, positivism and constructivism presented a trade-off between generalisability and capturing complex psychological constructs (e.g. anxiety) within the individual experience. Therefore, critical realism was considered as an appropriate approach. Critical realism integrates the ideas of the positivist and empiricist perspectives, facilitating communication between quantitative and qualitative methods and increasing the usefulness of each perspective. Critical realism unifies three ideas: the realist ontology, constructivist epistemology and the reality of mental phenomena (186). The realist ontology assumes that there is a real word which we can study. The constructivist epistemology takes the view that our understanding of the world is an inevitable construction based upon our own unique perspectives. The reality of mental phenomena is the idea that there is value interpreting and studying psychological processes.

In unifying these three ideas, critical realism assumes that there is a real social world that we can research and attempt to understand. However, there are multiple valid perspectives of this world based on the context of an individual which have value in the construction of scientific knowledge (186). Therefore, critical realism attempts to uncover a combination of objective truths and subjective experiences, aiming to develop a deeper understanding of the world or a phenomena (193). This can provide a framework for understanding the relationships between individual perspective and their actual situations (186). This approach works well in the context of the thesis.
when trying to understand the complex, individual experiences of women receiving benign biopsy result whilst considering the implications within the wider context of the NHSBSP. Taking the critical realism approach and a mixed-methods design allows for the collection of both objective and subjective data, which can be triangulated to provide 'confirmation' and 'completeness' to our understanding of the impact of communication methods on women receiving a benign biopsy result (193). Some researchers argue that critical realism does not offer a clear ontological perspective and is limited in how useful it is as an approach (186, 194). However, I believe that this approach is best suited to the context of the thesis, helping to address the flaws of quantitative and qualitative methods and valuing both objective and subjective knowledge.
4. Models for effective communication

There are various models for effective communication. An early model, Laswell’s (195, 196) model of communication, was based on a one-way or linear process answering five questions:

- Who (said) it?
- What was said?
- In what channel?
- To whom?
- With what effect?

From this, we can see that communication channels were taken into account in early models. Another similar model is the Shannon-Weaver model of communication (197) (see Figure 4). This model has a five step process:

1) The sender intends to send a message to a receiver.
2) The message is encoded
3) A channel (method) is used to deliver a message
4) The message is received by the intended audience and decoded
5) The message reaches the receiver

![The Shannon-Weaver Model of Communication](image)

*Figure 4: The Shannon-Weaver Model of Communication*
The Shannon-Weaver model added the feedback loop, taking into consideration that communication is not a one-way process. During the message transmission, ‘noise’ interruptions from external sources may distort the transition of the message e.g. receiving a telephone call whilst in a busy, noisy supermarket and not clearly hearing all the information. Noise may also be ‘psychological noise’, for example, anxiety impacting upon the ability to receive the message. However, the Shannon-Weaver model missing various barriers to achieving effective communication including the message not being well formulated at the source, being poorly encoded by the sender or social/cultural differences influencing the interpretation of the message by the receiver.

The main criticism of these early models was that they tended to be too linear and ignored the interactional processes of communication (198). Over time, these models have moved from being linear models of communication towards transactional models of communication. Transactional models incorporate the idea that communication processes are dependent on individual factors such as prior experiences, attitudes and beliefs. Furthermore, they expand on the idea that communication is a two-way and dyadic process, with both individuals involved in the process being senders and receivers of a message (199).

An example of a transitional model of effective communication is the Schramm model (200, 201) (see Figure 5). This model incorporates elements of earlier models with the addition of the ‘field of experience’ of the transmitter of the message and the receiver. Each individual brings their own prior experiences and beliefs to the moment of communication, which may impact upon how the message is decoded. However, Schramm does not elaborate further on how these individual experiences may impact upon communication. Furthermore, this model does not consider the impact that the communication has on the receiver, beyond decoding the message.
Effective communication and impact on health outcomes

General models of communication can be useful in aiding our understanding of communication in the healthcare context. We know from previous research that good communication is essential in healthcare and has been shown to have a positive influence on patient health outcomes (202). A model by Street et al (202) (see Figure 6) indicates that functions of communication can have a direct and indirect impact on many patient outcomes including proximal outcomes (such as understanding) and health outcomes (such as emotional well-being). In this model, the communication functions are factors that may be influenced by the method of communication selected. For example, “information exchange” may become more challenging when communicating by telephone due the lack of non-verbal cues (as discussed in Chapter 1). Therefore, although this model does not reference communication methods specifically, there is scope to apply these concepts in this thesis.
Figure 6: Pathways linking clinician–patient communication to health outcomes (adapted from Street, Makoul, Arora & Epstein, 2009)
4.2 Information-processing model of medical consultation

In 1993, Frederikson (203) developed the information-processing model of medical consultation (see Figure 7). This model combines elements from transactional communication models (such as the input of the individual) alongside the impact on healthcare outcomes (such as patient understanding, concern, and satisfaction).

Figure 7: The information-processing model of medical consultation (Frederikson, 1993)
4.3 Thesis model

To produce a model to guide the thesis, I have drawn upon what is known in the literature (discussed in Chapter 1) and the models discussed in this chapter. I have integrated the key concepts and specifically applied these to the context of receiving a results from breast screening to produce a theoretical model (see Figure 8). This model presents the patient experience of receiving a biopsy result from screening. Each woman has her own ‘input’, which is her psychological state prior to receiving results. This consists of her current levels of uncertainty regarding her health identity, her fear about breast cancer, what she expects will be the outcome of her results, her preferences for results communication and also individual differences in her own beliefs, personality, coping strategies for dealing with anxiety and demographic factors. Each woman’s individual ‘input’ or context will impact upon the results giving process.

The results process is at the core of the model. Key elements of communication are used during the delivery of results to facilitate understanding and reduce anxiety. These include ensuring clarity, using body language to add meaning, asking questions and using empathy. The method of communication is also at the core of this model, as this thesis aims to address potential differences between telephone and in-person results.

The final part of the model relates to patient outcomes. Following the delivery of results, there are three key outcomes which were found during Chapter 1; understanding, preferences for future communication and anxiety. These three outcomes will be directly influenced by the results delivery process. This thesis also aims to identify if the communication method itself influences these key outcomes. Based upon this model, the method of communication used to deliver results should:

- Allow results to be clearly understood
- Be acceptable (and ideally preferred) by the patient population
- Not cause additional anxiety
Figure 8: Theoretical model underpinning the thesis
4.4 Bridging the gap

In Chapter 1 of the thesis, the association between anxiety, the healthy identity and uncertainty was discussed. Women attend screening as ‘healthy’ individuals. However, the abnormal mammogram result disrupts this identity, leading to uncertainty and anxiety. The purpose of a benign result is to reassure women that they do not have cancer, resolving uncertainty and facilitating the return to the ‘healthy’ identity. In this case, the communication method used to deliver results acts as a ‘bridge’ between uncertainty and certainty (see Figure 9). Some women receive results and return easily to the ‘healthy identity’, successfully ‘crossing the bridge’ (38, 43). Some women do not manage to ‘cross the bridge’, experiencing continuing uncertainty and anxiety. Different methods of communication may be metaphorically different ‘bridges’, facilitating or hindering the return to certainty and the healthy identity. For example telephone results may lack clarity and prevent the return to certainty. On the other hand, in-person results may be slower, thus preventing the timely return to certainty. This relates back to the ‘core’ of the model in Figure 8 where results communication directly impacts upon patient outcomes of understanding, preferences and anxiety. In this thesis, I investigated the difference between the ‘bridges’ of in-person and telephone communication.

Figure 9: The ‘bridge’ between uncertainty and certainty. A visual representation of how communication method ‘bridges’ the return to certainty and the healthy identity.
5. Development of questions and objectives

The research question and objectives for this thesis were developed from the following:

- Stakeholder involvement from key members of NHSBSP staff (204)
- Patient and Public Involvement (PPI) from women who have previously received a false-positive result from breast screening (205)

Key stakeholders from the NHSBSP included the National Programme manager, the National Quality Assurance Lead and a Clinical Nurse Specialist in Breast Care. Discussions with these stakeholders explored the motivations for the research and identified what the main focus should be. Their main priority was to minimise the anxiety women experience during the screening process. Other areas of interest for the NHSBSP were patient preferences for receiving results and also an assessment of the potential time and cost savings of telephone results. These were taken into consideration in the design of the research.

Patient and public involvement (PPI) in research is when the patient group or general public contribute their own knowledge and expertise to co-produce research (206). PPI was used in this thesis to develop the research questions and design, in order to ensure that the approach would be acceptable to women attending screening. The PPI group involved with the thesis was recruited from the charity Independent Cancer Patient Voices (ICPV); a patient advocate group led by patients for patients (207). The group consisted of women who had previously received a false-positive result from breast screening. This group was selected as, having experienced screening and receipt of a false-positive result, they had unique insights into what improvements could be made in communicating results, as well as what methods of research might be acceptable during the screening process and assessment clinic.

PPI allows research to be designed in collaboration, with the target group actively participating and engaging with the research team, making decisions
to help focus the questions, design, scope and dissemination of research (208). This makes research more patient-centred and relevant (209) which is particularly important in the thesis when considering the impact of breast screening services on attendees.
6. Research question, objectives and approach

The overall research question to be answered by the thesis was:

What is the impact of the communication methods used to deliver results on patient anxiety, understanding of results and preferences for communication in the NHSBSP?

To answer this research question, I conducted five phases of research. A diagram presenting these phases and how they link together can be seen in Figure 10.

**Figure 10: Diagram of the research phases**

These phases used multiple methods and a combination of quantitative, qualitative and mixed-methods data. Each phase of the thesis aimed to address specific objectives, forming an overall picture of the impact of telephone results services in the NHSBSP. The research objectives were as follows:
PHASE 1: Systematic review (Chapter 3)

- Objective - To systematically review research exploring which communication methods are used for the delivery of results in cancer screening programmes, and how women prefer to have their results delivered
- Objective - To systematically review evidence of how the communication method used to deliver results impacts upon attendee anxiety and understanding of results

PHASE 2: Centre survey of current practice (Chapter 4)

- Objective - To survey breast screening centres to record how often telephone results are delivered and who delivers these results, for benign and cancer screening results.
- Objective - To compare the time taken to deliver a result by telephone versus. results delivered in-person

PHASE 3: Cluster randomised crossover trial (Chapter 5a & 5b)

- Objective - To compare the immediate and long-term effects of communication method (telephone or in-person) on the anxiety experienced by women receiving a benign biopsy result from breast cancer screening using a cluster randomised crossover trial
- Objective – To compare the effect of communication method (telephone or in-person) on how well women understand their benign biopsy result from breast cancer screening using a cluster randomised crossover trial

PHASE 4: Communication preferences: surveys and interviews (Chapter 6)

- Objective – To survey women attending breast assessment to record their communication preferences, before and after receipt of a benign biopsy result
Objective - To interview women who have received a benign biopsy result from breast screening to explore their reasons for communication preferences

Phase 5: Integration (Chapter 6)

Objective - To integrate the data to explain communication preferences and expand on reasons for these preferences

I will now summarise each phase of the research and justify the approach used.
6.1 Phase 1: systematic review

Reviewing the research evidence is one of the key ways in which policy makers make evidence-based decisions (210). Systematic reviews are seen as the ‘gold standard’ review method, using a rigorous and transparent process to compile, evaluate and synthesise research evidence (211-213). The systematic review process involves summarising and evaluating a wide range of literature, allowing policy makers to glean insights from the findings, using the knowledge to guide evidence-based decisions (210, 214, 215). Furthermore, due to rigor and transparency, systematic review evidence allows for future updates to be made when more research evidence becomes available.

In Chapter 1 of the thesis, the background literature revealed very little evidence about communication methods in breast screening. To date, there has been no systematic review focusing specifically on the impact of communication method of results in the NHSBSP. Therefore, a review was conducted to collate the international evidence that currently exists to inform the direction of the thesis.

As the evidence in breast screening is limited, this review included evidence from all cancer screening programmes involving a female population. The focus on the outcomes of preferences, anxiety and understanding emerged from the general background literature and NHSBSP stakeholder motivations. The review took a mixed methods approach. This allowed the synthesis of quantitative and qualitative data to give a deeper understanding of the impact of communication methods of attendees.
6.2 Phase 2: centre survey of current practice

As mentioned in Chapter 1, anecdotal evidence from the Breast Care Nurses Advisory Group suggested that centres were delivering results by telephone. However, there was no empirical record of how telephone results services were used in the NHSBSP, including how frequently they were used. Currently, there are gaps in our knowledge regarding how NHSBSP centres are delivering results, meaning that we cannot thoroughly investigate what impact current communication used may have upon the women involved. Therefore, a centre survey was conducted as part of this thesis to identify and record current practice in communicating results in English breast screening centres.

This phase contained two objectives. The first objective was to record current communication practice for English breast screening centres, including how often telephone results are delivered and who delivers these results. The aim of this objective was to update and improve upon a previous centre survey of communication practice conducted by Margaret Casey in 2014-15. The second objective was to compare the time taken to deliver a result by telephone versus. results delivered in-person. This was achieved by comparing the average time between MDT and results delivery for centres who identified as routinely, occasionally or never giving results by telephone. This objective aimed to give the NHSBSP an indication if telephone results are delivered more quickly in practice, in comparison to results delivered in-person. This will indicate if telephone results have a time advantage over results delivered in-person. Speed is one of the potential benefits of telephone results services so these findings may have implications for the cost vs. benefit of implementing telephone results services (216, 217).

6.2.1 Survey design

I chose to conduct this phase of the research using an online study design, combining tick-box questions (quantitative data) with free-text responses (qualitative data). There were three reasons for this choice. Firstly, the tick-box questions in the survey design allowed for the capture of brief answers
from each UK centre, making the survey easy and feasible for busy centre representatives to complete (218, 219). The optional free-text box responses gave centres the opportunity to give further details when appropriate and when time constraints allowed. Secondly, I decide to distribute the survey online to allow for a large number of surveys to be distributed across a wide geographical area (entirety of England), whilst keeping research expenses low (218, 220-223). Thirdly, the previously unpublished survey described in Chapter 1 had already successfully implemented survey methods with favourable centre response rates, despite survey research traditionally having lower response rates (224). Therefore, a decision was made to replicate this design choice, building on the existing tool whilst improving the survey content to answer the proposed research question. A similar dissemination process was also followed, with the survey link being distributed by the Quality Assurance Lead for Breast Screening in England.

6.2.2 Piloting
I conducted three rounds of piloting for the survey (225, 226). The first round consisted of a stakeholder review of the survey content. This was to ensure that the content reflected the research question and objectives. Furthermore, this piloting stage allowed key stakeholders from within the breast screening programme to view the content through their own expert lens to give insight into any changes that needed to be made. The first round of piloting also simplified the language used and optimised the order of the questions (226). The second round of piloting involved testing the online layout, checking for typos and any usability issues (227). The third round of piloting involved cognitive interviewing with a layperson to ensure that the questions were easily understood. This also gave an indication of the length of response time needed to complete the survey (226).
6.3. Phase 3: cluster randomised crossover trial
The overall aim of this thesis was to investigate the impact of the communication method used to deliver results on patient anxiety, understanding of results and preferences for communication in the NHSBSP. Therefore, a direct comparison between telephone and in-person results was needed to explore any potential differences in anxiety, understanding of results and preferences for communication.

6.3.1 Method selection
The aim of Phase 3 was to directly compare telephone and in-person methods of results communication in the context of the NHSBSP. I decided to compare the two methods of communication based upon the outcomes of anxiety and understanding. This decision was made based upon the background literature and meetings with key stakeholders. I decided that the best approach for measuring these outcomes was to measure anxiety and understanding prospectively using a sample of women attending breast assessment following a positive mammogram result. By measuring key outcomes during the screening process, I hoped to avoid the issues associated with retrospectively measuring anxiety (228). In order to do this, I decided to use a simple survey design repeated at four key time points (see Table 4). These time points were selected to record patient outcomes at key moments throughout the screening process (e.g. before and after the delivery of results) alongside follow-up data to assess the longitudinal impact of anxiety.
I chose a survey design to allow the research to be cost-effective and easily replicated at multiple centres, reducing the potential risk of staff error by offering a standardised process. This allowed multiple centres to be involved in the research, recruiting a larger sample size and making the findings more generalizable than previous research only involving one study site. This design was also chosen, in collaboration with key stakeholders, in order to minimise potential disruptions within the assessment clinic setting for both staff and patients. During the development of this phase of research, the low response rates often associated with survey research was considered. Therefore, monitoring procedures were put into place to ensure recruitment targets were met.

### 6.3.2 Measurement of anxiety

To measure anxiety in this phase of the research, I selected the Psychological Consequences Questionnaire, PCQ, see Appendix 1 (90). The PCQ is a disease-specific measure of anxiety, consisting of 12 statement-based questions across three dimensions: emotional, social and physical anxiety. Participants rate each statement on a scale of 0 (not at all) to 3 (quite a lot of the time). The maximum score on the PCQ is 36.

The PCQ was chosen for four reasons. Firstly, the PCQ is disease specific towards breast cancer, avoiding the lack of reliability that may be found using
more generic measures of anxiety (91). Secondly, using a validated and widely used measure of anxiety makes the current research replicable and comparable (90). Thirdly, the PCQ has been used successfully in previous research, indicating the acceptability and ease of use of the measure (15). Fourthly, the PCQ is a brief measure of anxiety, designed to be quickly completed by participants. This will facilitate the collection of data during the busy breast assessment clinic.

For the purposes of this research, the total PCQ score was the only outcome considered, with no analysis at the subscale level. The main reason for this decision is that previous research has found the subscale dimensions to be highly correlated and measuring the same construct (16). This is further supported by other research which has found variability across studies in relation to the dimensional structure of the PCQ and states that the PCQ subscales are not based upon theoretical constructs (91, 229). Other papers have therefore presented the total PCQ score as the only outcome (15).

Bond et al. (41) stated that papers who use the PCQ as a measure do not always make it clear how the PCQ was used in the context of the research. For transparency, in this research, the PCQ measure was used as a total score with no focus on the subscale dimensions which may lack theoretical underpinning and validity.

### 6.3.3 Trial

During the development of the project, I considered several difference approaches for this phase of research including discrete choice experiments and cohort designs. However, I decided that a trial would be the most appropriate method for answering the objectives for this phase of research. Randomised control trials (RCTs) are seen as the ‘gold standard’ in research, offering control over confounding factors (230). RCTs allow direct comparisons to be made, which is ideal for this thesis which aims to inform future policy guidance. However, in some research it is not possible to
randomise at the level of the individual (231). Therefore, I used a cluster randomised crossover trial design.

The main reason for this was that it was ethically problematic to randomise the method of communication for results at the individual level. This was due to the sensitive recruitment timeframe during the assessment clinic. Women attending the breast assessment clinic do not know if they will be diagnosed with cancer or not. When women were recruited into the study who went on to have a cancer diagnosis, we wanted to make sure that these women were contacted in-person as per policy guidance. Randomisation at the individual level was risky, with more potential for error and the possibility of causing extra anxiety for women diagnosed with cancer. Furthermore, individual randomisation may have caused extra staff workload when running the trial day-to-day.

There was a potential for issues of contamination between centres if clustering was not taken into consideration in the design. It was speculated that different centres may vary by how confident and skilful they feel when delivering results by telephone. There may also have been differences over time, with centres becoming more confident in delivering telephone results with more practice. These centre-level differences may have impacted upon the outcome measures of interest.

6.3.4 Crossover
Traditionally, cluster randomised trials will allocate one intervention per cluster. However, this trial needed a crossover element in the design. This meant that each centre would deliver both methods of communication (telephone and in-person) on a month-by-month basis e.g. one method in the first month, one method in the second month etc. I made this decision due to the potential baseline differences that might exist between centres. Different centres may vary by how confident and skilful they feel when delivering results by telephone due to differing levels of previous experience. Furthermore, there may be differences/changes that occur over time where
staff may become more confidence in delivering telephone results due to practice. These centre-level differences may have impacted upon the outcome measures of interest. Therefore, the crossover design was selected for the allocation of the randomisation, in order to minimise the impact of centre-level differences.

See Chapter 5a for the full trial protocol.

6.3.5 Considerations of cluster randomised crossover trial designs

Individuals within the same cluster are likely to be more similar to one another than a random sample. Therefore, observations cannot be regarded as independent and this needs to be factored into the analysis of the data (232, 233). If clustering is not taken into account, this may lead to narrow confidence intervals and increased Type 1 error. The methods used for analysing cluster trials naturally lead to wider confidence intervals. Therefore, a larger sample size is needed in a cluster randomised trial than a traditional RCT.

6.3.6 Number of centres and feasibility

In 2016-17, 40,255 women were recalled from screening and had a core biopsy. Of the women that had a biopsy, 18,402 were found to have cancer. Therefore, a total of 21,853 women had a false-positive (or benign) result. There are 79 breast screening centres in England. This means that each centre will deliver approximately 276 benign biopsies per year. However, some centres serve a significantly larger population. The recruitment sample size aim was 457 women. Therefore, four large breast screening centres were involved in year-long recruitment, to balance the generalisability of the findings alongside keeping data collection feasible for a PhD project. Even with a 50% recruitment drop-out rate, this was considered to be a feasible number of women to recruit to the trial.
6.4 Phase 4: communication preferences: surveys and interviews

Phase 4 used a combination of qualitative survey data from the cluster randomised crossover trial and telephone interviews. The qualitative survey data involved free-text responses from participants, explaining their reasons for their communication preferences. The aim of the survey data was to collect preference reasons from a large sample size.

Telephone interviews were used in this phase of the thesis to explore the qualitative experience of women attending screening who receive a false-positive result (see full method in Chapter 6). Qualitative research methods are well-established and valued in the health sciences (189, 234-237). The purpose of qualitative methods is to allow the researcher to gain ‘insight into the worlds of others’ (238). Some research questions cannot be answered by quantitative methods alone, and require the use of qualitative methods that allow a deeper exploration of individual and personal experiences (234-236). For example, preferences are complex because they are based on the values, attitudes and beliefs of an individual. This can be difficult to explore quantitatively, with the majority of research into preferences favouring qualitative methods (112, 118, 132, 147, 239). Here, quantitative data alone was insufficient in capturing the nuances of individual preferences because quantitative data only describes what communication method women might prefer without exploring the reasons for these preferences. Qualitative data is based upon the participants own subjective experience and categories of meaning, driving the data from a participant rather than researcher perspective (188). This is useful in areas of research where very little is currently known, such as the current understanding of communication preferences in breast screening.

Therefore, qualitative data will be used to explore why women prefer certain communication methods over others. This information will add a deeper, richer understanding to the quantitative data, which will merely report what the majority of women prefer. This will allow the NHSBSP to inform their approaches to communication preferences and policy.
Telephone interviews were chosen as the most appropriate method for three reasons. Firstly, telephone interviews are low-cost to conduct and allowed for a geographically diverse population to be reached with ease (240). Secondly, although group interviews were considered as an option, the sensitive subject matter lent itself to individual interviews (241). Furthermore, various logistical issues and barriers are involved in focus group research (240). Thirdly, as a young researcher, conducting interviews over the telephone potentially minimised the influence of researcher bias.

Approaching these interviews from a critical realist perspective, a semi-structured interview guide was developed. The guide allowed for a combination of structured questions, probes and prompts, whilst giving the interviewer the opportunity to explore any new issues that women mentioned during the interview (242). The semi-structured questions were theory-based, coming from the background literature regarding communication methods in other areas of healthcare (242). Several standardised questions allowed the consistent measurement of specific concepts (e.g. the understanding of results – all women were asked how well they understood their result). Whereas other questions allowed women to tell ‘stories’ about their specific experience. This allowed for women to recall their experiences but to also reflect on how their experience might have been different if they had received a different method of communication (242).
6.5 Phase 5: Integration

In the fifth and final phase of the research, a mixed methods approach was used to bring together the quantitative and qualitative findings relating to the outcome of patient preferences. A diagram of how mixed methods were used in this thesis can be seen in Figure 11 below (243).

The study design for the mixed methods phase of the study was sequential explanatory (244, 245). The quantitative and qualitative preference data were collected in separate phases of the project. During Phase 3, the quantitative data were collected to record preferences for results communication (expressed numerically). Next, during Phase 4 the qualitative telephone interview data were collected to explore preference formation, building on the quantitative findings. The sequential approach was chosen with the aim of using the qualitative data to explain the previous findings from the qualitative phase, expanding our understanding of communication preferences (246).

Furthermore, the collection of free-text responses during the initial quantitative cluster randomised crossover trial phase informed the development of the interview guide for the qualitative interviews. Each data set (quantitative and qualitative) was analysed separately before being integrated at the data interpretation stage.

Quantitative and qualitative data was integrated at the interpretation stage using narrative synthesis. This involved reporting the results of both the
quantitative and qualitative analysis together and drawing conclusions from this data (243). In integration, the priority of the datasets was given to the qualitative phase of the research. The justification for this decision was the overall objective of mixing the data (245). The objective was to explain communication preferences and expand on the reasons for these preferences. As such, the qualitative data offered deeper insight into answering this enquiry.
6.6 Summary of the mixed methods approach

To investigate the impact of communication method on the women involved, the dominant approach for the thesis was quantitative, providing statistically useful data to the NHSBSP regarding the magnitude of the potential impact on important patient outcomes (189). A quantitative approach was selected to control for potential confounding factors, allowing for the data to compare telephone and in-person communication based on key patient outcomes. Quantitative data could also be collected on a large scale, which would allow for generalisability of the findings; an important factor in the potential application of the research to future policy changes. A qualitative approach was used for expanding and contextualising the results of the quantitative study, by exploring the experiences and preferences of women involved in breast screening (189). This approach gave a richer and deeper insight into the factors involved in forming a communication preference.

Overall, this research strategy formed a mixed methods approach, using the qualitative data to expand our understanding of the quantitative findings. Expansion provided richness and detail, explaining why and how women form communication preferences and moving understanding of preferences beyond what quantitative data or qualitative data in isolation can elucidate (247-249). The end product of the mixed methods used in this thesis was to integrate the data so that it forms an understanding greater than the sum of its parts (250). Quantitative data alone would only tell us how many women prefer telephone results. Similarly, qualitative data alone would only tell us the reasons for communication preferences. Integrating the knowledge of both what women prefer and why is valuable because it adds completeness of our understanding of preferences. This will inform NHSBSP policy decisions, making them comprehensive and patient-centred.
7. Contribution to knowledge

The aim of the thesis was to contribute to knowledge through six outputs:

1) Phase 1 presents a systematic review of the current evidence surrounding the impact of communication method on patient outcomes in cancer screening. This is an area of research which has received very little focus, yet could be widely applicable in different screening contexts to reduce negative psychological consequences for attendees.

2) Phase 2 provides new insight into the current results communication practices of screening centres in the NHSBSP filling the gaps in our knowledge.

3) Phase 3 presents the first study focusing solely on the impact of communication method on patient outcomes when delivering results in breast screening. The study in this phase recruited women currently undergoing breast assessment, thus removing the potential biases associated with using a general sample. This study also recruited 4 breast screening centres in England, in order to make the results more generalizable than one centre studies.

4) Phase 3 also measures anxiety prospectively throughout the screening process, adding to our knowledge about how anxiety manifests during and after screening. This resolves the issues faced by previous studies when measuring anxiety retrospectively and using generic instead of disease specific measures.

5) This thesis is one of the first mixed methods designs in this area, using qualitative methods in Phase 4 to expand upon quantitative communication preferences giving a unique and deep insight into women’s experiences. The use of the multimethod approach of the thesis allows for complex phenomena (anxiety, understanding and preferences) to be understood and related back to the individual experience.
6) The most significant contribution that this thesis makes to knowledge is informing NHS Breast Screening Programme policy. The thesis was designed to inform future evidence-based change in practice, which is inclusive of empirical evidence alongside women’s views and personal experiences.
8. Research governance and funding statement

This PhD studentship was funded by the Economic & Social Research Council via the Warwick Doctoral Training Centre. Additional funding was provided by the NHSBSP via Public Health England. This funding was used towards essential research expenses during the PhD.

The timeline for the ethical approval for this project can be seen in Appendix 2. Ethical approval was granted by the following organisations:

- University of Warwick sponsorship (SC.68/16-17)
  - Approval granted on 19th May 2017 (Appendix 3)
- Biomedical & Scientific Research Ethics Committee (BSREC) at the University of Warwick (REGO-2017-1908)
  - Approval granted 2nd June 2017 (Appendix 4)
- Public Health England Breast Screening Programme Research Advisory Committee, BSPRAC_0013 (ODR1718_040)
  - Approval granted 4th August 2017 (Appendix 5)
- Health Research Authority (HRA) NHS West Midlands - Coventry & Warwickshire Research Ethics Committee (17/WM/0313)
  - Approval granted 18th October 2017 (Appendix 6)
- Local level approach at each site
  - Centre A – approval granted 11th December 2017
  - Centre D – approval granted 25th January 2018
  - Centre B – approval granted 23rd March 2018
  - Centre C – approval granted 5th July 2018
9. Chapter summary

In this chapter, I have provided a rationale for the thesis based upon false-positive anxiety in breast screening, the lack of evidence regarding the impact of communication methods in this setting, the current discordance between policy and practice and the methodological issues in previous research. I have outlined the theoretical models and philosophical assumptions for this thesis, explaining critical realism. I have described how the research developed from a real-world problem into a research question and objectives in collaboration with NHSBSP stakeholders and PPI. I have provided an overview of the research and described each phase in further detail, justifying the approach. I have summarised the contribution to knowledge provided by the output of the thesis and have given details of the ethical approval granted for the project. In the next chapter, I will describe and present the findings from Phase 1 of the thesis: the systematic review.
CHAPTER 3 - Communication of cancer screening results by letter, telephone or in person: A mixed methods systematic review of the effect on attendee anxiety, understanding and preferences
1. Chapter introduction

In this chapter, I present the findings from Phase 1 of thesis; a systematic review. This chapter has been published in Preventive Medicine Reports (251), see Appendix 25. Therefore, the content presented here is the same as the wording in the published paper. However, some additions have been made to expand upon the ideas presented, for the purpose of the thesis.

This chapter is presented in the standard format for a published article: abstract, introduction, systematic review methods, results (including a synthesis of quantitative and qualitative findings) and discussion of the findings. I also acknowledge the strengths and limitations of the research. Finally, I will draw conclusions about the review findings.
1.1 Research questions
This chapter of the thesis had two objectives, outlined in Chapter 2:

- Objective - To systematically review research exploring which communication methods are used for the delivery of results in cancer screening programmes, and how women prefer to have their results delivered
- Objective - To systematically review evidence of how the communication method used to deliver results impacts upon attendee anxiety and understanding of results

In order to comply with the requirements of the journal, these two objectives are reported in this chapter as the following aims:

- Explore which communication methods are used for the delivery of results in cancer screening programmes, and how women prefer to have their results delivered
- Systematically review evidence of how the communication method used to deliver results impacts upon attendee anxiety and understanding of results

These two aims reflect the same objectives set out in Chapter 2.
2. Abstract

Attending and receiving a result from screening can be an anxious process. Using an appropriate method to deliver screening results could improve communication and reduce negative outcomes for screening attendees. Screening programmes are increasingly communicating results by letter or telephone rather than in-person. We investigated the impact of communication methods on attendees.

We systematically reviewed the literature on the communication methods used to deliver results in cancer screening programmes for women, focusing on screening attendee anxiety, understanding of results and preferences for results communication. We included qualitative and quantitative research. We searched MEDLINE, PsycINFO, CINAHL, Cochrane Library and Embase. Results were analysed using framework synthesis. 10,558 papers were identified with seven studies meeting the inclusion criteria.

Several key ideas emerged from the synthesis including speed, accuracy of results, visual support, ability to ask questions, privacy of results location and managing expectations.

Verbal communication methods (telephone and in-person) were preferred and facilitated greater understanding than written methods, although there was considerable variability in attendee preferences. Findings for anxiety were mixed, with no clear consensus on which method of communication might minimise attendee anxiety.

The low number of identified studies and generally low quality evidence suggest we do not know the most appropriate communication methods in the delivery of cancer screening results. More research is needed to directly compare methods of results communication, focusing on what impact each method may have on screening attendees.
3. Introduction

In 2018, 9.6 million people are estimated to die from cancer worldwide (252). Cancer screening programmes aim to aid the early detection of cancer at the population level, with millions of people attending various screening services internationally. Examples of cancer screening programmes in the UK are breast, cervical and bowel screening. A screening programme should be ethically designed to provide a benefit whilst minimising potential physical and psychological harm. However, attending cancer screening can cause significant anxiety for attendees (41, 253, 254). This increase in anxiety is not only distressing for attendees but may also have a negative impact on future attendance at screening (15).

Effective communication of the screening result may minimise the potential anxiety associated with attending, impacting on patient perceptions, expectations and future behaviour (255). Test results need to be delivered quickly, clearly and accurately, in order to minimise anxiety for patients and, where a disease has been diagnosed, refer them on to the appropriate care pathway (10, 42, 116, 117).

Across different healthcare contexts, a variety of communication methods are used to deliver results, including face-to-face consultations, telephone, letters and email (99, 114, 117-122). Media theorist Marshall McLuhan coined the phrase ‘the medium is the message’ (123). The medium used to deliver a message cannot be separated from the message itself, with the medium influencing the perception of the message and the psychological consequences of this. In the health care context, this highlights the importance of understanding the communication methods (or mediums) used and the psychological impact on patients (124-126). The method of communication used to deliver test results is a potentially modifiable factor that may have a great impact on improving patient outcomes (86). It is easier to modify one element of a healthcare system or programme, than to modify the behaviour or anxiety of every individual attendee (58).
Beyond anxiety, the method of communication used to deliver results may also have an impact on factors such as screening attendees' knowledge and understanding of their result (167, 256). For example, telephone and face-to-face communication allow the attendee to clarify and ask questions which may increase understanding in comparison to receiving written results (134). However, communicating results over the telephone limits non-verbal cues, which have been previously associated with understanding (128). Attendee preferences may also contribute to the acceptability of different methods of communication (151).

The aim of this systematic review is to:

- Explore which communication methods are used for the delivery of results in cancer screening programmes, and how women prefer to have their results delivered
- Systematically review evidence of how the communication method used to deliver results impacts upon attendee anxiety and understanding of results

In order to thoroughly investigate the impact of communication methods, this review included evidence from all cancer screening programmes involving a female population (257). The focus was on females only, due to the potential gender differences in anxiety.

The review took a mixed methods approach, allowing the synthesis of quantitative anxiety and understanding measures with the qualitative experiences of screened women. The results from this review will inform further research, aiming to help update future policy guidelines for the communication of breast screening results in the National Health Service Breast Screening Programme (NHSBSP) in England. Due to the scope of this review, the results may also have a wider international application to the communication methods used in other screening programmes.
4. Methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Framework was used to guide the reporting of this review (258). The protocol was registered on the International Prospective Register of Systematic Reviews (PROSPERO), registration number #CRD42016042689.

4.1 Search strategy

Search terms were based on a combination of a scoping literature review, NHSBSP expert advice and assistance from a subject librarian. The initial search was developed in MEDLINE and was then adapted for PsycINFO, CINAHL (The Cumulative Index to Nursing and Allied Health Literature), Cochrane Library (Wiley) and Embase. This search was then adapted for the other databases. The four elements of the search focused on ‘general communication’, ‘communication methods’, ‘cancer screening’ and ‘outcome measure’ (see Appendix 7). These elements were combined into one search using AND between each element.

The reference lists for included studies were checked for any other relevant articles not identified by the electronic search. The original search was conducted on 10th January 2017 with an updated search conducted on 14th September 2018.

4.2 Eligibility criteria

Both qualitative and quantitative studies were included in the review.

To be included, studies needed to be set in a routine cancer screening programme defined as a population-level programme aimed at screening for cancer. Participants had to be within the eligible population for which the screening programme was targeted. This excluded all research where participants were already diagnosed.
To be included, studies also needed to explicitly report at least one communication method, be focused on the communication between a healthcare professional and screening attendee during the results delivery process and must report at least one of the outcomes of interest (anxiety, understanding, preferences). Studies focusing on any result (malignant, benign, and negative) from any stage of the screening process (screening/further diagnostic tests) were included. Only studies published in English were included. There were no date or methods restrictions. Only peer reviewed journal articles were included, excluding all books, conference abstracts, short notes, commentaries etc. For full eligibility criteria, see Appendix 8.

The abstracts of included papers were independently reviewed against the inclusion criteria by three reviewers (SW, RC & JP). Any papers for which consensus could not be met were taken forward for full text review. The resulting full texts were independently reviewed by two of the same authors (SW & JP) against the inclusion criteria. Any disagreements about eligibility of articles were discussed between the two reviewers, with assistance from a third reviewer (STP) where an agreement could not be reached.

4.3 Data extraction

The data were extracted by two independent reviewers (SW & JP) following the same process used during eligibility criteria assessment. The communication methods used to deliver results and the key outcomes of interest (anxiety, understanding and preferences) were extracted.

Data were extracted using predefined extraction forms – one for qualitative papers and one for quantitative papers.

