# Genomic Risk Assessment in Screening Pathways for Abdominal Aortic Aneurysms

# GRASP

Version V2.0_22/07/2025

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|---|---|
| **IRAS number:** | 357437 |
| **Sponsor:** | University of Leicester |
| **Sponsor number:** | 1078 |
| **Funder(s) number:** | N/A |
| **Study registration number** | N/A |

***This protocol has regard for the HRA guidance and the University of Leicester Sponsor Standard Operating Procedures (SOPs)***

## Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the study without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given. Any discrepancies and serious breaches of GCP from the study as planned in this protocol will be explained.

| **Chief Investigator:** | |
|---|---|
| Name: (please print): | Professor Matthew Bown |
| Signature: | |
| Date: | |

## Key Study Contacts

| | |
|---|---|
| Chief Investigator | Professor Matthew Bown |
| Student | Chloe Norman |
| Supervisor(s) | Professor Tracey Elliott |
| Sponsor | Research Governance Office<br>Research & Enterprise Division<br>University of Leicester<br>University Road<br>Leicester<br>LE1 7RH<br>RGOsponsor@le.ac.uk<br>0116 3736508 |
| Clinical Trials Unit | N/A |
| Funder(s) | Wellcome Trust (Wellcome Trust Doctoral Training Programme in Genetic Epidemiology) |
| Funding start and end date(s) | 23/09/2024 – 22/09/2028 |
| Key Protocol Contributors and Collaborators | Professor Tracey Elliott |
| Statistician | N/A |
| NIHR Portfolio adopted | No |

## Role of the Study Sponsor

The Sponsor for this research project is the University of Leicester.

The University of Leicester is responsible for the design, management and outputs of the research. Participating NHS sites are responsible for the conduct of the study within their organisation.

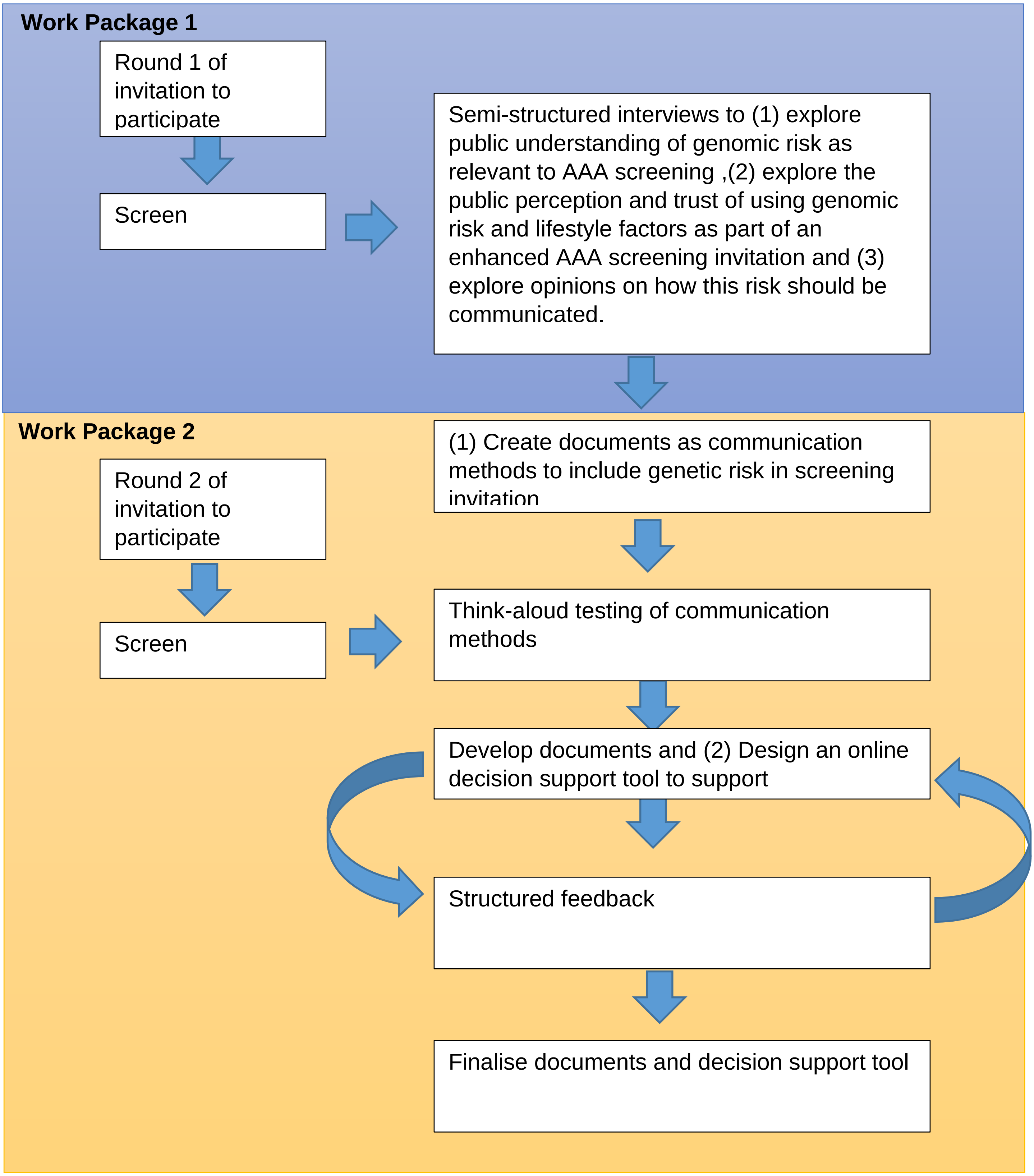
The Research Governance Office review and approve all iterations of the protocol as part of their initial Sponsor review and amendment review process. Further information is available from our Sponsor Standard Operating Procedures webpage.

