- **This protocol has regard for the HRA guidance and order of content;**

FULL/LONG TITLE OF THE STUDY
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

SHORT STUDY TITLE / ACRONYM

Patient centred AAA study: PCAAAS

PROTOCOL VERSION NUMBER AND DATE

Version 2.1 4.4.2023 **REFERENCE NUMBERS**

IRAS Number:	321528.
SPONSORS Number:	172849
FUNDERS Number:	NIHR135031

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 investigation 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; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Date:
12/04/2023

Signature: 

.....

Name (please print): Jennifer Burr

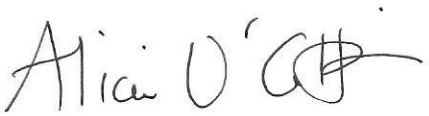
.....

Position: Research Governance Lead

.....

Chief Investigator:

Date:
12../04../2023...

Signature: 

.....

Name: (please print): Alicia O'Cathain

.....

LIST of CONTENTS

KEY STUDY CONTACTS

Chief Investigator	Prof Alicia O'Cathain, a.ocathain@sheffield.ac.uk
Study Co-ordinator	Dr Emily Wood, e.f.wood@sheffield.ac.uk
Sponsor	The University of Sheffield
Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	NIHR HS&DR
Key Protocol Contributors	pcaaas@sheffield.ac.uk
Committees	For all queries aimed at the research team, protocol contributors, steering group or PPI panel please email pcaaas@sheffield.ac.uk

STUDY SUMMARY

Study Title	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
Internal ref. no. (or short title)	Patient centred AAA study: PCAAAS
Study Design	Mixed methods
Study Participants	Men in AAA surveillance
Planned Size of Sample (if applicable)	1700 across all work packages
Follow up duration (if applicable)	n/a
Planned Study Period	28 months 01102022-31012025
Research Question/Aim(s)	<u>Aim</u> To improve the quality of care for men in the surveillance programme within NAAASP. <u>Research questions</u> How can we reduce the psychosocial consequences of being in surveillance in NAAASP? What are men's preferences for exiting surveillance?

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NIHR	**£643,271.90**

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor is the CIs substantive employer, The University of Sheffield. It will maintain responsibility for the governance of the research (and therefore the design and conduct of the research), throughout the study.

The funder is NIHR HS&DR.

Neither organisation has influence over the data analysis and interpretation, manuscript writing, and dissemination of results. They do not control the final decision regarding any of these aspects of the study.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Project Steering Group (PSG)

The PSG consists of a professor with renowned experience of AAA research, a screening programme manager, two clinicians, and two PPI members (one with lived experience of screening).

The purpose of the group is to advise the team about the project, check whether the project is running to timetable, and check that ethical and safety issues are being addressed.

The PPI group

The PCAAAS PPI group was set up before the study officially started in order to have meaningful involvement from patients and the public from the outset. It consists of six men, including the PPI co-applicant on the study. All have had lived experience of AAA repair or AAA screening. Not all were found to have AAA; two did not. Four of the group have had successful surgery to repair AAA. Three of the group have prior experience of PPI involvement. The group will be involved in development of study documentation to help acceptability to men in the study, co-design of the intervention, interpretation of the findings, and dissemination of the work. We hope to recruit further members to the group so that we have representation from family or partners who support men who attend for AAA screening.

PROTOCOL CONTRIBUTORS

Prof Alicia O'Cathain, a Mixed Methods Researcher, will lead the study, manage the team, and lead or co-lead the mixed methods research in WP1 and 2.

Prof Gerry Stansby, Professor of Vascular Surgery, and the Research Lead for NAAASP, will be joint Lead Investigator facilitating the research with Regional Screening Centres, as well as impact.

Mr Akhtar Nasim, National Clinical Lead for NAAASP, will offer advice about the screening programme, and will lead on impact.

Prof Jonathan Michaels, a retired Vascular Surgeon who led the NIHR Vascular Programme, will offer advice on vascular research and services (that the AAA screening programme works closely with because Vascular Surgeons repair AAAs) and work closely with PS on the preferences research in WP2.

Dr Phil Shackley, a Health Economist who is an expert in measuring preferences, will co-lead WP2 with AOC and lead the survey in WP2.

Dr Sue Baxter, Systematic Reviewer and Qualitative Researcher, will lead the qualitative research in WP1 and 2 and advice on literature search and quality in WP1.4.

Alan Elstone, Lead Nurse for NAAASP, will offer advice on NAAASP surveillance practice, working with men in surveillance, and facilitate impact within his health optimisation programme within NAAASP.

Professor Steve Radley, e-PAQ-AAA Developer, will offer advice on using and analysing e-PAQ-AAA.

Lizzie Lumley, Qualitative Researcher, undertook qualitative interviews with men with AAA in the NIHR Vascular Programme. She will be one of the two part-time Qualitative Researchers and PPI Lead, working closely with our PPI co-applicant and PPI panel.

Niall MacGregor-Smith, PPI member on NAAASP Research Committee, will facilitate excellent PPI on the project.