Data items that were extracted for both qualitative and quantitative papers included: screening programme, country, study aims, study design, sample characteristics, recruitment, response rates, communication methods and strengths/limitations.
Data items that were extracted for quantitative papers only included: outcome measures and results, eligibility criteria, confounding factors and adjusted/unadjusted odds ratios (if applicable).

Data items that were extracted for qualitative papers only included: data analysis approach.

4.4 Data synthesis

To bring together qualitative and quantitative findings, a combination of reciprocal translation and a framework synthesis approach was used. Reciprocal translation involves comparing the findings of different studies, to develop a consistent understanding (259-261). The translation of one study into another allows comparisons to be made between different pieces of research, whilst maintaining the integrity of each original study (262, 263).

Framework synthesis is a meta-matrix based approach to synthesising data, structuring the process of reciprocal translation by setting a priori outcomes of interest (264-267). A meta-matrix is a way to visually represent and compare data from framework synthesis (259, 268). In this review, the aim was to synthesise findings, stratified by the methods of communication used, versus the a priori outcomes of interest: anxiety, understanding and preferences.

Overall, this approach to synthesis offers a higher order understanding of review findings (264).

For the purpose of this review, a six-step process (see below) was followed to guide synthesis. These steps were created by the authors, drawing from elements of previous qualitative and mixed-methods research (234, 235, 244, 250, 259, 260, 262-265, 267-275).

1) Narrative synthesis of qualitative data: The extracted data from qualitative papers was summarised individually in a narrative synthesis, through a process of re-reading and immersion in the data.
The summaries were focused on answering the systematic review question, using the *a priori* outcomes as a guide for synthesis (anxiety, understanding, preferences).

2) **Narrative synthesis of quantitative data**: The extracted data from quantitative papers was summarised individually in a narrative synthesis, through a process of re-reading and immersion in the data. This involved transforming the quantitative data into textual data. The summaries were focused on answering the systematic review question, using the *a priori* outcomes as a guide (anxiety, understanding, preferences).

3) **Combining qualitative and quantitative summaries into meta-matrix**: The narrative syntheses from the quantitative and qualitative papers were combined into the pre-defined meta-matrix, using the framework synthesis approach. The meta-matrix was originally defined with three columns, with each column representing a different communication method (telephone, in-person, written).

4) **Reworking and redefining the meta-matrix** – Variations between *a priori*, defined categories and resulting categories were addressed.

5) **Discussion of findings within the research team** – The synthesis findings were compared with particular focus on the meta-matrix findings and analytical memos of the two reviewers.

6) **Summarising findings** – The final synthesis was presented in a final 3x4 meta-matrix (see Appendix 10).

### 4.5 Quality assessment

Quality assessment was undertaken by the same two reviewers (SW & JP). The quality of the included quantitative studies was assessed using the Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews – Checklist for Analytical Cross Sectional Studies (276). These eight questions assess outcomes used, validity, reliability and potential bias.

The quality of the included qualitative studies was assessed using the Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews.
Reviews – Checklist for Qualitative Research (272). These ten questions assess congruence between philosophical perspective, research methodology, research objectives, representation and analysis of data and interpretation of results. This tool also assesses potential researcher bias within the studies.

No study was excluded on the basis of quality (see Appendix 11).
5. Results

5.1 Included studies
The database search identified 16,237 citations. Following de-duplication, 10,558 papers remained. Of these, 10,544 were excluded at the title and abstract stage based on the inclusion criteria, leaving 14 citations to be taken to full-text review. The majority of papers that were excluded (8,480) did not include routine screening. Examples of papers excluded were papers focusing on different screening programmes and papers with a ‘generic’ sample population rather than a targeted screening population. A total of 7 studies met the eligibility criteria for the review (112, 122, 132, 166, 167, 239, 277). See Figure 12 for a flow chart of study selection as adapted from PRISMA guidelines (258).

Figure 12. Flow chart of paper selection
The characteristics for included studies can be seen in Appendix 9. The included studies were a mixture of quantitative (n=4) and qualitative research (n=3), from either a breast screening programme (n=4) or a cervical cancer screening programme (n=3). Most of the studies were in the USA (n=4), with other studies in Australia (n=2) and England (n=1).

5.2 Quality assessment
The area of highest quality across the four quantitative studies was the clear definition of participant inclusion criteria (112, 122, 166, 167). The area of lowest quality across the four quantitative studies was addressing the validity and reliability of the outcome measures (112, 122, 166, 167).

The areas of highest quality across the three qualitative studies were congruity between the research methodology and research question, methods, representation, analysis and interpretation of results (132, 239, 277). Other areas of high quality included the adequate representation of participant’s voices and the conclusions flowing from the research report (132, 239, 277). The area of lowest quality across the three qualitative studies was a lack of acknowledgement of the influence of researcher on the research, which may cause bias (132, 239, 277). The papers were also rated as low quality for the lack of a statement locating the researcher culturally or theoretically within the research (132, 277). It was unclear across the three included papers whether there was congruity between the authors stated philosophical perspective and the research methodology used (132, 239, 277).

5.3 Synthesis findings
The synthesis findings, combining the narrative synthesis from the qualitative and quantitative papers were presented in a meta-matrix (see Appendix 10). The matrix displays communication method by outcomes of interest, bringing together these insights in the final column.
This matrix was pre-defined and reworked as part of the synthesis process, with the final version presented in Appendix 10. In synthesising the study findings, an extra column was added to the communication methods ('verbal methods'). Variations on the meta-matrix included exploring differences between screening programmes and separating findings into positive and negative attendee outcomes. These explorations did not reveal any differences. The findings from each column (telephone, in-person, verbal and written) were then categorised into three rows relating to the *a priori* outcomes (anxiety, understanding and preferences).

The findings from the meta-matrix will now be discussed in more detail.

### 5.3.1 Anxiety

Two quantitative (112, 166) and three qualitative papers (132, 239, 277) provided data on anxiety. In the synthesis, four key ideas emerged: privacy, the link between understanding and anxiety, the anxious wait and managing expectations.

Overall, the review findings were mixed for the outcome of anxiety. Some evidence suggested that written results do not significantly increase anxiety (166) with others showing attendee distress at receiving a results letter (239, 277). Differences in anxiety between in-person and telephone results consultations were not discussed in the literature.

#### Anxiety and privacy

In some cases, written communication was associated with an increase in attendee anxiety, with one reason for this including a lack of privacy in the location in which the results were received (277).

> “*I just remember my mom freaking out. Her instant thought was cancer… I read the letter and it didn’t say she had cancer… it’s just when you get that cold, sterile letter… she automatically thought cancer.*” (239)
This is important to consider when thinking about telephone results too as, like written results, it is not always possible to control the setting in which results are received.

**Anxiety and understanding**

Another reason for increased anxiety associated with written results was the confusion caused by the language used in the letter (239). This suggests that the outcomes of anxiety and understanding might be related. This provides further support for considering the impact of communication methods because, if more effective communication is linked with increased understanding, this might be linked to lower anxiety.

**Anxiety and waiting: the ‘anxious wait’**

Reducing the ‘anxious wait’ was important to attendees. Women who received their screening results over the telephone were grateful that they didn’t have to wait anxiously for their results (277). However, no direct comparison was made between in-person and telephone anxiety. Therefore, it is not known whether a quicker result or a more personal face-to-face interaction would be more reassuring.

**Anxiety and managing expectations**

If women were expecting a telephone call, but were instead invited to attend an unexpected appointment in-person, this led to increased levels of anxiety (277). This suggests that, not only is the method of communication important, but also preparing the woman for how her results will be delivered, and managing these expectations appropriately.
5.3.2 Understanding

One quantitative (167) and three qualitative papers (132, 239, 277) provided data on understanding. In the synthesis, four ideas emerged: the differences between receiving only a letter vs. receiving an accompanying letter further explaining verbal results, visual support, the value of asking questions and valuing accuracy.

Overall, verbal methods of communicating results facilitate better understanding in screening attendees than communicating results by letter. However there was no research comparing different verbal communication methods, in order to establish any similarities or differences in attendee understanding.

Understanding: The differences between receiving only a letter vs. an accompanying letter, further explaining verbal results

Some women did not understand their results when they were provided in writing alone due to the content and language of the letter (277). This may be related to factors such as the education level of the screening attendee or even factors such as ethnicity (239). There will be other factors outside of communication method that will impact upon understanding. It may be that verbal results are the most appropriate method of delivery, but understanding is enhanced when used in combination with written communication.

Understanding and visual support

During face-to-face appointments, health care professionals can also use diagrams to further aid understanding (132). This would be missed in telephone consultations. However, we do not know how frequently diagrams are used in delivering screening results – this may be due to variability of ‘who’ delivers the result (e.g. physician, nurse, receptionist etc.).
Understanding and the value of asking questions

The review findings suggest that verbal methods of communication facilitate better attendee understanding than written notification methods (132, 167, 239, 277). This may be due to the two-way communication dynamic of verbal methods, allowing the opportunity for women to ask questions about their results (134).

“You have the opportunity to ask questions because you can't ask questions when you get a letter.” (239)

However, there was no clear comparison between telephone and in-person results, with the opportunity to ask questions present in both methods of communication.

Understanding and valuing accuracy

Women raised the issue of receiving incorrect information by telephone (239). This shows that women value results that are accurate, which is something to consider in results implementation services. However, incorrect results could also occur in-person. Therefore, this may not be directly linked to the method of communication used, but instead linked to an overall flaw in the communication process of the screening programme investigated.
5.3.3 Preferences

Four quantitative (112, 122, 166, 167) and three qualitative papers (132, 239, 277) investigated preferences. In the synthesis, the main idea that emerged was that preferences are individualised and tend to vary depending on if the result is normal or abnormal (112). Another idea that emerged was speed.

Overall, it appears that the general preference is for verbal communication, with written results linked with higher levels of dissatisfaction (166, 239). However, some women with normal results may be accepting of written communication and some women with abnormal results express a preference for in-person communication (112). This may be indicative of the personal and individualised nature of preferences.

“A phone call is best” (239)

“…There’s nothing like talking to someone face to face” (239)

“I think they [telephone results] work really well”. (277)

However, there was no evidence to directly compare the differences between telephone and in-person methods of results communication. Furthermore, reasons behind these communication preferences were not explored.

Preferences and speed

Women with ‘normal’ results tend to prefer quicker methods of communication, such as a letter or telephone call (112). However, written results are associated with a higher level of dissatisfaction than verbal results (166, 239).

Despite most women with ‘normal’ results preferring quicker methods of communication, some women prefer verbal notification even when their result is normal, even if this means a slower or delayed result. A reason for this might be the importance the individual woman places on screening. If screening is perceived as more important, communication preferences might

116
be more satisfactory when they are more personal. (239). This could lead to some women feeling unsatisfied with written communication, despite preferring results methods that might be quicker. This suggests there is a balance between speed and satisfaction.
6. Discussion

The aim of the review was to evaluate and synthesise literature regarding the impact of the communication method used to deliver results on attendee anxiety, understanding of results and preferences for communication in cancer screening programmes. Overall, this review has identified a lack of evidence investigating communication methods used to deliver results and the impact on patient outcomes. This review has also identified a lack of distinction between results delivered in-person and results delivered over the telephone, with studies tending to group these together as ‘verbal communication’. This masks the ability to distinguish the potential differences between telephone and in-person results.

Several key ideas emerged from the synthesis which may help to guide the direction of future research. These included speed, accuracy of results, visual support, ability to ask questions, privacy of results location and managing expectations.

The limited evidence from this review suggests that verbal methods of communicating results may have the most positive impact on people receiving results from cancer screening programmes. Verbal results (telephone or in-person) are associated with higher levels of understanding and tend to be preferred by attendees, although this may vary based upon whether the result was normal or abnormal. Very little is understood about the impact of communication method on anxiety. Although some evidence relating to written communication was found, the evidence is mixed, with no clear picture about which method of communication might minimise the anxiety experienced whilst receiving a screening result.

The majority of screening attendees state a preference for verbal methods of communication (e.g. in-person or over the telephone). In the review update, a commentary paper that did not meet the review criteria found a preference (71.2%) for telephone communication when delivering benign biopsy results in breast screening (278). However, attendee reasons for this preference were not explored.
The review also revealed additional general findings suggesting that screening attendees express a preference for timely and consistent results (132, 166). Quicker and more consistent results communication is associated with lower anxiety (166). However, more exploration is needed to explain the differences in individual preferences for results communication.

Other advantages and disadvantages of different communication methods did not emerge from the review data. Other research suggests that the cost-effectiveness and time efficiency of telephone results should be evaluated (128). Other research also highlights the role of social support in receiving a result, which might only be possible when results are delivered in-person (165). Consideration should also be given to who delivers results, as well as the method used. These factors did not emerge in the review, which may be due to limited evidence. Wider factors associated with communication may be important to consider in future research.

6.1 Strengths and limitations

A strength of this review is the method used to synthesise findings from both qualitative and quantitative papers. The method combined the rigour of a traditional systematic review with the flexibility of the framework synthesis approach, which has been applied in other research aiming to update policy guidelines (264, 266, 267). Having a second reviewer to check through the search strategy and pre-validated quality assessment tools minimised the potential for bias in the review findings (210, 212). Another strength of the review was the use of broad and inclusive search terms.

Only a small number of studies (n=7) were identified in this review. Furthermore, the quality of the evidence available was generally low as rated by the JBI quality assessment tools. This makes it difficult to draw any firm conclusions about the impact of communication method on attendee factors in cancer screening. Furthermore, the differences in anxiety between in-person and telephone results consultations did not appear in the literature. This is a major gap. Therefore, it is recommended that research is needed,
directly comparing telephone and in-person results for any differences in screening attendee outcomes.

This review only focused on a female population of screening attendees, due to the potential gender differences in anxiety. Future research should consider evidence from other screening programmes including other populations.
7. Conclusions

Overall, there is limited evidence regarding the impact of communication method on attendees at cancer screening. From the limited evidence, the review findings suggest that verbal methods of communication (telephone and in-person) are most favourable for facilitating understanding, in comparison to written methods of communication. However, there was not enough evidence to infer which method of communication may minimise anxiety for screening attendees. The majority of cancer screening attendees prefer verbal methods of communication. However, the reasons for this preference remain unexplored. Furthermore, there was not enough evidence to show the difference between communicating results in-person or over the telephone.

Further research is required to understand the impact of the delivery of results on screening attendees via different communication methods. This may become particularly salient as methods for communicating results become more technologically advanced, for example, the use of video consultations or interactive patient reports (279-281). Therefore, it is essential that researchers from psychology, communication and healthcare backgrounds come together using a multidisciplinary approach to ensure that we fully understand the impact of results communication on screening attendees.
8. Chapter summary

In this chapter, I have presented the methods and findings of the systematic review from Phase 1 of the thesis. This was presented as a research journal article that has been published. In the next chapter, I will present the methods and findings from Phase 2 of the thesis, which is a national survey of current communication practices in the NHSBSP.
CHAPTER 4: Current practice in English breast screening centres and staff perspectives of telephoning results
1. Chapter introduction

In this chapter, I present the findings from Phase 2 of the thesis; a survey of current communication practice in English breast screening centres. This chapter has been published in the BMJ Open (282), see Appendix 26. Therefore, the content presented here is the same as the wording in the published paper. However, some additions have been made to expand upon the ideas presented, for the purpose of the thesis.

This chapter is presented in the standard format for a published article: abstract, background, research methods, quantitative and qualitative results and discussion of the findings. I also acknowledge the strengths and limitations of the research. I will finish by drawing conclusions and referring to the research and practice implications.

1.1 Research question and objectives

This chapter of the thesis had two objectives, outlined in Chapter 2:

- Objective - To survey breast screening centres to record how often telephone results are delivered and who delivers these results, for benign and cancer screening results.
- Objective - To compare the time taken to deliver a result by telephone versus. results delivered in-person

In order to comply with the requirements of the journal, these two objectives are reported in this chapter as the following questions:

1) How often are telephone results delivered and by whom? Does this differ when results are non-cancer versus cancer?
2) Is there a time difference between results delivered by telephone versus results delivered in-person?

These two questions reflect the same objectives set out in Chapter 2.
2. Abstract

Objective

To record how breast screening centres in England deliver all biopsy results (cancer/non-cancer) from the breast assessment visit.

Design

Online survey of 63 of 79 breast screening centres in England from all regions (East Midlands, East of England, London, North East Yorkshire & Humber, North West, South East, South West, West Midlands). The survey contained quantitative measures of frequency for telephoning biopsy results (routinely, occasionally or never) and optional qualitative free-text responses. Surveys were completed by a staff member from each centre.

Results

There were no regional trends in the use of telephone results services, \( (X^2 (14, N = 63) = 11.55, p = .64) \), Centres who telephoned results routinely did not deliver results sooner than centres who deliver results in-person \( (X^2 (16, N = 63) = 12.76, p = .69) \).

When delivering cancer results, 76.2% of centres never telephone results and 23.8% of centres occasionally telephone results. No centres reported delivering cancer results routinely by telephone. Qualitative content analysis suggest that cancer results are only telephoned at patient request and under exceptional circumstances.

When delivering non-cancer results, 12.7% of centres never telephoned results, 38.1% occasionally telephoned results and 49.2% routinely telephoned results. Qualitative content analysis revealed different processes for delivering telephone results, including patient choice and scheduling an in-person results appointment for all women attending breast assessment, then ringing non-cancer results unexpectedly ahead of this pre-booked appointment.
Conclusions

In the National Health Service Breast Screening Programme, breast assessment results that are cancer are routinely delivered in-person. However, non-cancer breast assessment results are often routinely delivered by telephone, despite breast screening policy recommendations.

More research is needed to understand the impact of telephoning results on women attending breast assessment, particularly women who receive a non-cancer result. Future research should also consider how women themselves might prefer to receive their results.

Strengths and limitations

- This study gives an up-to-date picture of current results-giving practice of National Health Service Breast Screening Programme centres nationally.
- A high response rate was achieved, so results are generalizable to the English National Health Service Breast Screening Programme.
- The qualitative comments made by National Health Service staff gave deeper insight into how telephone results are delivered in practice.
- Survey responses were subjective and not checked against centre policy documents.
- Formal analysis of the concordance between communication practice and policy guidelines was not conducted.
3. Background

Breast cancer is one of the most common cancers internationally (283). The National Health Service Breast Screening Programme (NHSBSP) was launched to aid the early detection of breast cancer at the population level, because early detection is linked with better prognosis (54). At screening, a mammogram (x-ray) is performed on each breast (14). If an abnormality is found during this screening mammogram, women will be recalled to attend assessment for further tests. These tests can include a core needle biopsy, which involves the removal of sections of tissue from the suspicious breast region which are sent for cytological examination. A biopsy is the definitive test at breast assessment to confirm if the mammogram abnormalities found are cancer. In 2016-17, 2,199,342 women in England were screened by the NHSBSP. 89,104 of these women were referred for assessment and 40,255 women had a core biopsy (39).

In recent years, the NHSBSP has been considering which communication method might be preferable for delivering non-cancer biopsy results from breast assessment. The NHSBSP service specification recommends that all breast assessment results should be delivered in-person, which includes cancer and non-cancer results (284). Furthermore, the guidelines state that telephone results should only be used at the patients request and should not be standard practice (285). Despite these recommendations, some centres already routinely deliver non-cancer assessment results by telephone (28, 284). There is ongoing concern about the impact of delivering a non-cancer assessment result by telephone. One of the main concerns is how anxious women feel when receiving a result, even when the result is non-cancer (286). Another concern is the potential for miscommunication by telephone.

In other areas of healthcare, a variety of communication methods are used to deliver results, including in-person consultations, telephone, letters and email. Each method of communication used in results delivery presents different advantages, disadvantages and challenges in implementation. Results delivered in-person are often seen as the ‘gold standard’ (119). However, as technology advances, fewer healthcare results are now
delivered in-person. Liederman et al. (127) stated that ‘face-to-face contact is not necessary for effective communication’ (pg. 52). Most commonly, results delivery is moving towards telephone and telemedicine (287). Despite this, Cochrane review evidence suggests that we still do not know enough about the impact of telephone results services on healthcare outcomes (133).

There is no current record of how breast centres in England deliver biopsy results from breast assessment. Despite policy recommendations, some centres appear to routinely deliver non-cancer results by telephone. Furthermore, it is assumed that cancer results are all delivered in-person as guidelines recommend. There is a currently lack of evidence about how often telephone results are used to deliver breast assessment results (251).

In this study, we aimed to record how breast screening centres in England deliver biopsy results from breast assessment and answer the following questions:

1) How often are telephone results delivered and by whom? Does this differ when results are non-cancer versus cancer?
2) Is there a time difference between results delivered by telephone versus results delivered in-person?
4. Methods

4.1 Participants
A link to an online survey hosted by the Bristol Online Survey platform was sent to all breast screening centres in England on 2\textsuperscript{nd} June 2017. At this time, 79 breast screening units existed in England and were invited to participate. This differs from the number of centres (n=81) in a previously unpublished study (by co-author Margaret Casey), due to changes in the total number of breast screening centres over time. Reasons for this change in total number of centres were not explored and the correct number of current centres was verified using an official list from the Quality Assurance Lead for Breast Screening. Data collection ended on 28\textsuperscript{th} February 2018.

The survey link was distributed to the manager of each breast screening centre via the Quality Assurance lead for each region (East Midlands, East of England, London, North East Yorkshire & Humber, North West, South East, South West, West Midlands). The link was accompanied by a brief study description. The survey was completed by a representative member of staff from each breast screening centre.

Survey completion reminders were sent periodically by the Quality Assurance leads to nonresponding centres.

Ethical approval for the survey was obtained from the Biomedical & Scientific Research Ethics Committee at the University of Warwick (REGO-2017-1908).

4.2 Survey piloting and instrument
The survey was designed using a previous tool developed by Clinical Nurse Specialist in Breast Care (Margaret Casey) in combination with discussions with key stakeholders from the NHSBSP. Stakeholders included the programme manager for the NHSBSP, the Quality Assurance Lead for the NHSBSP, and a clinical nurse specialist in breast care. Following this, a draft version underwent three rounds of piloting: stakeholder review of content,
stakeholder piloting of the online layout and cognitive interviewing with a layperson.

The main questions in the survey focused on recording how often biopsy results were telephoned. The first question asked the frequency of delivering benign (non-cancer) biopsy results by telephone (never/occasionally/routinely). The second question asked the frequency of delivering cancer biopsy results by telephone (never/occasionally/routinely). After these two questions, a free text box was added to allow responders to comment on the answers provided. The survey also recorded who is responsible within the team for delivering telephone results at the centre (Clinical Nurse Specialist, Radiologist, Radiographer, Breast Care Surgeon, Administrative Staff, Other).

One question recorded the amount of time taken between clinic assessment and the delivery of a result (options spanning between 1 day and more than 12 days). These data were collected to compare the length of time taken to deliver results for centres who delivered results by telephone routinely versus those who never deliver telephone results.

The survey included 9 questions. It was expected that the survey would take 10 minutes to complete (see Appendix 12 for full survey).

4.3 Data analysis

Quantitative

Data cleaning processes were implemented. This involved checking for missing data, coding centres by region and removing duplicate responses. Descriptive statistics and response rates were calculated.

Percentages for delivering non-cancer results and cancer results by telephone were calculated separately, alongside frequencies for who delivers each type of results.
To identify whether there were any regional trends in the delivery of telephone results, a chi-square was calculated, comparing region (East Midlands, East of England, London, North East Yorkshire & Humber, North West, South East, South West, West Midlands) with telephone frequency (routinely, occasionally, never).

To identify any potential time differences between telephone and in-person results a chi-square was calculated, comparing telephone frequency (routinely, occasionally, never) to length of time between assessment and results (1 day – 12+ days).

Statistical significance was assumed at p<.05. Statistical analysis was conducted using IBM SPSS Statistics 24 software.

**Qualitative**

Qualitative free text comments were analysed using qualitative content analysis (288, 289). This approach allowed for commonalities amongst staff viewpoints to be identified and to be described narratively, in order to contextualise and expand upon the quantitative findings. Inter-coder reliability was used to ensure the rigour and trustworthiness of the analysis (288, 290). The analysis was conducted by the lead author (SW) and checked by a second author (DE) to ensure that the meaning of original staff comments was retained. Any disputes in interpretation were resolved by a third author (HS). Qualitative analysis was conducted using NVivo 12.
5. Results

5.1 Respondents

Of the 79 breast screening centres in England, 63 (79%) responded to the online survey. All regions were represented in the quantitative survey (see Table 5). However, some regions were less responsive e.g. 50% of South East centres did not respond. No London centres provided qualitative responses to the survey.

Data relating to the mean age of women screened at each centre were removed from the data set due to 61.4% of responses being ‘I don’t know’.
Table 5: Number of centres who responded to the online survey and provided optional qualitative comments

<table>
<thead>
<tr>
<th>Centres in each region (n=79)</th>
<th>Centres who responded to the survey (n=63)</th>
<th>Centres who commented on telephoning non-cancer results (n=28)</th>
<th>Centres who commented on telephoning cancer results (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>East Midlands (n=9)</td>
<td>7</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>East of England (n=11)</td>
<td>10</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>London (n=6)</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>North East Yorkshire &amp; Humber (n=12)</td>
<td>10</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>North West (n=11)</td>
<td>8</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>South East (n=8)</td>
<td>4</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>South West (n=13)</td>
<td>11</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>West Midlands (n=9)</td>
<td>9</td>
<td>6</td>
<td>3</td>
</tr>
</tbody>
</table>

1 The total number of centres within each region of England.
2 The number of centres who completed the survey from each region, providing quantitative data.
3 The number of centres who provided comments in the 1st qualitative free-text box, asking about telephoning non-cancer results. This was not a mandatory question and not all centres who completed the survey provided qualitative data.
4 The number of centres who provided comments in the 2nd qualitative free-text box, asking about telephoning cancer results. This was not a mandatory question and not all centres who completed the survey provided qualitative data.
5.2 Quantitative findings

5.2.1 Frequency of results by telephone

When delivering non-cancer results, the majority of centres routinely telephoned results (see Table 6) and most of these results were delivered by Clinical Nurse Specialists (see Table 7).

When delivering cancer results, the majority of centres never telephoned results (see Table 6). When cancer results were delivered by telephone, most of these results were delivered by Clinical Nurse Specialists (see Table 7).

Table 6: Frequency and percentage of centres who routinely, occasionally or never deliver results by telephone for non-cancer and cancer results (n=63)

<table>
<thead>
<tr>
<th></th>
<th>Routinely</th>
<th>Occasionally</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-cancer</td>
<td>31 (49.2%)</td>
<td>24 (38.1%)</td>
<td>8 (12.7%)</td>
</tr>
<tr>
<td>Cancer</td>
<td>0 (0%)</td>
<td>15 (23.8%)</td>
<td>48 (76.2%)</td>
</tr>
</tbody>
</table>
Table 7: Frequency of who delivers results by telephone, for non-cancer and cancer results (n=63)

<table>
<thead>
<tr>
<th></th>
<th>Clinical Nurse Specialist</th>
<th>Radiologist</th>
<th>Radiographer</th>
<th>Breast Surgeon</th>
<th>Administrative staff</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-cancer</td>
<td>42</td>
<td>17</td>
<td>5</td>
<td>5</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Cancer</td>
<td>13</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

N.B. Centres could select multiple responses to this question.

5.2.2 Regional differences – frequency of telephone results
No relationship was found between region and the frequency of non-cancer telephone results, \((X^2 (14, N = 63) = 11.55, p = .64)\). This indicates no regional trends in the use of telephone results services.

5.2.3 Time difference – telephone results vs. in-person results
The mean time to deliver results for all centres was 7.03 days (SD = 2.03). See Table 8 for all means (SDs). No relationship was found between frequency of telephone results and length of time from assessment to receipt of results, \((X^2 (16, N = 63) = 12.76, p = .69)\). This indicates that centres delivering results by telephone do not deliver them sooner after the assessment visit than centres delivering results in-person (or never telephone).
Table 8: Mean (SDs) number of days between assessment and delivery of results for centres who routinely, occasionally and never benign (non-cancer) telephone results

<table>
<thead>
<tr>
<th>Mean (SDs) number of days between assessment and delivery of results</th>
<th>Routinely telephone</th>
<th>Occasionally telephone</th>
<th>Never telephone</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.77 (1.76)</td>
<td>7.13 (2.09)</td>
<td>7.75 (2.81)</td>
<td></td>
</tr>
</tbody>
</table>
5.3 Qualitative findings

In the survey, NHS staff had the option to comment in free-text boxes after two questions. The results are presented in two sections, with one focusing on first question (non-cancer) and one focusing on the second question (cancer). All regions (excluding London) provided qualitative free-text responses (see Table 5).

When delivering benign (non-cancer) biopsy results are women never telephoned with results, occasionally telephoned with results or routinely telephoned with results?

This section presents the qualitative findings following the first survey question (n=28), which asked the frequency of delivering non-cancer biopsy results by telephone (never/occasionally/routinely).

Content analysis revealed that 7 centres scheduled for all women to return to receive results in-person. Then, if the test results for these women are confirmed as non-cancer, centres attempt to ring women with telephone results ahead of the pre-scheduled in-person appointment. Example comments include:

“Women have a scheduled face to face appointment for results but if it’s benign we ring them.” (Centre ID 02)

“Our aim is to call all the benign results and offer to cancel the booked appointment.” (Centre ID 50)

“All women are given a results appointment during assessment clinic. Following MDT, all those with benign biopsy results are contacted by telephone. If contact is made, the result is discussed and the results appointment cancelled.” (Centre ID 38)

1 centre (Centre ID 25) commented that they “normally see women face to face”, with this being their routine practice. This suggests that breast
screening centres differ in how they deliver non-cancer breast assessment results.

**Option to still attend**

Content analysis revealed 5 centres who commented that, when women are contacted by telephone with a non-cancer result, they are still offered the option to attend in-person if they have further questions. Example comments include:

“All patients are given an appointment to attend for results we do telephone with results but patients are still able to attend, and some do.” (Centre ID 45)

“After the MDT. Patients are telephoned with benign results by a qualified Breast Care Nurse. They are then offered an OPA with a consultant surgeon if they have concerns.” (Centre ID 31)

**Rare and exceptional circumstances**

Content analysis revealed 5 centres only deliver non-cancer results by telephone in exceptional circumstances. Example comments include:

“Only in exceptional circumstances” (Centre ID 59)

“This is not done routinely and very rarely occurs.” (Centre ID 78)

Reasons given for giving non-cancer results by telephone included if the woman finds it difficult to attend in-person and so the woman can be where she wants to be to receive results.
Giving women a choice or at patient request

Content analysis revealed 5 centres ask women how they would like their result to be delivered if it is not cancer. Example comments include:

“We will always offer them an appointment to come in, but the BCNs will ask if they want a telephone call at the time of assessment” (Centre ID 63)

“Women are asked at assessment if they would like a telephone call or they can come back for results if they do not wished to be telephoned” (Centre ID 29)

“Women are given a choice about how they receive their results when the imaging suggests a benign process” (Centre ID 42)

One centre commented that non-cancer results are only delivered by telephone at the request of the patient:

“This is not routine practice but happens if a patient requests it and the probability of a benign result is very high.” (Centre ID 73)

5.3.1 Summary of non-cancer content analysis

Content analysis revealed conflicting centre comments. Some centres schedule in-person results appointments for all women, but then attempt to contact women with non-cancer results by telephone instead. However, one centre commented that delivering non-cancer results by telephone was not routine practice. Other centres commented that telephoning non-cancer results only happens under exceptional circumstances, such as the woman being unable to attend in-person.

Content analysis revealed that some women who are telephoned with results are still offered the option to attend if they have further questions. Some centres ask women how they would prefer to be contacted with their result if it is not cancer.
When delivering cancer biopsy results are women never telephoned with results, occasionally telephoned with results or routinely telephoned with results?

This section presents the qualitative findings following the second survey question n=20), which asked the frequency of delivering cancer biopsy results by telephone (never/occasionally/routinely).

Content analysis revealed 4 centres routinely deliver cancer results in-person. Example comments include:

“Cancer diagnoses are always communicated face to face.” (Centre ID 39)

“[telephone results] This would never be planned.” (Centre ID 09)

“All positive results or complicated cases are invited back to be given results by the Breast Surgery Team.” (Centre ID 26)

Rare and exceptional circumstances

Content analysis revealed 11 centres only deliver cancer results by telephone in exceptional circumstances. Example comments include:

“Rarely telephoned with a cancer diagnosis always at the patients request in extenuating circumstances.” (Centre ID 45)

“This is a rare occurrence and is only agreed to with the patients prior consent on the understanding they may be receiving a cancer diagnosis.” (Centre ID 11).

“Very rare - this would only happen with prior agreement if a woman is to be away for an extended period of time.” (Centre ID 38)

Reasons for delivering cancer results by telephone under these exceptional circumstances were if the woman finds it difficult to attend in-person and if the woman was going to be away for an extended period of time.
Giving women a choice or at patient request

Content analysis revealed 2 centres ask women how they would like their result to be delivered if it is cancer. Example comments include:

“They are asked if the result was a surprise and was a breast cancer would you still wish to get that news over the phone.” (Centre ID 01)

“Women are asked at assessment if they would like a telephone call or they can come back for results if they do not wished to be telephoned. (Centre ID 29)”

Content analysis revealed 5 centres only deliver cancer results by telephone at the request of the patient. Example comments include:

“Patient request only” (Centre ID 33)

“Only very rarely and at patient's specific request” (Centre ID 08)

Unexpected results and a negative reaction

One centre (Centre ID 60) addressed the issue of how to deal with an unexpected result. At the breast assessment visit, this centre informs women with a high suspicion of a non-cancer result that they will have their result delivered by telephone. However, if “If there is a positive result which was unexpected a Breast Care Nurse rings the woman to advise an appointment is required to discuss the results”.

One centre (Centre ID 15) commented about a woman who “reacted extremely badly on telephone” when receiving a cancer result.
5.3.2 Summary of cancer content analysis

For cancer results, in-person results are routine. Telephoning cancer results is only being offered under rare or exceptional circumstances such as when women have difficulty in attending. These telephone results are only given at the request of the patient.

Content analysis revealed the potential difficulties in delivering and scheduling results by telephone. One comment highlighted the negative reaction of a woman who received her cancer result by telephone. Another comment addressed the issue of how to deal with a result which was presumed to be non-cancer but turned out to be cancer.
6. Discussion

The aim of this research was to record how breast screening centres in England deliver biopsy results from breast assessment, by assessing how often telephone results are delivered and by whom. This research also aimed to see if telephone results delivery differs when assessment results are non-cancer versus cancer. Furthermore, this research aimed to assess if there is a time difference between results delivered by telephone versus results delivered in-person.

Our research suggests that centres routinely delivering results by telephone do not deliver them sooner than centres who deliver results in-person. This contradicts articles citing ‘speed’ as one of the potential advantages of telephone results (62, 117, 119).

Our study found that delivering cancer results by telephone is not common practice for breast screening centres in England. Telephoning cancer results is only used in exceptional circumstances and only at the request of the patient. For example, telephone results might be used if the woman is physically unable to attend in-person (e.g. health issues or away from the country for an extended period). When cancer results are telephoned, most of the results are delivered by Clinical Nurse Specialists. The reason why cancer results are rarely telephoned is probably due to the emotional impact of receiving a cancer diagnosis (291). The extensive literature on “breaking bad news” in healthcare places importance on the location where results are received to ensure no disturbances (292). This may help to explain the one comment in the current study where a centre reported the negative reaction of a woman who received a cancer result by telephone. However, this comment was only made by one centre in the study and may not be representative of the population as a whole so this finding should be interpreted with caution.

Another comment in the study highlighted the issues of how to deal with a result which was presumed to be non-cancer at the assessment stage but turned out to be cancer. At the stage of breast assessment, it is unknown if a
woman will receive a cancer or non-cancer result. However, breast assessment tests may indicate a higher chance of a non-cancer result. These women might be informed of the lower likelihood of cancer and are offered the opportunity to receive results by telephone. If the biopsy result then confirms an unexpected cancer, women may then be telephoned with a cancer result. This may have implications for anxiety and may be avoided by not offering telephone results. However, this was an issue only highlighted by one centre in the study and does not represent the centre comments as a whole.

Our study found that delivering non-cancer results by telephone is routine practice for roughly half of the breast screening centres in England, with most of the results being delivered by Clinical Nurse Specialists. This appears to contrast with breast screening policy guidelines, which state that telephone results should only be used at the patients request and should not be routinely offered. However, the qualitative findings clarified that some of these centres offer women a choice of how they would prefer to receive their results. This suggests that some centres are still acting within the guidelines by only telephoning women who choose this communication. Offering women the choice between telephone and in-person communication may not be feasible for all centres (293). For centres who already routinely telephone results, there may be a reduced capacity to provide results in-person if this is requested by the woman. From the content analysis in the current study, a compromise is to telephone all non-cancer results routinely but to also offer the option for the woman to still attend the clinic in-person. Offering patients a choice of communication method of results at the assessment visit might also be problematic due to heightened anxiety with some women not wanting to make a decision (294, 295).