## Contents

## Study Summary

| | |
|---|---|
| Short Study Title or Acronym | GRASP |
| Study Design | Qualitative Methods |
| Study Participants | Men aged 60-70 |
| Sample Size | 20-25 (or until saturation) |
| Planned Study Period | 01/09/2025 – 31/12/2026 |
| Research Question/Aim(s)/Objectives | |
| Primary | To determine the public acceptability, perception and preferences for introducing genomic risk assessment into AAA screening pathways |

## Study Flow Charts



**Work Package 1**

Round 1 of invitation to participate

Screen

Semi-structured interviews to (1) explore public understanding of genomic risk as relevant to AAA screening ,(2) explore the public perception and trust of using genomic risk and lifestyle factors as part of an enhanced AAA screening invitation and (3) explore opinions on how this risk should be communicated.

**Work Package 2**

Round 2 of invitation to participate

Screen

(1) Create documents as communication methods to include genetic risk in screening invitation

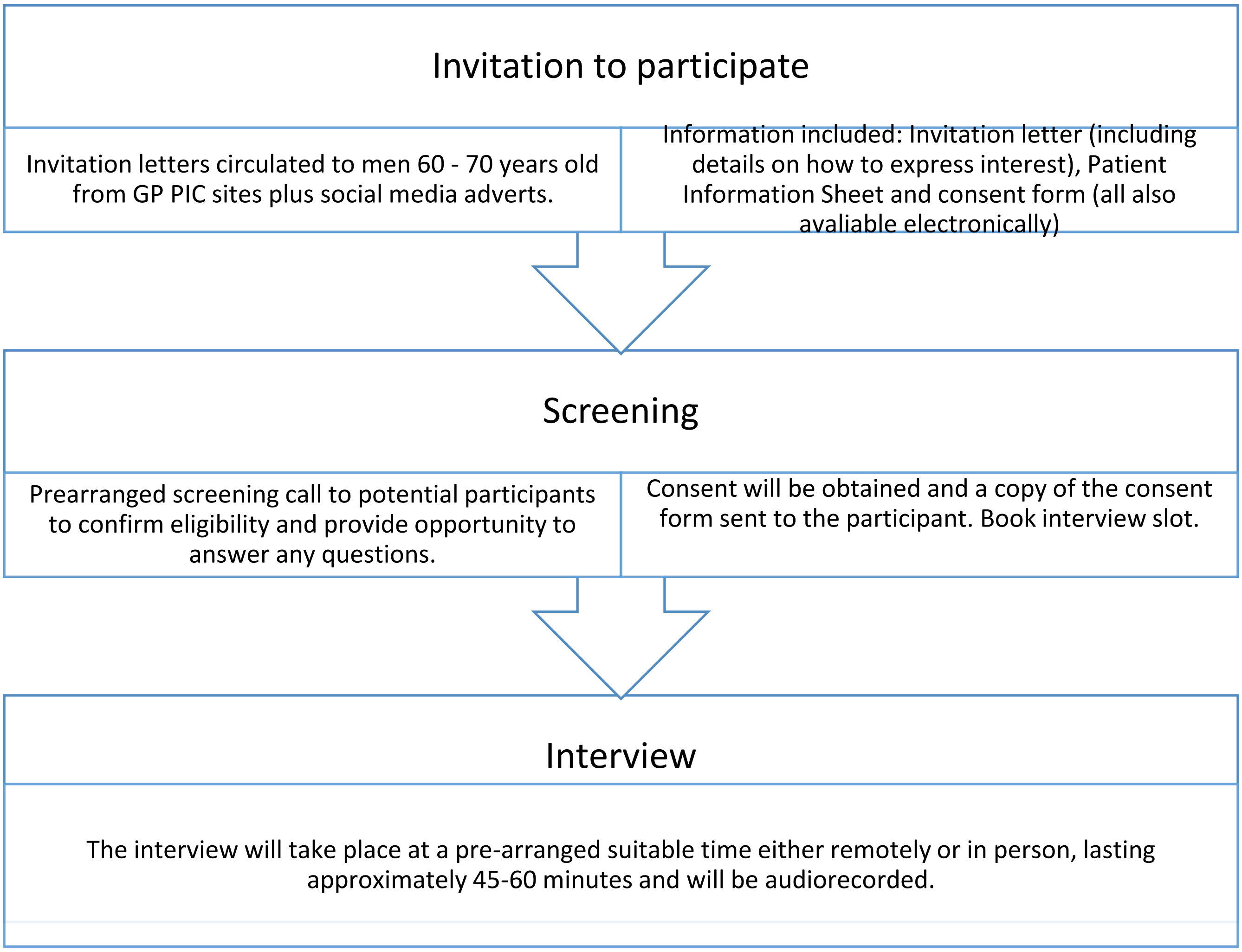
Think-aloud testing of communication methods

Develop documents and (2) Design an online decision support tool to support

Structured feedback

Finalise documents and decision support tool

Work Package 1



Invitation to participate

Invitation letters circulated to men 60 - 70 years old from GP PIC sites plus social media adverts.

