ISRCTN10623216 https://doi.org/10.1186/ISRCTN10623216

Introducing a home-based genomic risk test to screening pathways for abdominal aortic aneurysms

Submission date 24/09/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 21/10/2025	**Overall study status** Ongoing	
Last Edited 20/10/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
The abdominal aortic aneurysm (AAA) NHS screening programme invites men aged 65 to attend a local clinic for an ultrasound scan to check them for an AAA. One of the things that can increase the risk of someone having an AAA is their genetics. This study will talk to men aged 60-70 to find out what they think about adding a simple home-based spit test to assess their genetic risk for AAA. This will become part of the NHS AAA screening pathway, and their opinions will be sought on communication strategies about sharing this risk.

This study involves two stages: the first being an online interview to help understand how acceptable the inclusion of genetic assessments in the AAA screening might be, and how people should be informed about their personal genetic risk of AAA, if this were to be introduced. The second stage is helping design the documents to communicate this in the future. Taking part in this research study could potentially benefit others by providing more robust research on patients' perspectives on providing a more personalised approach to AAA screening and the best methods of communication for this approach to patients. It is hoped that this will encourage those patients most at risk of developing an AAA to attend screening appointments in the future.

Who can participate?
Healthy volunteer men who are 60 to 70 years old

What does the study involve?
Participants who choose to take part in this part of the research will be invited to a one-off interview to share their views on the potential use of genetic risk assessments in the pathways and invitations for AAA screening. The interview will last approximately 45–60 minutes and will be audio recorded.

Interviews will be conducted online via Microsoft Teams at a time and date that suits the participant. If preferred, an in-person interview can be arranged at the University of Leicester. In such cases, travel and parking expenses will be reimbursed upon receipt of valid proof of payment.

Before the interview, a phone call will be arranged to explain the study in more detail, answer any questions, and confirm the participant's eligibility. Participants in this part of the study will also have the opportunity to take part in a second stage (work package 2), which involves helping to develop documents and a decision support tool to improve how screening invitations are communicated to the public. This is entirely optional. Those interested can indicate this on the consent form and will be contacted later with more information. A separate consent form will be required for participation in work package 2. Expressing interest at this stage does not commit participants to taking part.

What are the possible benefits and risks of participating?
Taking part in this research study could potentially benefit others by providing more robust research on patients' perspectives on providing a more personalised approach to AAA screening and the best methods of communication for this approach to patients. It is hoped that this will encourage those patients most at risk of developing an AAA to attend screening appointments in the future. There are no direct risks or side effects to taking part, but understand that a 45-60 minute time commitment for the interview, plus the earlier eligibility call, may be inconvenient.

Where is the study run from?
The University of Leicester, UK

When is the study starting and how long is it expected to run for?
January 2025 to October 2026

Who is funding the study?
The Wellcome Trust, UK

Who is the main contact?
Chloe Norman, cgn9@leicester.ac.uk

Contact information

Type(s)
Public, Scientific

Contact name
Ms Chloe Norman

ORCID ID
https://orcid.org/0000-0002-3275-3141

Contact details
University of Leicester
University Road
Leicester
United Kingdom
LE3 9QP

+44 (0)7722192848
cgn9@leicester.ac.uk

Type(s)
Principal investigator

Contact name
Prof Matthew Bown

Contact details
University of Leicester
University Road
Leicester
United Kingdom
LE3 9QP
+44 (0)116 252 3190
m.bown@le.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
357437

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
179223, Wellcome Trust funding Reference number 337446/Z/25/Z

Study information

Scientific Title
Genomic risk assessment in screening pathways for abdominal aortic aneurysms

Acronym
GRASP

Study objectives
To determine the public acceptability, perception and preferences for introducing genomic risk assessment into AAA screening pathways

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 29/07/2025, South Central - Hampshire B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8088; hampshireb.rec@hra.nhs.uk), ref: 25/SC/0243

Study design
Single-centre qualitative cohort study

Primary study design
Observational

Study type(s)
Other, Prevention

Health condition(s) or problem(s) studied
Abdominal aortic aneurysm population screening

Interventions
This study is a qualitative study split into two distinct work packages. All packages are to be undertaken in the community, coordinated by the University of Leicester. GPs in Leicestershire will be used as a Participant Identification Centre (PIC) site to identify participants to invite, and adverts on social media will offer opportunities for nationwide participation. 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 surrounding areas of the county are very different. Therefore, a purposive sampling approach through a 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.
The research team will also be using adverts on social media to invite men nationally to express interest in participating. Expression of interest can be made through an online form, email or phone. Initial recruitment will begin in work package one, and participants will be invited to take part as described above. Following a participant's expression of interest, an eligibility call will be arranged to provide further information about the study and to check their 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 the English language

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

Work Package One
Once consent has been obtained, participants partaking in WP1 will take part in a semi-structured interview lasting 45- 60 minutes conducted by a researcher at a pre-arranged, convenient time. 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. 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.

Demographic data, including age, ethnicity, and previous experience with AAA screening appointments, will also be obtained during the interviews to provide context during analysis. Reflexive thematic analysis will be used to analyse transcribed interviews in WP1 to identify themes and the depth of understanding. This will be done using the 6-step approach to thematic analysis outlined by Braun and Clarke to include familiarisation, coding, theme development, refinement, defining and naming and producing a report. The documents and details for WP2 will be added via an amendment once the data has been collected and analysed.

Work Package 2
WP2 is a six-step co-design process based on other previous studies designing and improving documentation for patients, including the CanRisk model for cancer screening, to ensure active collaboration and input from the public when creating a process being designed for them. Separate information sheets will be provided for WP2, and separate consent will be taken. 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, which will be video or audio-recorded and transcribed verbatim in the same method as above. 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 before finalisation. Due to the nature of WP2 requiring input from the findings of WP1, the documents for WP2 will be created in due course and will be submitted for regulatory approval via an amendment.

Intervention Type
Mixed

Primary outcome(s)
1. Public perception and trust of using genomic risk and lifestyle factors as part of an enhanced AAA screening invitation will be measured using data collected during semi-structured interviews in WP1 at a one-off interview following consent
2. Appropriate and publicly acceptable methods for the communication of genomic risk during WP2 will be measured using data collected and documents co-produced during think-aloud testing in WP2 at a focus group and 2 points of structured feedback

Key secondary outcome(s))
W1:
1. Public understanding of genomic risk will be measured using data collected during semi-structured interviews in WP1 at a one-off interview following consent
2. Public perception and trust in using genomic risk and lifestyle factors will be measured using data collected during semi-structured interviews in WP1 at a one-off interview following consent
3. Preferences for communication of genomic and lifestyle risk information will be measured using data collected during semi-structured interviews in WP1 at a one-off interview following consent
W2:

4. Design of an online decision support tool will be measured using data collected and documents co-produced during think-aloud testing in WP2 at a focus group, and 2 points of structured feedback

Completion date
20/10/2026

Eligibility

Key inclusion criteria
1. Men aged 60 – 70 years
2. Able to provide informed consent
3. Speak and understand the English language

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 years

Upper age limit
70 years

Sex
Male

Key exclusion criteria
Unable to speak or understand the English language

Date of first enrolment
01/11/2025

Date of final enrolment
01/10/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Leicester
University Road
Leicester
United Kingdom
LE1 7RH

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Research council

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet version 2.0	11/11/2025	11/11/2025	No	Yes
Protocol file		22/07/2025	03/10/2025	No	No