Some centres who routinely deliver non-cancer results by telephone do not offer patient choice. A common practice is for centres to give all women who attend breast assessment an in-person appointment to return for results, but then telephone women with non-cancer results ahead of this scheduled appointment. The centres commented that this process has the potential to
reduce the expected wait time for women to receive results, thus minimising the amount of time spent anxiously waiting (64). However, the psychological impact of receiving an ‘unexpected’ communication method has not been considered in this setting. When a telephone result is not expected, it is possible that women may feel unprepared or not in the right mind-set to comprehend the information given (156). This may contribute to the anxiety associated with screening and might be an avoidable harm. However, from the current research we do not know if this is the case.

6.1 Strengths
This study formally reports the national communication practice of NHSBSP centres for delivering non-cancer and cancer breast assessment results. The high response rate indicated that this is an important issue for staff working within the screening programme.

The content analysis of qualitative comments allowed for expansion of quantitative survey data, which gave greater insight into how telephone results were implemented in practice.

6.2 Limitations
The time difference between telephone results and in-person results was quantified to allow the survey to be easily answered. This was quantified by the difference in days between clinic assessment and the delivery of a result for centres who either routinely, occasionally or never telephone results. However, other factors could be involved in the speed of results delivery.

The survey responses completed by centre staff were subjective and could not be validated by records. Furthermore, the staff member completing each survey was not recorded as part of the study. Therefore, quantitative data may not accurately reflect current communication practice due to the potential for human error or level of experience of the staff member completing the survey.
It is possible that centres who did not respond to the survey may be systematically different from those centres who did. Therefore, the results from the survey may not be representative of all breast screening centres in England. For example, no London centres provided qualitative data. Centres in London may serve a more ethnically diverse population than the rest of England, and therefore, women attending these centres may have psychological, cultural and language differences which could impact their experiences of screening. This may also reflect differences in communication practice at centres in this region.

A formal analysis of the concordance between communication practice and policy guidelines was not conducted. This was considered in the discussion but future research could consider a formal comparison-based analysis.
7. Conclusion

In the NHSBSP, breast assessment results that are cancer are routinely delivered in-person, as recommended by policy guidelines. However, non-cancer breast assessment results are often routinely delivered by telephone despite the recommendations made in policy guidelines. Despite this, telephone results do not appear to be quicker than in-person results in practice.

A common process is to give all women attending breast assessment an appointment to come back to receive results in-person, to then telephone all women with non-cancer results ahead of this appointment. Some centres offer women a choice, although this might not be feasible for all centres and it is possible that women might be too anxious to make an informed decision.

7.1 Research and practice implications

Now that we have a record of current practice, more research is needed in order to fully understand what impact telephone results services have on women attending breast assessment, and whether variations in the results giving process also have an impact. This would be particularly beneficial to consider for non-cancer results, where results are being routinely delivered by telephone to large numbers of women every year. Further research should also consider how women themselves might prefer to receive their results and focus upon the patient perspective.
8. Chapter summary

In this chapter, I have presented the methods and findings of the centre survey of current communication practice from Phase 2 of the thesis. This was presented as a research journal article that has been published. In the next chapter, I will present the methods of Phase 3 of the thesis, which is a protocol for a cluster randomised crossover trial comparing in-person and telephone methods of communication for women attending the NHSBSP.
CHAPTER 5A: Communicating benign biopsy results by telephone in the NHS Breast Screening Programme - a protocol for a cluster randomised crossover trial
1. Chapter introduction

In this chapter, I present the protocol for Phase 3 of the thesis; a cluster randomised crossover trial comparing telephone and in-person communication of benign results in breast screening. This chapter has been published in the BMJ Open (296), see Appendix 27. Therefore, the content presented here is the same as the wording in the published paper. However, some additions have been made to expand upon the ideas presented, for the purpose of the thesis.

This chapter is presented in the standard format for a published article: abstract, introduction, trial methods (including study design, participants, settings, measures, randomisation, blinding, imbedded qualitative telephone interviews, sample size considerations and analysis plan) and ethical approval details. I will finish by reporting the dissemination plan for the trial.

1.1 Research question and objectives

This chapter of the thesis had two objectives, outlined in Chapter 2:

- **Objective** - To compare the immediate and long-term effects of communication method (telephone or in-person) on the anxiety experienced by women receiving a benign biopsy result from breast cancer screening using a cluster randomised crossover trial
- **Objective** – To compare the effect of communication method (telephone or in-person) on how well women understand their benign biopsy result from breast cancer screening using a cluster randomised crossover trial

In order to comply with the requirements of the journal, these two objectives are reported in this chapter as the following research aim:

- **The aim of this study is to compare anxiety in women receiving benign biopsy results from the NHSBSP via telephone results or in-person.**

This aim reflects the same objectives set out in Chapter 2.
2. Abstract

Introduction – One of the main harms from breast cancer screening is the anxiety caused by false positive results. Various factors may be associated with false-positive anxiety. One modifiable factor may be the method of communication used to deliver results. The aim of this study is to measure the effect on anxiety of receiving benign biopsy results in-person or by telephone.

Methods and analysis – This is a multi-centre cluster randomised crossover trial in the English NHS Breast Screening Programme (NHSBSP) involving repeated survey measures at four time points. Participants will be women of screening age who have a biopsy following a suspicious mammography result, who ultimately receive a benign or normal (B1) result.

Centres will trial both telephone and in-person results on a month-by-month basis, being randomised to which communication method will be trialled first. Women will be blinded to the method of communication they will receive.

The analysis will compare women who have received telephone results and women who have received in-person results. The primary outcome measure will be anxiety (measured by the Psychological Consequences Questionnaire) after receiving results, whilst controlling for baseline anxiety. Secondary outcome measures will include anxiety at 3 and 6 months post-results, understanding of results and patient preferences for how results are communicated. Qualitative telephone interviews will also be conducted to further explore women’s reasons for communication preferences. Qualitative and quantitative data will be integrated after initial separate analysis using the Pillar Integration Process.

Ethics and dissemination – This study has been approved by the Public Health England Breast Screening Programme Research Advisory Committee, (BSPRAC_0013, ODR1718_040) and the Health Research Authority (HRA) NHS West Midlands - Coventry & Warwickshire Research Ethics Committee (17/WM/0313). The findings from this study will be
disseminated to key stakeholders within the NHSBSP and via academic publications.

**Registration details**
ISRCTN36997684 [https://doi.org/10.1186/ISRCTN36997684](https://doi.org/10.1186/ISRCTN36997684)

**Trial sponsor** – This research is part of a PhD award and is funded by the Economic and Social Research Council (ESRC) Doctoral Training Centre at the University of Warwick and Public Health England. The sponsor for this research is Jane Prewett (sponsorship@warwick.ac.uk).

**Strengths and limitations of this study**

- This is the first cluster randomised crossover trial to measure the impact of communication method on patient outcomes when delivering results in breast screening
- The mixed-methods design adds depth to our understanding of communication preferences and the mechanisms by which anxiety may be affected
- The study is in English breast screening centres and generalisability to other contexts should be carefully considered
3. Introduction

The UK National Health Service Breast Screening Programme (NHSBSP) is a population-based screening programme that aims to detect early signs of breast cancer. Asymptomatic women aged 50-70 are invited to attend every three years for a mammogram. The results of the mammogram take a maximum of two weeks as per NHSBSP guidelines (21). If a suspected abnormality is found on the mammogram then the woman is invited back to the clinic for follow-up tests, usually within the next 2 weeks.

Follow-up tests can include clinical examination, a further mammogram or ultrasound. If these indicate suspicion of cancer then the woman receives a core needle biopsy, involving the removal of sections of tissue from the suspicious breast region. This tissue can then be pathologically analysed. Although the procedure is designed to be minimally invasive, leaving only minor bruising, some women find the experience painful and distressing. It is standard practice to perform all follow-up tests (clinical exam, mammogram, ultrasound and biopsy) on the same day in an assessment clinic to avoid unnecessary extra waiting time for patients. Results of diagnostic tests are discussed on a case-by-case basis at multidisciplinary team meetings (MDT) using a triple-assessment of clinical examination, imaging and biopsy report. Clinical guidelines recommend that all follow-up results should be delivered to the woman within one week (28). These results are delivered by either telephone or in-person, depending on the procedure at the breast screening centre.

Screening programmes should provide benefit that outweighs both physical and psychological harm (4, 9). One of the main harms from breast screening is the anxiety caused by false positive results (41). A false-positive result is when a woman has been identified at the screening phase as potentially having cancer, but follow up tests have revealed no abnormalities. Receiving a false-positive result from screening is very common, with the majority of women who are recalled ultimately being given a false-positive result (36). In England, around half of women receive the all clear results at the time of the follow-up tests. Women who are invited to be screened have no symptoms of
breast cancer at the time of their initial mammogram. Telling a woman that something suspicious has been found in the mammogram and that further tests are needed can make her feel very anxious and believe that she might have cancer (51). For some women, once results confirm the absence of cancer, anxiety declines. However, anxiety can remain elevated for much longer, lasting up to three years after receiving the benign result and leading into the next screening invitation (15). This is an issue, as the NHSBSP has a duty to minimize the harm caused by screening.

There are various factors that may be associated with heightened anxiety during screening such as family history, lower education, younger age and individual differences in personality (21, 58, 97, 98, 100, 101). These factors are unmodifiable and tend to be focused at the level of the individual, which makes the minimisation of screening anxiety a challenge. However, it is possible that there are modifiable changes that can be made at the organisational level of screening that may minimise the impact of anxiety. One of these changes is the method of communication used to deliver results.

NHSBSP guidelines for communicating results state that telephone results ‘should not be routinely offered’ (285). However, most breast screening centres in the UK deliver benign results to the woman over the telephone. Some breast care nurses remain concerned about how the communication method used to deliver results may contribute to the anxiety experienced by women attending screening (28). Telephone results may offer advantages, eliminating the stress and costs associated with transport, parking and anxiously waiting in a clinic for results. However, telephone results eliminates the in-person encounter, meaning all communication is verbal only. Research from other areas has shown that non-verbal communication plays a key role in enhancing understanding and minimising anxiety (170).

The communication methods used to deliver benign results in the NHSBSP has not yet been explored. Therefore, the impact of this communication on women receiving a benign result is unknown.
3.1 Aim of the study
The aim of this study is to compare anxiety in women receiving benign biopsy results from the NHSBSP via telephone results or in-person.

4. Methods and analysis

4.1 Study design
Patient and public involvement from the charity Independent Cancer Patient Voices was used to guide the design of the study to ensure the acceptability of the method and appropriateness of the participant materials.

The study design chosen was a multi-centre cluster randomised crossover trial. The randomisation allows for the direct comparison of study outcomes between women who received telephone results and women who received in-person results, whilst controlling for confounding factors such as education, age and individual differences in baseline anxiety.

Cluster randomisation was chosen, as opposed to individual randomisation. This approach was chosen due to the potential difficulties in randomising individuals and scheduling results appointments accordingly, but also to avoid communication errors. A disadvantage of using a cluster design is that the sample size required is substantially larger, due to greater correlation between individuals from the same cluster (297, 298). However, the predicted sample size and recruitment for this trial were theoretically feasible based upon stakeholder feedback, PPI input and data from previous screening years. A second disadvantage of using a cluster design in this trial was that double blinding was not possible, due to NHSBSP staff needing to know who to telephone with results. Therefore, biases may occur during recruitment due to lack of staff blinding (299). This will be taken into consideration when evaluating the findings.

The crossover element of the trial allowed for both communication methods to be trialled within each cluster. This approach was chosen to minimise the bias between clusters (300). For example, if one centre was delivering results based on their usual approach and another centre was delivering
results in a new and different way than usual, differences between the
centres could be based on varying levels of experience, rather than the
method itself. A disadvantage of this approach was the complexity this added
to the design of the study, which made the trial more challenging to
implement by breast screening staff. I monitored crossover on a monthly
basis, created a schedule of crossover dates and notified centres with
crossover date reminders via email, in order to minimise this challenge.

4.2 Participants and settings
This trial will be conducted in a breast screening centre setting. The study
will take place in the UK where women are invited to attend breast screening
every 3 years for digital mammography. The study will take place across four
time points (see

Table 9) with a survey completed by participants at each stage. The study
participants will be recruited from 4 English Breast Screening centres across
different regions.

Participants will be women between the ages of 47-73 attending the
NHSBSP for further tests following a suspicious mammogram. This includes
women offered routine screening between ages 50-70 and those receiving
extra rounds of screening between the ages of 47-49 or 71-73 as part of the
UK age extension trial (18). Women will be recruited at the assessment clinic
pre-biopsy. However, only women who have receive a benign (B2) or normal
(B1) biopsy result will be included in the longitudinal data collection.
Participants will not be included in the study if they presented
symptomatically to the breast clinic, if they are not the recommended
screening age, if they do not receive a biopsy, if they do not have English as
a first or second language and if they do not have the capacity to consent.

Women who had a family history of breast cancer were not approached to
participate in the study. Breast care nurses, responsible for recruiting
participants, used their clinical judgement and did not approach women who
were deemed ‘too anxious’ e.g. visibly upset. This was to ensure that extra anxiety was not caused for these women.

Table 9: Time points for the study

<table>
<thead>
<tr>
<th>Time point</th>
<th>Sample</th>
<th>Survey content</th>
<th>Method</th>
</tr>
</thead>
</table>
| Time point 1 – at assessment clinic | Women attending assessment follow-up clinic | Demographic information  
Communication preferences  
Baseline anxiety score (PCQ)  
Contact details | In-person |
| Time point 2 – after receiving results | Women from time point 1 who had a normal or benign biopsy | Communication preferences  
Repeat anxiety score (PCQ)  
Measure of understanding | By post |
| Time point 3 – Three month follow-up | Women from time point 1 who had a normal or benign biopsy | Repeat anxiety score (PCQ) | By post |
| Time point 4 – Six month follow-up | Women from time point 1 who had a normal or benign biopsy | Repeat anxiety score (PCQ) | By post |
4.3 Measuring anxiety

The Psychological Consequences Questionnaire (PCQ) was selected as the most appropriate measure of anxiety in the breast screening setting (90) and was embedded in the participant surveys. The PCQ is a disease specific measure, focusing on breast cancer specific anxiety across 12 questions on three dimensions: emotional, social and physical anxiety. The disease specific measure avoids the contrast-validity that is associated with using generic anxiety measures in the breast screening context (35). The PCQ is widely used in the breast screening setting (15, 21, 75, 85, 301).

Participants will rate their anxiety on the PCQ by judging each statement on a scale of 0 (not at all) to 3 (quite a lot of the time). Women will be asked “Over the last week how often have you experienced the following things because of thoughts and feelings about breast cancer:”
4.4 Randomisation and blinding

Each centre will be randomised to one of two intervention arms by computer generated random numbers from the trial team base at the University of Warwick (see Table 10). The arm relates to whether the first month at each centre will be telephone or in-person results. Each centre will commence with the communication method randomised in month 1 and continue to alternate between the two communication methods for the duration of the study. This approach allowed for each centre to use both methods of communication, controlling for previous experience (e.g. centres who already telephone are more experienced and therefore women receiving telephone results from this centre might be less anxious).

This approach was selected instead of a block approach, where each centre would deliver 6 months in-person followed by 6 months of telephone. The reason for this was to avoid potential bias from unforeseen centre drop out.

Table 10: Allocation of communication method by arm of the trial

<table>
<thead>
<tr>
<th>Month</th>
<th>Arm 1</th>
<th>Arm 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Telephone</td>
<td>In-person</td>
</tr>
<tr>
<td>2</td>
<td>In-person</td>
<td>Telephone</td>
</tr>
<tr>
<td>3</td>
<td>Telephone</td>
<td>In-person</td>
</tr>
<tr>
<td>4</td>
<td>In-person</td>
<td>Telephone</td>
</tr>
<tr>
<td>5</td>
<td>Telephone</td>
<td>In-person</td>
</tr>
<tr>
<td>6</td>
<td>In-person</td>
<td>Telephone</td>
</tr>
</tbody>
</table>

This design was chosen to ensure balance between trial arms at each site whilst addressing practical constraints. Balance between trial arms at each site is important to account for centre level confounders such as staff communication skills and centre level processes.

159
Individual randomisation was not possible as it interfered with screening centres workflow and fail-safe mechanisms to ensure that every woman was contacted with the correct information within the correct time frame.

Women will be allocated to receive their result based on the date of their attendance at the assessment visit. However, participants will be blinded to the randomisation month. Participants will only become aware of the communication method allocated when the results are received (see ‘Allocation of communication method’ section below for further detail). Breast screening staff will not be blinded, as they will be delivering the results and scheduling the appointments.

4.5 Allocation of communication method
There are two types of centres who may be involved in the research: centres who currently deliver benign results in-person and centres who currently deliver benign results by telephone.

For centres currently delivering results in-person, the following process for scheduling a results appointment will be observed: During in-person study months, all consenting women at time point 1 will be given an appointment to re-attend to receive their results in-person and will receive the result in-person. During telephone study months, all consenting women at time point 1 will be given an appointment to re-attend to receive their results in person. However, they will instead be telephoned prior to their scheduled appointment. Only benign women will be telephoned, with all women receiving other results (e.g. cancer) attending their scheduled appointment.

For centres currently delivering results by telephone, the following process for scheduling a results appointment will be observed: All consenting women will be informed that, when their results are ready, they will be contacted by telephone to arrange an appointment to come back for their results. During the ‘telephone’ months of the study, women will be telephoned as expected. However, instead of arranging an appointment during this telephone call, results will be delivered. This means that, for women who go on to have a
cancer result, they can be telephoned to arrange an appointment to attend in-person, as expected. This is in-line with standard practice at these centres. During the in-person months, all consenting women will be informed that, when their results are ready, they will be telephoned to arrange an appointment to come back for their results. These women will be telephoned to arrange an appointment to come back in-person, and at that appointment they will receive their benign/normal result.

All women not enrolled in the study will receive their screening result based on the current standard practice at the attended centre.

4.6 Data collection

**Time point 1**

Participant recruitment at time point 1 will occur concurrently at each breast screening centre.

Women will be approached during their assessment visit by breast care nurses with Good Clinical Practice (GCP) training. These women will have been recalled from a previous mammogram and may have a biopsy as part of the assessment clinic. The study will be explained to potential participants and nurses will go through the informed consent process (Appendix 13 Time 1 PIS and Appendix 14 Time 1 consent). Consenting women will fill out the Time point 1 survey (Appendix 15) with study responses collected and stored securely before the participant leaves the assessment clinic.

**Multi-disciplinary team meeting**

At the local level multi-disciplinary team meeting for breast screening staff, women recruited into the study will be included in further time points if they receive a benign (B2) or normal (B1) result. A breast care nurse will compile the contact details of eligible women into a spreadsheet to be sent securely to the research team.
**Time point 2**

The research team will distribute Time point 2 surveys (Appendix 16 PIS Time 2 and Appendix 17 Time 2 survey) to eligible women with a pre-paid return envelope. If no response is received within a week, the research team will contact women by telephone as a reminder. A maximum of two telephone contact attempts will be made. This is to ensure anxiety and understanding are measured at the crucial post-results stage of the screening process.

As part of Time point 2 survey, women will be asked if they would like to participate in further research involving an interview about their experience of receiving a screening result.

**Time point 3**

The research team will distribute Time point 3 surveys (Appendix 18 Time 3 PIS and Appendix 19 Time 3 survey), three months after the biopsy result was received.

**Time point 4**

The research team will distribute Time point 4 surveys (Appendix 20 Time 4 PIS and Appendix 21 Time 4 survey), six months after the biopsy result was received.
4.7 Qualitative telephone interviews

The qualitative telephone interviews will explore why women prefer certain methods of communication. Women will be recruited from the time point 2 survey. Women who express an interest in participating will be sent further information about the interviews (Appendix 22). If they wish to participate, women will return the consent form in the pre-paid envelope (Appendix 23). Women will then be contacted by telephone by the research team to be interviewed.

The semi-structured telephone interviews will each take 10-20 minutes. Questions will encompass the woman’s experience of receiving a result from screening. This will involve asking how the woman felt, whether she understood her result and an exploration of her views on different methods for communicating results. See Appendix 24 for the interview guide. Interviews will be audio-recorded and transcribed verbatim. Data collection will cease once no further themes emerge and data saturation is reached.

4.8 Mixed methods integration

Using a mixed methods approach, the quantitative preference survey data will be combined with the findings from the qualitative interviews. The quantitative data asks a binary choice question regarding women’s communication preferences (telephone or in-person), whilst the qualitative interviews expand on this by exploring how women justify certain preferences for communication. In mixing the data, the qualitative data will be used to expand the understanding of the findings from the quantitative surveys (189). Expansion provides richness and detail, expanding why and how women form communication preferences and moving understanding of preferences beyond what quantitative data or qualitative data in isolation can elucidate. The value added by integrating the knowledge of both what women prefer and why is in the completeness of our understanding of preferences, making the evidence that will inform the NHSBSP policy decisions comprehensive and patient-centred.
4.9 Sample size considerations

In order to determine the sample size for a clustered randomised cross-over study, a full specification of the important within-cluster (centre) between-period and within-period correlations is required (231). There is currently no available evidence on the magnitude of these correlations in our selected setting, so rather than arbitrarily selecting values we adopt a conservative approach and assume that the (within-centre) between-period correlations are zero and proceed to power as if the design were a cluster randomised design. Although the cross-over aspect of the design is not explicitly accounted for in the sample size calculation, it is incorporated fully in the analysis of the primary study outcome (PCQ anxiety score at time point 2).

The aim of the study was to be able to detect a clinically significant difference of 3 points in the PCQ between treatment groups. This was considered a clinically significant difference and was selected based upon a discussion via email with one of the creators of the PCQ scale (90). No previous research has defined a clinical cut-off, so for this thesis, a difference in score on one PCQ statement (being 0, not at all, and 3, quite a lot of the time) was deemed to be a clinically ‘significant’ change – going from no anxious to quite a lot.
This was the approach used. I aimed to report this approach clearly so future research can learn lessons about using this cut off with the PCQ.

Figure 13: Flow of required sample size for the study (total sample size, not considering clusters/cluster size) with design effect applied
Assuming the primary outcome is approximately normally distributed, and the test is at the 5% significance level with 80% power to detect an effect of the specified size, 194 participants are required at time point 2 i.e. 97 participants per arm. Allowing for attrition rate between time point 1 and time point 2 due to participant withdrawal (15%) and participant eligibility (50%), a total of 457 participants will be recruited at time point 1. Participant withdrawal was calculated based upon a mean response rate of 60% from previous research using postal surveys in a medical setting (302) with a loss of 15% at each time point as a conservative estimate.

In order to account for clustering due to the recruiting centre, design effect was applied that inflated the sample size. The intra-cluster (within-centre) correlation coefficient (ICC) was set to be 0.01 and the number of observations within each cluster were assumed to be equal. ICC values are normally determined by previous research (303). However, due to a lack of previous research, this ICC was determined based upon a recommendation from a statistician as a conservative estimate. With the sample size of 194 women, divided by the number of centres (4) and then divided by the number of interventions (2), this led to the number of observations within a cluster being 48.2. This gave a design effect of 1.49. Taking this into account, the sample size needed to achieve statistical significance (194 women) was multiplied by the design effect, giving a total sample of 290 women at time point 2 when rounded up (see Figure 13).

31,926 women are recalled for a biopsy each year. If half of the 31,926 biopsies come back as benign, this leaves a potential sample of 15,963. This means that, on average across 80 breast screening centres, each centre will have around 200 benign biopsy results each year. Therefore, assuming 50% participation rates of eligible women, recruitment will require four centres for one year.
4.10 Planning, designing and monitoring to increase recruitment
The recruitment strategy was planned prior to applying for ethical approval and co-designed with key stakeholders from the NHSBSP, including staff members from potential research sites. Across several meetings, discussions were had about the feasibility of participant recruitment within the breast screening setting. Alongside these meetings, historical figures from breast screening were used to estimate the number of women who attend screening, receive a biopsy and have a benign result (see Chapter 5a for more detail). All stakeholders agreed that the sample size in the protocol was conservative enough to feasibly recruit in this population. PPI input was also used to ensure that the recruitment process would be acceptable to women attending assessment following a suspicious mammogram. Co-designing research with stakeholders and PPI input was key in planning recruitment (304).

The design of the trial aimed to retain eligible participants for all study time points. This included the use of telephone calls to prompt women to return the follow-up postal surveys from Time point 2 onwards. This also included an opt-out procedure for the follow-up stages of research, where all women were contacted with surveys from Time point 2 onwards unless they specifically withdrew from further involvement. These two approaches are associated with increased participant retention in trial research (305).

The design of the trial aimed to increase participant recruitment wherever possible. Gul et al (306) stated that “appropriate recording and reporting of the problems faced while recruiting and retaining the participants in research studies can help not only in understanding the challenge, but will also help in devising the strategies to overcome this problem.” Therefore, monitoring of the trial was built into the research schedule in order to facilitate successful trial co-ordination (307). This involved having a named coordinating staff member at each research site and being in regular contact (through visits, telephone calls and email) to resolve logical issues and provide updates on
recruitment (308, 309). This ensured that recruiters remained engaged throughout the recruitment process (310).

### 4.11 Outcomes and study measures (primary outcome, secondary outcomes)

#### 4.11.1 Primary outcome

The primary outcome is the PCQ anxiety score at time point 2.

A comparison in anxiety score will be made between women who receive results in-person and women who receive results over the telephone.

#### 4.11.2 Secondary outcomes

Secondary outcomes are:

- PCQ anxiety score at 3 month follow-up (time point 3)
- PCQ anxiety score at 6 month follow-up (time point 4)
- Subjective understanding of results (time point 2)
  - Measured using a survey question designed in collaboration with NHSBSP stakeholders
- Objective understanding of results (time point 2)
  - Measured using a survey question designed in collaboration with NHSBSP stakeholders
- Quantitative preferences for results communication before results (time point 1)
- Quantitative preferences for results communication after results (time point 2)
- Qualitative preferences for results communication before results (time point 1)
- Qualitative preferences for results communication after results (time point 2)
5. Analysis

5.1 Quantitative data - Statistical analysis
A formal and more detailed statistical analysis plan (SAP) will be developed by the trial team prior to the completion of recruitment.

5.1.1 Primary outcome
The primary analysis will use a mixed effects linear regression model to estimate the effects of communication method on anxiety (time point 2), after adjusting for baseline anxiety (time point 1). PCQ score will be treated as a continuous variable and to be approximately normally distributed for all analyses.

The model set-up and fixed and random effects are as follows:

- Response variable – Anxiety at time point 2 (PCQ)
- Baseline – Anxiety at time point 1 (PCQ)
- Fixed explanatory effects (model covariates) – age, ethnicity, previous attendance, previous biopsy, education, marital status.
- Random effects – centre and temporal (period) effects
- Comparator variable - Method of communication received – telephone or in-person

Statistical significance will be assessed at the 5% level.
5.1.2 Secondary outcomes

Longitudinal anxiety scores at 3 and 6 months will be analysed in the same way as the primary anxiety outcome.

Differences in understanding score between communication methods groups will be assessed using a logistic regression model, adjusting for fixed effects.

- Outcome variable – Subjective understanding score (binary – yes or no), objective understanding score (binary – right or wrong)
- Fixed effects – age, ethnicity, previous attendance, previous biopsy, education, marital status.
- Comparator variable - Method of communication received (telephone/in-person)

Preference data from the quantitative surveys will be presented in the form of percentages. All analyses will be implemented using IBM SPSS Statistics 25.

5.2 Qualitative data analysis

Qualitative preference data from the time point 1 and time point 2 surveys and data from the telephone interviews will be analysed using inductive thematic analysis (311), managed using NVivo10.

5.3 Mixed-methods integration

To integrate the quantitative and qualitative preference data, the Pillar Integration Process will be used (312). This analytical integration technique uses four systematic stages (listing, matching, checking and pillar-building) to identify and examine connections and discrepancies in qualitative and quantitative findings. It allows for the visual display of the data and findings; this enhances overall transparency of the integration approach and the results of such an integration.
6. Ethics

Attention was given to the various ethical challenges of the trial. The main ethical issue will be the use of sensitive patient information (addresses, telephone numbers). Participants will be told explicitly how their contact details will be used and stored throughout the data collection process. Participants will give informed consent for their contact details to be used for the purposes of the study.

All electronic data will be transferred securely in a password protected excel document from secure email accounts. All raw survey data will be collected directly from the centres by the lead researcher and be transferred in a secure lock-box.

Ethical approval for this study was granted by the following organisations:

- Public Health England Breast Screening Programme Research Advisory Committee, BSPRAC_0013 (ODR1718_040)
- Health Research Authority (HRA) NHS West Midlands - Coventry & Warwickshire Research Ethics Committee (17/WM/0313)
7. Dissemination

Results from the trial will disseminated directly to key stakeholders within the NHSBSP. This will encourage discussion regarding how benign results are communicated in breast screening, and how this might best be implemented in order to minimise the anxiety women experience.

The results will also be disseminated via academic publications.
8. Chapter summary

In this chapter, I have presented the protocol for the cluster randomised controlled trial from Phase 3 of the thesis. This was presented as a research journal article that has been published. In the next chapter, I will present the findings from Phase 3 of the thesis.
CHAPTER 5B: TRIAL RESULTS – THE IMPACT OF COMMUNICATION METHODS ON ANXIETY AND UNDERSTANDING
1. Chapter introduction

In this chapter, I aim to present the findings from the randomised cluster crossover trial described in the protocol in Chapter 5a. I will begin by outlining the research questions and objectives for this phase of the research. I will then report the results of the study. I will describe the key findings of the study and relate these findings to the research literature. I will also identify the strengths and limitations of this study. Finally, I will present my conclusions and ideas for future research.

1.1 Research questions and objectives

This chapter of the thesis had two objectives, outlined in Chapter 2:

- Objective - To compare the immediate and long-term effects of communication method (telephone or in-person) on the anxiety experienced by women receiving a benign biopsy result from breast cancer screening using a cluster randomised crossover trial
- Objective – To compare the effect of communication method (telephone or in-person) on how well women understand their benign biopsy result from breast cancer screening using a cluster randomised crossover trial

The aim of this study was described in Chapter 5a:

- The aim of this study is to compare anxiety in women receiving benign biopsy results from the NHSBSP via telephone results or in-person.
2. Results

2.1 Centre characteristics
Breast screening centres were recruited following an expression of interest during the survey of current practice (see Chapter 3). From the survey, 27 out of 63 centres expressed an interest in being contacted about further research. All centres were contacted with further information. Initial meetings were made with the teams at each centre to discuss further details. Following these meetings, an agreement was made with the centre team about the setting up of the research site (e.g. who was the ‘research champion’, how the protocol would fit into practice, storage of data etc.) These agreements were used to apply for research and development ethical approval at each research site. For an overview of the time line of ethical approval, see Appendix 2. Despite the large amount of interest, many centres could not participate. The main reason for this was the feasibility of randomising to both methods of communication. Another reason was that centres felt they did not have the adequate amount of staffing to follow the proposed protocol.

In total, 4 breast screening centres were recruited as research sites. Three of the centres currently deliver benign results in-person. One of the centres currently delivers benign results by telephone. To feasibly implement the study protocol, slight variations in the recruitment process were necessary. These are outlined in Table 11 and will be reflected upon in the discussion. Recruitment for the trial began on 1st February 2018 and ended on 20th February 2019.
Table 11: Differences in recruitment process between research sites

<table>
<thead>
<tr>
<th>Centre</th>
<th>Current practice</th>
<th>Differences in process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centre A</td>
<td>In-person</td>
<td>Recruiting women before biopsy</td>
</tr>
<tr>
<td>Centre B</td>
<td>In-person</td>
<td>Recruiting women before biopsy</td>
</tr>
</tbody>
</table>
| Centre C | In-person | Recruiting women before biopsy.  
2 hospital sites – women may attend both sites as part of their screening assessment. |
| Centre D | Telephone | Recruiting women after biopsy. |
2.2 Sample description – Time 1
Across the four research sites, 190 women were approached to participate in the trial. At time point 1 of the study, 104 women consented and completed the initial questionnaire during their screening assessment appointment. 9 participants were removed from analysis due to missing data. A total of 95 women remained in the analysis for the time point 1 data point. See Figure 14.

Figure 14: Flowchart of the total sample recruited
The mean age of women recruited into the study at Time point 1 was 56 years. The distribution of ages can be seen in Figure 15.

![Distribution of age for women recruited at Time point 1](image)

**Figure 15: Distribution of age for women recruited at Time point 1**

The baseline characteristics of women recruited at Time point 1 can be seen in *Table 12.*
Table 12: Baseline characteristics of women recruited at Time point 1, presented as percentages

<table>
<thead>
<tr>
<th>Previous attendance</th>
<th>Time point 1 (n=95)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
</tr>
<tr>
<td>• Yes</td>
<td>57 (60%)</td>
</tr>
<tr>
<td>• No</td>
<td>38 (40%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Previous biopsy</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Yes</td>
<td>46 (48%)</td>
</tr>
<tr>
<td>• No</td>
<td>49 (52%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Education</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• No schooling</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>• High school</td>
<td>28 (30%)</td>
</tr>
<tr>
<td>• Some college</td>
<td>34 (36%)</td>
</tr>
<tr>
<td>• Degree*</td>
<td>25 (26%)</td>
</tr>
<tr>
<td>• Other</td>
<td>8 (8%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Marital status</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Single</td>
<td>11 (12%)</td>
</tr>
<tr>
<td>• Domestic partnership</td>
<td>13 (14%)</td>
</tr>
<tr>
<td>• Married</td>
<td>63 (66%)</td>
</tr>
<tr>
<td>• Divorced</td>
<td>4 (4%)</td>
</tr>
<tr>
<td>• Widowed</td>
<td>3 (3%)</td>
</tr>
<tr>
<td>• Separated</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>• Missing data</td>
<td>1 (1%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• White British</td>
<td>90 (95%)</td>
</tr>
<tr>
<td>• White – Any other White background</td>
<td>3 (3%)</td>
</tr>
<tr>
<td>• Asian/Asian British</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>• Black - Caribbean</td>
<td>1 (1%)</td>
</tr>
</tbody>
</table>

*Degree includes: bachelors, masters, doctoral, professional*
2.3 Sample description – Time point 2 onwards

A total of 48 women from time point 1 were eligible to continue with the study, receiving either a B1 or B2 result following screening assessment. 87.5% of the sample were successfully randomised as per study protocol. 12.5% of the sample received telephone results when allocated to receive in-person results. Following the intention-to-treat principle which preserves the integrity of randomisation (313), 23 women were in the telephone arm of the study and 25 women were in the in-person arm of the study.

The baseline characteristics for each arm are presented in Table 13. This includes baseline characteristics for responders and non-responders. Non-responders were women who had been recruited at time point 1, were eligible for randomisation, received but did not respond to the follow-up postal questionnaires and telephone calls.
Table 13: Baseline characteristics for participants in Time point 2

<table>
<thead>
<tr>
<th></th>
<th>Telephone arm (n=23)</th>
<th>In-person arm (n=25)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Responders (n=15)</td>
<td>Non-responders (n=8)</td>
</tr>
<tr>
<td>Mean response time</td>
<td>16 days</td>
<td>-</td>
</tr>
<tr>
<td>Mean distance (SD) from centre*</td>
<td>12.28 miles (9.74), range: 1.4 – 42.3 miles</td>
<td></td>
</tr>
<tr>
<td>Mean age</td>
<td>55</td>
<td>54</td>
</tr>
<tr>
<td>Mean anxiety – PCQ (SD)</td>
<td>10.82 (11.02)</td>
<td>-</td>
</tr>
<tr>
<td>Previous attendance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Yes</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>• No</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Previous biopsy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Yes</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>• No</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>• Missing data</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• No schooling</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>• High school</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>• Some college</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>• Degree**</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>• Other</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Single</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>• Domestic partnership</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>• Married</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>• Divorced</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>• Widowed</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>• Separated</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• White British</td>
<td>14</td>
<td>8</td>
</tr>
<tr>
<td>• White***</td>
<td>1</td>
<td>-</td>
</tr>
</tbody>
</table>

*Mean distance from breast screening centre from participant home address
**Higher degree includes: bachelors, masters, doctoral, professional
*** Any other white background
2.3.1 Age of responders and non-responders
The median age of responders in the telephone arm was 53 years old (range, 47 to 75 years old). The median age of non-responders in the telephone arm was 53 years old (range, 47 to 65 years old).

The median age of responders in the in-person arm was 55 years old (range, 48 to 69 years old). The median age of non-responders in the in-person arm was 52 years old (range, 49 to 58 years old).
2.4 Missing data
Some participants provided survey responses with incomplete data on the PCQ anxiety measure. I removed participants from the analysis if they were missing 3 or more responses on the PCQ measure. If they were missing less than 3 data points, I created an average for the missing responses. 9 participants were removed from the data, based on this criterion. 16 participants had average responses calculated for their PCQ measure.

Some participant responses were missing demographic information. Due to the small sample size, these participants were retained for analysis. Instances of missing demographic information have been reported.