Information included: Invitation letter (including details on how to express interest), Patient Information Sheet and consent form (all also avaliable electronically)

Screening

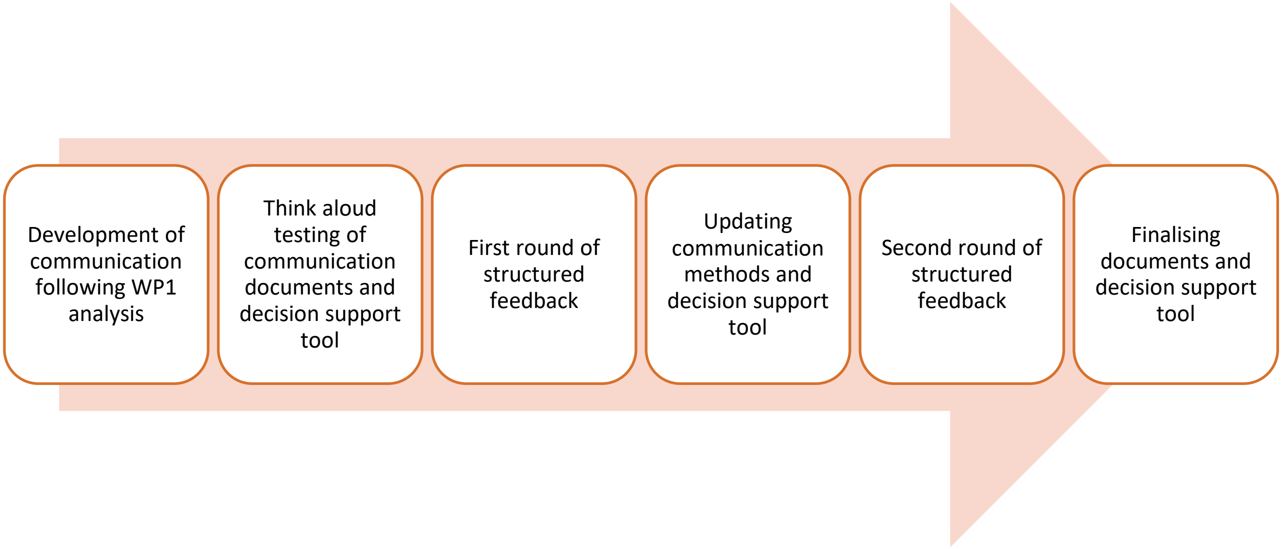
Prearranged screening call to potential participants to confirm eligibility and provide opportunity to answer any questions.

Consent will be obtained and a copy of the consent form sent to the participant. Book interview slot.

Interview

The interview will take place at a pre-arranged suitable time either remotely or in person, lasting approximately 45-60 minutes and will be audiorecorded.

Work Package 2



## List of Abbreviations

| | |
|---|---|
| AAA | Abdominal Aortic Aneurysm |
| AE | Adverse Event |
| CI | Chief Investigator |
| CRF | Case Report Form |
| GCP | Good Clinical Practice |
| HRA | Health Research Authority |
| ICF | Informed Consent Form |
| ISF | Investigator Site File |
| NHS R&D | National Health Service Research & Development |
| PI | Principal Investigator |
| PIC | Participant Identification Centre |
| PIS | Participant Information Sheet |
| PRS | Polygenic Risk Score |
| QC | Quality Control |
| REC | Research Ethics Committee |
| SAE | Serious Adverse Event |
| SOP | Standard Operating Procedure |
| TMF | Trial Master File |

## Key Words

Abdominal Aortic Aneurysm, Polygenic Risk Score, Population Screening

## Protocol Amendment History

| Amendment Reference | Protocol version no. | Protocol Date | Author(s) of changes | Summary of changes made |
|---|---|---|---|---|
| | | | | |

# 1 Background and Rationale

An abdominal aortic aneurysm (AAA) is a localised widening or dilation of the abdominal aorta which can lead to rupture and potentially death [1]. It is estimated that 1 in 70 men over 65 has an AAA and there are around 3,000 deaths each year in men aged 65 and over in England and Wales from ruptured AAA [2]. As an AAA is often asymptomatic, there may be no warning signs of having this condition prior to rupture and diagnosis is key to preventing premature death from ruptured AAA.

Since 2013, all men in the England are invited for an ultrasound scan to screen them for AAA in the year of their 65th birthday as part of the NHS Abdominal Aortic Aneurysm Screening Programme, with other similar programmes operating around the UK. In 2023/24 NHS England (NHSE) invited 330,473 men for screening, 271,399 (82.1%) attended and 2,004 men (0.7%) were found to have an AAA [3]. Men invited for screening and their families strongly value the benefits of AAA screening despite some negative psycho-social consequences in those receiving a diagnosis, and they recognise the benefit of early diagnosis and the prevention of AAA rupture through surveillance and elective surgical repair [4].

Whilst uptake of AAA screening is good, with 82.1% of men invited 2023/24 attending [3], the prevalence of AAA is decreasing, and attendance is variable depending on socio-economic status. Men from socially deprived areas are the least likely to attend the screening appointment, but also the risk of disease and mortality has been shown to be highest in those groups [5].

