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Improving the quality of care for men with Abdominal Aortic Aneurysms (AAA) who undergo regular screening: reducing the psychosocial consequences of screening and developing a patient-centred Exit Strategy from surveillance

Submission date	**Recruitment status**	[X] Prospectively registered
26/01/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/02/2023	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/06/2025	Circulatory System	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Abdominal Aortic Aneurysm (AAA) is a swelling in the aorta, a vessel that runs from the heart down through the chest and stomach. AAA can increase in size and burst. Most people who have a burst AAA die before they get to hospital or do not survive emergency surgery. 4000 people die each year in England and Wales from a burst AAA. Screening can pick up an AAA before it bursts. It saves lives and is cost-effective. The National AAA Screening Programme (NAAASP) offers screening to all men aged 65. It invites 300,000 men for scans each year. Some men have a small AAA and are checked each year to see how much it has grown. Some men have a medium AAA and are checked every three months. There are now 15,000 men 'in surveillance', that is, having scans regularly. When men have a large AAA they are offered surgery to stop it bursting. There are two challenges to ensure that the benefits of screening outweigh harms. First, men and their partners can suffer anxiety, distress, burden from protecting others from worrying, guilt, helplessness, and uncertainty. We need to find ways to reduce these problems. Second, as men get older, they may become unfit for surgery and cannot have treatment. We need to understand men's preferences for leaving the surveillance programme.
The study aims to improve the quality of care for men who have regular screening to check on the growth of their Abdominal Aortic Aneurysm.

Who can participate?
Adult men who are in AAA screening.

What does the study involve?
There are several components to the study. We will do a survey of 1200 men in the surveillance programme to find out who is anxious and when this is worse. We will identify 20 men with

problems and interview them and their partners about what might help them manage anxiety. Then staff, men and their partners will co-design an intervention. We will make this intervention and assess if men use it and like it.

What are the possible benefits and risks of participating?
The benefits would be having the opportunity to have input into improving the support of men in the screening programme and being able to support the development of an intervention.
The risks may be that for participants who might already be highly anxious, talking about the issue may create further anxiety. There are specific plans for this eventuality. The interviewees are experienced in speaking to men with AAA. The interview/group may be stopped (temporarily or permanently) and the participant may be directed to speak to their AAA nurse or GP.

Where is the study run from?
University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
February 2022 to September 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Prof Alicia O'Cathain, a.ocathain@sheffield.ac.uk

Study website
https://www.sheffield.ac.uk/scharr/research/centres/hcru/pcaaas

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
321528

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55062, NIHR135031, IRAS 321528

Study information

Scientific Title
Person centred abdominal aortic aneurysm study (PCAAAS)

Acronym
PCAAAS

Study objectives
Overall aim - To improve the quality of care for men in the surveillance programme within NAAASP.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/02/2023, Health and Care Research Wales (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB; +44 2920230457; HCRW.approvals@wales.nhs.uk), ref: 23/WA/0019

Study design
Mixed methods

Primary study design
Observational

Secondary study design
Mixed methods

Study setting(s)
Community, Home, Internet/virtual, Telephone, University/medical school/dental school

Study type(s)
Quality of life, Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
Current interventions as of 13/02/2025:

In the first work package we will develop a new intervention to reduce the psychological consequences of screening. We will do a survey of men 'in surveillance' to measure who has problems and when this is worse (n=1200). We will identify men with problems and interview them (n=20-24) and their partners/family (n=12-20) about what might help them manage anxiety. Then service providers, men and their partners/family will co-design an intervention to reduce the potential negative effects of being in surveillance. We will create this intervention and assess its feasibility and
acceptability. Its effectiveness would be measured in a future study if appropriate.
In the second work package we will interview men (n=20-24) 'in surveillance' and their partners (n=12-20) about their preferences for exiting surveillance under different circumstances. Then we will undertake two Deliberative Engagement Workshops with around 20-40 men and their supporters, healthcare professionals and PPI members to evaluate the intervention and develop it further. We will then conduct a phone survey of men in surveillance (n=20) to measure their preferences and the intensity of their preferences. We will feed this into NAAASP to help them develop a patient-centred Exit Strategy.

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Previous interventions:

In the first work package we will develop a new intervention to reduce the psychological consequences of screening. We will do a survey of men 'in surveillance' to measure who has problems and when this is worse (n=1200). We will identify men with problems and interview them (n=20-24) and their partners/family (n=12-20) about what might help them manage anxiety. Then service providers, men and their partners/family will co-design an intervention to reduce the potential negative effects of being in surveillance. We will create this intervention and assess its feasibility and
acceptability. Its effectiveness would be measured in a future study if appropriate.
In the second work package we will interview men (n=20-24) 'in surveillance' and their partners (n=12-20) about their preferences for exiting surveillance under different circumstances. Then we will undertake a survey of men in surveillance (n=500) to measure their preferences and the intensity of their preferences. We will feed this into NAAASP to help them develop a patient-centred Exit Strategy.

Intervention Type
Other

Primary outcome measure
Identification of predictors of psychosocial problems - measures will include standardised measures such as the EQ5D-L, COS-AAA and e-PAQ-VAS as well as project-specific questions, qualitative interviews and focus groups.

Secondary outcome measures
Identify preferences for exit strategies. Measures will include a project-specific survey, focus groups and qualitative interviews.

Overall study start date
11/02/2022

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Initially men in AAA surveillance will be approached
2. For later work their partners/family will also be approached
3. For some parts of the study only men in surveillance who also describe anxiety will be included

Participant type(s)
Patient

Age group
Adult

Lower age limit
64 Years

Sex
Male

Target number of participants
1,350

Key exclusion criteria
Men who have not consented to be approached by researchers

Date of first enrolment
01/05/2023

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne

United Kingdom
NE7 7DN

Sponsor information

Organisation
University of Sheffield

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Sponsor type
University/education

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http://www.sheffield.ac.uk/

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Publication and dissemination plan
We will undertake academic dissemination by publishing a synopsis of the study in the NIHR Libraries Journal, publishing articles in academic journals targeted at the vascular clinical community (e.g. British Journal of Surgery), and presenting the research at relevant conferences and meetings. We will send summaries of findings to AAA Regional Screening Centres in England, and all national AAA screening programmes e.g. Scotland, Sweden.

We will use social media to disseminate our results to other relevant screening programmes. That is, we will look for relevant Twitter accounts and emails so we can send our results.
We will write Plain English summaries of findings and send them to interview, workshop and survey participants who indicate that they would like to see the findings.
We will work with our PPI members and screening centre staff to identify how to disseminate findings to men in surveillance e.g. posters, summaries in paper format available at the screening centres, giving talks at 'information days' held by NAAASP for patients and their families

Intention to publish date
31/01/2026

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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?
Protocol file	version 2.1	04/04/2023	15/05/2023	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 3.0	19/03/2024	13/02/2025	No	No