3. Results

3.1 Planned analysis
The statistical analysis plan was to conduct a mixed effects linear regression model. However, recruitment challenges were encountered during the trial, which led to a small study sample size. Subsequently, the sample size was not large enough to power the statistical analysis and the mixed linear regression model would not converge (314). Therefore, the planned analysis could not be completed and a comparison between the two trial arms was not made.

3.2 Mean anxiety scores and long-term anxiety
Due to the small sample size, a complex analysis of anxiety scores was not made. Instead, a mean anxiety score was calculated for each time point for telephone and in-person groups (see Table 14).
Table 14: Mean PCQ anxiety score and SDs comparing telephone and in-person groups

<table>
<thead>
<tr>
<th></th>
<th>Time point 1 Before results</th>
<th>Time point 2 Post-results</th>
<th>Time point 3 3 months post-results</th>
<th>Time point 4 6 months post-results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone (n=15)</td>
<td>10.74 (8.82)</td>
<td>10.81 (11.02)</td>
<td>6.60 (10.09)</td>
<td>2.75 (5.20)</td>
</tr>
<tr>
<td>In-person (n=19)</td>
<td>10.54 (9.37)</td>
<td>5.97 (8.53)</td>
<td>3.18 (7.35)</td>
<td>2.86 (6.72)</td>
</tr>
</tbody>
</table>

This indicates that women in both groups appear to experience a reduction in anxiety 3 months after results are received. However, results should be interpreted with caution due to the sample size. Furthermore, the large standard deviations suggest individual differences exist in the anxiety experienced at the different stages of screening.

3.3 Patients own understanding of their results

Frequencies were calculated for the measure of subjective understanding, which asked women, ‘Do you feel like you understand your screening result?’ 100% of all women from both the telephone (n=14) and the in-person (n=19) groups said ‘yes’. None of the women said “no”.

3.4 Objective understanding of results

Frequencies were calculated for the measure of objective understanding, which asked women to tick the statement that described their result (see Table 15).
Table 15: Objective understanding between telephone and in-person groups

<table>
<thead>
<tr>
<th></th>
<th>Correct statement – I do not have cancer and will be invited to re-attend screening in 3 years</th>
<th>Incorrect statement – I do not have cancer and do not need to return to screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>In-person</td>
<td>19</td>
<td>0</td>
</tr>
</tbody>
</table>

In both the telephone and in-person groups, most women selected the correct statement. This indicates that they objectively understood their result. In the telephone group, 2 women selected the incorrect statement. (These women were 47 and 48 years old and therefore, were eligible to re-attend screening in 3 years.) This indicates that these 2 women may not have objectively understood their result. This is in direct comparison to the women in the in-person group, who all answered the statement correctly. Overall, this suggests a higher likelihood of misunderstanding in the telephone group. However, results should be interpreted with caution due to the sample size.

3.4.1 Distance travelled

Of the 48 women who received a B1 or B2 screening result, the mean distance to travel to the screening centre was 12.28 miles (SD 9.74, range 1.4 miles to 42.3 miles).

3.5 Low sample size/issues in recruitment

Throughout the recruitment period, regular meetings were held with the dedicated research contact at each site. During these visits, issues with the trial were discussed, which primarily focused upon recruitment issues. No plans were made to formally analyse these notes. I will narratively present
some the reasons given by site staff for the issues experienced in recruitment. This will include opinions on the overall experience of the study and delivering results, recruitment challenges, opinions on the use of telephone results services in the future and suggestions for future research.

3.5.1 The overall experience of the study and delivering results
Centres reported enjoying participating and felt that the research question was important to their clinical practice (310, 315). For centres trialling telephone results for the first time as part of the study, they felt that women responded well to these telephone consultations. Centres commented that it felt good to have the flexibility to be able to telephone women with their results when benign, as this meant that women could receive their results sooner.

However, one centre commented that they felt they could provide better care when delivering results in-person. Reasons for this were the ability to pick up on body language and sense when a woman had questions. On the phone, nurses felt that the women were in a rush, believing they were causing a delay for the nurses delivering results.

3.5.2 Recruitment challenges
There were several key issues identified in recruitment. These included participant anxiety issues, participant time issues, participant preference issues, clinician time issues, clinician staff issues and clinician issues in identifying eligible participants.

Participant anxiety issues - Staff said that some ladies were visibly anxious and were not approached to participate. Other women felt unwell after biopsy, with some experiencing fainting issues. These women were also not approached for the study. For women who were approached, some wanted to know for definite how their results would be delivered. Women had concerns about getting bad news over the telephone, even when they were
reassured that participating in the study would not involve this. For some women, the trial was “one piece of information too many” and they dismissed participation because it was easier to not have something else to worry about.

**Participant time issues** – Staff said that women often refused to participate due to not wanting to fill out the surveys. This was often due to the women having been in the clinic for long periods of time (between 2 to 5 hours) at the point of the study being introduced. Women just wanted to go home at this time and some women said they had husbands waiting for them, or were worried that the paid parking on their cars might expire.

**Participant preference issues** – Staff said that some women did not want to participate because they preferred to be told their results in-person. There were many potential reasons for that were discussed. Some women were unable to take phone calls at work. Some women were concerned at the timing of the telephone call, such as being called when they were in the supermarket. Some women preferred in-person as they felt it was more reassuring. Some women refused to participate in the research due to fear of missing out on an in-person appointment or the fear of opting for something “outside of the norm”.

**Clinician time issues** – Staff did not want the research to slow the clinic down and some felt that the research was too difficult to explain in a short amount of time. Some staff said that introducing the study was challenging to imbed into their usual practice.

**Clinician staffing issues** – Staff identified that there were not enough clinicians involved in the project, and therefore were pressed for time. This was due to unpredicted staff absences due to illness and also due to lack of support from the wider clinical team. This resulted in lack of participation in study recruitment.

**Clinician issues in identifying eligible participants** – Staff expressed frustrations with the low levels of recruitment, as they felt they were trying hard to make the study a success. The issues involved in identifying eligible
women included no biopsy being performed, not attending the appointment or being late and not being able to gain informed consent (often due to language barriers). Staff noted that they had experienced higher numbers of cancers and B3 (indeterminate) results than in previous screening years, possibly due to changes in the mammography process.

3.5.3 Opinions on the use of telephone results services in the future

After participating in the research, centres who were trialling telephone results for the first time felt that telephone results had the potential to work in practice. However, centre staff stated that they could not identify the best process to achieve this. Women need to be told how their result will be delivered but at assessment the outcome is unknown. Staff said that it’s difficult to give women the choice at the time of the appointment. One option mentioned would be to give all women an appointment, ringing those who are benign but letting them know that they can still come in for their appointment if they would like. This is similar to the approach used in the trial. However, some staff noted that receiving an unexpected telephone call may cause additional anxiety for women, even if the news is good.

The one centre in the research who already routinely telephone benign results, felt that their approach was appropriate. The staff said that they prefer to telephone results due to the limited number of staff and also the remote geographical location of their centre. Seeing everyone in-person would take valuable time away from their cancer patients but also be inconvenient for benign women who travel long distance for a short in-person appointment. Staff said that some women even book a hotel for the night before their appointment to ensure they can arrive on time.

3.5.4 Suggestions for future research.

Staff were asked for suggestions or improvements that could be made in future research in order to facilitate recruitment. These were the suggestions:
• Staff suggested that the design of the research could be improved and simplified – this would make the research easier to explain during the busy breast clinic and improve patient understanding of the study, thus improving potential for recruitment.

• Reduce the eligibility criteria to include B3 women who have repeat tests but ultimately have a benign diagnosis (complex cases)

• Improve engagement with the wider clinical team

• Allow women to take the survey home to be returned in a pre-paid envelope

• Invite women to an earlier time slot to allow the survey to be completed in the clinic waiting room prior to the assessment appointment

• Introduce double-blinding for nurses to reduce subconscious potential bias – one staff member felt that she was more successful in recruiting women during the ‘in-person month’, which was usual practice at her centre. She speculated that this was due to her feeling more confident in this procedure.

• Different approaches not involving randomisation – improving audits of results communication or measuring retrospective experience of receiving results.
4. Discussion

Recruitment to the study was low and no statistical comparison between telephone and in-person groups was made. These findings are based on basic frequency calculations and should be considered with caution. Anxiety appears to reduce after results are received and at 3 and 6 month follow-up. However, anxiety may have begun to reduce before results were received, directly after completion of the breast assessment visit. There were individual differences in the individual experience of anxiety, which is supported by other findings in the research literature (49). All women believed that they understood their screening result but some women who received results by telephone incorrectly believed that they no longer needed to attend screening. Other research suggests a reason for this may be the absence of non-verbal cues leading to patients not fully understanding their result (170). This concern was also raised in the current study by breast centre staff. However, due to the low sample size, these findings should be considered with caution as they may be due to Type 1 error. Overall the main finding of this study was the low sample size and issues in recruitment.

Less than one third of clinical trials reach their recruitment targets (305, 316). Most trials only reach their recruitment targets by extending the study duration (305). Unfortunately, due to the time constraints of the thesis, it was not possible to increase the length of the trial, although this was an option that was considered (305). Furthermore, the beginning of recruitment was delayed due to the amount of time needed to gain ethical approval, at the national and local level, and also set up the study at each site (316). Blanton et al (317) makes reference to “Lasagna’s law on planning clinical trials” which states that researchers overestimate the pool of participants available for recruitment. This is one of the main reasons why clinical trials are abandoned early (318).

Some researchers have debated about whether low recruitment to trials is unethical (319). Low sample size leads to an underpowered study, which may indicate a waste of patient and clinician time in collecting the data. However, several underpowered trials can be meta-analysed to give
conclusive results. Furthermore, the recruitment issues raised in the current study may help to answer the research questions in a different way than anticipated. McDonald et al (316) suggest that success in answering the trial question may be more important than recruitment figures. One of the reasons women gave for not wanting to participate was due to their preference for in-person communication. Other women were too anxious to be approached or self-identified as preferring in-person communication due to their uncertainty and anxiety. Although the groups could not be compared statistically, this suggests there is an emotional impact of how results are communicated that may be linked to women’s preferences (315). This will be explored further in Chapter 6 of the thesis, where women who were recruited from this trial were interviewed further about their experience of receiving a result from screening.

Unlike other trials, this study held minimal risk in participation (320). For drug studies, an underpowered sample may raise moral and ethical issues such as unnecessary treatment or side effects. However, despite our lack of knowledge regarding the impact of telephone results on women attending screening, there is a lower risk of negative consequences. The low risk helps justify the low levels of recruitment (321).

There were several reasons identified by the staff when discussing the low recruitment of the study including anxiety, time (patient and clinician), preferences, staffing and identification of eligible participants. Previous research has identified similar issues in recruitment relating to participant and clinician barriers (310, 315, 322, 323).

In the current study, staff identified challenges in describing the trial to participants, particularly in the time limited setting of the assessment clinic (310, 324). Training and support were provided to staff in order to facilitate recruitment, but the struggle to communicate the study to potential participants remained an issue (315, 325). Women not understanding the study might explain their reluctance to participate (317). This may partially be due to the uncertainty of the outcome of the assessment, with women unsure if they may be facing a future cancer diagnosis (38, 51, 315). In this
circumstance, it may have been difficult for participants to understand that they might not have cancer and might receive good news, and that they would only receive good news by telephone. Some women just wanted to be told for definite how their results would be delivered, not understanding the purpose of the randomisation (326, 327). Staff thought this may be due to the amount of information being too much to take in during this anxious time.

Staff may also have struggled with recruitment due to the challenges faced in describing study equipoise to potential participants (328). Breast Care Nurses want to reduce the anxiety experienced by women during the assessment visit. If they felt the study was causing additional anxiety, they would be less motivated to recruit participants into the trial, acting as a gatekeeper (310, 323, 329). Despite this issue not being obvious during the recruitment period itself, during site close some staff reflected on the subconscious bias that might have been present during recruitment (323). For example, some nurses might have been more proactive in recruiting during the month of communication which was usual practice for their centre, due to feeling subconsciously more confident and in control of minimising anxiety for their patients (329).

Overall, the findings from this study offer valuable lessons to be learned about evaluating the communication methods used to deliver results in breast screening (318). This includes the challenges that may be faced when recruiting this population, including patient and clinician barriers.

4.1 Suggestions for future research

In the study, staff had suggestions to improve the research in the future and reduce recruitment barriers. One suggestion for future research was to improve study engagement with the wider clinical team, which has been mentioned in previous research (330, 331). However, this was in a challenge in the current research due to the difficulties in scheduling multiple meetings with large numbers of team members, although this was attempted on several occasions. With a larger trial management team, engagement with
the clinical team might have been more successful. Despite these suggestions, it is important to note that the removal of perceived barriers might not increase recruitment in trials. Fletcher et al (310) speculated that recruitment barriers might be used as ‘excuses’, so staff can focus singularly on their main clinical role. Therefore, staff suggestions for completely different approaches to the research question (such as improving audits or conducting retrospective studies) might be more appropriate and fit better into clinical practice.

4.2 Study strengths
This study reports issues and lessons to be learned when recruiting this population of women, who are attending for a biopsy following a suspicious mammogram. This is useful information in considering future research attempting to evaluate the impact of the communication methods used to deliver breast screening results. This study also gives new insight into the emotional experience of attending breast screening assessment, and how the communication of results might be linked into this.

4.3 Study limitations
This study was underpowered due to low recruitment and therefore, a comparison between groups was not made. Upon reflection, this research could have benefited from a feasibility or pilot stage, prior to commencing a full trial (332). This would have allowed for potential issues to be identified during this stage and to be addressed in the full trial design.

Further research is needed, if possible, to compare telephone and in-person groups. However, due to the issues in recruitment that this study raised, we believe a RCT may not be the best approach. Instead, research that improves the auditing process or measures the retrospective impact of communication might be more appropriate.
4.4 Study conclusions
This study aimed to compare the impact of telephone and in-person results delivery for women attending the NHSBSP. However, recruitment was low, despite best efforts maximise the sample size during the planning and monitoring of the study. There were issues for both the participants and clinicians in recruitment to the study, which included patient anxiety, time and preferences and clinician time, staffing and participant identification issues. This study reports lessons to be learned when recruiting women attending assessment following breast screening. Suggestions for future research to evaluate communication methods are improving audits and using retrospective study designs.
5. Chapter summary

In this chapter, I have reported the results from Phase 3 of the thesis. This included sample characteristics, reasons for low recruitment, basic frequencies for the main outcomes and a discussion of the overall results. I have highlighted the planning and monitoring procedures that were used to help with recruitment, and also the challenges that were faced during this study. I concluded by summarising the reasons for low recruitment and suggesting areas for future research to evaluate the communication methods used to deliver results in the NHSBSP.

In the next chapter, I will present the findings from Phases 4 and 5 of the thesis. This was a qualitative interview study exploring women’s experiences of receiving a result from the NHSBSP.
CHAPTER 6: Communication preferences for benign biopsy results – Frequencies, free-text comments and telephone interviews.
1. Chapter introduction

In this chapter I describe the findings relating to the outcome of patient preferences. This includes data from within the RCT survey (Phase 3) and data from the telephone interviews (Phase 4). I will present the findings for both data sets for the outcome of patient preferences. I will then integrate these findings within this chapter (Phase 5) using narrative synthesis.

I will begin by stating the research questions that will be answered in this chapter. I will then describe the methods used, including the sample, instruments, procedure, ethics and analysis.

I will begin the results section by presenting the survey data for the preference outcome. This includes the number of women who prefer telephone versus in-person communication for benign biopsy results. This also includes the qualitative free-text comments made by women in the RCT survey, relating to their reasons for their communication preference.

In the next section of the results, I will present the thematic findings from the telephone interviews. This will be followed by a narrative synthesis, integrating the survey frequencies, free-text comments and telephone interviews.

In the discussion I will explain the overall findings and how these relate to previous research and theories of uncertainty. I will discuss the strengths and limitations of the research. I will finish the chapter by drawing conclusions and highlighting how this study adds to our understanding of communication preferences for results delivery in the NHSBSP.
2. Research questions and objectives

The objectives for these phases of research (see in Chapter 2) were as follows:

PHASE 4: Communication preferences: surveys and interviews (Chapter 6)

- Objective – To survey women attending breast assessment to record their communication preferences, before and after receipt of a benign biopsy result
- Objective - To interview women who have received a benign biopsy result from breast screening to explore their reasons for communication preferences

PHASE 5: Integration (Chapter 6)

- Objective - To integrate the data to explain communication preferences and expand on reasons for these preferences
3. Methods

3.1 Design
A mixed methods survey across two time points (Time point 1, before results and Time point 2, after results) and semi-structured qualitative telephone interviews. Justification of approach and methods used can be found in Chapter 2 of the thesis.

3.2 Participants
The survey sample was recruited from the trial presented in Chapters 5a and 5b. Therefore, the sample inclusion and exclusion criteria were used (see Chapter 5a). The qualitative interview participants were recruited from within this sample.

3.3 Survey instruments
Two surveys were used a two study time points. Time point 1 of the study was during the woman’s assessment clinic, before results. Time point 2 of the study was after women had received their result.

The first survey (completed during Time point 1 of the study) included a binary choice question of women’s communication preferences. Women were asked ‘How would you prefer to receive your results from screening?’ Women were asked to select between either ‘in-person at the screening centre’ or ‘by telephone’. This question was followed by another asking ‘Why would you prefer to receive your results this way?’ Women were asked to write a brief explanation in the free text box. As part of the survey, women provided their address for follow-up postal surveys to be sent to (Appendix 15).

The second survey (completed during Time point 2 of the study) repeated the questions asked in the first survey. The second survey also included an additional question to recruit interview participants. The question asked
‘Would you be interested in taking part in a telephone interview to discuss your experience of receiving results from screening?’ (Appendix 17)

3.4 Interviews
The telephone interviews were used to explore what reasons women gave for their communication preferences, following their recent breast screening experience and involvement in the trial. A guide was used to conduct the interviews, which included questions and prompts (Appendix 24). These questions related specifically to the research questions, drawing from the background literature and systematic review findings.

3.5 Procedure
Women were recruited into this study during the trial and provided written consent (Chapter 5a). Women completed the first survey at Time point 1 during their visit to the assessment clinic. Once all tests were completed, women were sent home to wait for results.

Women were sent the second survey at Time point 2, after their results had been delivered. Successful delivery of the results was confirmed by research sites. The second survey was sent by post and returned by women in a pre-paid envelope. If no response was received within a week, the research team telephoned women as a reminder.

Women who completed the second survey, who expressed an interest in interview participation were sent further details of the study (Appendix 22). Two consent forms were also sent (Appendix 23). If women wanted to participate, they were instructed to return one completed consent form and to keep the second copy for their records. Women who consented were contacted by telephone to arrange a suitable time to be interviewed.

The aim was to recruit approximately 10-15 women to be interviewed. The interviews were conducted between 4th May 2018 and 11th January 2019.
3.6 Ethical approval

Ethical approval was granted by the Public Health England Breast Screening Programme Research Advisory Committee, BSPRAC_0013 (ODR1718_040) on 4th August 2017 and Health Research Authority (HRA) NHS West Midlands - Coventry & Warwickshire Research Ethics Committee (17/WM/0313).

3.7 Analysis

3.7.1 Surveys

Quantitative data relating to communication preferences were analysed and presented in the form of percentages. Distance from the participant address to the research site address was calculated for each woman. This was to indicate how far women travel to receive their results. This was presented by mean distance travelled and range (least/furthest distance travelled).

Qualitative explanations of communication preferences were analysed using qualitative content analysis (288, 289). This involved coding reasons for communication preferences. These reasons were refined into categories and presented as frequencies. The analysis was conducted by the lead author (SW) and checked by a second author (DE) to ensure that the meaning of original staff comments was retained. Any disputes in interpretation were resolved by a third author (HS).

3.7.2 Interviews

Interview data were analysed using inductive thematic analysis, managed using NVivo10 (311). A list of initial codes were generated during the first stage of analysis on hard copies of the transcripts using a paper and pen method. Each paper was coded individually, after each interview was transcribed, developing codes in an iterative process. Once initial coding was completed using the paper method, the transcripts were reviewed again to compare against the coding on previous or subsequent transcripts. This ensured that instances of ‘new codes’ which were found in later transcripts
were not missed in earlier transcripts. The initial paper coding was then inputted into NVivo10.

After generating this initial long list of codes, a process of refining and reducing these codes took place. This process involved printing the current list of codes, and cutting them with scissors in order to physically ‘move’ the codes around. This allowed the researcher to explore which codes may have been explaining the same phenomena and could be reduced to a single code. This was based upon similarity of the codes and the wording used for coding. For example, 7 codes (“Asking questions by telephone”, “Asking questions by telephone but just practical”, “Asking questions being easier in-person”, “Other people might have wanted to ask questions”, “Didn’t have any questions”, “Felt able to ask questions”, “No need to ask questions”) were reduced into 1 code (“Asking questions”). The process of reducing codes was recorded in a coding log for transparency and to facilitate discussion with a second reviewer (DE).

Once the codes were reduced, they were further refined into categories based on code similarity and overlap. A similar process involving printing the codes and ‘moving’ them around was used for categorisation. Finally, the categories were refined into themes, exploring the reasons women give for their communication preferences. A similar process involving printing the codes and ‘moving’ them around was also used to refine the categorises into themes.

Transcripts were cross-examined to ensure that themes were inclusive of all instances within the data. Codes, categories and themes were discussed with a second reviewer (DE) to ensure congruence of understanding. Any disagreements in the coding were discussed and resolved between reviewers, with a third author being involved if an agreement could not be met (HS).
3.7.3 Integration

Following the individual analysis of the survey and interview data, findings were integrated using narrative synthesis. This process involved reading and re-reading of the data from the survey and interview findings, using constant comparison. Similarities and differences were noted, and integration was used to explain what communication methods women might prefer and what reasons they give for these preferences.
4. Results

101 women responded to the first survey at Time point 1. Of the 48 women who received a B1 or B2 screening result who were sent the follow-up survey at Time point 2, 38 women responded.

4.1 Communication preferences

At Time point 1, participants expressed a preference for receiving results by telephone (see Table 16).

Table 16: Women's preferences for results communication (all participants)

<table>
<thead>
<tr>
<th></th>
<th>Time point 1 (n=101)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone</td>
<td>70</td>
</tr>
<tr>
<td>In-person</td>
<td>25</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
</tr>
</tbody>
</table>

Participants who received a benign result and completed surveys at Time point 1 and Time point 2 of the study also expressed a preference for receiving results by telephone (see Table 17). Despite the survey being a binary choice between telephone and in-person, women annotated the surveys to indicate different answers. This included choosing both communication options or writing in a third ‘other’ choice of communication method. These annotations indicated that women were either undecided on a communication preference or had an alternative suggestion.
Table 17: Women's preferences for results communication (Women who received a benign result only)

<table>
<thead>
<tr>
<th></th>
<th>Time point 1 (n=48)</th>
<th>Time point 2 (n=34)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Telephone</strong></td>
<td>37</td>
<td>21</td>
</tr>
<tr>
<td><strong>In-person</strong></td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

4.2 Qualitative results
Of the 101 women who responded to the first survey at Time point 1, 99 women explained the reasons for their communication preference. Of the 38 women who responded to the second survey at Time point 2, 35 women explained the reasons for their communication preference.

4.2.1 Reasons for telephone preference
Women who preferred telephone communication gave several reasons for this preference (see Table 18). The most common reason was that telephone results are perceived to be quicker, reducing the amount of time spent waiting for results. The second most common reason was that telephone results avoid the need to travel, sometimes long distances, for an extra hospital visit. Some other reasons for preferring telephone results included saving time, no parking, convenience, less anxiety, no time off work needed and saving money. See Table 18.
Table 18: Qualitative survey data - reasons for telephone preference (n=99)

<table>
<thead>
<tr>
<th>Reason</th>
<th>Number of mentions</th>
<th>Example quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>No wait, quicker</td>
<td>36</td>
<td>Waiting for results is the hardest part of any medical examination. (PID 013)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sometimes less of a wait if it's by telephone and I think the waiting is what causes the stress and anxiety. (PID 361)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Would just like to know ASAP (PID 482)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If all ok, you just want to know quickly. (PID 204)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Would rather know quickly. The wait to be told it's fine seems more stressful. (PID 406)</td>
</tr>
<tr>
<td>Travel, distance, no hospital visit</td>
<td>32</td>
<td>Not having to visit the hospital another time. (PID 363)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>It is a very long way to travel there and back (PID 359)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Driving to the appointment would have been torture (PID 209)</td>
</tr>
<tr>
<td>Saves time</td>
<td>23</td>
<td>Save time with appointment, both for myself and hospital staff (PID 452)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Over the phone would be obvious to be because it would release time in the system for the people who need further treatment (PID 480)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>I wouldn't want to waste clinician's time in a clinic (PID 358).</td>
</tr>
<tr>
<td>Parking</td>
<td>15</td>
<td>Parking is always a problem. (PID 467)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Car parking is also an issue to be considered. (PID 357)</td>
</tr>
<tr>
<td>Convenience</td>
<td>14</td>
<td>It would be more convenient for me to be told these non-cancer results by telephone (PID 355)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Less inconvenience (PID 304)</td>
</tr>
<tr>
<td>Less anxiety</td>
<td>13</td>
<td>Easier and less stressful over the phone. (PID 552)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Less worry. (PID 007)</td>
</tr>
<tr>
<td>No time off work</td>
<td>11</td>
<td>Easier than taking time off. (PID 004)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Complicated rota at work and not always able to get time off for appointments. (PID 402)</td>
</tr>
<tr>
<td>Reason</td>
<td>Frequency</td>
<td>Comment</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-----------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Money</td>
<td>7</td>
<td>It’s easier with working so you don’t lose any pay. (PID 253)</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Could hopefully save the NHS some money.</em> (PID 111)</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Paying for parking.</em> (PID 004).</td>
</tr>
<tr>
<td>Disability</td>
<td>3</td>
<td><em>I can no longer drive as I am partially sighted.</em> (PID 008)</td>
</tr>
<tr>
<td>Home comforts</td>
<td>3</td>
<td><em>Feel more comfortable in own surroundings.</em> (PID 305)</td>
</tr>
<tr>
<td>No late appointments</td>
<td>2</td>
<td><em>This would be preferable to having to attend the clinic, where appointments are often running late.</em> (PID 357)</td>
</tr>
<tr>
<td>Environment</td>
<td>2</td>
<td><em>Environment.</em> (PID 209)</td>
</tr>
<tr>
<td>Unfamiliar place</td>
<td>1</td>
<td><em>I suffer with anxiety when traveling or in unfamiliar places.</em> (PID 351)</td>
</tr>
<tr>
<td>Medical knowledge</td>
<td>1</td>
<td><em>I am a medical doctor and so I understand the medical information.</em> (PID 355)</td>
</tr>
<tr>
<td>Short appointment</td>
<td>1</td>
<td><em>It is a very long way to travel there and back for a very short, if very positive appointment</em> (PID 359)</td>
</tr>
</tbody>
</table>

### 4.2.2 Reasons for in-person preference

Women who preferred in-person communication gave several reasons for this preference (see Table 19). The most common reason was that women find it easier to ask questions in-person and feel as though they have more time to prepare these questions. Another common reason was that women feel that in-person communication is more friendly, personal and supportive, particularly during the anxious period when they were unsure if they had cancer or not. Other reasons for preferring in-person results included less anxiety, a safe location for receiving results, avoiding miscommunication, the ability to explain things well and in-person appointments fitting in better with working schedule.
<table>
<thead>
<tr>
<th>Reason</th>
<th>Number of mentions</th>
<th>Example quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asking questions</td>
<td>13</td>
<td><em>I can ask questions which I might forget to if on the telephone.</em> (PID 052)</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>I believe that a pre-empted appointment enables you to prepare questions you may have.</em> (PID 456)</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Any questions I may have I would sooner ask face to face.</em> (PID 102)</td>
</tr>
<tr>
<td>Friendly, personal,</td>
<td>13</td>
<td><em>In-person seems more of a friendly, calming way of receiving results.</em> (PID 006)</td>
</tr>
<tr>
<td>supportive</td>
<td></td>
<td><em>I feel this is a much more personal service and at a very difficult and stressful time it feels a much nicer way of delivering results</em>(PID 107)</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>I think when you have worries about possible cancer diagnosis is much more reassuring when you see someone in-person, even if results are negative. Being there allows you to be treated with human touch.</em> (PID 457)</td>
</tr>
<tr>
<td>Less anxious or emotional</td>
<td>8</td>
<td><em>If I was waiting for a phone call that didn’t come I would be more worried.</em> (PID 358)</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>If I knew I would get a phone call to say clear I would worry about not getting it.</em> (PID 307)</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Too emotional to take it all in. So upsetting. You don’t listen. You just hear no cancer but you don’t understand what was found.</em> (PID 207)</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>If you get a telephone call for non-cancer and an appointment for cancer, this would create anxiety by not receiving a telephone call, implying that you have cancer because you didn’t get a call.</em> (PID 451)</td>
</tr>
<tr>
<td>Safe location</td>
<td>4</td>
<td><em>If it is bad news it is better to be told at centre as on telephone I could be anywhere or with anyone.</em> (PID 303)</td>
</tr>
<tr>
<td>Avoid miscommunication</td>
<td>2</td>
<td><em>Also face to face also reduces the possibility of miscommunication.</em> (PID 456)</td>
</tr>
<tr>
<td>Explain things well</td>
<td>1</td>
<td><em>Can be explained clearly.</em> (PID 109)</td>
</tr>
<tr>
<td>Working</td>
<td>1</td>
<td><em>I am working person therefore it is better for me if I get my results in person.</em> (PID 106)</td>
</tr>
</tbody>
</table>
4.2.3 Quantitative survey – other comments

Some comments made by the women in the quantitative surveys did not directly give reasons for preferring telephone or in-person communication. Despite a binary choice option, some women opted to annotate the survey to express a different opinion. These opinions covered three key ideas: having no preference, having a preference that depended on the result and being open to the idea of receiving a malignant diagnosis by telephone.

Four women gave comments explaining that they do not have a preference for communication. For example, one woman commented ‘I don’t mind either in-person or telephone’ (PID 459).

Ten women commented that their preference would change depending on the outcome of the screening result. Although the question we asked focused specifically on a good news result, these women felt it important to specify that their preference would differ if the result was cancer. For example, one woman said “If not cancer, happy to get a phone call. If it is would prefer to talk to someone face to face.” (PID 203).

Finally, 2 women commented that they preferred telephone communication, even if the result was cancer. One woman said “if at home result would be better to handle if it was a negative result” (PID 405). The second woman said “Prefer by telephone. If my results are not good, can compose myself and deal with the future.” (PID 109).
4.3 Qualitative interviews

Of 11 women who expressed an interest in being interview, 8 women consented to participate and 7 women were successfully interviewed. The interviews ranged from 10 minutes to 30 minutes in length.

3 women received their results from Centre A, 3 women received their results from Centre C and 1 woman received her results from centre D. All women were of screening age, ranging between 49 to 69 years. 4 of the women had previously attended breast screening and 3 of the women were first time attendees. Only 1 woman had previously had a biopsy. Sample characteristics can be seen in Table 20.

Table 20: Sample characteristics of telephone interview participants

<table>
<thead>
<tr>
<th>PID</th>
<th>Centre ID</th>
<th>Age</th>
<th>Previous attendance</th>
<th>Previous biopsy</th>
<th>Marital status</th>
<th>Education</th>
<th>Method received – Time point 1</th>
<th>Method received – Time point 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>009</td>
<td>Centre A</td>
<td>57</td>
<td>Yes</td>
<td>No</td>
<td>Married</td>
<td>Professional degree</td>
<td>In-person</td>
<td>Telephone</td>
</tr>
<tr>
<td>207</td>
<td>Centre D</td>
<td>50</td>
<td>No</td>
<td>No</td>
<td>Married</td>
<td>Some college</td>
<td>Telephone</td>
<td>In-person</td>
</tr>
<tr>
<td>355</td>
<td>Centre A</td>
<td>49</td>
<td>No</td>
<td>No</td>
<td>Domestic partnership</td>
<td>Professional degree</td>
<td>In-person</td>
<td>Telephone</td>
</tr>
<tr>
<td>357</td>
<td>Centre A</td>
<td>69</td>
<td>Yes</td>
<td>No</td>
<td>Married</td>
<td>Other</td>
<td>In-person</td>
<td>Telephone</td>
</tr>
<tr>
<td>451</td>
<td>Centre C</td>
<td>57</td>
<td>No</td>
<td>No</td>
<td>Domestic partnership</td>
<td>Some college</td>
<td>In-person</td>
<td>Telephone</td>
</tr>
<tr>
<td>455</td>
<td>Centre C</td>
<td>60</td>
<td>Yes</td>
<td>No</td>
<td>Domestic partnership</td>
<td>Some college</td>
<td>In-person</td>
<td>In-person</td>
</tr>
<tr>
<td>457</td>
<td>Centre C</td>
<td>63</td>
<td>Yes</td>
<td>Yes</td>
<td>Widowed</td>
<td>Some college</td>
<td>Telephone</td>
<td>Telephone</td>
</tr>
</tbody>
</table>
4.4 Qualitative interviews: Overall thematic findings

The qualitative interviews aimed to explore the reasons women give for their communication preferences in more detail, contextualising this within the individual patient experience. The data from these interviews was explored using thematic analysis (see section 3.7.2 Interviews in this chapter for details of the analysis process). The thematic analysis involved a second reviewer (DE) for discussions about coding, category and theme decisions. There were no discrepancies encountered during this process. From the thematic analysis of the data, three key themes were found in relation to reasons for communication preferences and experiences of receiving results from screening. The three themes were:

- Convenience – practical reasons for preferring to be telephoned
- The emotional experience – individual differences in responding to results (composed of three components)
  - Waiting
  - Asking questions
  - Perceptions of breast screening and cancer
- The importance of being prepared

I will now discuss each theme, providing examples to illustrate the findings.
4.4.1 Convenience – practical reasons for preferring to be telephoned

The first theme was related to the convenience associated with receiving results by telephone, as opposed to receiving results in-person. For women who expressed a preference for telephone communication, the reasons given were primarily practical and related to convenience. These reasons included knowing the way around the hospital, travel and parking, saving time and money, time off work and issues with receiving a result when away on holiday.

Women perceived hospitals to be busy places that are not easy to access. One woman said she preferred telephone results because in-person ‘you need to know your way around’ the hospital (PID 009, received in-person, preferred telephone). Women also commented on how telephone results may save them time, relating this to the length of time taken to travel to an in-person appointment and the issues of parking at a busy hospital.

“I had to make sure I got there early enough to get a parking space so that I had time to find a parking space so I was early there” – PID 009

“It’s a journey for me where I live in a rural area so for me to go for my result is about an hour and a half to the hospital” – PID 207

Women commented on how telephone results have the potential to save the NHS time and money, which can be redirected to patients who need further help and treatment:

“The health service diverting time and money where it can save it really is what I’m interested in doing because it’s not just my time and money, it’s the health services time and money and the focus should be on those that need the help, that need the treatment” – PID 009
Taking time off work was an issue raised by some women. One woman (PID 207) said that ‘you don’t always necessarily have a job where you can’ take time off work and ‘if you have to take time off work it can also be quite stressful’. However, another woman (PID 009) said that, although taking time off work was ‘a little inconvenient… it was easy enough to do’. One woman (PID 457) preferred telephone results because she knew she ‘couldn’t be at the appointment in-person’ due to going away on holiday.

4.4.2 Summary
Overall, the reasons women gave for preferring telephone results appeared to be related to the inconvenience associated with an in-person appointment. For these women, telephone results offer a practical solution and also saved the NHS time and money.
4.4.3 The emotional experience – individual differences in responding to results

The second theme related to the emotions experienced during screening and receiving a result. Through this theme, it became clear that women experience receiving results in different ways. The majority of women said they felt ‘relieved’ when the results were received. However, one woman stated that she was in ‘awful shock’ (PID 207). The emotional experiences demonstrating the individual differences in the interview data fall broadly into three component parts: waiting, asking questions and the link between screening and cancer.

Waiting

One woman (PID 355) commented that she preferred telephone results because she ‘didn’t have to wait a long time for the results’. Another woman spoke about her experience of receiving results by telephone and how receiving her results earlier helped to relieve her anxiety:

“I think I didn’t realise how much it must have been on my mind, I was just trying to play it down a bit because you just weren’t sure if it was cancer or not and it was going to be another week before I could get the actual face to face appointment so over the phone it was a great weight had been lifted off my shoulders when she said it was all clear.” – PID 457

One woman said that waiting for results ‘was the worst bit’ of the screening experience. Despite this, she still expressed a preference to receive results in-person. For her, the extra waiting time in the clinic to be seen in-person was not a factor in her preference:

“To ME it doesn’t matter how long you wait, whether it’s a doctors surgery or whatever I feel that I’ve been given extra time when I’ve needed it so I don’t mind waiting, and some people go ‘it’s a minute past my appointment, why haven’t I been seen?’ But I’m not like that, I appreciate that the system doesn’t work like that.” – PID 455
The potential for telephone results to be quicker was stated as one of the main reasons for preferring the method. However, one women identified that telephone results themselves could cause anxiety in another way, with women waiting anxiously for the telephone to ring:

“It was just the apprehension really and then they said I might get a call so I was hanging with my phone wherever I was going, I was making sure I could hear it. Making sure that if I did get a call I didn't want to miss it.” – PID 457

Another women expressed the opposite opinion and did not feel nervous about waiting for a call:

“I didn’t know whether the phone was going to ring or what was going to happen so [...] I wasn’t sat worried about the whole thing.” – PID 451

One woman identified an issue with telephone results, if women were aware they might receive results this way:

“If you tell somebody that you’re getting an appointment, not getting an appointment means everything is alright but if it was bad news, you’re getting an appointment, everybody would know that they were having bad news before they’d got there so it’s a bit of a catch 22 really isn’t it? […] If I’d have got that phone call to say here’s your appointment, obviously then I would have known there was something wrong before I got there.” – PID 455
Asking questions

One woman (PID 009) said she preferred telephone results and ‘would have been happy to have [her results] by phone’. Her reason for this is that she ‘didn’t really have any questions’ she wanted to ask. Another woman (PID 451) expressed a similar viewpoint and said she did not feel the need to ask questions. When asked why she thought this was, the woman said ‘partly it was relief… I was partly just a bit stunned’.