An AAA is 6 times more common in men than in women which is why only men are screened for AAA as part of the NHS Abdominal Aortic Aneurysm Screening Programme in England. Other risk factors include smoking status, BMI, cholesterol levels. [6] AAA is a genetic disease. AAA demonstrates substantial heritability and genetic risk factors are important to consider [7, 8]. It is rare for an AAA to be caused by a mutation in a single gene. More commonly the genetic background for AAA is due to a combined genetic risk caused by multiple low impact genetic variants from across the whole genome. This combined genomic risk for disease can be summarised in a Polygenic Risk Score (PRS). The calculation of PRS is adding up all the small risks due to individual genetic variants from across an individual's genome and summarise it as a single measure [9]. Current research in PRS use for AAA is focused on men and we do not have enough information to reliably expand this to women at this time, as results may be inaccurate or misleading for that group.

PRS is starting to be used as a factor for risk stratification to identify patient or population groups who could then be targeted for screening. Understanding genetic and other risk factors of disease can identify those higher risk patients who may benefit from earlier screening, increased surveillance or risk reducing interventions. A current example of this is a study into breast cancer reviewing the CanRisk tool [10], developed from BOADICEA (Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm), which is an example of a tool using genetic and lifestyle factors to predict disease and to be used to enhance the current breast cancer screening pathways in the NHS and invite those more at risk to earlier appointments or to be screening more frequently.

A recent scoping review into using genetic risk and PRS in screening programmes identified a variety of studies discussing the potential of using PRS to personalise a screening programme for a variety of diseases. Whilst the majority were focused on PRS with cancer screening, such as the CanRisk model above, one study focused on the potential of using PRS in AAA screening [11] recommending further investigation to use in the future to potentially improve outcomes. Many other studies reported a potential in improved outcomes due to a more personalised screening approach to target those most at risk [12, 13] but that more research is needed to address potential barriers reported including that the majority of genomic information currently held in public databases are that of European ancestry, lack of guidelines and uncertainty in the accuracy [14, 15]. One study [16] interviewed participants to discuss the use of PRS and other risk factors to accompany screening invitation for cancer screening and the majority (85%) of those told they were high risk reported it would make them more likely to attend a screening appointment.

A more targeted screening approach to identify those more at risk and highlight this could ensure those most at risk attend appointments and being offered treatment in a way that remains cost-effective to ensure the screening programme can continue in the NHS and reduce health inequalities. The aim of this research is to determine the public perception of using genomic risk and other risk factors to offer a more personalised approach to screening for AAA and how this risk should be communicated from the perspective of those who would be invited for screening. The terms ‘genetic risk’ or ‘genomic risk’ will both be used in this study when discussing risk with patients to aim to meet all audiences and understanding . This study has been designed to focus on the current population invited to AAA screening, and could be amended to include a wider population should the NHS screening programme change. This project will be split into two distinct work packages to initially understand and explore public perception, and then to develop acceptable communication methods and example documentation using a co-design process.

### 1.1 Theoretical framework

The theoretical framework that has guided the design of this study is an interpretivist theory to understand both the subjective and objective reality, and how the participants lived experience may impact their interpretation of information [17]. An exploratory and reflexive qualitative design has been selected to inform each of the work packages including the semi-structured interviews that will be analysed using reflexive thematic analysis, and a co-design process including the think-aloud method [18] to develop documentation to include genetic risk information in screening invitation information.

## 2 Research Question/Objective

The aim of this research is to determine the public acceptability, perception and preferences for introducing genomic (and other) risk assessment into AAA screening pathways and to develop communication strategies and a decision support tool to enhance uptake of AAA screening, particularly in those who are most at risk. This will be met via the delivery of six key objectives split into two distinct work packages:

### 2.1 Primary objective

Work Package 1 (WP1):

1. Explore the public perception and trust of using genomic risk and lifestyle factors as part of an enhanced AAA screening invitation.

Work Package 2 (WP2):

2. Design appropriate, and publicly acceptable, methods for communication of genomic risk

### 2.2 Secondary objectives

WP1

- Explore public understanding of genomic risk as relevant to AAA screening
- Explore the public perception and trust of using genomic risk and lifestyle factors as part of an enhanced AAA screening invitation.
- Explore how the public would like this information to be communicated.

WP2

- Design an online decision support tool to support understanding of risk communication for AAA

### 2.3 Exploratory Objective

In addition to work focusing on the existing AAA screening pathway, generic methods for genomic risk communication that could be employed in alternative contexts will be undertaken as exploratory research.

## 3 Study Design

This study is a single centre qualitative study to be undertaken in the community (remotely), coordinated by researchers at the University of Leicester (UoL). GPs in Leicestershire will be used as a Participant Identification Centres (PIC) to identify and invite potential participants.

### 3.1 Methodology

This exploratory interpretivist qualitative study involves two work packages.