One woman had an emotional response to being asked if she had enough time to ask questions:

“Erm no I wasn’t in the [gets upset], I’m sorry [crying]. I was just too emotional really to ask anything.” – PID 207

Perceptions of breast screening and cancer

Throughout the interviews, several women mentioned feeling ‘worried’, ‘nervous’, ‘anxious’ and ‘apprehensive’ about what their screening result might be. One woman said:

“I was more concerned about, if the results were bad, how I was going to tell my son so that’s what was on my mind more than anything.” – PID 455

Women made the link between screening and breast cancer, and were concerned about their screening outcome. For one woman, this was the reason why she stated a preference for results being delivered in-person:

“I think it’s quite a serious thing, I think we all speak a lot about cancer, people you know refer to the ‘c word’ and I think it just feels more appropriate to have that communicated face to face. I just think maybe we’re just not ready for a telephone confirmation yet.” – PID 451
Despite some women feeling very anxious and worried about the possibility of a cancer diagnosis, some women were less impacted by this experience:

“I suppose at the time I felt confident that there wasn’t anything. I didn’t think the biopsy would come back as abnormal… I did have anxiety, probably a little bit less than other people because I sort of felt it was all going to be alright.” – PID 355

4.4.4 Summary
There were two clearly different emotional responses to receiving a screening result. All women felt anxious, but some women felt more confident that their outcome would be benign. Others felt highly anxious about a potential cancer outcome and this factored into their preference for receiving results in-person.
4.4.5 The importance of being prepared

Women commented that they felt well prepared to receive their results because of how well the screening process was explained. When discussing their experience at breast screening, women commented about how well the staff explained everything:

“I found them all very approachable and they explained everything, about the steps and why I was going in to one room, why I was waiting in-between, and who I would be seeing next and then when I was seen next and that person explained why I was seeing them and so on. So it was all very easy to understand even in layman’s terms. There wasn’t anything that I didn’t understand because they made a point of making it easy to understand.” – PID 455

“I had two very nice nurses who talked me through all the time and explained everything that was happening.” – PID 357

Some women did not have any questions they wanted to ask during the results appointment or telephone call because they felt well prepared throughout the screening process. One woman said:

“The results could have been explained in a similar way by telephone because I’d had such good communication in the run up to it.” – PID 009

This highlights the importance of how women are prepared for their result, by taking time to explain things well throughout the screening process.

4.4.6 Summary

If a woman feels well prepared for her result, she may prefer to hear this news by telephone and not have any further questions to ask. These findings highlight the importance of how women are prepared for their result, by taking time to explain things well throughout the screening process. This may be more important than the method used to communicate the results.
4.5 Integration of quantitative and qualitative findings

Most women attending and receiving results from breast screening preferred telephone communication at both study time points (69.3%, 57.9%). The main reasons for this preference related to the perception that telephone results are more convenient than attending in-person. The factors associated with the convenience of a telephone call included travel, saving time (for the NHS and the woman), not having to take time off work and telephone results being quicker. Distances to travel varied but some women travelled up to 42 miles to attend screening.

However, although most women preferred telephone results, some women preferred in-person results. At both study time points, some women expressed a preference for in-person communication (24.8%, 31.6%). The factors associated with preferring to receive results in-person included being able to ask questions more easily, wanting a more personal encounter with a friendly staff member, receiving results in a safer location and avoiding the miscommunication that is associated with telephone communication.

Reducing anxiety was a reason that women gave for both in-person and telephone communication preferences. In this split, women who preferred telephone believed that telephone results would reduce their anxiety by limiting the amount of time spent anxious waiting. Women who preferred in-person communication seemed to want more reassurance about their results. They believe that in-person results offer more emotional support at an anxious and uncertain time, when facing the potential of a breast cancer diagnosis. They also felt that it is easier to ask questions when seen in-person. Women who preferred in-person communication also highlighted that waiting for telephone results may have unanticipated consequences for anxiety. This included the negative impact of waiting for a telephone call that never comes.

Some women commented that their preference for communication was linked to how well prepared they felt to receive their results. These women felt that everything had been explained well to them throughout the screening
process and, therefore, the results could have been delivered by telephoned as no further questions were necessary.
5. Discussion

Overall, women prefer to be telephoned with benign biopsy results from breast screening due to telephone results being more convenient. However, some women still preferred to be contacted in-person, even with good news results. The findings from this study suggest that there are two different experiences of receiving a result from screening, which may impact upon what method of communication women prefer in this context. These two experiences were ‘the practical experience’ and ‘the emotional experience’. This is supported by previous research which has found individual differences in anxiety, with some women being less anxious (or not anxious at all) in comparison to other women (51, 241).

The ‘practical experience’ is had by women who appear to be less anxious about their screening outcome. Although all women in the study mentioned feeling some degree of anxiety during screening, some women appeared to cope better with this anxiety. These women preferred to receive telephone results and gave reasons for their preferences that were practical and based on convenience. Linsell et al. found similar convenience based preferences when women were asked about where they would prefer to attend breast screening, with factors such as travel being important (175). Choudhry et al. also found similar reasons for preferences given by patients receiving skin biopsy results (119). This was supported by the current study in the opinions given by women but also the large distances to travel to the centre.

‘The emotional experience’ is had by women who appear to be more anxious about their screening outcome and the potential of a cancer diagnosis. These women preferred to receive in-person results and gave reasons for their preferences that were based on emotion. Previous research has found that patients who are more anxious prefer to be seen in-person with results (117, 142) and this may be due to wanting a clearer explanation of results (278) which provides more reassurance. This may also relate to the uncertainty associated with the breast screening process.
Before screening, women begin in a state of certainty, identifying as healthy individuals and experiencing low levels of anxiety. However, after attending screening, women have moved towards a state of uncertainty and high anxiety (Figure 16). This may be due to the disruption of their ‘healthy identity’, with recall from screening causing women to associate with a ‘breast cancer identity’. This was seen in the current study, as women were concerned about how they would tell their family if the results were cancer. These women were mentally preparing themselves for a cancer diagnosis and experienced heightened anxiety.

![Figure 16: Model of uncertainty in population-based screening programmes (adapted from Marteau, 1994)](image)

For women attending breast screening, receiving good news should facilitate a return to the ‘healthy identity’ and a reduction in anxiety (38, 43). Therefore, the communication method used to deliver results should bridge the gap between uncertainty and certainty (333). The findings from this study suggest that some women return to a ‘healthy identity’ more easily, thus preferring telephone results as a more convenient option. Some women, however, find the return to a ‘healthy identity’ more difficult. These women
require more reassurance to bridge the gap between uncertainty and certainty, preferring to receive results in-person.

Women who preferred telephone results felt that everything had been explained to them throughout the screening process. Women said that the different stages of the assessment were described using lay language and that they understood what was happening and why. It may be that these women felt reassured by this information which made them feel more certain and less anxious. Therefore, these women felt well prepared to receive their result, regardless of the method of communication used.

Preparation may also explain why some women felt ‘shocked’ when receiving good news by telephone. If women are given an appointment to attend in-person to receive results, but instead get telephoned ahead of this appointment, this is unexpected. Some women may experience this positively, feeling relieved and having spent less time anxious waiting. However, some women might not have been prepared for this unexpected telephone call, being left with unanswered questions and remaining in a state of uncertainty. Knowing how and when results will be received may offer a sense of certainty during an uncertain time.

5.1 Strengths
The combination of quantitative and qualitative methods gave a deeper understanding of women’s communication preferences for receiving a breast screening result. Binary preferences alone were insufficient in capturing the nuances of preferences, with women annotating the survey in order to answer the question in their own way. Considering preferences within the context of experiencing a screening result gave more insight into why women prefer one method of communication over the other.
5.2 Limitations

Women were not recruited into the trial if they were extremely anxious on the day of the assessment clinic, in order to reduce the harm associated with conducting the research. However, this means that the sample of women involved in the research may be less anxious than the general breast screening population. This is important to consider when interpreting these results, as anxiety played a key role in reasons for communication preferences. Furthermore, women who had a family history of breast cancer were also excluded. It is possible that women with a family history may be more anxious when attending breast screening than women attending asymptptomatically with no previous experiences of breast cancer. Based upon the findings from this study, the sample recruited may be biased towards preferring telephone communication due to feeling less anxious.

There may have been a bias in the study population towards telephone results, as women had to consent to being randomised to either telephone or in-person as part of the trial. If they did not consent, they received their results in-line with the usual practice at that centre. For most women, this meant receiving a result in-person. Therefore, the sample may be biased by only including women who did not mind being contacted by telephone. It is possible that, if all women attending were recruited, the split between telephone and in-person preferences might be more equal or in favour of in-person communication. This has been seen in previous research in disclosure of genetic testing for breast cancer (173).

The interview sample size was small, although findings were integrated with survey data containing a larger number of participants.
6. Conclusion

Communication preferences for how breast screening results are delivered differ between individuals, with some women preferring telephone and some women preferring in-person. Women who prefer telephone results cite practical reasons for their preferences and seem to experience less anxiety. Women who prefer in-person results cited more emotional reasons for their preferences, experiencing heightened anxiety and needing more reassurance.

The NHSBSP should be aware of the individual differences in patient preferences and consider these differences in relation to the communication methods used. Consideration should be given to preparing women well for their result. This is particular important in resolving the uncertainty that women experience during breast screening. The implications of these results for communication policy in the NHSBSP will be discussed in more detail in Chapter 7.
7. Chapter conclusion

In this chapter, I have presented the findings relating to patient preferences. This included quantitative and qualitative preference data from the Phase 3 surveys, and qualitative interview data from Phase 4. I have reported the number of women who prefer each method of communication (telephone versus. in-person) and presented the reasons women gave for their preferences. I also reported the thematic findings from the qualitative interviews, which revealed two different experiences of receiving results and added further details to women’s reasons for communication preferences. I discussed how communication preferences may relate to the uncertainty women experience during breast screening.

In the next chapter, I will summarise and synthesise the findings from each chapter of the thesis, discussing the overall implications of this research.
CHAPTER 7: Discussion, conclusion and implications for policy
1. Chapter introduction

In this chapter, I will synthesize the findings of the thesis and draw overall conclusions. I will begin by providing an overview of the research. Next, I will summarise and synthesise the key research findings. Then, I will report the overall strengths and limitations of the thesis. Following this, I will provide policy recommendations and ideas for future research based on the thesis findings. Finally, I will draw my overall conclusions and summarise the contribution of the thesis.
2. Overview of the research

This thesis aimed to investigate the impact of the communication method used to deliver results on patient anxiety, understanding of results and preferences for communication in the NHSBSP. The research was conducted in five phases, addressing the following research objectives:

PHASE 1: Systematic review (Chapter 3)

- Objective - To systematically review research exploring which communication methods are used for the delivery of results in cancer screening programmes, and how women prefer to have their results delivered
- Objective - To systematically review evidence of how the communication method used to deliver results impacts upon attendee anxiety and understanding of results

PHASE 2: Centre survey of current practice (Chapter 4)

- Objective - To survey breast screening centres to record how often telephone results are delivered and who delivers these results, for benign and cancer screening results.
- Objective - To compare the time taken to deliver a result by telephone versus. results delivered in-person

PHASE 3: Cluster randomised crossover trial (Chapter 5a & 5b)

- Objective - To compare the immediate and long-term effects of communication method (telephone or in-person) on the anxiety experienced by women receiving a benign biopsy result from breast cancer screening using a cluster randomised crossover trial
- Objective – To compare the effect of communication method (telephone or in-person) on how well women understand their benign biopsy result from breast cancer screening using a cluster randomised crossover trial
PHASE 4: Communication preferences: surveys and interviews
(Chapter 6)

- Objective – To survey women attending breast assessment to record their communication preferences, before and after receipt of a benign biopsy result
- Objective - To interview women who have received a benign biopsy result from breast screening to explore their reasons for communication preferences

PHASE 5: Integration (Chapter 6)

- Objective - To integrate the data to explain communication preferences and expand on reasons for these preferences

To address these objectives, several different methods were used. This included a systematic review, surveys, a cluster randomised crossover trial, qualitative telephone interviews and a mixed-methods synthesis.
3. Summary and synthesis of research findings

3.1 Uncertainty and ‘bridging the gap’
Northouse et al. (334, 335) said that ‘a benign biopsy is not a benign experience’. In Chapter 1 of the thesis, the association between anxiety, the healthy identity and uncertainty was discussed. The overall findings of this thesis link with previous research which has investigated how people navigate uncertain situations (333). Women attend screening as asymptomatic and ‘healthy’ individuals. The abnormal mammogram disrupts this perception and leads to a conflict of identity (22, 38, 42, 51). Poole et al (334) describe the uncertainty of awaiting medical results as ‘a stormy ocean through which people are buffeted and tossed, until they are washing upon the shore of either kingdom: the well or the sick’. In the context of breast screening, the process of recall, assessment and receiving a result is a journey of uncertainty for women (301).

My thesis hypothesised that the communication method used to deliver results acts as a ‘bridge’ between uncertainty and certainty (see Figure 17). Women who have attended breast assessment perceive receiving results as the critical link to their future (26). Some women receive results and return easily to the ‘healthy identity’, successfully ‘crossing the bridge’ (38, 43). Some women do not manage to ‘cross the bridge’, experiencing continuing uncertainty and anxiety. Different methods of communication may be metaphorically different ‘bridges’, facilitating or hindering the return to certainty and the healthy identity. For example telephone results may lack clarity and prevent the return to certainty. On the other hand, in-person results may be slower, thus preventing the timely return to certainty. In this thesis, I investigated the difference between the ‘bridges’ of in-person and telephone communication.
The findings from all research phases of the thesis were taken into consideration and narratively synthesised. Overall, there were four key findings from the thesis: 1) There is an overall lack of evidence-based research about the impact of communication methods used to deliver results in breast cancer screening, despite policy recommendations and current practice; 2) Despite some women preferring quicker results, telephone results might not reduce anxiety overall; 3) Women have practical and emotional reasons for their communication preferences, which might be linked to their anxiety; 4) If unexpected, telephone results may cause heightened anxiety and uncertainty after breast screening assessment.

Figure 17: The 'bridge' between uncertainty and certainty. A visual representation of how communication method bridges the return to certainty and the healthy identity
3.2 Finding 1: A lack of evidence about the impact of communication methods

In the thesis, the Phase 1 systematic review identified very few articles exploring the impact of communication methods in cancer screening. This was even more limited when considering the impact in breast screening specifically. The main finding from the review was that there was a lack of evidence, particularly when comparing telephone and in-person communication which tended to be considered jointly as ‘verbal methods’. Despite this, evidence from other areas of the thesis show that there are individual differences in the experience of receiving results from the breast assessment clinic, which may be associated with anxiety, understanding and patient preferences. This is adds to the wider research literature discussed in Chapter 1, which showed mixed findings for differences between in-person and telephone methods of communication (see section 1.4.4 in Chapter 1).

This holds significance due to the current discord between NHSBSP communication policy guidelines and how centres already deliver results in practice, as seen in the results of Phase 2. There is a gap in the research, which needed to be addressed in order to minimise negative psychological outcomes for women attending breast assessment. This highlights the importance of adding to the research evidence in this area, evaluating the impact of communication methods in breast screening and considering why communication methods for delivering results matter in the current context. Future research should consider further investigating the impact of communication methods in this setting and also in other screening programmes.
3.3 Finding 2: Telephone results might not be quicker or reduce the anxious wait

During Phase 2 of the thesis, the findings showed that the majority of breast screening centres in England routinely deliver benign results by telephone. Some centres justified this decision as wanting to deliver results more quickly to women and reduce the amount of time spent anxiously waiting. Previous research states that speed is a key advantage of telephone results (117, 119, 134, 145, 147, 148), although some studies found no link between quicker results and a reduction in anxiety (64).

In the thesis, during Phase 3 and Phase 4, some women identified speed as one of their main reasons for preferring telephone results, wanting to spend less time anxiously waiting. However, not all women prioritised speed. Some women preferred to be seen in-person even when the results were good news. This supports previous research, which has found individual differences in preferences for results communication with some women valuing speed and some women being willing to wait longer for their results to be seen in-person (118). This is a finding that is not supported by some of the previous research, which retrospectively measured anxiety and communication preferences. The prospective measurement of these outcomes in the current research adds to the literature and minimises the biases associated with retrospective recall.

Despite speed being a justification for centres providing telephone results and some women preferring quicker communication, the findings from Phase 2 of the thesis indicated that telephone results might not be delivered sooner than results in-person (see Chapter 4, section 5.2.4 Time difference – telephone results vs. in-person results). Reasons for this lack of time difference were not explored in this thesis. More research is needed to investigate the speed of results delivery in breast screening and whether this differs between telephone and in-person communication. Future research should also consider potential reasons for any time differences.
3.4 Finding 3: The link between anxiety and communication preferences

In this thesis, a key finding suggested that there is a link between how anxious women feel and they prefer to receive results. The findings from Phase 5 of the thesis suggested that there are two different types of reasons that women give for their preferences; practical and emotional (see Figure 18). Women who prioritise practical reasons for their preferences (such as travel and parking) tend to be less anxious about receiving their result. Women who prioritise emotional reasons for their preferences (such as wanting to see a friendly face or desiring further emotional support) tend to be more anxious about receiving their result (117). These women are more likely to prefer in-person communication. This is finding which is supported by previous research, which has found a link between heightened anxiety and a preference for in-person disclosure of genetic testing results (336). This also links to the recruitment challenges faced in Phase 3, where some women did not want to participate due to their high levels of anxiety and subsequent preference to be seen in-person (173, 336).

A possible reason for this association between heightened anxiety and a preference for in-person communication may link to certainty. Based upon the thesis findings and previous research, when women feel uncertain about their breast assessment outcome they will experience anxiety (66, 333). This anxiety leads to women favouring an in-person preference, due to emotional reasons. Women might feel it is easier to ask questions in-person than over the telephone, which may help to resolve their uncertainty (145). Even if when the result is ‘good news’ (benign), these women may prefer in-person results as they provide more reassurance. Conversely, women who feel more certainty and stability might not need to ask questions, instead favouring telephone results which are quicker and more convenient.
Figure 18: How emotional and practical reasons for communication preferences may be influenced by uncertainty/certainty and anxiety/stability
3.5 Finding 4: Unexpected telephone results in a time of uncertainty

Women receiving a breast assessment result may experience heightened uncertainty and anxiety (301). This was reflected in the thesis findings, particularly from Phases 4 and 5. When some women recalled receiving their benign result, they were emotional and audibly upset, despite expressing ‘relief’ at not having cancer. The thesis findings suggested that some women were upset because they did not expect to receive their result by telephone, due to an in-person appointment already being arranged during the assessment visit. This process of arranging results appointments in-person but then telephoning unexpectedly is common practice, as shown in Phase 2.

Some women were grateful to receive their results sooner. However, some women were ‘shocked’, feeling that they were not in the right location or the right frame of mind to receive their results. This is supported by previous research, which has found that patients who receive results in private locations, may be able to absorb information more clearly, may feel less anxious and also feel more valued (147, 151). Previous research investigating how a prenatal Down syndrome diagnosis should be delivered to expectant mothers, found that mothers were able to prepare themselves for telephone results if this was a pre-arranged telephone appointment. However, women who received an unexpected telephone call experienced intense resentment towards their healthcare professionals (156).

For women, it seems that being told upfront about the communication method of results delivery can offer a sense of certainty during the uncertainty of the breast screening process. This was reflected in the findings from Phase 3, where some women declined participation in the trial due to wanting to be told for certain how their results would be communicated and where they would be when they received this news.
4. Discussion

The aim of this thesis was to investigate the impact of communication method used to deliver results (telephone vs. in-person) on patient anxiety, understanding of results and preferences for communication in the NHSBSP. The low recruitment in the trial meant that a statistical comparison could not be made to identify the differences in patient outcomes between in-person and telephone results. The implication of the low recruitment means that the findings from this thesis should be considered with caution. However, this thesis has still highlighted the potential negative impact that unexpected telephone results may have on some women. Furthermore, this thesis highlights that some women who are more anxious tend to prefer in-person communication, in order to provide further reassurance. This warrants further exploration in the future and an opportunity to offer feasible recommendations to the NHSBSP, for improving results communication for attendees.

One finding of this thesis is that most women want to know how they will receive their breast assessment result, as this provides some form of certainty in an uncertain and anxious time. For the NHSBSP, this desire for certainty is an issue. To accommodate this desire for information on how results will be communicated, the NHSBSP could consider standardising the mode of delivery, informing all women that they will be telephoned with their biopsy result. However, as biopsy results are unknown at the time of assessment, standardising telephone communication would inevitably involve telephoning women who have cancer. During this phone call, women could receive a cancer diagnosis. Although research suggests that some women may prefer to receive their cancer diagnosis sooner by telephone (337), receiving results in this way may be perceived as lacking empathy and not providing enough emotional support. Alternatively, the telephone call could be used to invite the woman to receive results at the clinic. However, in this thesis some women said that, although the result would not be confirmed by telephone, they would assume that they had cancer. Women also stated that they would prefer to receive a cancer diagnosis in-person. Therefore,
standardising telephone communication for all women could cause additional anxiety for women receiving a cancer biopsy result.

Another option could be to deliver all results in-person. However, from the Phase 2 findings of this thesis, we already know that centres routinely deliver telephone results. Standardising in-person results and removing telephone results services may not be possible in the NHSBSP due to logistical reasons such as provision of clinic space, staffing and training (31). Previous research has shown that using telephone clinics can reduce the burden on staff and minimise the impact on workflow of patients who do not attend their appointments (135).

Taking the above into account, recommending the standardisation of one communication method over another is problematic. However, if one method is not recommended then current practice for most NHSBSP centres will remain as unexpected telephone results. The findings of this thesis suggest that this is not the best approach due to the additional anxiety this may cause for women.

4.1 Preparation, support and follow-up
A recurring theme throughout the thesis findings was providing preparation, support and follow-up for women receiving a biopsy result from breast assessment. Preparation relates to the information women are given during breast assessment, allowing women to prepare for their future result. Support relates to the clarity of the information women are given during the communication of results, allowing women to understand their result and feel able to ask questions. Follow-up relates to providing opportunities for further information and support for women who may still feel anxious about their experience at breast screening. Preparation, support and follow-up may provide insight into how to resolve the issues faced when considering the best method to communicate biopsy results.

In Phase 4 of the thesis, some women said they felt well prepared to receive their biopsy result. They felt everything had been well explained at the breast
assessment visit and therefore felt able to understand their results, regardless of the method of communication used. This prepared women to feel able to cope with their breast assessment outcome, allowing these women to remain separate from the ‘cancer identity’, remaining emotionally stable and returning to certainty. Previous systematic review findings have suggested that waiting for results sustains anxiety rather than increasing it (26). This implies that reducing anxiety at breast assessment via preparation will reduce the overall anxiety women experience when waiting for results. The need for psychological support prior to breast biopsy has also been highlighted by other research (15, 22, 338-340).

The findings from this thesis also suggest that providing follow-up support may be beneficial. In Phase 2, some centres who routinely telephone benign results offer women the option to still attend in-person if they require further support. Some women take this opportunity in order to discuss their results further and ask questions. Further support was also an idea raised by women in Phase 5, who liked the idea of a follow-up letter or even a telephone number they could contact if they had ongoing concerns.

4.2 How this relates to communication method
This thesis demonstrates that preparing women for their results, providing support during the results appointment and providing follow-up reassurance may mitigate the anxiety associated with receiving a breast biopsy result and facilitate the return to the ‘healthy identity’. Reducing anxiety may allow women to cope with unexpected telephone results. The reason for this that women who feel more prepared, certain and emotionally stable will require less reassurance when receiving results. This may allow women to have a positive experience with receiving a benign biopsy result by telephone. This is reflected in the findings from Phase 5, which suggested that women have either emotional or practical reasons for preferences, with anxious women preferring in-person communication. Reducing anxiety at breast assessment, during results and after results are received may improve the overall
experience for women. This will also facilitate the use of telephone results services whilst minimising patient anxiety.

This can be explained theoretically by revisiting the ‘bridge’. The purpose of a benign result is reassured these women and to bridge the gap between uncertainty and a return to certainty and the healthy identity. Preparing, supporting and providing follow-up for these women may allow women to ‘cross the bridge’ successfully, regardless of the method of communication used (see Figure 19).

Figure 19: The ‘bridge’ between uncertainty and certainty. A visual representation of how preparation, support and follow-up facilitate the return to certainty
5. Strengths and limitations

Throughout the thesis, the strengths and limitations of each study have been detailed. In this section, I highlight the overall strengths and limitations of the thesis.

5.1 Strengths

This thesis used a multimethod approach to data collection and analysis including staff surveys, patient surveys and patient interviews including both quantitative and qualitative data. This approach is the main strength of the thesis as the multiple methods used allowed for the exploration of a complex topic, spanning several disciplines including health screening, psychology and communication. I used a multimethod approach in this thesis to triangulate the data, creating new knowledge through the integration of several phases, increasing the completeness of the data and confidence in the findings (244). This approach helped to add depth to our understanding of women’s preferences for communication methods, which could not have been answered by quantitative data alone (188, 247, 248, 250). The qualitative data revealed that communication preferences are not only individualised, but also complex. For example, some women expressed a clear preference for telephone results but, once they acknowledged the difficulties in scheduling these appointments, stated a new preference for in-person results. The qualitative data also helped to summarise the two different approaches to reasons for preferences, which adds our understanding of how women navigate the uncertainty of the results giving process.

Although recruitment targets were not met (see 4.2 for further discussion), the challenges faced during this thesis add to our understanding of research in this population. There is much to be learned from the reason’s women gave for declining participation, which may help guide the design of future research projects in this area. Furthermore, the reasons women gave were intrinsically linked to the research question (for example, preferring a certain
method due to levels of anxiety or a desire for certainty). This added knowledge to a previously unanswered and unexplored area of research in a different way than anticipated. This validates the research question as valuable and may inform future studies exploring communication methods used in the delivery of results.

A strength of the thesis was the measurement of anxiety and preferences at multiple time points. By measuring anxiety prospectively, this helps to limit the impact of selective memory or recall bias. Furthermore, measuring preferences at multiple time points allowed women to choose a preference both before and after results were known. Women also gave qualitative reasons for their preferences at both time points. If women had only been asked for their preference after results were received, the knowledge that this was ‘good news’ may have impacted their decision. By measuring preferences during the time of uncertainty, this reflects how women think and feel at breast screening assessment about how their results will be delivered. This reduced the possibility of recall bias.

My background in psychology and health psychology could be considered as a strength of the thesis. I was able to draw upon this background to make decisions regarding the approach and design of the research. My professional background also allowed me to approach the research in a sensitive way. There is the potential that my approach may be biased based upon on my professional background, which may have influenced how I interpreted the results, particularly from the qualitative interviews. However, this bias was limited by involving second researchers in the coding and interpretation of findings.

5.2 Limitations
The main limitation of the thesis was the low sample size in Phase 3, which meant a statistical comparison between telephone and in-person results could not be made. One reason for the low sample size was the overestimation of the number of benign participants available. This was
estimated during study design via collaboration with NHSBSP staff and cross-referencing with historical data. However, during the study itself, staff noted that there were less eligible participants than originally anticipated. Previous research has reported that trials often overestimate the sample available (317, 318). Under other circumstances, the trial may have been extended to allow for further recruitment. However, this was not possible due to the time restrictions of the PhD.

Another reason for the low sample size was recruitment challenges. Many women who were approached for the study declined participation. This was due to factors such as anxiety, having a preference and wanting to be told for certain how results would be communicated. Although the reasons for declining gave insight into the impact of communication methods in this setting, such as the association with uncertainty, this was not the original intent of the study. Staff also commented that there were logistical issues in identifying eligible participants due to the time restrictions of the assessment clinic. It may also be possible that staff were demotivated by the lower number of eligible women and the number of women declining participation. Although efforts were made to keep staff engaged in the research, this may have had an impact on recruitment.

The sample that was recruited for Phases 3, 4 and 5 might be unrepresentative due to several reasons. Firstly, complex cases (such as women receiving repeat biopsies) were not included in the sample. This happens commonly in breast screening and therefore, the experiences of these women were not included in the thesis.

The sample was homogenous in terms of ethnicity, with most of the participants being White British. This is not representative of the range of ethnicities in the UK (341). The inclusion criteria used meant that non-English speakers were excluded. Due to this, important issues associated with communication and translation issues when involving non-English speakers in the NHSBSP could not be considered. There may also have been important cultural differences in the experience of breast screening, anxiety and the healthy identity that this thesis cannot address.
The sample was more representative in terms of participant’s educational background. However, a larger sample would help to determine if any differences in understanding of results are related to participant education. This is a finding seen in other research literature (21).

The sample might be biased as very anxious women were not recruited into the study. This was due to this approach being deemed unethical, approaching women during this uncertain time and adding additional anxiety. Staff used their clinical judgement to decide when it was inappropriate to recruit women into the study. Therefore, the sample will be less anxious than the general breast screening population and the findings may not be representative. It is possible that women who were not recruited had a preference for in-person communication due to feeling more anxious and perhaps requiring further reassurance. If this was the case, the split between telephone and in-person preferences for communication might have been more balanced or even in favour of in-person communication.

The Phase 3 study used a validated measure of breast-cancer specific anxiety, the PCQ (90). Although this measure has been used successfully in previous research (15, 85), there were a few issues in the current study. Firstly, the use of a self-report measure of anxiety might not truly reflect the experience of women. For example, in the interviews, some women discussed their experiences with more references to anxiety than anticipated based on their PCQ outcome. A further issue with the PCQ was that several participants did not answer all questions on the scale. We do not know if this was due to the survey layout or the content of the questionnaire itself. However, this led to the exclusion of several participants from the analysis due to incomplete data. This is important to consider in the design and selection of anxiety measures in future research.

Finally, although the ‘healthy identity’ was used throughout this thesis to describe the emotions experienced during screening recall and receiving a benign result, it is important to acknowledge that this may not apply to all women. For example, some women may attend asymptomatic screening when prompted by symptoms. Some women may have other health co-
mORBIdities. Some women may know close friends or family members who have experienced breast cancer. Therefore, these women may have different perceptions of their own health identity and also different perceptions of breast cancer itself, which may impact upon their anxiety, understanding of results and also preferences for communication. The ‘healthy identity’ and bridge model proposed by this thesis, may be too simplistic to explain the experience of all women who attend breast screening.
6. Policy recommendations and future research

The intention of the thesis was to explore the impact of the communication methods used to deliver results in the NHSBSP. The aim was to use the findings of this thesis to inform future policy guidelines. Due to the low sample size recruited in the main trial and telephone interviews, findings and recommendations should be considered with caution. Further research may be required to determine the best approach for improving the communication of benign biopsy results in the NHSBSP.

Reversal of telephone results services may not be feasible in the current context of the NHSBSP. Due to the large number of centres already providing telephone results, there may not be adequate resources (e.g. space, staffing, training) to deliver all results in-person. Therefore, I have made the following recommendations based upon the findings of this thesis, aiming to be feasibly implemented within the current context of the NHSBSP.

Based on the findings from this research, three key recommendations are made. Firstly, I recommend that staff focus upon preparing women at breast assessment to facilitate certainty and understanding. This may allow women to feel reassured, less anxious and therefore able to cope with an unexpected telephone call. There are often time pressures in the assessment clinic, so to achieve this would require careful workforce planning.

Secondly, when telephone results are used, I recommend that support is provided. This would involve emotional support during the telephone results (e.g. checking how the woman is feeling) and confirming verbal understanding of the outcome of results. This may help to alleviate anxiety when receiving results and may also facilitate women to be able to ask questions over the telephone if they have any concerns.

Thirdly, in the telephone call, women should be offered the opportunity of a follow-up appointment to explain the results in-person if they wish. As demonstrated in the findings from Chapter 3, some centres already offer this
appointment, but this is not standard practice. My findings suggest that a subset of women experience heightened anxiety, and an extra appointment may be necessary for these women to achieve a return to the healthy identity. This would also provide an extra opportunity to ensure understanding, although such as opportunity might not be taken by women who have misunderstood their results, as some in our study did not realise they had misunderstood.

I also recommend that these telephone appointments are followed-up by a confirmatory letter. This may help to alleviate any lingering doubts or anxiety associated with an unexpected telephone call, and importantly give a second opportunity to achieve correct understanding. This is a process currently used by some centres and is recommended in the breast screening specification. However, my research found that not all centres implement follow-up letters, with some women suggesting this as an area for improvement.

There are several future directions for research that are important in this context. Firstly, a further exploration of patient choice. Secondly, the consideration of ‘new’ methods of communication such as Skype and email. Thirdly, the improvement of auditing telephone results services.

6.1 Patient choice
Throughout the current study, women and NHS staff mentioned the option of patient choice. Some centres already offer women a choice of how they would prefer to receive their breast assessment result. Giving women a choice would remove unexpected telephone calls from current practice and potentially give women a sense of certainty and ownership about their results. The difficulty would be that some women may choose to be contacted by telephone, who then are given a cancer result. However, this is how some centres already deliver results. These centres suggest that, with appropriate support and counselling beforehand about the possibly of a cancer result by telephone, women can make an informed decision about
their communication preferences. However, findings from this thesis suggest that some women just want to be told how they will receive their results from screening. During Phase 3 women also did not want to participate in the trial due to an overload of information. Future research should consider exploring the impact of choice in this context, including how women make this choice and if women can understand the information given to make an informed decision.

6.2 Email and Skype results
Healthcare communication is continuing to evolve, with methods such as email and Skype being used in practice. Some research speculates that email may sufficiently meet patient needs at a much lower cost than face-to-face or telephone consultations (165). Patients appear to have become more accepting of email communication over time due to speed and convenience (116, 117, 342). However, concerns have been raised about data security issues (127, 147, 342, 343). Furthermore, although internet access has increased and continues to do so, some patients still do not have access or the skills necessary to use this technology (116, 127). This ‘digital divide’ creates issues of social inequality in the healthcare system and is something to be aware of in the future of communication (150). It is recommended that future research explores how women would feel about the use of email or Skype in delivering breast screening results before any consideration is given to these methods of communication.

6.3 Improving future audits of communication
From conversing with NHSBSP staff throughout this project, regular audits of telephone results services are conducted at individual centres. These audits show that women are satisfied with telephone results communication. However, the audits do not ask women about their preferences. Furthermore, the audits do not measure anxiety and how this might be associated with results communication. It is recommended that future research should
consider ways in which the breast screening auditing process may be improved. This would allow for regular monitoring of results communication to ensure that this process does not cause additional anxiety for women, meets their communication needs and facilitates the return to certainty and the healthy identity.
7. Conclusions and contribution of the thesis

There is currently a lack of evidence about the impact of communication methods when delivering benign breast screening results. Despite policy recommendations, most breast screening centres in the NHSBSP routinely deliver benign results by telephone, offering all women an appointment to re-attend in-person but telephoning women with a benign result unexpectedly ahead of time. The experience of attending breast screening, assessment and receiving a result is a journey of uncertainty. The communication method used to deliver a benign result acts as the ‘bridge’ between patient uncertainty and certainty. Women’s experiences of receiving a result from screening are individualised. For some women, they are less anxious and prefer telephone results as they are more convenient. Other women are more anxious and may prefer in-person results for further reassurance. Unexpected telephone results may cause additional anxiety for some women who feel unprepared for this news and might not be able to ask questions.

It is recommended that the NHSBSP focuses upon preparing women attending breast screening to help them understand the process with certainty. Secondly, when telephone results are used, it is recommended that support is provided. Thirdly, women should be offered a follow-up in-person visit alongside their telephone results appointment, followed by a letter confirming the results. These recommendations may help to reduce the uncertainty and anxiety experienced during breast screening assessment and receiving an unexpected telephone call. This may help women make a successful return to the certainty and the ‘healthy identity’. Future research should consider patient choice, new methods of communication (email/Skype) and improving the auditing of telephone results services.