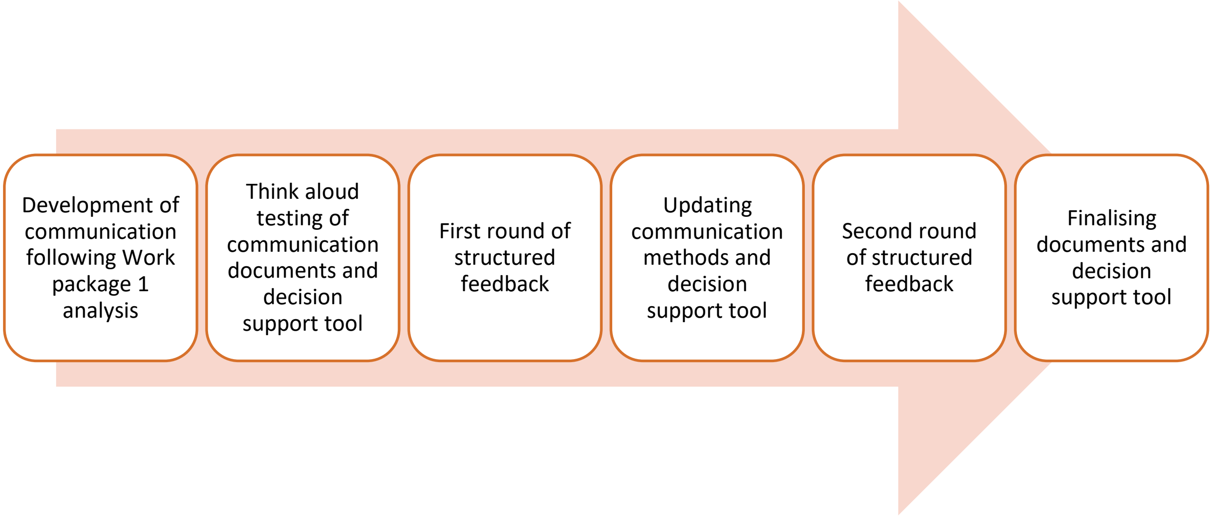
WP1

WP1 involves semi-structed interviews with participants around topic themes from existing literature such as communication methods [19] and health anxiety [20] due to screening and recent involvement in the REQUITE study reviewing how women felt about using genetic information for targeted radiotherapy in breast cancer treatment [21]. Participants will primarily undertake remote interviews conducted via Microsoft Teams however the option of face-to-face interviews will be offered on an ad hoc basis if required. Where face to face interviews occur, these will take place in approved University of Leicester spaces such as George Davies Centre Rooms 1.07 or 1.21 and will follow Sponsor guidelines with considerations to any specific requirements the participants may have.

WP2

WP2 is a six-step co-design process shown below in Figure 1. This is based on other previous studies designing and improving documentation for patients, including the CanRisk model for cancer screening [10] to ensure active collaboration and input from the public when creating a process being designed for them.

Figure 1 – overview of the co-design process



The documents including examples of communicating genomic risk and detail for WP2 will be added via an amendment once the data from WP1 has been collected and analysed.

## 4 Participant Eligibility Criteria

WP1 & WP2

### 4.1 Inclusion criteria

- Men aged 60 – 70 years
- Able to provide informed consent
- Speak and understand English language

## 5 Study Schedule

### 5.1 Schedule of procedures

**WP1:**

| Procedures | Visits | |
|---|---|---|
| | **Initial contact (telephone)** | **Visit 1 (remote or in person)** |
| Screening | x | |
| Informed consent | x | x |
| Demographics | | x |
| Interview | | x |

**WP2:**

| Procedures | Visits | | | |
|---|---|---|---|---|
| | **Screening** | **Visit 1 Think-aloud session** | **Visit 2 Feedback Session 1** | **Visit 3 Feedback Session 2** |
| Screening | x | | | |
| Informed consent | x | | | |
| Think aloud testing | | x | | |
| Structured feedback | | | x | x |

### 5.2 Recruitment

**WP1**

The recruitment phase will commence as soon as all necessary approvals have been received. Potential participants will be identified and/or contacted through the approaches described below. In all instances participants will be provided with a copy of the Participant Information Sheet.

A separate patient information sheet will be provided for those participating in WP2, but this will be generated following the outcomes of WP1 to best represent patient perspectives.

#### 5.2.1 Participant identification and invitation

**WP1 & WP2**

GP PIC sites

This study will be initially inviting men between the age of 60 and 70 years old from the Leicester area as a sample of the UK population. GP practices within Leicestershire will identify potentially eligible participants from their practices lists and will send a letter of invitation, copy of the Participant Information Sheet and a blank Consent Form. These invitation letters will be sent from a staff member at the GP site, who is part of the patient's direct care team.

Interested participants will be invited to either get in contact with the research team using the details on the PIS.

Social Media

The research team will also be using adverts on social media to invite men nationally to express an interest to participate. Expression of interest can be made through email or phone. The social media advert will include a link where individuals can access a copy of the full PIS online.

**WP2**

Initial invitations and adverts will be for participation in WP1, and all participants who take part in WP1 will have the option of being invited to take part in WP2. This will be captured on their consent form. Additional invitations and adverts may be circulated specifically for WP2 to cover any potential withdrawals or drop outs as per the participant identification methods detailed above.

### 5.2.2 Size of sample

This project is taking place in Leicestershire which offers a diverse population in both ethnicity and socio-demographic status, and the population in Leicester city and the surround areas of the county are very different. Therefore, a purposive sampling approach through geographical area has been selected to ensure the best representation of the research topic and help generate rich data. It is estimated that a sample of around 20-25 participants will ensure a representative sample of the population, but recruitment and interviews will continue until thematic saturation and information power across multiple ethnic groups.

This sample may increase if required following the completion of WP1.

### 5.2.3 Screening and eligibility assessment

Following a participant's expression of interest, an eligibility call will be arranged to provide further information about the study and to check an individual's suitability to take part in the study.

A pre-screening eligibility check will be conducted via telephone to check the following eligibility criteria:

- Men aged 60 – 70 years
- Able to provide informed consent
- Speak and understand English language

Where pre-screening eligibility is confirmed, the participant will be invited to continue with the study.

### 5.2.4 Informed consent

Consent will be obtained separately for both the work packages.

**WP1**

Participants will be provided with the participant information sheet and a blank copy of the consent form with the initial invite letter. The screening call detailed above will ensure all participants are given the opportunity to ask questions regarding taking part in WP1 of the study. Following this, if they would like to continue with the study, Informed Consent will be taken on the same day as, but prior to the interview taking place. It will include a discussion between the potential participant and a member of the research team which will detail no less than; the exact nature of the study, the implications and constraints of the protocol, and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason with no obligation to give the reason for withdrawal and without their legal rights being affected.

The person who obtains the consent will be suitably qualified and experienced, and will have been authorised to do so by the Principal Investigator as detailed on the Delegation of Authority and Signature Log for the study.

Where consent occurs remotely (over the phone)

The participant will already have received a copy of the blank consent form as part of their invitation pack so they can read and familiarise themselves with the document. On the day of the interview, before the interview commences, a member of the research team will go through each statement on the consent form and enter their (the researchers) initials in the relevant boxes next to each statement as per the participants responses. The consent form will include date and time of the call, participant name, and the name, date and signature of the person taking consent. A copy of this signed consent form will then be scanned and sent to the participant either during or immediately after the session (within 24 hours).

Where consent occurs face to face

On the day of the interview, before the interview commences, a member of the research team will go through each statement on the consent form with the participant and the participant will be asked to initial in each of the boxes as appropriate. The name, date and signature of the participant will be requested followed by the name, date and signature of the individual obtaining consent. A copy of the fully signed consent form will be provided to the participant during the visit.

**WP2**

Consent for WP2 will be taken separately following the same methods as those outlined above.

## 5.3 Methods of data collection and analysis

### 5.3.1 Data collection

WP1 – Interviews

Once consent has been obtained, participants will take part in a semi-structured interview lasting 45-60 minutes conducted by the researcher. Participants will be able to take breaks if required, and can choose to end the interview at any time.

The interviews will be offered initially via MS Teams but alternative methods can be offered to provide flexibility and ease of access to participants to best suit their needs.

A semi-structured interview guide has been developed around topic themes generated from existing literature, but this is flexible to ensure other unanticipated themes can emerge and the interview will begin with demographic data collection including age, ethnicity, and previous experience with AAA screening appointments. All definitions and additional information provided to the participants will be based on text from the protocol to ensure consistency. Participants will be reminded that they do not have to answer any questions they do not want to, and they can stop the interview at any time. Participants' silence, or refusal to answer a question, will be respected. If a participant appears particularly distressed, they may be signposted to local support groups or advocates such as those in Leicestershire outlined at https://www.leicspart.nhs.uk/support-and-advocacy/.

All interviews will audio-recorded and transcribed verbatim, with participant numbers assigned to avoid any personal identifiers. These recordings will not be used for any other purpose than transcription.

The data transcripts will be organised using the qualitative software package NVivo, and password protected and stored on the secure server at the University of Leicester.

WP2 – Co-design process

Following the completion of WP1, examples of potential document packs will be created using the outcomes of WP1 alongside a web-based decision support tool to aid understanding. These will then be used for think-aloud testing with participants during a workshop, which will be video or audio-recorded and transcribed verbatim in the same method as above. Think aloud methods ask participants to verbalise what they are thinking and doing as they perform tasks using and reviewing products and documentation. A round of structured feedback will follow to update the documents and decision support tool, which will then have a second round of structured feedback prior to finalisation.

### 5.3.2 Data analysis

WP1

Reflexive thematic analysis will be used to analyse transcribed interviews in WP1 to identify themes and depth of understanding. This will be done using the 6-step approach to thematic analysis outlined by Braun and Clarke [22] to include familiarisation, coding, theme development, refinement, defining and naming and producing report.

WP2

Results from WP1 will inform WP2, and full details of the WP2 analysis will be added as a later amendment. This will include a thematic analysis as outlined above for WP1

### 5.4 Expenses and benefits

Participants will be offered a £25 voucher for taking part in an interview in WP1 and a £25 voucher for any involvement in think-aloud sessions in WP2. Those participants who have their interview via MS Teams will not incur any expenses to take part as their participation study is taking place remotely and they will not be required to travel. This will be the preferred interview method, but if alternative methods are required to ensure accessibility any participant's travel and parking expenses will be reimbursed on the production of receipts.

### 5.5 Early discontinuation/Withdrawal of participants

Participants can withdraw from the study at any point, without giving a reason and without any prejudice. Participants can withdraw from either or both work packages depending on their involvement, and the withdrawal of a participant will be recorded on the subject enrolment log.

If a participant withdraws from the study, or loses the capacity to consent for themselves, data collected up until the point of withdrawal/loss of capacity will be retained and used in the study.

### 5.6 Definition of end of Study

The end of study will be declared once all the data has been collected, cleaned and analysed.