This thesis has added a unique contribution to knowledge through several key outputs. Firstly, this thesis identified a gap in the literature regarding the impact of communication methods in breast screening. This is important as communication method of results delivery is a potentially modifiable factor at the screening programme level, which may have a wide-spread impact on patients. Hopefully, this research will encourage further exploration of the
communication methods used to deliver results in breast screening, not only in England but also internationally. This thesis may also promote discussion in other areas of healthcare communication.

Secondly, this thesis has recorded the current communication practice of NHSBSP centres for delivering results. This has provided clear evidence of the difference between communication policy guidelines and current practice. This will promote discussion regarding communication methods within the breast screening service.

Thirdly, this thesis has identified recruitment challenges that may be faced when evaluating results communication in the breast screening context. Future research can be designed with this knowledge in mind to further explore the interaction between patient outcomes and methods of communication.

Fourthly, this thesis has used a mixed methods design to explore patient preferences for communication which has shown the complexity of this phenomena and how anxiety and uncertainty relate to women’s experiences. This evidence allows a deeper understanding of patient preferences in this context. Furthermore, the mixed methods approach gave new insights into how women navigate the journey of uncertainty through breast assessment.

Finally, this thesis has provided feasible recommendations for future policy guidelines in the NHSBSP and offered recommendations for future research. This includes how preparation, support and follow-up might be utilised, in order to facilitate certainty, minimise anxiety and still feasibly implement telephone communication to deliver biopsy results.
References

(HADS) in different groups of Dutch subjects. Psychological medicine. 1997;27(2):363-70.


149. McQueen A. Waiting for a cancer diagnosis: Anne McQueen examines the stress that a delayed diagnosis causes patients and assesses how effective UK policy initiatives have been in speeding up cancer diagnosis and treatment. Cancer Nursing Practice. 2009;8(4):16-23.


155. van-Velthoven MH, Car LT, Car J. Telephone communication of HIV testing results for improving knowledge of HIV infection status. Cochrane Database of Systematic Reviews.1.


161. Halkett GK, Kristjanson LJ, Lobb EA. ‘If we get too close to your bones they’ll go brittle’: women’s initial fears about radiotherapy for early breast cancer. Psycho-Oncology: Journal of the Psychological, Social & Behavioral Dimensions of Cancer. 2008;17(9):877-84.


200. Schram WE. The process and effects of mass communication. 1954.
222. Wright KB. Researching Internet-based populations: Advantages and disadvantages of online survey research, online questionnaire authoring software packages, and web survey services. Journal of Computer-Mediated Communication. 2005;10(3):00-.
238. Denzin NK, Lincoln YS. The Sage handbook of qualitative research: Sage; 2011.
281. Short RG, Middleton D, Befera NT, Gondalia R, Tailor TD. Patient-centered radiology reporting: using online crowdsourcing to assess the


314. Christley R. Power and error: increased risk of false positive results in underpowered studies. The Open Epidemiology Journal. 2010;3(1).
327. Featherstone K, Donovan JL. "Why don't they just tell me straight, why allocate it?" The struggle to make sense of participating in a randomised controlled trial. Social science & medicine. 2002;55(5):709-19.
Table 1. Items and layout of the PCQ

We would like to find out about women's experiences of the Breast X-ray Program. We would therefore like you to answer the questions on this questionnaire as best you can.

Over the last week how often have you experienced the following things because of thoughts and feelings about breast cancer?

<table>
<thead>
<tr>
<th>Item</th>
<th>Not at all</th>
<th>Rarely</th>
<th>Some of the time</th>
<th>Quite a lot of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>(P) had trouble sleeping</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>(P) experienced a change in appetite</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>(E) been unhappy or depressed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>(E) been scared and panicky</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>(E) felt nervous or strung up</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>(E) felt under strain</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>(S) found you have been keeping things from those who are close to you</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>(S) found yourself taking things out on other people</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>(S) found yourself noticeable withdrawing from those who are close to you</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>(P) had difficulty doing things around the house which you normally do</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>(P) had difficulty meeting work or other commitments</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>(E) felt worried about your future</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

All things considered, would you say your experiences at the Breast X-ray Program have caused any of the following:

...
Appendix 2 – Timeline of ethical approval

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethical Approval from BSREC (REGO-2017-1908)</td>
<td></td>
</tr>
<tr>
<td>Application submitted</td>
<td>31\textsuperscript{st} January 2017</td>
</tr>
<tr>
<td>Provisional ethical opinion requiring further clarifications received</td>
<td>28\textsuperscript{th} February 2017</td>
</tr>
<tr>
<td>Application resubmitted</td>
<td>10\textsuperscript{th} April 2017</td>
</tr>
<tr>
<td>Application chased</td>
<td>27\textsuperscript{th} April 2017</td>
</tr>
<tr>
<td>Further clarifications needed</td>
<td>2\textsuperscript{nd} May 2017</td>
</tr>
<tr>
<td>Application resubmitted</td>
<td>5\textsuperscript{th} May 2017</td>
</tr>
<tr>
<td>Ethical approval granted</td>
<td>2\textsuperscript{nd} June 2017</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast Advisory Group Committee BSPRAC_0013 (ODR1718_040)</td>
<td></td>
</tr>
<tr>
<td>Confirmation of application</td>
<td>23\textsuperscript{rd} May 2017</td>
</tr>
<tr>
<td>Date for review</td>
<td>20\textsuperscript{th} June 2017</td>
</tr>
<tr>
<td>Delay of review – email from panel</td>
<td>21\textsuperscript{st} June 2017</td>
</tr>
<tr>
<td>Approval granted</td>
<td>4\textsuperscript{th} August 2017</td>
</tr>
<tr>
<td>Event</td>
<td>Date</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>HRA NHS West Midlands - Coventry &amp; Warwickshire Research Ethics Committee</td>
<td></td>
</tr>
<tr>
<td>REC reference 17/WM/0313</td>
<td></td>
</tr>
<tr>
<td>sponsorship submitted</td>
<td>2(^{nd}) May 2017</td>
</tr>
<tr>
<td>sponsorship approved (SC.68/16-17)</td>
<td>19(^{th}) May 2017</td>
</tr>
<tr>
<td>application submitted</td>
<td>25(^{th}) July 2017</td>
</tr>
<tr>
<td>initial assessment letter received</td>
<td>15(^{th}) August 2017</td>
</tr>
<tr>
<td>initial assessment letter response</td>
<td>19(^{th}) August 2017</td>
</tr>
<tr>
<td>initial assessment letter further query</td>
<td>25(^{th}) August 2017</td>
</tr>
<tr>
<td>initial assessment letter further query response</td>
<td>28(^{th}) August 2017</td>
</tr>
<tr>
<td>ethics panel attended</td>
<td>27 September 2017</td>
</tr>
<tr>
<td>provisional ethical opinion requiring further clarifications received</td>
<td>5(^{th}) October 2017</td>
</tr>
<tr>
<td>application resubmitted</td>
<td>9(^{th}) October 2017</td>
</tr>
<tr>
<td>REC Ethical approval granted</td>
<td>16(^{th}) October 2017</td>
</tr>
<tr>
<td>HRA Ethical approval granted</td>
<td>18(^{th}) October 2017</td>
</tr>
</tbody>
</table>
- Non-substantial amendment submitted 4\textsuperscript{th} December 2017
- Amendment granted 2\textsuperscript{nd} January 2018
- Substantial amendment submitted 13\textsuperscript{th} February 2018
- Amendment granted 20\textsuperscript{th} March 2018
- Non-substantial amendment submitted 12\textsuperscript{th} April 2018
- Amendment granted 18\textsuperscript{th} May 2018
- Substantial amendment submitted 4\textsuperscript{th} June 2018
- Amendment granted 5\textsuperscript{th} July 2018

<table>
<thead>
<tr>
<th>Local approval of capacity and capability</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>CENTRE A</td>
<td></td>
</tr>
<tr>
<td>- Centre meeting</td>
<td>12\textsuperscript{th} September 2017</td>
</tr>
<tr>
<td>- Application submitted</td>
<td>20\textsuperscript{th} October 2017</td>
</tr>
<tr>
<td>- Chase up application</td>
<td>17\textsuperscript{th} November 2017</td>
</tr>
<tr>
<td>- Approval granted</td>
<td>11\textsuperscript{th} December 2017</td>
</tr>
<tr>
<td>- Pre-study centre meeting</td>
<td>16\textsuperscript{th} January 2018</td>
</tr>
<tr>
<td>- Study launch</td>
<td>1\textsuperscript{st} February 2018</td>
</tr>
<tr>
<td>Event</td>
<td>Date</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Centre meeting</td>
<td>5th October 2017</td>
</tr>
<tr>
<td>Application submitted</td>
<td>20th October 2017</td>
</tr>
<tr>
<td>Chase up application</td>
<td>17th November 2017</td>
</tr>
<tr>
<td>Chase up application</td>
<td>15th January 2018</td>
</tr>
<tr>
<td>Chase up application, Re-sent application</td>
<td>19th January 2018</td>
</tr>
<tr>
<td>Application reassigned, Re-sent application</td>
<td>6th February 2018</td>
</tr>
<tr>
<td>Chase up application, annual leave delay from</td>
<td>13th February 2018</td>
</tr>
<tr>
<td>team</td>
<td></td>
</tr>
<tr>
<td>Request for further documents, submitted</td>
<td>19th February 2018</td>
</tr>
<tr>
<td>Chase up application</td>
<td>5th March 2018</td>
</tr>
<tr>
<td>Documents request, documents sent</td>
<td>21st March 2018</td>
</tr>
<tr>
<td>Approval granted</td>
<td>23rd March 2018</td>
</tr>
<tr>
<td>Pre-study centre meeting</td>
<td>29th March 2018</td>
</tr>
<tr>
<td>Study launch</td>
<td>4th April 2018</td>
</tr>
<tr>
<td>Event Description</td>
<td>Date</td>
</tr>
<tr>
<td>--------------------------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>Centre meeting</td>
<td>14&lt;sup&gt;th&lt;/sup&gt; November 2017</td>
</tr>
<tr>
<td>Application submitted</td>
<td>27&lt;sup&gt;th&lt;/sup&gt; November 2017</td>
</tr>
<tr>
<td>Requested documents, documents sent</td>
<td>5&lt;sup&gt;th&lt;/sup&gt; January 2018</td>
</tr>
<tr>
<td>Approval granted</td>
<td>25&lt;sup&gt;th&lt;/sup&gt; January 2018</td>
</tr>
<tr>
<td>Amendment to documents</td>
<td>7&lt;sup&gt;th&lt;/sup&gt; March 2018</td>
</tr>
<tr>
<td>HRA amendment approval received by R&amp;D</td>
<td>28&lt;sup&gt;th&lt;/sup&gt; March 2018</td>
</tr>
<tr>
<td>Pre-study centre meeting</td>
<td>3&lt;sup&gt;rd&lt;/sup&gt; April 2018</td>
</tr>
<tr>
<td>Study launch</td>
<td>17&lt;sup&gt;th&lt;/sup&gt; April 2018</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centre meeting</td>
<td></td>
</tr>
<tr>
<td>Application submitted</td>
<td>20&lt;sup&gt;th&lt;/sup&gt; October 2017</td>
</tr>
<tr>
<td>Chase up application</td>
<td>17&lt;sup&gt;th&lt;/sup&gt; November 2017</td>
</tr>
<tr>
<td>Telephone chase up and re-sent documents</td>
<td>22&lt;sup&gt;nd&lt;/sup&gt; January 2018</td>
</tr>
<tr>
<td>Re-sent application</td>
<td>20&lt;sup&gt;th&lt;/sup&gt; February 2018</td>
</tr>
<tr>
<td>Chase up application</td>
<td>5&lt;sup&gt;th&lt;/sup&gt; March 2018</td>
</tr>
<tr>
<td>Chase up application, assigned staff member left on 16&lt;sup&gt;th&lt;/sup&gt; March with no handover</td>
<td>23&lt;sup&gt;rd&lt;/sup&gt; March 2018</td>
</tr>
<tr>
<td>Event</td>
<td>Date</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Application reassigned, GCP certificates requested</td>
<td>3rd April 2018</td>
</tr>
<tr>
<td>Meeting with staff for GCP certificates</td>
<td>27th April 2018</td>
</tr>
<tr>
<td>Chase up GCP certificates</td>
<td>15th May 2018</td>
</tr>
<tr>
<td>Chase up GCP certificates</td>
<td>8th June 2018</td>
</tr>
<tr>
<td>Query regarding data storage and transfer</td>
<td>11th June 2018</td>
</tr>
<tr>
<td>Provisional approval</td>
<td>18th June 2018</td>
</tr>
<tr>
<td>Approval granted</td>
<td>5th July 2018</td>
</tr>
<tr>
<td>Pre-study meeting</td>
<td>27th July 2018</td>
</tr>
<tr>
<td>Study launch (site 1)</td>
<td>1st August 2018</td>
</tr>
<tr>
<td>Study launch (site 2)</td>
<td>10th September 2018</td>
</tr>
</tbody>
</table>
Appendix 3 – University of Warwick Sponsorship

Dr Sian Taylor-Phillips
Health Sciences
Warwick Medical School
University of Warwick
Coventry
CV4 7AL
United Kingdom

19th May 2017

Project Title: The communication of benign biopsy results in the NHS Breast Screening Programme
Chief Investigator: Dr Sian Taylor-Phillips
Our Ref: SC 68/16-17

Dear Dr Sian Taylor-Phillips,

I confirm that the University of Warwick will act as research sponsor for the above project, in accordance with the Department of Health’s Research Governance Framework for Health and Social Care (2005), and, where appropriate, UK Statutory Instrument Number 1031, that implements the Medicines for Human Use (Clinical Trials) Directive 2004 and subsequent amendments; effective from 17th May 2017.

I confirm that the University holds Public and Products Liability Insurance, and, where appropriate, Clinical Trial Insurance, which will provide cover for this study.

Any researcher involved in the project is required at all times to comply with the University of Warwick’s Research Codes of Practice and Policies, available on the Research and Impact Services website via the following link:
http://www2.warwick.ac.uk/services/ris/research_integrity/code_of_practice_and_policies/

Researchers are also required to comply with all relevant requirements of Standard Operating Procedures (SOPs), which are applicable to all University of Warwick sponsored studies and are available via the following link:
http://www2.warwick.ac.uk/fac/med/research/hscience/cw/conducting/planning/sop/

In particular, please ensure that you are familiar with the relevant safety and reporting requirements applicable to your study, as set out in SOP 17 ‘Safety Reporting’ and SOP 31 ‘Deviations, Violations, Misconduct and Serious Breaches of GCP and/or Trial Protocol’.

Please notify the Research Governance Team via email to sponsorship@warwick.ac.uk of any key changes to your University sponsored study throughout its lifecycle, in particular if your study requires amendment, changes status, closes, is completed or if there are any changes to the proposed or anticipated closure date. Please also copy the above email
address into any Annual Progress Reports or End of Study Notifications sent to the Health Research Authority (HRA) or Research Ethics Committee (REC), where appropriate.

If you have any queries regarding these responsibilities or research sponsorship more generally, please contact the Research Governance Team via email at:
sponsorship@warwick.ac.uk

Kind regards,

[Name redacted]

Professor Aileen Clarke
Chair of Sponsorship Committee

The University of Warwick
Coventry
CV4 7AL
E: sponsorship@warwick.ac.uk
T: +44 (0)24 761 50189
PRIVATE
Miss Sam Williamson
PhD Student
Warwick Medical School
University of Warwick
Coventry
CV4 7AL

2 June 2017

Dear Miss Williamson

Study Title and BSREC Reference: The communication of benign biopsy results in breast screening: a survey of current practice in English Breast Screening Centres – REGO-2017-1908

Thank you for submitting your revisions to the above-named study to the University of Warwick’s Biomedical and Scientific Research Ethics Sub-Committee for approval. I am pleased to confirm that approval is granted and that your study may commence.

In undertaking your study, you are required to comply with the University of Warwick’s Research Data Management Policy, details of which may be found on the Research and Impact Services’ webpages, under “Codes of Practice & Policies” → “Research Code of Practice” → “Data & Records” → “Research Data Management Policy” at: http://www2.warwick.ac.uk/services/rs/research_integrity/code_of_practice_and_policies/research_code_of_practice/data_collection_retention/research_data_management_policy

You are also required to comply with the University of Warwick’s Information Classification and Handling Procedure, details of which may be found on the University’s Governance webpages, under “Governance” → “Information Security” → “Information Classification and Handling Procedure”, at: http://www2.warwick.ac.uk/services/gov/informationsecurity/handling

Investigators should familiarise themselves with the classifications of information defined therein, and the requirements for the storage and transportation of information within the different classifications:

Information Classifications:
http://www2.warwick.ac.uk/services/gov/informationsecurity/handling/classifications
Handling Electronic Information:
http://www2.warwick.ac.uk/services/gov/informationsecurity/handling/electronic/
Handling Paper or other media:
http://www2.warwick.ac.uk/services/gov/informationsecurity/handling/paper/

Please also be aware that BSREC grants ethical approval for studies. The seeking and obtaining of all other necessary approvals is the responsibility of the investigator.

These other approvals may include, but are not limited to:

www.warwick.ac.uk
1. Any necessary agreements, approvals, or permissions required in order to comply with the University of Warwick's Financial Regulations and Procedures.
2. Any necessary approval or permission required in order to comply with the University of Warwick's Quality Management System and Standard Operating Procedures for the governance, acquisition, storage, use, and disposal of human samples for research.
3. All relevant University, Faculty, and Divisional/Departmental approvals, if an employee or student of the University of Warwick.
4. Approval from the applicant's academic supervisor and course/module leader (as appropriate), if a student of the University of Warwick.
5. NHS Trust R&D Management Approval, for research studies undertaken in NHS Trusts.
6. NHS Trust Clinical Audit Approval, for clinical audit studies undertaken in NHS Trusts.
7. Approval from Departmental or Divisional Heads, as required under local procedures, within Health and Social Care organisations hosting the study.
8. Local ethical approval for studies undertaken overseas, or in other HE institutions in the UK.
9. Approval from Heads (or delegates thereof) of UK Medical Schools, for studies involving medical students as participants.
10. Permission from Warwick Medical School to access medical students or medical student data for research or evaluation purposes.
11. NHS Trust Caldicott Guardian Approval, for studies where identifiable data is being transferred outside of the direct clinical care team. Individual NHS Trust procedures vary in their implementation of Caldicott guidance, and local guidance must be sought.
12. Any other approval required by the institution hosting the study, or by the applicant's employer.

There is no requirement to supply documentary evidence of any of the above to BSREC, but applicants should hold such evidence in their Study Master File for University of Warwick auditing and monitoring purposes. You may be required to supply evidence of any necessary approvals to other University functions, e.g. The Finance Office, Research & Impact Services (RIS), or your Department/School.

May I take this opportunity to wish you success with your study, and to remind you that any Substantial Amendments to your study require approval from BSREC before they may be implemented.

Yours sincerely

pp.

Professor John Davey
Chair
Biomedical and Scientific
Research Ethics Sub-Committee

Biomedical and Scientific Research Ethics Sub-Committee
Research & Impact Services
University of Warwick
Coventry, CV4 8UW
E: BSREC@warwick.ac.uk
http://www2.warwick.ac.uk/services/risa/research_integrity/researchethicscommittees/biomed
Appendix 5 - Public Health England Breast Screening Programme
Research Advisory Committee

04 August 2017

Dear Sian,

Re: BSP RAC Outcome letter - BSPRAC_0013 (ODR1718_040)

The Breast Screening Programme Research Advisory Committee (BSP RAC) have discussed your proposed research. The communication of benign biopsy results in the NHS Breast Screening Programme – Research protocol BSPRAC_0013 (ODR1718_040)

The BSP RAC gave their provisional approval to the research project, with the following condition:

- Please provide details of the Breast Screening Units that will be involved. The Breast Screening Units identified must have sufficient resources to carry out this project.

As a condition of support, the BSP RAC requires you to keep them informed of developments with the project, including any changes of status, any significant adverse events, when completed, and when written up.

As previously stated, PHE ODR approval is not required for this project as it is managed and run without access to PHE held data.
The BSP RAC requires you to notify them promptly of any incidents that would be recorded on the Health Research Authority (HRA) Breaches Register. Undertaking research within the Screening Programme following receipt of this letter of support assumes your agreement to fulfil this obligation. HRA has the potential to share information with the BSP RAC regarding any breaches of ethics related to projects involving the BSP.

The Committee wishes you well with your research.

Yours sincerely

Rachel Crowther MSc BMedSci
Research & Evaluation Coordinator
On behalf of the NHS BSP Research Advisory Committee
Appendix 6 - Health Research Authority (HRA) NHS West Midlands - Coventry & Warwickshire Research Ethics Committee

Dr Sian Taylor-Phillips
University of Warwick - WMS
Gibbet Hill
Coventry
CV4 7AL

18 October 2017

Dear Dr Taylor-Phillips

Letter of HRA Approval

Study title: The communication of benign biopsy results in the NHS Breast Screening Programme
IRAS project ID: 212999
REC reference: 17/WM/0313
Sponsor University of Warwick

I am pleased to confirm that HRA Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England
The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. Please read Appendix B carefully, in particular the following sections:

- Participating NHS organisations in England – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- Confirmation of capacity and capability - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria) - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.
It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices
The HRA Approval letter contains the following appendices:
• A – List of documents reviewed during HRA assessment
• B – Summary of HRA assessment

After HRA Approval
The document 'After Ethical Review – guidance for sponsors and investigators', issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:
• Registration of research
• Notifying amendments
• Notifying the end of the study
The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:
• HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
• Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the After Ethical Review document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website and emailed to hra_amendments@ehs.net.
• The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope
HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-nd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback
The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application
procedure. If you wish to make your views known please use the feedback form available on the HRA
website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training
We are pleased to welcome researchers and research management staff at our training days – see
details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is 212999. Please quote this on all correspondence.

Yours sincerely

Miss Helen Penistone
Assessor

Email: hra.approval@nhs.net

Copy to: Mrs Jane Prewett (sponsor)
## Appendix 7 – Search terms

<table>
<thead>
<tr>
<th>Mesh terms and keywords</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1) General communication</strong> search</td>
</tr>
<tr>
<td>• exp communication or communicat* OR</td>
</tr>
<tr>
<td>• comm* adj5 result* OR</td>
</tr>
<tr>
<td>• deliver* adj6 result* OR</td>
</tr>
<tr>
<td>• exp health communication</td>
</tr>
<tr>
<td><strong>AND</strong></td>
</tr>
<tr>
<td><strong>2) Communication methods’ search</strong></td>
</tr>
<tr>
<td>• method* adj5 communicat* OR</td>
</tr>
<tr>
<td>• mode* adj5 communicat* OR</td>
</tr>
<tr>
<td>• method* adj5 not* OR</td>
</tr>
<tr>
<td>• mode* adj5 not* OR</td>
</tr>
<tr>
<td>• exp Telephone OR</td>
</tr>
<tr>
<td>• exp Office Visits OR</td>
</tr>
<tr>
<td>• internet OR text messaging OR email OR web</td>
</tr>
<tr>
<td><strong>AND</strong></td>
</tr>
<tr>
<td><strong>3) ‘Cancer screening’ search</strong></td>
</tr>
<tr>
<td>• cancer or exp Neoplasms OR</td>
</tr>
<tr>
<td>• screen* or exp Mass Screening OR</td>
</tr>
<tr>
<td><strong>AND</strong></td>
</tr>
<tr>
<td>• exp Mammography or mammogra* OR</td>
</tr>
<tr>
<td>• pap* or exp Pap smears</td>
</tr>
<tr>
<td><strong>AND</strong></td>
</tr>
<tr>
<td><strong>4) ‘Outcome measure’ search</strong></td>
</tr>
<tr>
<td>• exp Anxiety or anxiety OR</td>
</tr>
<tr>
<td>• exp Stress, Psychological or psychological impact OR</td>
</tr>
<tr>
<td>• Psychological consequence* or Psychological adj5 consequence* OR</td>
</tr>
<tr>
<td><strong>OR</strong></td>
</tr>
<tr>
<td>• Psychosocial OR</td>
</tr>
<tr>
<td>• exp Psychology or psychology* or exp Psychological Theory</td>
</tr>
<tr>
<td>• exp Comprehension or comprehend*</td>
</tr>
<tr>
<td>• understand*</td>
</tr>
<tr>
<td>• knowledge*</td>
</tr>
<tr>
<td>• interpret*</td>
</tr>
<tr>
<td><strong>OR</strong></td>
</tr>
<tr>
<td>• perception*</td>
</tr>
<tr>
<td>• perceive*</td>
</tr>
<tr>
<td>• exp Patient Preference or patient* pref</td>
</tr>
<tr>
<td>• exp Patient Satisfaction or patient* sati*</td>
</tr>
<tr>
<td>• patient* attitude*</td>
</tr>
<tr>
<td>• women* adj5 pref</td>
</tr>
<tr>
<td>• women* adj5 sati*</td>
</tr>
<tr>
<td>• women* adj5 attitude*</td>
</tr>
</tbody>
</table>
### Appendix 8 – Eligibility criteria

**Inclusion criteria**

- Must mention a routine cancer screening programme
- Must explicitly mention at least one communication method
- The communication must involve a healthcare professional within the screening programme delivering a result to a screening attendee
- Any screening result is eligible (e.g. malignant, benign)
- Must mention at least one of the outcomes of interest (anxiety, understanding, preferences)
- No date restrictions
- No methods restrictions

**Exclusion criteria**

- Doesn’t mention a routine cancer screening programme e.g. symptomatic, diagnostic or genetic screening
- Participants do not reflect the target screening population
- Does not include a communication method
- Outcome data is not extractable in relation to communication methods used
- Any communication that is not about delivering results e.g. general cancer care, discussions about treatment options etc.
- Articles not written in English
- Articles where a full-text cannot be attained
- Books, theses, conference abstracts, grey literature, commentary
## Characteristics of included studies

<table>
<thead>
<tr>
<th>Citation</th>
<th>Type</th>
<th>Screening programme</th>
<th>Location</th>
<th>Study methods</th>
<th>Type of results</th>
<th>Sample description</th>
<th>Study outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goldsmith et al. (2018)</td>
<td>Qualitative</td>
<td>Cervical</td>
<td>England</td>
<td>Focus groups.</td>
<td>Normal, inadequate, borderline and abnormal</td>
<td>Women that had recently been for cervical screening or attended a colposcopy appointment (n=30)</td>
<td>Anxiety, Understanding, Preferences</td>
</tr>
<tr>
<td>Kallberg et al. (2005)</td>
<td>Quantitative</td>
<td>Breast</td>
<td>USA</td>
<td>A cross-sectional telephone survey</td>
<td>Abnormal results</td>
<td>Women identified with abnormal mammograms (n=970)</td>
<td>Understanding, Preferences</td>
</tr>
<tr>
<td>Lind et al. (1992)</td>
<td>Quantitative</td>
<td>Breast</td>
<td>USA</td>
<td>Surveys: One pre-examination and one post-examination.</td>
<td>Normal and abnormal results</td>
<td>Women having a mammogram as part of a routine screening test (n=495)</td>
<td>Anxiety, Preferences</td>
</tr>
<tr>
<td>Marcus et al. (2012)</td>
<td>Qualitative</td>
<td>Breast</td>
<td>USA</td>
<td>Focus groups.</td>
<td>Negative results</td>
<td>Women recruited through flyers at clinics, hospitals and church-based groups (n=34)</td>
<td>Anxiety, Understanding, Preferences</td>
</tr>
<tr>
<td>McCaffrey et al. (2006)</td>
<td>Qualitative</td>
<td>Cervical</td>
<td>Australia</td>
<td>In-depth unstructured interviews</td>
<td>Positive results</td>
<td>Women were recruited from general practice, family planning clinics and specialist gynaecologists (n=28)</td>
<td>Anxiety, Understanding, Preferences</td>
</tr>
<tr>
<td>Pires et al. (2011)</td>
<td>Quantitative</td>
<td>Breast</td>
<td>USA</td>
<td>Telephone survey</td>
<td>Normal and abnormal results</td>
<td>Women having screening and diagnostic mammograms (n=624)</td>
<td>Anxiety, Preferences</td>
</tr>
<tr>
<td>Schofield et al. (1994)</td>
<td>Quantitative</td>
<td>Cervical</td>
<td>Australia</td>
<td>Retrospective telephone survey</td>
<td>Normal and abnormal results</td>
<td>Women with a recent Pap result (n=315)</td>
<td>Preferences</td>
</tr>
<tr>
<td>Anxiety</td>
<td>Telephone</td>
<td>In-person</td>
<td>Verbal</td>
<td>Written</td>
<td>Synthesis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------</td>
<td>-----------</td>
<td>-----------</td>
<td>--------</td>
<td>---------</td>
<td>-----------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women felt less worried about having to wait for results (McCaffrey, 2005)</td>
<td>Telephoning women to come in only when results are abnormal unexpectedly causes high levels of anxiety. Women knew something was wrong but didn’t know what – and then had to wait to be seen in-person. This causes unnecessary anxiety. (McCaffrey, 2005) Notifying participants by phone is preferred but may be difficult if attendees are caught unaware (Lind, 1992)</td>
<td></td>
<td>Does not significantly impact anxiety (Priyanath, 2001) More than one third of respondents (38%) indicated that written notification reduced their anxiety. 47.4% noted no change and 14.8% experienced an increase in anxiety (Priyanath, 2001) Although anxiety remained unchanged, many patients appeared to benefit from better and timelier communication (Priyanath, 2001) For women who did not receive accompanying written materials with their results, uncertainty was heightened (Goldsmith, 2008) Anxiety if letter was not understood and if letter was not opened in private. The ambiguous wording used in written communication made women ‘fear the worst’, causing unnecessary anxiety (Marcus, 2012) Women felt distressed. Recommended that written communication should not be used to deliver sensitive information (McCaffrey, 2005) Women notified in writing remember feeling anxious even if the result was normal (Marcus, 2012)</td>
<td>*This letter is really just a piss-off letter, it’s really to get you upset (Marcus, 2012)</td>
<td>Privacy - Lack of privacy in the location in which results are received is associated with increased anxiety. Understanding and anxiety - Lower levels of understanding are associated with increased anxiety. The anxious wait - Reducing the ‘anxious wait’ was valued by attendees. Managing expectations - When patients receive results by a method which they weren’t expecting, anxiety is elevated.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Understanding</td>
<td>Telephone</td>
<td>In-person</td>
<td>Verbal</td>
<td>Written</td>
<td>Synthesis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td>-----------</td>
<td>-----------</td>
<td>--------</td>
<td>---------</td>
<td>-----------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women value the opportunity to ask questions, which telephone results allow (Marcus, 2012)</td>
<td>Diagrams aid understanding (Goldsmith, 2008)</td>
<td>The only method-based predictor of improved understanding and comprehension of results in breast screening was the woman being notified of her results verbally, either over the telephone or in-person in comparison to in writing (adjusted OR (95% CI) 2.3 (1.2 to 4.8)) (Karniner, 2005)</td>
<td>For women who did not receive accompanying written materials with their results, uncertainty was heightened (Goldsmith, 2008)</td>
<td>Some women do not understand the language used in the letter, or did not open the letter in private. This leads to anxiety (see above). (Marcus, 2012) Letters are confusing and impersonal (Marcus, 2012) Women lacked understanding and felt confused – this was due to the content and language of the letter (McCaffrey, 2005) Receiving a letter left women needing further clarification and information (Marcus, 2012) Women are more likely to misunderstand their result if they are told by letter alone. This is particularly salient for populations where lower literacy levels are common (Marcus, 2012)</td>
<td>Letter alone vs. accompanying letter - Women did not understand their results when they were provided in writing alone. Receiving materials alongside verbal results was associated with lower levels of uncertainty. Opportunity to ask questions is valued - Women value the opportunity to ask questions when telephoned with results. Accuracy is valued - Women reported several instances of receiving incorrect information by telephone. Visual support - Diagrams drawn in-person may help to aid understanding. Verbal methods facilitated improved understanding.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preferences</td>
<td>Telephone</td>
<td>In-person</td>
<td>Verbal</td>
<td>Written</td>
<td>Synthesis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------</td>
<td>-----------</td>
<td>-----------</td>
<td>--------</td>
<td>---------</td>
<td>-----------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women received the wrong information by phone, leading to several instances of unsatisfactory results reporting (Goldsmith, 2008)</td>
<td>Women are fairly satisfied with pre-booked appointments (McCaffrey, 2005)</td>
<td>Patients preferred to be told their mammography result by their own physician, either in the office or over the phone (when abnormal) (Lind, 1992)</td>
<td>For normal results, a rapid mailed report is acceptable (Lind, 1992). Written notification was associated with approximately half the likelihood of overall dissatisfaction with results reporting (Priyanath, 2001)</td>
<td>Variation for normal/abnormal results - Results communication preferences vary depending on if the result is normal or abnormal. In general, verbal results tend to be most preferred across all results severities. However, some women with normal results find a letter acceptable and some women with abnormal results prefer being seen in person.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women wanted to be called with results, even if results were normal because they perceived mammograms to be ‘important’ (Marcus, 2012)</td>
<td>When receiving an abnormal screening result, attendees expressed a clear preference for being told by the physician in person in comparison to other methods of telling (p &lt; 0.001) (Lind, 1992)</td>
<td>Women prefer personal contact by telephone or consultation when abnormal result, 49%. However, several telephone calls might be needed before contact is made. (Schofield 1994)</td>
<td>Women prefer written notification for normal results, 40%. Advantages of written communication are that it minimises staff workload, and can be completed the same day the physician is notified, leaving the delivery in the hands of administrative staff (Schofield, 1994)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women who were notified by telephone had a positive experience and valued the time to ask questions and seek reassurance from a healthcare professional (McCaffrey, 2005)</td>
<td>When receiving a normal screening result, the preferred communication method was for the physician to telephone the attendee, in comparison to other methods of telling (p &lt; 0.001) (Lind, 1992)</td>
<td>Other studies found that women want to be told verbally (Marcus, 2012 citing Karliner, 2005)</td>
<td>Dissatisfaction was a theme expressed by those who were notified in writing only (Marcus, 2012)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>When receiving a normal screening result, the preferred communication method was for the physician to telephone the attendee, in comparison to other methods of telling (p &lt; 0.001) (Lind, 1992)</td>
<td></td>
<td>Women prefer to be told results directly (Karliner, 2005)</td>
<td>Written notification alone is ‘inappropriately impersonal’ (Marcus, 2012)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surprisingly, patients informed by mail were just as pleased as those told in-person (when considering their previous screening results delivery retrospectively) (Lind, 1992)</td>
<td></td>
<td></td>
<td>Surprisingly, patients informed by mail were just as pleased as those told in-person (when considering their previous screening results delivery retrospectively) (Lind, 1992)</td>
<td>Speed - For normal results, women are more accepting of ‘rapid’ methods (e.g. letter). However, women were more likely to be dissatisfied with written results. Some women who are willing to wait, perhaps due to finding written results not personal enough, perceiving mammograms to be ‘important’ enough to wait to be told verbally.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Appendix 11 – Quality assessment for systematic review

### Qualitative studies

Table 21: Quality assessment of qualitative studies included in the systematic review, assessed using the Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews – Checklist for Qualitative Research.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is there congruity between the stated philosophical perspective and the research methodology?</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Unclear</td>
</tr>
<tr>
<td>2. Is there congruity between the research methodology and the research question or objectives?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>3. Is there congruity between the research methodology and the methods used to collect data?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>4. Is there congruity between the research methodology and the representation and analysis of data?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>5. Is there congruity between the research methodology and the interpretation of results?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>6. Is there a statement locating the researcher culturally or theoretically?</td>
<td>No</td>
<td>Unclear</td>
<td>No</td>
</tr>
<tr>
<td>7. Is the influence of the researcher on the research, and vice- versa, addressed?</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>8. Are participants, and their voices, adequately represented?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>9. Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body?</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Yes</td>
</tr>
<tr>
<td>10. Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

(Individually assessed and agreed upon by SW and JP)
Figure 20: Overall quality assessment and risk of bias for the qualitative studies included in the systematic review
Quantitative studies

Table 22: Quality assessment of qualitative studies included in the systematic review, assessed using the Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews – Checklist for Analytical Cross Sectional Studies.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Were the criteria for inclusion in the same clearly defined?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2) Were the study subjects and setting described in detail?</td>
<td>Yes</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Yes</td>
</tr>
<tr>
<td>3) Was the exposure measured in a valid and reliable way?</td>
<td>Unclear</td>
<td>Yes</td>
<td>Yes</td>
<td>Unclear</td>
</tr>
<tr>
<td>4) Were objective, standard criteria used for measurement of the condition?</td>
<td>Yes</td>
<td>Unclear</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>5) Were confounding factors identified?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6) Were strategies to deal with confounding factors stated?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>7) Were the outcomes measured in a valid and reliable way?</td>
<td>No</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Unclear</td>
</tr>
<tr>
<td>8) Was appropriate statistical analysis used?</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
</tr>
</tbody>
</table>

(Individually assessed and agreed upon by SW and JP)
Figure 21: Overall quality assessment and risk of bias for the quantitative studies included in the systematic review
Appendix 12 – Online centre survey

The communication of benign biopsy results in the NHS Breast Screening Programme – Online centre survey

CENTRE CHARACTERISTICS

1. Please state the official name of your breast screening centre:

__________________________________________________________________

2. What age group of women does your centre screen most frequently? (this information for your centre can be found in the KC62)

☐ <=44
☐ 45-49
☐ 50-52
☐ 53-54
☐ 55-59
☐ 60-64
☐ 65-69
☐ 70
☐ 71-74
☐ >=75

1st April 2017 – V.3
COMMUNICATION OF RESULTS

3. When delivering benign biopsy results...
   - Women are never telephoned with results [ ]
   - Women are occasionally telephoned with results [ ]
   - Women are routinely telephoned with results [ ]

   Please add any additional comments below:

   ________________________________
   ________________________________
   ________________________________

4. If women are telephoned with benign results, who delivers these results? (Tick all that apply)
   - Clinical nurse specialist [ ]
   - Radiologist [ ]
   - Radiographer [ ]
   - Breast care surgeon [ ]
   - Administrative staff [ ]
   - Other (please specify): [ ]

   ________________________________

1st April 2017 – V.3
5. When delivering a cancer result...