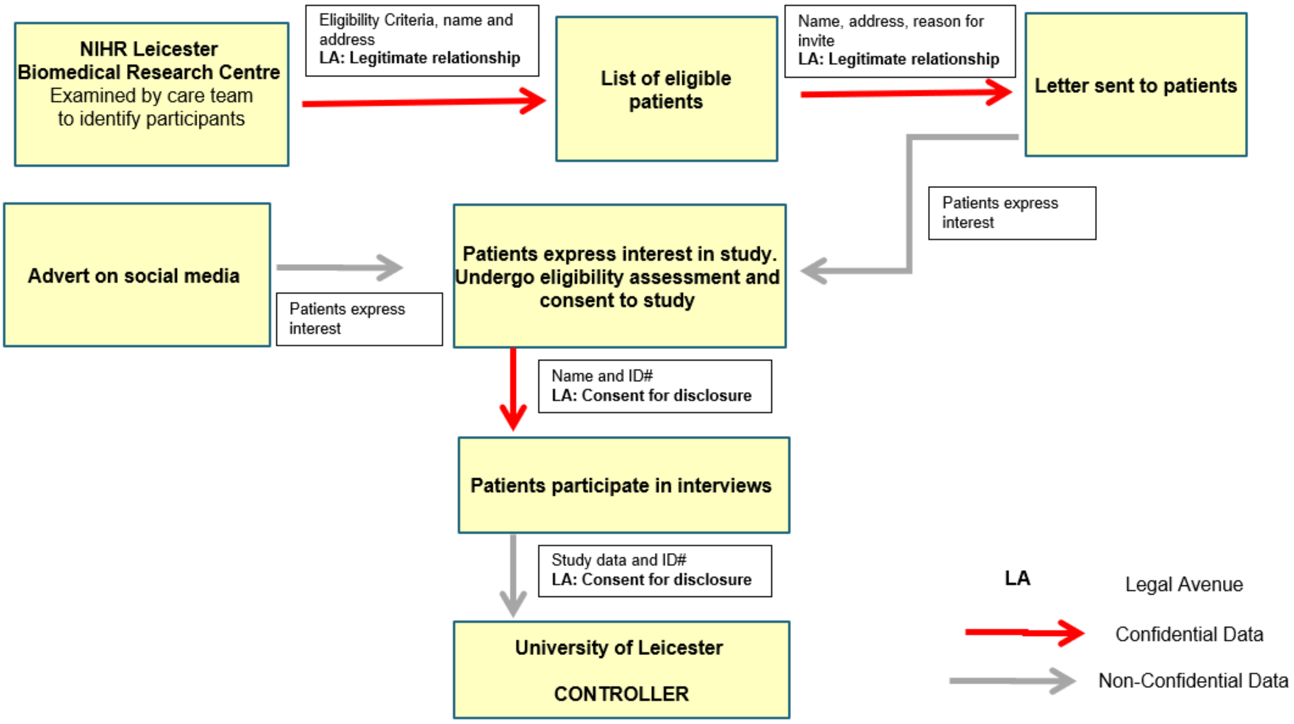
## 6 Safety reporting

This study will not be subject to Safety Reporting and as such, adverse events will not be recorded and serious adverse events will not be reported to the sponsor.

## 7 Data Management

### 7.1 Data flow diagram

Work Package 1



## 7.2 Data handling and record keeping

Each participant will be assigned a unique identification number upon consent and this will be added to all study documents and recordings in place of the participant's name.

Participants will be made aware that the interviews will be recorded, that we are using an encrypted Digital Recorder or recording via MS Teams, and their permission will be granted before any recordings commence. All recordings will be pseudonymised during transcription with any names, places or other identifying information mentioned removed during transcription. The recordings will be deleted from the recorder as soon as they are transferred to the University of Leicester secure servers, where they will be stored in restricted access folders. Digital/audio recordings will be deleted from the server following transcription. The recordings will be transcribed verbatim by a member of the research team.

A contacts database (which contains participant contact details) will be held separately from the study database. Participant's contact details will be held securely in accordance with data protection regulations. This will be password protected, held on University of Leicester secure servers managed at the site by the research team.

All data handling and record keeping will be kept in adherence to University of Leicester's policies. All study documentation containing identifiable patient data will be managed in accordance with ICH-GCP, The UK Policy for Health and Social Care Research and the Data Protection Act.

## 7.3 Access to data

The Chief Investigator and Student will have access to the full dataset. Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit project-related monitoring, audits and inspections.

### 7.4 Archiving

Research data and archived files will be stored for a minimum of 6 years after the study has ended. Storage will comply with the University of Leicester archiving Standard Operating Procedure. Details can be found at: https://le.ac.uk/research/regi/standard-operating-procedures. Destruction of essential documents will require authorisation from the Sponsor.

## 8 Quality Assurance Procedures

The study will be conducted in accordance with the current approved protocol, ICH GCP, the principles of the Declaration of Helsinki, relevant regulations and standard operating procedures (SOPs). The Principal Investigator (or their delegate) will be responsible for maintaining the Trial Master File (TMF) and Investigator Site File (ISF) and ensuring it is kept ‘inspection ready’ at all times.

### 8.1 Monitoring, audit and inspection

The University of Leicester as Sponsor operates a risk-based monitoring programme which this study will be subject to.

## 9 Protocol compliance

### 9.1 Protocol deviations

A study related deviation is a departure from the ethically approved study protocol or other study document or process (e.g. consent process or administration of study intervention) or from Good Clinical Practice (GCP) or any applicable regulatory requirements. Any deviations from the protocol will be documented in a protocol deviation form and filed in the Trial Master File/Investigator Site File as applicable.