Women are never telephoned with results □
Women are occasionally telephoned with results □
Women are routinely telephoned with results □

Please add any additional comments below:

________________________________________________________

6. If women are telephoned with cancer results, who delivers these results? (Tick all that apply)

Clinical nurse specialist □
Radiologist □
Radiographer □
Breast care surgeon □
Administrative staff □
Other (please specify): □

________________________________________________________

1st April 2017 – V.3
7. From assessment to delivering a result, how long does this process take (on average)?
   1 day  ☐
   2 days  ☐
   3 days  ☐
   4 days  ☐
   5 days  ☐
   6 days  ☐
   7 days  ☐
   8 days  ☐
   9 days  ☐
   10 days ☐
   11 days ☐
   12 days ☐
   More than 12 days ☐

8. We are currently recruiting breast screening centres to take part in our main study, which will involve surveying women attending breast screening, who go to receive a benign result. The surveys will be assessing patient anxiety and understanding of results, examining whether the method of communication used (telephone or in-person) to deliver benign results influences these patient outcomes. We are looking for two centres to participate, to allocate women to receive benign results via either telephone or in-person. We are currently in the process of finalising the design of methodology and submitting for ethical approval.

Would you be interested in involvement in this research?

   Yes ☐
   No  ☐

*If you select yes, you may be contacted soon with further details of the main study.*

9. Would your centre like to know the results from this survey? (If yes, please provide an email address for a summary sheet to be sent upon completion of the research).

   No  ☐
   Yes ☐

   Email address: _________________________________

*1st April 2017 – V.3*
Thank you for taking the time to participate in this survey.

If you have any questions, feel free to contact the lead researcher:

Lead researcher: Sian Williamson
Email: s.williamson@warwick.ac.uk
Telephone: 07891319509
Appendix 13 – Time 1 PIS

Time 1 Information sheet: the communication of results in breast screening

We’d like to invite you to take part in our research. Taking part in the research is entirely up to you. This document will give you information about the study and what you will be asked to do, should you volunteer to take part.

Please keep this document for future reference. If you have any questions, please feel free to ask or contact Sian Williamson (s.williamson@bham.ac.uk).

What is the purpose of the research?

This research is being conducted to evaluate how results are currently being given in the NHS Breast Screening Programme in order to inform future policy changes. It is unknown what impact communication may have on women who attend breast screening and how they might prefer to receive their results.

What would taking part involve today?

Stage 1: Today, you will be asked to complete a short survey prior to your screening follow-up tests. This will take around 10-15 minutes to complete. This survey will ask questions about how you feel about screening, your preferences for communication, your contact details and also some basic information about who you are.

If you wish to complete your survey in private, please ask a member of staff who will give you access to a separate room. Once you’ve completed your answers, return them to the reception desk. Your answers will be stored securely and confidentially by the staff at the screening centre, in an area away from public access, separate from your NHS patient record.

Once you have had your follow-up tests today, you will be given an appointment to come back to receive your results. If you choose to take part in our study, you may be contacted by telephone before your scheduled appointment to receive your result. We will not be phoning everyone who takes part in this research. If you do not receive a telephone call, just attend your scheduled appointment.

What would taking part involve in the future?

We will not be sending follow-up surveys to everyone who takes part in the survey today, due to the criteria we have for study participants. We will only be sending you a follow-up survey if your result shows nothing is found in your screening tests today.

If we do not send you follow-up surveys, we will still use your responses from today’s survey (stage 1) in our research.

Stage 2: Once you have received your screening results, you will receive a survey in the post to complete and return in a pre-paid envelope. If no response is received within a week of your survey being sent, the researcher will attempt to contact you by telephone. This contact will be attempted a maximum of two times. No reply from you at both of these stages

IRAS ID: 212099
will be taken as withdrawal of consent from this stage of the research. You will still receive postal surveys for stages 3 and 4 (see below), unless you ask to be withdrawn from the study.

Stage 3: Three months after you've received your results, you will receive another survey in the post to complete and return in a pre-paid envelope.

Stage 4: Six months after you've received your results, you will receive another survey in the post to complete and return in a pre-paid envelope.

At each stage of the research, return of the completed questionnaire will be taken as confirmation of your continued consent for this project.

How long will it take?

Each survey will take around 10-15 minutes to complete. In total the research will take you approximately 40-60 minutes across the six months of the study.

Who will have access to my survey responses?

A research team at the University of Warwick will be responsible for analysing the responses to this study.

How will my information be kept confidential?

The only individuals who will see your NHS patient details are the breast screening staff who access this data on a day-to-day basis. They will only use information about your screening result which is necessary for the study. This information will then be passed on to the University of Warwick team to enable the study to be conducted.

What will my contact details be used for?

During today’s survey, you will be asked to provide your name, address and telephone number. Your address will be used to send out the follow up surveys at stage 2-4 of the study. Your telephone number will be used to attempt contact to prompt completion of the stage 2 study. Your contact information will only be used for the purposes of this study. Once the research project has been completed, all contact information will be destroyed.

This information will remain confidential, and will only be shared between your breast screening centre and the research team at the University of Warwick.

IRAS ID: 212599
What happens if I change my mind about taking part?
You are free to leave the study at any time, as participation is voluntary. Choosing not to take part in the research will NOT have an impact on the care you receive during or after your breast screening appointment.
If you wish to drop out of the study, contact Sian Williamson (s.williamson@warwick.ac.uk). You will be given the option to allow your previous responses to be used or you can choose to have all your responses removed from the project, which will then be destroyed. If you choose to withdraw from the study, your contact details will be destroyed. Please note that your data can only be withdrawn from the project during the data collection period. This is anticipated to end in June 2019.

What are the possible benefits of taking part?
Your experiences and opinions will be used to make improvements in how we communicate results to women attending breast screening in the future.

What are the possible disadvantages and risks of taking part?
We do not anticipate any disadvantages other than giving up your time. It is possible some individuals may be uncomfortable or feel anxious answering questions about how they feel, but you are free to withdraw from the study at any time before the end of data collection in June 2019.

If you do feel anxious, or have any other concerns, and would like to talk to someone about this, we recommend that you telephone your Breast Care Nurse at your screening centre. Alternatively, you may wish to contact the charity ‘Independent Cancer Patient Voices’, for support (telephone number: 07885 825034).

What will happen to the results of this study?
Results from this study will be used to inform policy change in breast screening and will also be published in scientific journals. All results will be published in an anonymised format. If you wish to find out the results of the study when it’s finished, we can send you a postal copy. You will have the option to decide if you want to do this during the survey.

Who do I contact if I have a complaint about this research?
If you have a complaint about this research, please contact:

Deputy Director/ Head of Research Governance
Research & Impact Services
University House
University of Warwick
Coventry
CV4 6UW
Tel: 024 76 522746
Email: researchgovernance@warwick.ac.uk

IRAS ID: 212999
Thank you for considering taking part in this study and for taking the time to read this information sheet.

If you have any questions, feel free to contact the lead researcher or to ask a member of staff at your screening centre.

Lead researcher: Sian Williamson
Email: s.williamson@warwick.ac.uk
Telephone: 07470063357

Public Health England

Cancer Screening Programmes

IRAS ID: 212999
Appendix 14 – Time 1 consent

Consent Time 1 - V.7 12.11.2018

IRAS ID: 212999
Participant ID number: ________

CONSENT FORM
Title of Project: The communication of results in breast screening
Name of Researcher: Sian Williamson

1. I confirm that I have read and understand the information sheet dated 12.11.2018 (V.7) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

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

3. I understand that I may be contacted by telephone with my results, ahead of my scheduled appointment. However, not everyone who participates with be contacted by telephone. If I am not contacted, I know to attend my scheduled appointment.

4. I understand that my screening result will be looked at by staff from the breast screening programme to enable this study to be conducted, and that this information will be passed on to the research team at the University of Warwick.

5. I understand that the data collected during the study will be accessed by the research team at the University of Warwick. I give permission for this team to have access to my data.

6. I understand that I may be contacted via post for the follow-up of this study. If I do not respond, I give permission for telephone contact to be attempted a maximum of two times.

7. I understand that my name and contact details will be stored securely and only used by the University of Warwick team to follow-up in this study. I understand that once the study is complete, my name and contact details will be destroyed in a secure manner.

8. I understand that returning my completed questionnaire will be taken as confirmation of my continued consent for this project for the follow-up postal surveys.

The original copy of the consent form should be kept by the patient, with a second copy being kept by the research team.
9. I understand that I can drop out of the study at any time.

10. I understand that I can choose to withdraw my data from the study up until June 2019.

11. I agree to take part in the above study.

Name of Participant __________________________ Date __________________________ Signature __________________________

Name of Person taking consent __________________________ Date __________________________ Signature __________________________

The original copy of the consent form should be kept by the patient, with a second copy being kept by the research team.
Appendix 15 – Time 1 survey

Communicating results in breast screening:
Research survey – Time 1

PARTICIPANT NAME: __________________________
(Please ensure this is completed)

For researcher use only:
Participant ID number: ________________________
B1 or B2 result:
☐ Yes
☐ No
### Participant information

<table>
<thead>
<tr>
<th>1) What is your age?</th>
<th>2) Have you attended screening before?</th>
</tr>
</thead>
<tbody>
<tr>
<td>____________ years</td>
<td>□ Yes</td>
</tr>
<tr>
<td></td>
<td>□ No</td>
</tr>
</tbody>
</table>

2a) If yes, did you have a biopsy (a needle inserted into the breast to remove tissue)?

|                     | □ Yes                                |
|                     | □ No                                 |
|                     | □ Can’t remember                      |

<table>
<thead>
<tr>
<th>3) Please tick the highest level of education you have achieved:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ No schooling completed</td>
</tr>
<tr>
<td>□ High school or equivalent</td>
</tr>
<tr>
<td>□ Some college</td>
</tr>
<tr>
<td>□ Bachelor’s degree</td>
</tr>
<tr>
<td>□ Master’s degree</td>
</tr>
<tr>
<td>□ Doctoral degree</td>
</tr>
<tr>
<td>□ Professional degree</td>
</tr>
<tr>
<td>□ Other</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4) Please tick your marital status:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Single</td>
</tr>
<tr>
<td>□ Domestic partnership</td>
</tr>
<tr>
<td>□ Married</td>
</tr>
<tr>
<td>□ Divorced</td>
</tr>
<tr>
<td>□ Widowed</td>
</tr>
<tr>
<td>□ Separated</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5) What is your ethnic group?</th>
</tr>
</thead>
</table>

**White:**
- □ English/Welsh/Scottish/Northern Irish/British
- □ Irish
- □ Gypsy or Irish Traveller
- □ Any other White background

**Mixed/multiple ethnic groups:**
- □ White and Black Caribbean
- □ White and Black African
- □ White and Asian
- □ Any other Mixed/Multiple ethnic background

**Black/African/Caribbean/Black British:**
- □ African
- □ Caribbean
- □ Any other Black/African/Caribbean background

**Other ethnic group:**
- □ Arab
- □ Any other ethnic group
Preferences for communication

When a screening result is not cancer, some centres deliver these results in-person and some deliver these results over the telephone. We want to know how you would prefer to receive screening results, if you were given the choice.

Please note, if you tick a preference, you may not necessarily get your result delivered this way.

6) How would you prefer to receive your results from screening?

☐ In-person at the screening centre
☐ By telephone

7) Why would you prefer to receive your results this way?

Please write a brief explanation:

_____________________________________________________________________________________________________________________

_____________________________________________________________________________________________________________________

_____________________________________________________________________________________________________________________
**Survey (time 1) – V.6 05.04.2018**

**How do you feel?**

8) *Over the last week* how often have you experienced the following things because of *thoughts and feelings about breast cancer*:

<table>
<thead>
<tr>
<th>Feeling</th>
<th>Not at all</th>
<th>Rarely</th>
<th>Some of the time</th>
<th>Quite a lot of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Had trouble sleeping</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Experienced a change in appetite</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Been unhappy or depressed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Been scared and panicky</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Felt nervous or stung up</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Felt under strain</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Found you have been keeping things from those who are close to you</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Found yourself taking things out on other people</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Found yourself noticeably withdrawing from those who are close to you</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Had difficulty doing things around the house that you normally do</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Had difficulty meeting work or other commitments</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Felt worried about your future</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
9) Please provide a contact name and address for follow-up surveys to be sent:

(Please note that this address will remain anonymous and all contact information will be destroyed once the study is complete. This address will only be used for the purposes of this research to post follow-up surveys.)

______________________________

______________________________

______________________________

______________________________

10) Please provide a contact telephone number:

(Please note that this contact number will remain anonymous and all contact information will be destroyed once the study is complete. This telephone number will only be used for the purposes of this research to remind you of the first follow-up survey.)

______________________________

11) Would you like to hear about the results from this research?

(If you choose yes, you will be sent a copy of the results from this research via the address provided)

☐ Yes
☐ No
 Appendix 16 – Time 2 PIS

Time 2 Information sheet: the communication of results in breast screening

PLEASE READ THIS INFORMATION BEFORE DECIDING WHETHER TO COMPLETE YOUR SURVEY

Dear participant,

You recently took part in the first stage of our research project. Thank you for taking part. This is the first follow-up survey. Taking part in the research is entirely up to you. This document will remind you about the study and what you will be asked to do, should you volunteer to take part.

Please keep this document for future reference. If you have any questions, please feel free to ask or contact Sian Williamson (s.williamson@warwick.ac.uk).

What is the purpose of the research?

This research is being conducted to evaluate how results are currently being given in the NHS Breast Screening Programme in order to inform future policy changes. It is unknown what impact communication may have on women who attend breast screening and how they might prefer to receive their results.

What would taking part involve today?

This is stage 2 of the project. You have received a postal-survey, which will ask you questions about how your screening results were delivered, what you understand about your result, your preferences for communication and how you feel about your screening experience. This survey should only take around 10 – 15 minutes to complete. Once you’ve completed your responses, please return your survey in the pre-paid envelope provided.

If no response is received within a week of your survey being sent, the researcher will attempt to contact you by telephone a maximum of two times. No reply from you at both of these stages will be taken as withdrawal of consent from this stage of the research. You will still receive postal surveys for stage 3 and 4 (see below), unless you ask to be withdrawn from the study.

Return of your completed survey will be taken as confirmation of your continued consent for the study.

What would taking part involve in the future?

Stage 3: You will receive another survey in the post to complete and return in a pre-paid envelope in around 3 months.

Stage 4: You will receive another survey in the post to complete and return in a pre-paid envelope in around 6 months.

At each stage of the research, return of the completed questionnaire will be taken as confirmation of your continued consent for this project.

In the survey, you will be asked if you would like to be involved in further research where we will be conducting telephone interviews, asking women about their screening experience. If
you would like to be involved in this research, you will have the option to express your interest in the survey.

Who will have access to my survey responses?
A research team at the University of Warwick will responsible for analysing the responses from this study.

How will my information be kept confidential?
Your contact details will be stored securely and remain confidential.

What happens if I change my mind about taking part?
You are free to leave the study at any time, as participation is voluntary. Choosing not to take part in the research will NOT have an impact on the care you receive during or after your breast screening appointment.

If you wish to drop out, contact Sian Williamson (s.williamson@warwick.ac.uk). You will be given the option to allow your previous responses to be used or you can choose to have all your responses removed from the project, which will then be destroyed. If you choose to withdraw from the study, your contact details will be destroyed. Please note that your data can only be withdrawn from the project during the data collection period. This is anticipated to end in June 2019.

What are the possible benefits of taking part?
Your experiences and opinions will be used to make improvements in how we communicate results to women attending breast screening in the future.

What are the possible disadvantages and risks of taking part?
We do not anticipate any disadvantages other than giving up your time. It is possible some individuals may be uncomfortable or feel anxious answering questions about how they feel, but you are free to withdraw from the study at any time before the end of data collection in June 2019.

If you feel anxious, or have any other concerns, and would like to talk to someone about this, we recommend that you telephone your Breast Care Nurse at your screening centre. Alternatively, you may wish to contact the charity ‘Independent Cancer Patient Voices’, for support (telephone number: 07960 853064).
Who do I contact if I have a complaint about this research?

If you have a complaint about this research, please contact:

Deputy Director/ Head of Research Governance
Research & Impact Services
University House
University of Warwick
Coventry
CV4 6UW
Tel: 024 76 522746
Email: researchgovernance@warwick.ac.uk

Thank you for considering taking part in this study and for taking the time to read this information sheet.

If you have any questions, feel free to contact the lead researcher:

Lead researcher: Sian Williamson
Email: s.williamson@warwick.ac.uk
Telephone: 07470063357

Public Health England
WARWICK
Cancer Screening Programmes

IRAS ID: 212999
Appendix 17 – Time 2 survey

Survey (time 2) – V.2 17.11.2017

Communicating results in breast screening:
Research survey – Time 2

Public Health England
WARWICK
Cancer Screening Programmes

Participant ID number: 001
Your results

1) How were your results delivered?
- Telephone
- In-person appointment

2) When did you receive your results?
- Less than a week ago
- 1-2 weeks ago
- More than 2 weeks ago

3) Do you feel like you understand your screening result?
- Yes
- No
- Unsure

4) Please tick the statement that best describes your screening result:
- I do not have cancer and do not need to return to screening
- I do not have cancer and will be invited to re-attend screening in 3 years
- I do not understand what my screening result means
Preferences for communication

5) How would you prefer to receive your results from screening?

☐ In-person at the screening centre
☐ By telephone
☐ Other (please specify):

6) Why would you prefer to receive your results this way?

*Please write a brief explanation:*

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
How do you feel?

7) Over the last week, how often have you experienced the following things because of thoughts and feelings about breast cancer:

<table>
<thead>
<tr>
<th>Feeling</th>
<th>Not at all</th>
<th>Rarely</th>
<th>Some of the time</th>
<th>Quite a lot of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Had trouble sleeping</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Experienced a change in appetite</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Been unhappy or depressed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Been scared and panicky</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Felt nervous or strung up</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Felt under strain</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Found you have been keeping things from those who are close to you</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Found yourself taking things out on other people</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Found yourself noticeably withdrawing from those who are close to you</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Had difficulty doing things around the house that you normally do</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Had difficulty meeting work or other commitments</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Felt worried about your future</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
Future research

8) Would you be interested in taking part in a telephone interview to discuss your experience of receiving results from screening? (If you tick yes, you will be sent a separate information sheet for this project to the address you gave during the first stage of this research)

☐ Yes
☐ No
Appendix 18 - Time 3 PIS

Time 3 Information sheet: the communication of results in breast screening

PLEASE READ THIS INFORMATION BEFORE DECIDING WHETHER TO COMPLETE YOUR SURVEY

Dear participant,

You are receiving this survey as you took part in our research project a few months ago. Thank you for taking part. This is the third follow-up survey. Taking part in the research is entirely up to you. This document will remind you about the study and what you will be asked to do, should you volunteer to take part.

Please keep this document for future reference. If you have any questions, please feel free to ask or contact Sian Williamson (s.williamson@warwick.ac.uk).

What is the purpose of the research?

This research is being conducted to evaluate how results are currently being given in the NHS Breast Screening Programme in order to inform future policy changes. It is unknown what impact communication may have on women who attend breast screening and how they might prefer to receive their results.

What would taking part involve today?

This is stage 3 of the project. You have received a postal survey, which will ask you questions about how you feel about your screening experience. This survey should only take around 5–10 minutes to complete. Once you’ve completed your responses, please return your survey in the pre-paid envelope provided.

Return of your completed survey will be taken as confirmation of your continued consent for the study. You will still receive postal surveys for stage 4 (see below), unless you ask to be withdrawn from the study.

What would taking part involve in the future?

Stage 4: You will receive another survey in the post to complete and return in a pre-paid envelope in around 6 months.

At each stage of the research, return of the completed questionnaire will be taken as confirmation of your continued consent for this project.

Who will have access to my survey responses?

A research team at the University of Warwick will be responsible for analysing the responses from this study.

IRAS ID: 212999
How will my information be kept confidential?

Your name will not be on your responses and you will be assigned a unique participant ID number, so that your data is not individually identifiable.

What happens if I change my mind about taking part?

You are free to leave the study at any time, as participation is voluntary. Choosing not to take part in the research will NOT have an impact on the care you receive during or after your breast screening appointment.

If you wish to drop out, contact Sian Williamson (s.williamson@warwick.ac.uk). You will be given the option to allow your previous responses to be used or you can choose to have all your responses removed from the project, which will then be destroyed. If you choose to withdraw from the study, your contact details will be destroyed. Please note that your data can only be withdrawn from the project during the data collection period. This is anticipated to end in June 2019.

What are the possible benefits of taking part?

Your experiences and opinions will be used to make improvements in how we communicate results to women attending breast screening in the future.

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages other than giving up your time. It is possible some individuals may feel uncomfortable or feel anxious answering questions about how they feel, but you are free to withdraw from the study at any time before the end of data collection in June 2019.

If you feel anxious, or have any other concerns, and would like to talk to someone about this, we recommend that you telephone your Breast Care Nurse at your screening centre. Alternatively, you may wish to contact the charity ‘Independent Cancer Patient Voices’, for support (telephone number: 07800 653004).

Who do I contact if I have a complaint about this research?

If you have a complaint about this research, please contact:

Deputy Director/Head of Research Governance
Research & Impact Services
University House
University of Warwick
Coventry
CV4 8UL
Tel: 024 76 522746
Email: researchgovernance@warwick.ac.uk

IRAS ID: 212999
Thank you for considering taking part in this study and for taking the time to read this information sheet.

If you have any questions, feel free to contact the lead researcher:

Lead researcher: Sian Williamson
Email: a.williamson@warwick.ac.uk
Telephone: 07470063357

Public Health England

Cancer Screening Programmes

IRAS ID: 212999
Communicating results in breast screening:
Research survey – Time 3

Participant ID number: 001
1) **Over the last week** how often have you experienced the following things because of thoughts and feelings about breast cancer:

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Rarely</th>
<th>Some of the time</th>
<th>Quite a lot of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Had trouble sleeping</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Experienced a change in appetite</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Been unhappy or depressed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Been scared and panicky</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Felt nervous or strung up</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Felt under strain</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Found you have been keeping things from those who are close to you</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Found yourself taking things out on other people</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Found yourself noticeably withdrawing from those who are close to you</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Had difficulty doing things around the house that you normally do</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Had difficulty meeting work or other commitments</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Felt worried about your future</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
Appendix 20 - Time 4 PIS

PIS (Time 4) – V.8 12.11.2018

Time 4 Information sheet: The communication of results in breast screening

PLEASE READ THIS INFORMATION BEFORE DECIDING WHETHER TO COMPLETE YOUR SURVEY

Dear participant,

You are receiving this survey as you took part in our research project this year. Thank you for taking part. This is the third follow-up survey. Taking part in the research is entirely up to you. This document will remind you about the study and what you will be asked to do, should you volunteer to take part.

Please keep this document for future reference. If you have any questions, please feel free to ask or contact Sian Williamson (s.williamson@warwick.ac.uk).

What is the purpose of the research?

This research is being conducted to evaluate how results are currently being given in the NHS Breast Screening Programme in order to inform future policy changes. It is unknown what impact communication may have on women who attend breast screening and how they might prefer to receive their results.

What would taking part involve today?

This is stage 4 of the project. You have received a postal-survey, which will ask you questions about how you feel about your screening experience. This survey should only take around 5 minutes to complete. Once you’ve completed your responses, please return your survey in the pre-paid envelope provided.

Return of your completed survey will be taken as confirmation of your continued consent for the study.

Who will have access to my survey responses?

A research team at the University of Warwick will be responsible for analysing the responses from this study.

How will my information be kept confidential?

Your name will not be on your responses and you will be assigned a unique participant ID number, so that your data is not individually identifiable.

IRAS ID: 212999
What happens if I change my mind about taking part?
You are free to leave the study at any time, as participation is voluntary. Choosing not to take part in the research will NOT have an impact on the care you receive during or after your breast screening appointment.

If you wish to drop out, contact Sian Williamson (s.williamson@qmul.ac.uk). You will be given the option to allow your previous responses to be used or you can choose to have all your responses removed from the project, which will then be destroyed. If you choose to withdraw from the study, your contact details will be destroyed. Please note that your data can only be withdrawn from the project during the data collection period. This is anticipated to end in June 2019.

What are the possible benefits of taking part?
Your experiences and opinions will be used to make improvements in how we communicate results to women attending breast screening in the future.

What are the possible disadvantages and risks of taking part?
We do not anticipate any disadvantages other than giving up your time. It is possible some individuals may be uncomfortable or feel anxious answering questions about how they feel but you are free to withdraw from the study at any time before the end of data collection in June 2019.

If you do feel anxious, or have any other concerns, and would like to talk to someone about this, we recommend that you telephone your Breast Care Nurse at your screening centre. Alternatively, you may wish to contact the charity “Independent Cancer Patient Voices”, for support (telephone number: 07880 883004).
Who do I contact if I have a complaint about this research?

If you have a complaint about this research, please contact:

Deputy Director/ Head of Research Governance
Research & Impact Services
University House
University of Warwick
Coventry
CV4 6UL
Tel: 024 76 522746
Email: researchgovernance@warwick.ac.uk

Thank you for considering taking part in this study and for taking the time to read this information sheet.

If you have any questions, feel free to contact the lead researcher:

Lead researcher: Sian Williamson
Email: s.williamson@warwick.ac.uk
Telephone: 07470063357

Cancer Screening Programmes
Communicating results in breast screening: Research survey – Time 4

Participant ID number: 001
How do you feel?

1) *Over the last week* how often have you experienced the following things because of thoughts and feelings about breast cancer:

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Rarely</th>
<th>Some of the time</th>
<th>Quite a lot of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Had trouble sleeping</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Experienced a change in appetite</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Been unhappy or depressed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Been scared and panicky</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Felt nervous or strung up</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Felt under strain</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Found you have been keeping things from those who are close to you</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Found yourself taking things out on other people</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Found yourself noticeably withdrawing from those who are close to you</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Had difficulty doing things around the house that you normally do</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Had difficulty meeting work or other commitments</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Felt worried about your future</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
Appendix 22 - Qualitative interviews PIS

Qualitative interviews – information sheet V.5 17.11.2017

Information sheet: the communication of results in breast screening – Telephone interview

You recently completed a survey for our research and expressed an interest in being involved in a telephone interview. We’d like to invite you to take part in our research. Taking part in the research is entirely up to you. This document will give you information about the study and what you will be asked to do, should you volunteer to take part.

Please keep this document for future reference. If you have any questions, please feel free to ask or contact Sian Williamson (s.williamson@warwick.ac.uk).

What is the purpose of the research?

This research is being conducted to evaluate how results are currently being given in the NHS Breast Screening Programme in order to inform future policy changes.

What would taking part involve?

You will be contacted by a researcher for a telephone interview. When they call, they will confirm your identity and confirm your consent to participate. The interview will then commence, asking questions about your experience of receiving results from breast screening.

You do not have to participate if the phone call is inconvenient for you, and we can arrange to call you back at a more suitable time. We will leave an answerphone message if you are unable to answer. We will attempt to contact you a maximum of two times.

The interview will be audio-recorded. The audio recording will be written up by a third-party service, who will only hear the data in anonymised form. This third-party transcription service also have a policy for keeping your data anonymous and confidential.

How long will it take?

The telephone interview will take between 10 to 20 minutes.

What will my contact details be used for?

We will only use your telephone number (provided in survey 1) for the purposes of contacting you for the telephone interview. Once the telephone interview is complete and the research project has concluded, your contact details will be destroyed in a secure manner.

IRAS ID: 212999
Qualitative interviews – information sheet V.5 17.11.2017

What are the possible benefits of taking part?
Your experiences and opinions will be used to make improvements in how we communicate results to women attending breast screening in the future.

What are the possible disadvantages and risks of taking part?
We do not anticipate any disadvantages other than giving up your time. It is possible some individuals may be uncomfortable or feel anxious answering questions about how they feel, but you are free to withdraw from the study at any time.

How do I consent to take part?
If you wish to take part, please return the completed consent form in the pre-paid postal envelope provided.

Thank you for considering taking part in this study and for taking the time to read this information sheet.

If you have any questions, feel free to contact the lead researcher:

Lead researcher: Sian Williamson
Email: s.williamson@warwick.ac.uk
Telephone: 07891319509

Public Health England
Warwick University
NHS
Cancer Screening Programmes

IRAS ID: 212999
Appendix 23 - Qualitative interviews consent

Consent for qualitative interview V6 12.11.2018

NHS

Public Health
England

Warwick
University of Warwick

Cancer Screening Programmes

IF YOU WISH TO TAKE PART, PLEASE RETURN THIS COMPLETED CONSENT FORM IN THE PRE-PAID ENVELOPE PROVIDED.

PLEASE KEEP THE SECOND CONSENT FORM FOR YOUR RECORDS.

IRAS ID: 212999
Participant ID number: 361

CONSENT FORM

Title of Project: The communication of results in breast screening – Telephone interview
Name of Researcher: Sian Williamson

Please read each statement and initial the boxes if you give your consent. Please write your name, the date and your signature at the bottom of this form.

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 12.11.2018 (V6) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

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

3. I understand that I will be contacted by the researcher by telephone and give permission for this contact.

4. I understand that the interview will be audio-recorded.

5. I understand that the interview will be written up by a third-party service, who will only hear the data in anonymised form.

6. I understand that I will be given a unique participant ID number and my responses will be anonymised.

7. I understand that my contact details will only be used for the purposes of this study. I understand that once the study is complete, my contact details will be destroyed in a secure manner.

8. I agree to take part in the above study.

________________________  _____________  _______________
Name of Participant          Date                  Signature
Appendix 24 - Qualitative interviews guide

Interview guide

Introduction

“Hello, I am ringing regarding the research project about communicating results in breast screening. Can I confirm that I am speaking to the participant of this research?”

Not the participant/participant not in/participant busy. “I am sorry to hear that. Is there another time more convenient to call back?”

If participant is available: “I received your written consent for this interview but just to confirm that you are still happy to participate? Can I confirm that you received the participant information sheet for this project? As you know, this research is looking at how results are communicated in breast screening. In the interview, I will be asking about your experience of receiving results from breast screening. This interview will be between 15-30 minutes long. Did you have any questions?”

“Just to remind you that this interview is being audio recorded.” Turn on audio recorder.
Interview questions

1) How would you describe your overall experience of breast screening?

Prompts: Could you explain what you meant by…, you mentioned that…, could you expand on what you meant…, tell me more…

2) How were your results communicated to you? What method?
3) Did you find this method acceptable? Tell me why.

Prompts: Could you explain what you meant by…, you mentioned that…, could you expand on what you meant…, tell me more…

4) How did you feel when you were told your result?

Prompts: Could you explain what you meant by…, you mentioned that…, could you expand on what you meant…, tell me more…

5) Did you feel like you understood your result? Was this explained well?

Prompts: Could you explain what you meant by…, you mentioned that…, could you expand on what you meant…, tell me more…

6) If you had a choice, would you prefer any other method of communication (for example…)? Tell me why.

Prompts: Could you explain what you meant by…, you mentioned that…, could you expand on what you meant…, tell me more…
Concluding the interview

"Is there anything you'd like to ask me before we end this conversation?"

Thanking participant for their time.

Turn off audio recorder

What do following the interview?

- Check audio recording
- Make notes, summarise key data
- Store data
Appendix 25 – Systematic review publication (Preventive Medicine Reports)
Communicating biopsy results from breast screening assessment: current practice in English breast screening centres and staff perspectives of telephoning results

Sian Z Williamson, Rebecca Johnson, Harbinder K Sandhu, David R Ellard, Jacqui Jenkins, Margaret Casey, Olive Kearins, Sian Taylor-Phillips

ABSTRACT

Objective: To record how breast screening centres in England deliver all biopsy results (cancer/non-cancer) from the breast assessment visit.

Design: Online survey of 63 of 79 breast screening centres in England from all regions (East Midlands, East of England, London, North East Yorkshire and Humber, North West, South West, West Midlands). The survey contained quantitative measures of frequency for telephoning biopsy results (routinely, occasionally or never) and optional qualitative free-text responses. Surveys were completed by a staff member from each centre.

Results: There were no regional trends in the use of telephone results services. X(2) (15, n=63)=11.56, p=0.44. Centres who telephoned results routinely did not deliver results sooner than centres who delivered results in-person (X(2) (10, n=63)=12.76, p=0.09).

When delivering cancer results, 75.2% of centres never telephoned results and 23.8% of centres occasionally telephoned results. No centres reported delivering cancer results routinely by telephone. Qualitative content analysis suggests that cancer results are not telephoned at the patient request and under exceptional circumstances. When delivering non-cancer results, 12.7% of centres never telephoned results, 38.1% occasionally telephoned results and 49.2% routinely telephoned results.

Qualitative content analysis revealed different processes for delivering telephone results, including patient choice and scheduling an in-person results appointment for all women attending breast assessment, then ringing non-cancer results unexpectedly ahead of this prebooked appointment.

Conclusions: In the National Health Service Breast Screening Programme, breast assessment results that are cancer are routinely delivered in-person. However, non-cancer breast assessment results are often routinely delivered by telephone, despite breast screening policy recommendations. More research is needed to understand the impact of telephoning results on women attending breast assessment, particularly women who receive a non-cancer result. Future research should also consider how women themselves might prefer to receive their results.

Strengths and limitations of this study

- This study gives an up-to-date picture of current results-giving practice of National Health Service Breast Screening Programme centres nationally.
- A high response rate was achieved, so results are generalisable to the English National Health Service Breast Screening Programme.
- The qualitative comments made by National Health Service staff gave deeper insight into how telephone results are delivered in practice.
- Survey responses were subjective and not checked against centre policy documents.
- Formal analysis of the concordance between communication practice and policy guidelines was not conducted.

BACKGROUND

Breast cancer is one of the most common cancers internationally. The National Health Service Breast Screening Programme (NHSBSP) was launched to aid the early detection of breast cancer at the population level because early detection is linked with better prognosis. At the screening, a mammogram (x-ray) is performed on each breast. If an abnormality is found during this screening mammogram, women will be recalled to attend an assessment for further tests. These tests can include a core needle biopsy, which involves the removal of sections of tissue from the suspicious breast region which are sent for cytological examination. A biopsy is the definitive test at breast assessment to confirm if the mammogram abnormalities found are cancer. In 2016–2017, a total of 2 199 342 women in England were screened by the NHSBSP. Of these, 89 104 women were referred for assessment and 40 255 women had a core biopsy.
In recent years, the NHSBSP has been considering which communication method might be preferable for delivering non-cancer biopsy results from breast assessment. The NHSBSP service specification recommends that all breast assessment results should be delivered in-person, which includes cancer and non-cancer results. Furthermore, the guidelines state that telephone results should only be used at the patients request and should not be standard practice. Despite these recommendations, some centres already routinely deliver non-cancer assessment results by telephone. There is ongoing concern about the impact of delivering a non-cancer assessment result by telephone. One of the main concerns is how anxious women feel when receiving a result, even when the result is non-cancer. Another concern is the potential for miscommunication by telephone.

In other areas of healthcare, a variety of communication methods are used to deliver results, including in-person consultations, telephone, letters and email. Each method of communication used in results delivery presents different advantages, disadvantages and challenges in implementation. Results delivered in-person are often seen as the ‘gold standard’. However, as technology advances, fewer healthcare results are now delivered in-person. Lideorman et al stated that ‘face-to-face contact is not necessary for effective communication’ (pg. 52). Most commonly, results delivery is moving towards telephone and telemedicine. Despite this, Cochrane review evidence suggests that we still do not know enough about the impact of telephone results services on healthcare outcomes.

There is no current record of how breast centres in England deliver biopsy results from breast assessment. Despite policy recommendations, some centres appear to routinely deliver non-cancer results by telephone. Furthermore, it is assumed that cancer results are all delivered in-person as guidelines recommend. There is a current lack of evidence about how often telephone results are used to deliver breast assessment results.

In this study, we aimed to record how breast screening centres in England deliver biopsy results from breast assessment and answer the following questions:
1. How often are telephone results delivered and by whom? Does this differ when results are non-cancer versus cancer?
2. Is there a time difference between results delivered by telephone versus results delivered in-person?