If a protocol deviation occurs, then the CI (or delegate) will document this in accordance with the University’s Standard Operational Procedure (SOP) Identifying and Reporting Deviations and Serious Breaches of GCP and/or the Protocol.

Deviations from the protocol which are found to frequently recur will be explored and where necessary an amendment to the protocol will be made.

### 9.2 Serious breach

A “serious breach” is a breach of the protocol or of the conditions or principles of Good Clinical Practice which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the trial subjects; or

(b) the scientific value of the research.

In the event that a serious breach is suspected the Sponsor will be contacted within one working day. In collaboration with the CI, the serious breach will be reviewed by the Sponsor and, if appropriate, the Sponsor will report it to the approving REC committee and the relevant NHS host organisation within seven calendar days.

## 10 Ethical and Regulatory Considerations

### 10.1 Research Ethics Committee (REC) and Regulatory Review, Approvals/Permissions/Support, Compliance and Reports

Once the initial sponsor review process is complete and a sponsor reference number has been allocated, and all requested documentation has been received and checked, authorisation from the University of Leicester's Research Governance Office will be issued to book further regulatory review of the proposed research. The NHS Research Ethics Committee and the Health Research Authority will then review the proposal. Agreement in principle is subject to the research receiving all relevant regulatory permissions. Submission for regulatory approvals will occur via the Integrated Research Application System (IRAS). The Chief Investigator will ensure that all regulatory approvals and sponsor green light are in place before participants are approached.

For any required amendment to the study, amendments will be submitted to the sponsor in the first instance for review and approval to submit the amendment for external regulatory approval. Amendments must be implemented in line with Sponsor Standard Operating Procedures.

The Research Governance Office's Standard Operating Procedures will be followed for the duration of the study.

The Chief Investigator will notify the REC when the study has ended by completing the end of study notification form and will submit a final report of the results within one year after notifying REC.

A study master file will be maintained for the duration of the study and will be stored for a minimum of 6 years after the study has ended. The only time this could be exceeded, is if samples are being retained beyond the scope of the original study i.e. there is consent for future research. In this circumstance ICFs would have to be retained for as long as the samples are in existence, as we have a legal requirement to prove the samples were obtained with consent.

### 10.2 Peer review

As part of the research ethics submission process peer review was completed internally within the Cardiovascular Sciences at the University of Leicester. A member of course staff undertook an initial review of the research idea. Amendments to the protocol were made based on suggestions.

### 10.3 Patient and public involvement

| | |
|---|---|
| **Who was involved?** | This study is part of a larger programme of research that emerged following PPI discussions in a group formed for vascular research in changes to AAA screening. |
| **How and when have they been involved?** | One of the highlighted objectives for future research was to gain a wider patient and public perspective to the changes through interviews and to focus on communication methods. This study is centred around patient and public involvement to ensure they are at the centre of the development of a new process and method of communication, and therefore they are involved at every stage. |
| **How has the input of the people you involved made the study ethically acceptable?** | This study is directly following the objectives outlined by previous PPI discussions, and the main objective is WP1 is to explore the public perception and trust of using genomic risk and lifestyle factors as part of an enhanced AAA screening invitation. |

### 10.4 Assessment and management of risk

All members of the research team will have had GCP training as part of their role, and all study activities will be carried out by these individuals.

No study activities will start until the receipt of full approval and ethical review. The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

### 10.5 Data protection and patient confidentiality

The Chief Investigator will be the data custodian.

All information collected in the study will be kept strictly confidential.

The Chief Investigator and research team staff will comply with the requirements of the Data Protection Act and General Data Protection Regulation (and other applicable regulations) with regard to the collection, storage, processing and disclosure of personal information and will uphold the Act’s core principles.

Analysis of the data generated will be undertaken by the research student via a secure managed University of Leicester machine using VPN and secure servers.

Pseudonymised research data will be stored for six years after the study has ended.

Consent forms, enrolment logs and details of record linkage* (i.e., participant ID numbers/pseudonyms) will be kept for a minimum of 6 years after the study has ended as part of the research data so that in the event of the data being challenged, this will allow for verification of the quality of the data. At the end of this period approval from the Sponsor will be requested for the destruction of the data.

While participants are taking part in the study their contact details will be available to the researchers so that they can contact the participant to arrange the details of their research involvement. These will be deleted once they have been used for their agreed purpose. Where individuals have consented to receive a copy of the research findings, contact details will be retained until this time. Contact details will be stored securely and separately from participants research data and clinical information.

The Trial Master File (TMF) will be kept at the University of Leicester in a secure and lockable cabinet with access limited to relevant members of the research team.

Long-term storing will comply with the University of Leicester archiving Standard Operating Procedure.

## 11 Finance and Insurance

### 11.1 Funding

This project is funded by the Wellcome Trust as part of a Wellcome Trust Doctoral Training Programme grant.

### 11.2 Indemnity

Sponsorship and insurance for study design, management and conduct will be provided by the University of Leicester.

. If a study participant wishes to make a complaint about any aspects of the way they have been treated or approached during the research project, the standard National Health Service complaint system will be available to them. Details of this are made available to participants in the PIS.

### 11.3 Contractual arrangements

A Participant Identification Centre (PIC) site agreement will be in place between the sponsor and the GP sites prior to any research activity taking place.

## 12 Dissemination Policy

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

Research participants will have the opportunity to receive a summary of the study findings. If they wish to receive a copy, this will be indicated on their consent form.

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