METHODS
Participants
A link to an online survey hosted by the Bristol Online Survey platform was sent to all breast screening centres in England on 2 June 2017. At this time, 79 breast screening units existed in England, as confirmed by a list from the Quality Assurance Lead for Breast Screening. Data collection ended on 28 February 2018.

The survey link was distributed to the manager of each breast screening centre via the Quality Assurance lead for each region (East Midlands, East of England, London, North East Yorkshire & Humber, North West, South East, South West, West Midlands). The link was accompanied by a brief study description. The survey was completed by a representative member of staff from each breast screening centre.

Survey completion reminders were sent periodically by the Quality Assurance leads to non-responding centres.

Ethical approval for the survey was obtained from the Biomedical & Scientific Research Ethics Committee at the University of Warwick (REGO-2017-1008).

Survey piloting and instrument
The survey was designed using a previous tool developed by Clinical Nurse Specialist in Breast Care (Margaret Casey) in combination with discussions with key stakeholders from the NHSBSP. Stakeholders included the programme manager for the NHSBSP, the Quality Assurance Lead for the NHSBSP, and a clinical nurse specialist in breast care. Following this, a draft version underwent three rounds of piloting stakeholder review of content, stakeholder piloting of the online layout and cognitive interviewing with a layperson.

The main questions in the survey focused on recording how often biopsy results were telephoned. The first question asked about the frequency of delivering benign (non-cancer) biopsy results by telephone (never, occasionally, routinely). The second question asked about the frequency of delivering cancer biopsy results by telephone (never, occasionally, routinely). After these two questions, a free text box was added to allow respondents to comment on the answers provided. The survey also recorded who is responsible within the team for delivering telephone results at the centre (clinical nurse specialist, radiologist, radiographer, breast care surgeon, administrative staff, other).

One question recorded the amount of time taken between clinic assessment and the delivery of a result (options spanning between 1 day and >12 days). These data were collected to compare the length of time taken to deliver results for centres who delivered results by telephone routinely versus those who never deliver telephone results.

The survey included nine questions. It was expected that the survey would take 10 min to complete (see the online supplementary appendix 1 for a full survey).

Data analysis
Quantitative
Data cleaning processes were implemented. This involved checking for missing data, coding centres by region and removing duplicate responses. Descriptive statistics and response rates were calculated. Percentages for delivering non-cancer results and cancer results by telephone were calculated separately, alongside frequencies for who delivers each type of results.

To identify whether there were any regional trends in the delivery of telephone results, a chi-square was calculated, comparing region (East Midlands, East of England, London, North East Yorkshire & Humber, North West, South East, South West, West Midlands) with telephone frequency (routinely, occasionally and never).

To identify any potential time differences between telephone and in-person results a $\chi^2$ was calculated, comparing telephone frequency (routinely, occasionally and never) with the length of time between assessment and results (1–12 days).

Statistical significance was assumed at $p<0.05$. Statistical analysis was conducted using IBM SPSS Statistics 24 software.

Qualitative
Qualitative free-text comments were analysed using qualitative content analysis. This approach allowed for commonalities among staff viewpoints to be identified and to be described narratively, in order to contextualise and expand on the qualitative findings. Intercoder reliability was used to ensure the rigour and trustworthiness of the analysis. The analysis was conducted by the lead author (SW) and checked by a second author (DE) to ensure that the meaning of original staff comments was retained. Any disputes in interpretation were resolved by a third author (HS). Qualitative analysis was conducted using NVivo 12.

RESULTS
Respondents
Of the 79 breast screening centres in England, 63 (79%) responded to the online survey. All regions were represented in the quantitative survey (Table 1).

Data relating to the mean age of women screened at each centre were removed from the data set due to 61.4% of responses being ‘I do not know’.

Quantitative findings
Frequency of results by telephone
When delivering non-cancer results, the majority of centres routinely telephoned results (Table 2) and most of these results were delivered by clinical nurse specialists (Table 3).

When delivering cancer results, the majority of centres never telephoned results (Table 2). When cancer results were delivered by telephone, most of these results were delivered by clinical nurse specialists (Table 3).

Regional differences: frequency of telephone results
No relationship was found between region and the frequency of non-cancer telephone results, ($X^2$ (4, $n=63$)=11.55, $p=0.06$). This indicates no regional trends in the use of telephone results services.

Time difference: telephone results vs. in-person results
The mean time to deliver results for all centres was 7.03 days (SD=2.05). See Table 4 for all means (SDs). No relationship was found between the frequency of telephone results and length of time from assessment to receipt of results, ($X^2$ (16, $n=63$)=12.76, $p=0.69$). This indicates that...
centres delivering results by telephone do not deliver them sooner after the assessment visit than centres delivering results in-person (or never telephone).

**Qualitative findings**

In the survey, NHS staff had the option to comment in free-text boxes after two questions. The results are presented in two sections, with one focusing on the first question (non-cancer) and one focusing on the second question (cancer). All regions (excluding London) provided qualitative free-text responses see (table 1). See the online supplementary appendix 2 for a tabular representation of all qualitative comments from the content analysis.

**WHEN DELIVERING BENIGN (NON-CANCER) BIOPSY RESULTS ARE WOMEN NEVER TELEPHoned WITH RESULTS, OCCASIONALLY TELEPHoned WITH RESULTS OR ROUTINELY TELEPHoned WITH RESULTS?**

This section presents the qualitative findings following the first survey question (n=28), which asked the frequency of delivering non-cancer biopsy results by telephone (never/occasionally/routinely).

Content analysis revealed that seven centres scheduled for all women to return to receive results in-person. Then, if the test results for these women are confirmed as non-cancer, centres attempt to ring women with telephone results ahead of the prescheduled in-person appointment. Example comments include:

- Women have a scheduled face to face appointment for results but if it’s benign we ring them. (Centre ID 92)
- Our aim is to call all the benign results and offer to cancel the booked appointment. (Centre ID 50)
- All women are given a results appointment during assessment clinic. Following MDT, all those with benign biopsy results are contacted by telephone. If contact is made, the result is discussed and the results appointment cancelled. (Centre ID 38)

One centre (Centre ID 25) commented that they ‘normally see women face to face’, with this being their routine practice. This suggests that breast screening centres differ in how they deliver non-cancer breast assessment results.

**Option to still attend**

Content analysis revealed five centres who commented that, when women are contacted by telephone with a non-cancer result, they are still offered the option to attend in-person if they have further questions. Example comments include:

- All patients are given an appointment to attend for results we do telephone with results but patients are still able to attend, and some do. (Centre ID 45)
- After the MDT, Patients are telephoned with benign results by a qualified Breast Care Nurse. They are then offered an OPA with a consultant surgeon if they have concerns. (Centre ID 31)

**Rare and exceptional circumstances**

Content analysis revealed five centres only deliver non-cancer results by telephone in exceptional circumstances. Example comments include:

- Only in exceptional circumstances (Centre ID 59)
- This is not done routinely and very rarely occurs. (Centre ID 78)
- Reasons given for giving non-cancer results by telephone included if the woman finds it difficult to attend in-person and so the woman can be where she wants to be to receive results.

**Giving women a choice or at patient request**

Content analysis revealed five centres ask women how they would like their results to be delivered if it is not cancer. Example comments include:

- We will always offer them an appointment to come in, but the BCNs will ask if they want a telephone call at the time of assessment (Centre ID 63)
- Women are asked at assessment if they would like a telephone call or they can come back for results if they do not wish to be telephoned. (Centre ID 29)
Women are given a choice about how they receive their results when the imaging suggests a benign process (Centre ID 42).

One centre commented that non-cancer results are only delivered by telephone at the request of the patient:

This is not routine practice but happens if a patient requests it and the probability of a benign result is very high. (Centre ID 73)

**SUMMARY OF NON-CANCER CONTENT ANALYSIS**

Consent analysis revealed conflicting centre comments. Some centres schedule in-person results appointments for all women, but then attempt to contact women with non-cancer results by telephone instead. However, one centre commented that delivering non-cancer results by telephone was not routine practice. Other centres commented that telephoning non-cancer results only happens under exceptional circumstances, such as the woman being unable to attend in-person.

Content analysis revealed that some women who are telephoned with results are still offered the option to attend if they have further questions. Some centres ask women how they would prefer to be contacted with their result if it is not cancer.

**WHEN DELIVERING CANCER BIOPSY RESULTS ARE WOMEN NEVER TELEPHONED WITH RESULTS, OCCASIONALLY TELEPHONED WITH RESULTS OR ROUTINELY TELEPHONED WITH RESULTS?**

This section presents the qualitative findings following the second survey question (n=29), which asked the frequency of delivering cancer biopsy results by telephone (never/occasionally/routinely).

Content analysis revealed four centres routinely deliver cancer results in-person. Example comments include:

- Cancer diagnoses are always communicated face to face. (Centre ID 39)
- Telephone results: This would never be planned. (Centre ID 09)
- All positive results or complicated cases are invited back to be given results by the Breast Surgery Team. (Centre ID 26)

**Rare and exceptional circumstances**

Content analysis revealed 11 centres only deliver cancer results by telephone in exceptional circumstances. Example comments include:

- Rarely telephoned with a cancer diagnosis always at the patient's request in extenuating circumstances. (Centre ID 45)
- This is a rare occurrence and is only agreed to with the patients prior consent on the understanding they may be receiving a cancer diagnosis. (Centre ID 11)

Very rare - this would only happen with prior agreement if a woman is to be away for an extended period of time. (Centre ID 38)

Reasons for delivering cancer results by telephone under these exceptional circumstances were if the woman finds it difficult to attend in-person and if the woman was going to be away for an extended period of time.

**Giving women a choice or at patient request**

Content analysis revealed two centres ask women how they would like their result to be delivered if it is cancer. Example comments include:

- They are asked if the result was a surprise and was a breast cancer would you still wish to get that news over the phone. (Centre ID 01)
- Women are asked at assessment if they would like a telephone call or they can come back for results if they do not wish to be telephoned. (Centre ID 29)

Content analysis revealed 11 centres only deliver cancer results by telephone at the request of the patient. Example comments include:

- Patient request only (Centre ID 33)
- Only very rarely and at patient's specific request (Centre ID 08)

**Unexpected results and a negative reaction**

One centre (Centre ID 60) addressed the issue of how to deal with an unexpected result. At the breast assessment visit, this centre informs women with a high suspicion of a non-cancer result that they will have their result delivered by telephone. However, if ‘If there is a positive result which was unexpected a Breast Care Nurse rings the women to advise an appointment is required to discuss the results’.

One centre (Centre ID 15) commented about a woman who ‘reacted extremely badly on telephone’ when receiving a cancer result.

**SUMMARY OF CANCER CONTENT ANALYSIS**

For cancer results, in-person results are routine. Telephoning cancer results is only being offered under rare or exceptional circumstances such as when women have difficulty in attending. These telephone results are only given at the request of the patient.

Content analysis revealed the potential difficulties in delivering and scheduling results by telephone. One comment highlighted the negative reaction of a woman who received her cancer result by telephone. Another comment addressed the issue of how to deal with a result which was presumed to be non-cancer but turned out to be cancer.

**DISCUSSION**

The aim of this research was to record how breast screening centres in England deliver biopsy results from
breast assessment by assessing how often telephone results are delivered and by whom. This research also aimed to see if telephone results delivery differs when assessment results are non-cancer versus cancer. Furthermore, this research aimed to assess if there is a time difference between results delivered by telephone versus results delivered in-person.

Our research suggests that centres routinely delivering results by telephone do not deliver them sooner than centres who deliver results in-person. This contradicts articles citing ‘speed’ as one of the potential advantages of telephone results.3,7,8

Our study found that delivering cancer results by telephone is not a common practice for breast screening centres in England. Telephoning cancer results are only used in exceptional circumstances and only at the request of the patient. For example, telephone results might be used if the patient is physically unable to attend in-person (eg, health issues or away from the country for an extended period). When cancer results are telephoned, most of the results are delivered by Clinical Nurse Specialists. The reason why cancer results are rarely telephoned is probably due to the emotional impact of receiving a cancer diagnosis.13 The extensive literature on ‘breaking bad news’ in healthcare places importance on the location where results are received to ensure no disturbances.20 This may help to explain the one comment in the current study where a centre reported the negative reaction of a woman who received a cancer result by telephone. However, this comment was only made by one centre in the study and may not be representative of the population as a whole so this finding should be interpreted with caution.

Another comment in the study highlighted the issues of how to deal with a result which was presumed to be non-cancer at the assessment stage but turned out to be cancer. At the stage of breast assessment, it is unknown if a woman will receive a cancer or non-cancer result. However, breast assessment tests may indicate a higher chance of a non-cancer result. These women might be informed of the lower likelihood of cancer and are offered the opportunity to receive results by telephone. If the biopsy result then confirms unexpected cancer, women may then be telephoned with a cancer result. This may have implications for anxiety and may be avoided by not offering telephone results. However, this was an issue only highlighted by one centre in the study and does not represent the centre comments as a whole.

Our study found that delivering non-cancer results by telephone is routine practice for roughly half of the breast screening centres in England, with most of the results being delivered by Clinical Nurse Specialists. This appears to contrast with breast screening policy guidelines, which state that telephone results should only be used at the patient’s request and should not be routinely offered. However, the qualitative findings clarified that some of these centres offer women a choice of how they would prefer to receive their results. This suggests that some centres are still acting within the guidelines by only telephoning women who choose this communication. Offering the choice between telephone and in-person communication may not be feasible for all centres.23 For centres who already routinely telephone results, there may be a reduced capacity to provide results in-person if this is requested by the woman. From the content analysis in the current study, a compromise is to telephone all non-cancer results routinely but to also offer the option for the woman to still attend the clinic in-person. Offering patients a choice of a communication method of results at the assessment visit might also be problematic due to heightened anxiety with some women not wanting to make a decision.22,23

Some centres who routinely deliver non-cancer results by telephone do not offer patient choice. A common practice is for centres to give all women who attend breast assessment an in-person appointment to return for results, but then telephone women with non-cancer results ahead of this scheduled appointment. The centres commented that this process has the potential to reduce the expected wait time for women to receive results, thus minimising the amount of time spent anxiously waiting.24 However, the psychological impact of receiving an ‘unexpected’ communication method has not been considered in this setting. When a telephone result is not expected, it is possible that women may feel unprepared or not in the right mindset to comprehend the information given.25 This may contribute to the anxiety associated with screening and might be avoidable harm. However, from the current research, we do not know if this is the case.

**Strengths**

This study formally reports the national communication practice of NHSBSP centres for delivering non-cancer and cancer breast assessment results. The high response rate indicated that this is an important issue for staff working within the screening programme. The content analysis of qualitative comments allowed for the expansion of quantitative survey data, which gave greater insight into how telephone results were implemented in practice.

**Limitations**

The time difference between telephone results and in-person results was quantified to allow the survey to be easily answered. This was quantified by the difference in days between clinic assessment and the delivery of a result for centres who either routinely, occasionally or never telephone results. However, other factors could be involved in the speed of results delivery.

The survey responses completed by centre staff were subjective and could not be validated by records. Furthermore, the staff member completing each survey was not recorded as part of the study. Therefore, quantitative data may not accurately reflect current communication practices due to the potential for human error or level of experience of the staff member completing the survey.
CONCLUSIONS

In the NHBSBP, breast assessment results that are cancer are routinely delivered in-person, as recommended by policy guidelines. However, non-cancer breast assessment results are often routinely delivered by telephone despite the recommendations made in policy guidelines. Despite this, telephone results do not appear to be quicker than in-person results in practice.

A common process is to give all women attending breast assessment an appointment to come back to receive results in-person, to then telephone all women with non-cancer results ahead of this appointment. Some centres offer women a choice, although this might not be feasible for all centres and it is possible that women might be too anxious to make an informed decision.

Research and practice implications

Now that we have a record of current practice, more research is needed in order to fully understand what impact telephone results have on women attending breast assessment and whether variations in the results giving process also have an impact. This would be particularly beneficial to consider for non-cancer results, where results are being routinely delivered by telephone to large numbers of women every year. Further research should also consider how women themselves might prefer to receive their results and focus on the patient perspective.

REFERENCES

Appendix 27 – Trial protocol paper (BMJ Open)

**BMJ Open**
Communicating benign biopsy results by telephone in the NHS Breast Screening Programme: a protocol for a cluster randomised crossover trial

Sian Zena Williamson,1 Rebecca Johnson,2 Harbinder Kaur Sandhu,3 Nicholas Parsons,1 Jacqui Jenkins,2 Margaret Casey,6 Olive Kearins,7 Sian Taylor-Phillips8

**ABSTRACT**

**Introduction** One of the main harms from breast cancer screening is the anxiety caused by false-positive results. Various factors may be associated with false-positive anxiety. One modifiable factor may be the method of communication used to deliver results. The aim of this study is to measure the effect on anxiety of receiving benign biopsy results in person or by telephone.

**Methods and analysis** This is a multi-centre cluster randomised crossover trial in the English National Health Service Breast Screening Programme (NHBSGP) involving repeated survey measures at four time points. Participants will be women of screening age who have a biopsy following a suspicious mammography result, who ultimately receive a benign or normal (BI) result. Centres will trial both telephone and in-person results on a month-by-month basis, being randomised to which communication method will be trialled first. Women will be blinded to the method of communication they will receive. The analysis will compare women who have received telephone results and women who have received in-person results. The primary outcome measure will be anxiety (measured by the Psychological Consequences Questionnaire) after receiving results, while controlling for baseline anxiety. Secondary outcome measures will include anxiety at 3 and 6 months post-results, understanding of results and patient preferences for how results are communicated. Qualitative telephone interviews will also be conducted to further explore women’s reasons for communication preferences. Qualitative and quantitative data will be integrated after initial separate analysis using the pillar integration process.

**Ethics and dissemination** This study has been approved by the Public Health England Breast Screening Programme Research Advisory Committee, (BSPAC 0013, ODR/17/18, 040) and the National Health Service Health Research Authority (HRA) West Midlands—Coventry & Warwickshire Research Ethics Committee (17/WM/0313). The findings from this study will be disseminated to key stakeholders within the NHBSGP and via academic publications.

**Trial registration number** ISRCTN36997664

**Trial sponsor** This research is part of a PhD award and is funded by the Economic and Social Research Council (ESRC) Doctoral Training Centre at the University of Warwick and...

**Strengths and limitations of this study**

- This is the first cluster randomised crossover trial to measure the impact of communication method on patient outcomes when delivering results in breast screening.
- The mixed-methods design adds depth to our understanding of communication preferences and the mechanisms by which anxiety may be affected.
- The study is in English breast screening centres and generalisability to other contexts should be carefully considered.

Public Health England. The sponsor for this research is Jane Frevert (sponsorship@warwick.ac.uk).

**INTRODUCTION**

The UK National Health Service Breast Screening Programme (NHBSGP) is a population-based screening programme that aims to detect early signs of breast cancer. Asymptomatic women aged 50–70 years are invited to attend every 5 years for a mammogram. The results of the mammogram take a maximum of 2 weeks as per NHBSGP guidelines.3 If a suspected abnormality is found on the mammogram then the woman is invited back to the clinic for follow-up tests, usually within the next 2 weeks.

Follow-up tests can include clinical examination, a further mammogram or ultrasound. If these indicate suspicion of cancer then the woman receives a core needle biopsy, involving the removal of sections of tissue from the suspicious breast region. This issue can then be pathologically analysed. Although the procedure is designed to be minimally invasive, leaving only minor bruising, some women find the experience painful and distressing. It is standard practice to perform all follow-up tests (clinical exam,
mammogram, ultrasound and biopsy) on the same day in an assessment clinic to avoid unnecessary extra waiting time for patients. Results of diagnostic tests are discussed on a case-by-case basis at multidisciplinary team meetings using a triple-assessment of clinical examination, imaging and biopsy report. Clinical guidelines recommend that all follow-up results should be delivered to the woman within 1 week. These results are delivered by either telephone or in-person, depending on the procedure at the breast screening centre.

Screening programmes should provide benefit that outweighs both physical and psychological harm. One of the main harms from breast screening is the anxiety caused by false positive results. A false-positive result is when a woman has been identified at the screening phase as potentially having cancer, but follow-up tests have revealed no abnormalities. Receiving a false-positive result from screening is very common, with the majority of women who are recalled ultimately being given a false-positive result. In England, around half of women receive the all clear results at the time of the follow-up tests. Women who are invited to be screened have no symptoms of breast cancer at the time of their initial mammogram. Telling a woman that something suspicious has been found in the mammogram and that further tests are needed can make her feel very anxious and believe that she might have cancer. For some women, once results confirm the absence of cancer, anxiety declines. However, anxiety can remain elevated for much longer, lasting up to 3 years after receiving the benign result and leading into the next screening invitation. This is an issue, as the NHSBSP has a duty to minimise the harm caused by screening.

There are various factors that may be associated with heightened anxiety during screening such as family history, lower education, younger age and individual differences in personality. Factors are unmodifiable and tend to be focused at the level of the individual, which makes the minimisation of screening anxiety a challenge. However, it is possible that there are modifiable changes that can be made at the organisational level of screening that may minimise the impact of anxiety. One of these changes is the method of communication used to deliver results.

NHSBSP guidelines for communicating results state that telephone results ‘should not be routinely offered’. However, most breast screening centres in the UK deliver benign results to the woman over the telephone. Some breast care nurses remain concerned about how the communication method used to deliver results may contribute to the anxiety experienced by women attending screening. Telephone results may offer advantages, eliminating the stress and costs associated with transport, parking and anxiously waiting in a clinic for results. However, telephone results eliminate the in-person encounter, meaning all communication is verbal only. Research from other areas has shown that non-verbal communication plays a key role in enhancing understanding and minimising anxiety.

The communication methods used to deliver benign results in the NHSBSP have not yet been explored. Therefore, the impact of this communication on women receiving a benign result is unknown.

**Aim of the study**
The aim of this study is to compare anxiety in women receiving benign biopsy results from the NHSBSP via telephone results or in-person.

**METHODS AND ANALYSIS**

**Study design**
The study design chosen was a multi-centre cluster randomised crossover trial. The randomisation allows for the direct comparison of study outcomes between women who received telephone results and women who received in-person results, while controlling for confounding factors such as education, age and individual differences in baseline anxiety.

Patient and public involvement from the charity Independent Cancer Patients’ Voice was used to guide the design of the study to ensure the acceptability of the method and appropriateness of the participant materials.

**Participants and settings**

This trial will be conducted in a breast screening centre setting. The study will take place in the UK where women are invited to attend breast screening every 3 years for digital mammography. The study will take place across four time points (see table 1) with a survey completed by participants at each stage. The study participants will be recruited from four English Breast Screening centres across different regions.

Participants will be women between the ages of 47 and 73 attending the NHSBSP for further tests following a suspicious mammogram. This includes women offered routine screening between ages 50 and 70 and those receiving extra rounds of screening between the ages of 47 and 49 or 71 and 73 as part of the UK age extension trial. Women will be recruited at the assessment clinic pre-biopsy. However, only women who have received a benign (B2) or normal (B1) biopsy result will be included in the longitudinal data collection. Participants will not be included in the study if they presented symptomatically to the breast clinic, if they are not the recommended screening age, if they do not receive a biopsy, or if they do not have English as a first or second language and if they do not have the capacity to consent.

**Measuring anxiety**

The Psychological Consequences Questionnaire (PCQ) was selected as the most appropriate measure of anxiety in the breast screening setting and was embedded in the participant surveys (see online supplementary appendix 1). The PCQ is a disease-specific measure, focusing on breast cancer specific anxiety across 12 questions on three dimensions: emotional, social and physical anxiety.
Table 1  Time points for the study

<table>
<thead>
<tr>
<th>Time point</th>
<th>Sample</th>
<th>Survey content</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time point 1 — at assessment clinic</td>
<td>Women attending assessment follow-up clinic</td>
<td>Demographic information</td>
<td>In-person</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Communication</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>preferences</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Baseline anxiety</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>score (PCQ)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Contact details</td>
<td></td>
</tr>
<tr>
<td>Time point 2 — after receiving results</td>
<td>Women from time point 1 who had a normal or benign biopsy</td>
<td>Communication</td>
<td>By post</td>
</tr>
<tr>
<td></td>
<td></td>
<td>preferences</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Repeat anxiety score</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(PCQ)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Measure of understanding</td>
<td></td>
</tr>
<tr>
<td>Time point 3 — 3-month follow-up</td>
<td>Women from time point 1 who had a normal or benign biopsy</td>
<td>Repeat anxiety score</td>
<td>By post</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(PCQ)</td>
<td></td>
</tr>
<tr>
<td>Time point 4 — 6-month follow-up</td>
<td>Women from time point 1 who had a normal or benign biopsy</td>
<td>Repeat anxiety score</td>
<td>By post</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(PCQ)</td>
<td></td>
</tr>
</tbody>
</table>

PCQ, Psychological Consequences Questionnaire.

The disease-specific measure avoids the contrast validity that is associated with using general anxiety measures in the breast screening context. The PCQ is widely used in the breast screening setting.

Participants will rate their anxiety on the PCQ by judging each statement on a scale of 0 (not at all) to 3 (quite a lot of the time). Women will be asked “Over the last week how often have you experienced the following things because of thoughts and feelings about breast cancer?”

Randomisation and blinding

Each centre will be randomised to one of two intervention arms by computer generated random numbers from the trial team base at the University of Warwick (see Table 2). The arm relates to whether the first month at each centre will be telephone or in-person results. Each centre will commence with the communication method randomised in month 1 and continue to alternate between the two communication methods for the duration of the study. This approach allowed for each centre to use both methods of communication, controlling for previous experience (eg, centres who already telephone are more experienced and therefore women receiving telephone results from this centre might be less anxious).

Allocation of communication method

There are two types of centres who may be involved in the research: centres who currently deliver benign results in-person and centres who currently deliver benign results by telephone.

For centres currently delivering results in-person, the following process for scheduling a results appointment will be observed: During in-person study months, all consenting women at time point 1 will be given an appointment to re-attend to receive their results in-person and will receive the result in-person. During telephone study months, all consenting women at time point 1 will be given an appointment to re-attend to receive their results by telephone.
in person. However, they will instead be telephoned prior to their scheduled appointment. Only benign women will be telephoned, with all women receiving other results (eg, cancer) attending their scheduled appointment.

For centres currently delivering results by telephone, the following process for scheduling a results appointment will be observed: All consenting women will be informed that, when their results are ready, they will be contacted by telephone to arrange an appointment to come back for their results. During the telephone months of the study, women will be telephoned as expected. However, instead of arranging an appointment during this telephone call, results will be delivered. This means that, for women who go on to have a cancer result, they can be telephoned to arrange an appointment to attend in-person, as expected. This is in line with standard practice at these centres. During the in-person months, all consenting women will be informed that, when their results are ready, they will be telephoned to arrange an appointment to come back for their results. These women will be telephoned to arrange an appointment to come back in-person, and at that appointment they will receive their benign/normal result.

All women not enrolled in the study will receive their screening result based on the current standard practice at the attended centre.

Data collection
Time point 1
Participant recruitment at time point 1 will occur concurrently at each breast screening centre.

Women will be approached during their assessment visit by breast care nurses with good clinical practice training. These women would have been recalled from a previous mammogram and may have a biopsy as part of the assessment clinic. The study will be explained to potential participants and nurses will go through the informed consent process. Consenting women will fill out the time point 1 survey with study responses collected and stored securely before the participant leaves the assessment clinic.

Multidisciplinary team meeting
At the local level multidisciplinary team meeting for breast screening staff, women recruited into the study will be included in further time points if they receive a benign (B2) or normal (B1) result. A breast care nurse will compile the contact details of eligible women into a spreadsheet to be sent securely to the research team.

Time point 2
The research team will distribute time point 2 surveys to eligible women with a pre-paid return envelope. If no response is received within a week, the research team will contact women by telephone as a reminder. A maximum of two telephone contact attempts will be made. This is to ensure anxiety and understanding are measured at the crucial post-results stage of the screening process.

As part of time point 2 survey, women will be asked if they would like to participate in further research involving an interview of their experience of receiving a screening result.

Time point 3
The research team will distribute time point 3 surveys, 3 months after the biopsy result was received.

Time point 4
The research team will distribute time point 4 surveys, 6 months after the biopsy result was received.

Qualitative telephone interviews
The qualitative telephone interviews will explore why women prefer certain methods of communication. Women will be recruited from the time point 2 survey. Women express an interest in participating will be sent further information about the interviews. If they wish to participate, women will return the consent form in the pre-paid envelope. Women will then be contacted by telephone by the research team to be interviewed.

The semi-structured telephone interviews will each take 10–20 min. Questions will encompass the women’s experience of receiving a result from screening. This will involve asking how the woman felt, whether she understood her result and an exploration of her views on different methods for communicating results. Interviews will be audio-recorded and transcribed verbatim. Data collection will cease once no further themes emerge and data saturation is reached.

Mixed-methods integration
Using a mixed-methods approach, the quantitative preference survey data will be combined with the findings from the qualitative interviews. The quantitative data ask a binary choice question regarding women’s communication preferences (telephone or in-person), while the qualitative interviews expand on this by exploring how women justify certain preferences for communication. In mixing the data, the qualitative data will be used to expand the understanding of the findings from the quantitative surveys. Expansion provides richness and detail, expanding why and how women form communication preferences and moving understanding of preferences beyond what quantitative data or qualitative data in isolation can elucidate. The value added by integrating the knowledge of both what women prefer and why is in the completeness of our understanding of preferences, making the evidence that will inform the NHSBSP policy decisions comprehensive and patient-centred.

Sample size considerations
In order to determine the sample size for a clustered randomised crossover study, a full specification of the important within-cluster (centre) between-period and within-period correlations is required. There is currently no available evidence on the magnitude of these correlations in our selected setting, so rather than arbitrarily
selecting values we adopt a conservative approach and assume that the (within-centre) between-period correlations are zero and proceed to power as if the design were a cluster randomised design. Although the crossover aspect of the design is not explicitly accounted for in the sample size calculation, it is incorporated fully in the analysis of the primary study outcome (PCQ anxiety score at time point 2). The aim of the study is to be able to detect a clinically significant difference of 5 points in the PCQ (the difference between the score on one statement being 0, not at all, and 5, quite a lot of the time).

Assuming the primary outcome is approximately normally distributed, and the test is at the 5% significance level with 80% power to detect an effect of the specified size, 194 participants are required at time point 2, that is 97 participants per arm. Allowing for attrition rate between time point 1 and time point 2 due to participant withdrawal (15%) and participant eligibility (50%), a total of 457 participants will be recruited at time point 1. Participant withdrawal was calculated based on a mean response rate of 60% from previous research using postal surveys in a medical setting with a loss of 15% at each time point as a conservative estimate.

In order to account for clustering due to the recruiting centre, design effect was applied that inflated the sample size. The intra-cluster (within-centre) correlation coefficient was set to be 0.01 and the number of observations within each cluster was assumed to be equal. With the sample size of 194 women, divided by the number of centres and then divided by the number of interventions, this led to the number of observations within a cluster to be 48.2. This gave a design effect of 1.49. Taking this into account, the sample size needed to achieve statistical significance (194 women) was multiplied by the design effect, giving a total sample of 290 women at time point 2 when rounded up (see figure 1).

31,926 women are recalled for a biopsy each year. If half of the 31,926 biopsies come back as benign, this leaves a potential sample of 15,963. This means that, on average across 80 breast screening centres, each centre will have around 200 biopsy results each year. Therefore, assuming 50% participation rates of eligible women, recruitment will require four centres for 1 year.

**Outcomes and study measures (primary outcome, secondary outcomes)**

**Primary outcome**
The primary outcome is the PCQ anxiety score at time point 2.

A comparison in anxiety score will be made between women who receive results in-person and women who receive results over the telephone.

**Secondary outcomes**
Secondary outcomes are:
- PCQ anxiety score at 3-month follow-up (time point 3).
- PCQ anxiety score at 6-month follow-up (time point 4).
- Subjective understanding of results (time point 2).
- Measured using a survey question designed in collaboration with NHSBSP stakeholders.
- Objective understanding of results (time point 2).
- Measured using a survey question designed in collaboration with NHSBSP stakeholders.
- Quantitative preferences for results communication before results (time point 1).
- Quantitative preferences for results communication after results (time point 2).
- Qualitative preferences for results communication before results (time point 1).
- Qualitative preferences for results communication after results (time point 2).

**Analysis**
Quantitative data—statistical analysis
A formal and more detailed statistical analysis plan will be developed by the trial team prior to the completion of recruitment.

**Primary outcome**
The primary analysis will use a mixed effects linear regression model to estimate the effects of communication method on anxiety (time point 2), after adjusting for baseline anxiety (time point 1). PCQ score will be treated as a continuous variable and to be approximately normally distributed for all analyses.

The model set-up and fixed and random effects are as follows:
- Response variable—anxiety at time point 2 (PCQ).
- Baseline—anxiety at time point 1 (PCQ).
Open access

- Fixed explanatory effects (model covariates)—age, ethnicity, previous attendance, previous biopsy, education, marital status.
- Random effects—centre and temporal (period) effects.
- Comparator variable—method of communication received—telephone or in-person.

Statistical significance will be assessed at 5% level.

Secondary outcomes

Longitudinal anxiety scores at 3 and 6 months will be analysed in the same way as the primary anxiety outcome. Differences in understanding score between communication methods groups will be assessed using a logistic regression model, adjusting for fixed effects.

- Outcome variable—subjective understanding score (binary—yes or no), objective understanding score (binary—right or wrong).
- Fixed effects—age, ethnicity, previous attendance, previous biopsy, education, marital status.
- Comparator variable—method of communication received (telephone or in-person).

Preference data from the quantitative surveys will be presented in the form of percentages. All analyses will be implemented using IBM SPSS Statistics V.25.

Qualitative data analysis

Qualitative preference data from time point 1 and time point 2 surveys and data from the telephone interviews will be analysed using thematic analysis, managed using NVivo V.10.

Mixed-methods integration

To integrate the quantitative and qualitative preference data, the pillar integration process will be used. This analytical integration technique uses four systematic stages (listing, matching, checking, and pillar-building) to identify and examine connections and discrepancies in qualitative and quantitative findings. It allows for the visual display of the data and findings, this enhances overall transparency of the integration approach and the results of such an integration.

Ethics

Attention was given to the various ethical challenges of the trial. The main ethical issue will be the use of sensitive patient information (addresses, telephone numbers). Participants will be told explicitly how their contact details will be used and stored throughout the data collection process. Participants will give informed consent for their contact details to be used for the purposes of the study.

All electronic data will be transferred securely in a password protected excel document from secure email accounts. All raw survey data will be collected directly from the centres by the lead researcher and be transferred in a secure lock-box.

Dissemination

Results from the trial will be disseminated directly to key stakeholders within the NHSBSP. This will encourage discussion regarding how benign results are communicated in breast screening, and how this might best be implemented in order to minimise the anxiety women experience.

The results will also be disseminated via academic publications.

Current study status

The trial began recruitment in February 2018. Data collection is due to conclude in March 2019. The trial statistician (SW and NP) have received recruiting data but no results will be transferred to the statistician until recruitment is closed in March 2019.

Author affiliations

1. Department of Health Sciences, Warwick Medical School, University of Warwick, Coventry, UK
2. Faculty of Health & Life Sciences, University of Warwick, Coventry, UK
3. Clinical Trials Unit, Warwick Medical School, University of Warwick, Coventry, UK
4. Statistics and Epidemiology, Warwick Medical School, University of Warwick, Coventry, UK
5. National Programme Manager—NHS Breast Screening Programme, Public Health England, Sheffield, UK
6. Clinical Nurse Specialist Breast Care, Royal Wolverhampton NHS Trust, Wolverhampton, UK
7. Population Evidence and Technologies, Warwick Medical School, University of Warwick, Coventry, UK
8. Contributions: SJW is the lead researcher. SW and ST-P drafted the manuscript. SJW, RL, HJS and ST-P participated in the design of the study. JU, MC and OK are key stakeholders in the NHSBSP who assisted with the study design. NR aided with the statistical analysis. All authors have reviewed and approved the manuscript.

Funding

This research is part of a PhD award and is funded by the Economic and Social Research Council Doctoral Training Centre at the University of Warwick. The funding has been awarded for the studentship to SJW for her PhD project for 4 years of full-time study. The award consists of payment of academic fees and maintenance award. A further contact between the University of Warwick, Public Health England and the PhD student (SJW) has secured £4000 in research expenses.

Competing interests

None declared.

Patient consent for publication

Not required.

Ethics approval

This study has been approved by the Public Health England Breast Screening Programme Research Advisory Committee, (BSPRAC, 2013, 0017/18, 040) and the National Health Service HRA West Midlands—Coventry & Warwickshire Health Research Ethics Committee (17/WM00313).

Provenance and peer review

Not commissioned; externally peer reviewed.

Open access

This is an open-access article distributed in accordance with the Creative Commons Attribution 4.0 Unported (CC BY 4.0) license, which permits others to copy, redistribute, remix, transform and build upon this work for any purpose, provided the original work is properly cited, a link to the licence is given, and indication of whether changes were made. See: https://creativecommons.org/licenses/by/4.0/.

REFERENCES