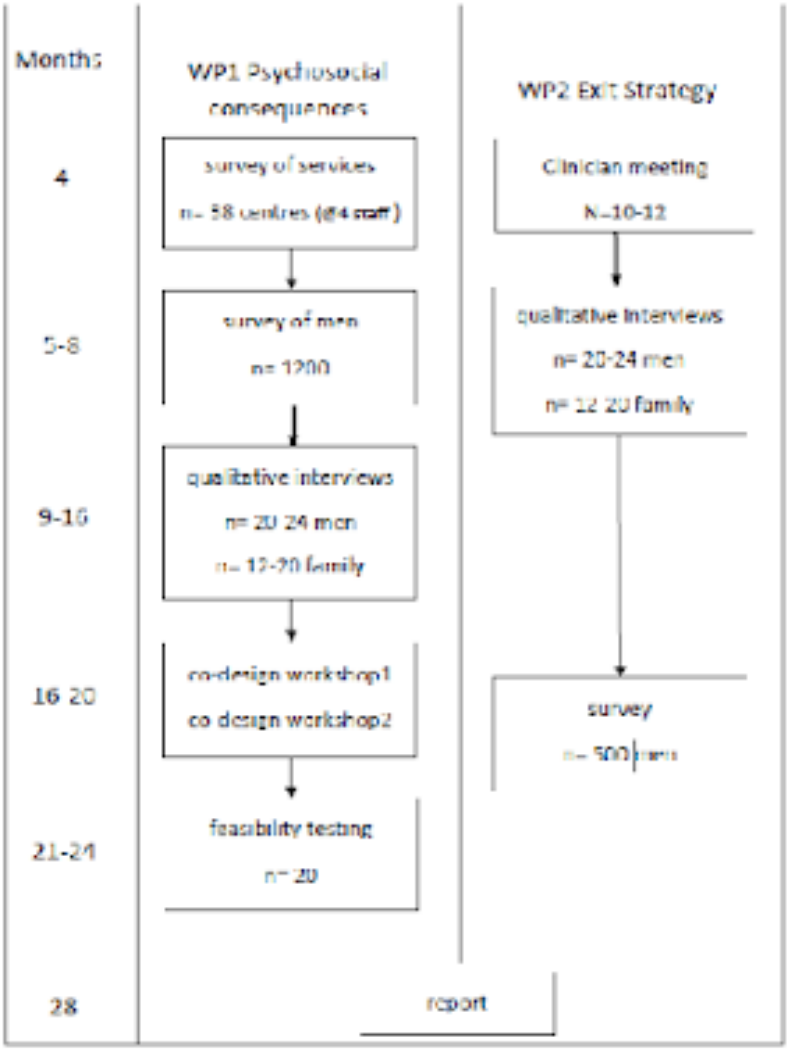
Dr Jo Hall, Principal Clinical Psychologist, will offer advice about managing anxiety and psychological interventions.

Dr Emily Wood, project manager, wrote the protocol from the project plan and will offer senior oversight of the project management.

KEY WORDS:

**Aneurysm, mass screening,
anxiety**

STUDY FLOW CHART



Patient centred AAA study: PCAAAS
Version 2.1 04.04.23

IRAS 321528

STUDY PROTOCOL

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

1 BACKGROUND

Screening for Abdominal Aortic Aneurysms (AAA)

There are 4000 deaths annually in England and Wales following Abdominal Aortic Aneurysm (AAA) rupture. Screening can pick up an AAA before it ruptures. The NHS AAA Screening Programme (NAAASP) in England was established to screen men because they are six times more likely to have an AAA than women. NAAASP has been offering screening routinely since 2009, becoming fully operational in 2013, at the cost of £14 million per year (Richards 2019). A recent analysis of outcomes of the screening programme showed that between 2009 and 2016 1.2 million men were screened, and 3000 had a large AAA and were referred for possible surgical intervention (Meecham 2021). Screening reduces AAA-related mortality and is cost-effective (Thompson 2009).

Men are invited to attend a screening clinic for an ultrasound scan in the year they turn 65. Approximately 300,000 men are invited annually. Uptake is high, at around 80%. Men are told the outcome at screening. If an AAA is detected, the recommended treatment depends on its size. The outcome of screening and its associated treatment is:

- No aneurysm – no further screening or treatment (98% of men screened).
- Small AAA (3 to 4.4cm) – ultrasound scans every year (1% of men screened).
- Medium AAA (4.5 to 5.4cm) – ultrasound scans every 3 months (0.5% of men screened).
- Large AAA (5.5cm or more) – surgery to stop it bursting is usually recommended.

Currently 15,000 men with small and medium AAAs are ‘in surveillance’, having scans annually or every three months.

Evidence about psychological consequences of screening

The psychosocial consequences of screening are often measured for different screening programmes so that harms do not outweigh benefits (Ericsson 2017). Experiences vary enormously by condition and screening programme, so it is important to consider what is known about AAA screening specifically. A systematic review of the psychological harms of being labelled as having AAA identified five quantitative studies and three qualitative studies (Cotter 2017). Both the qualitative and quantitative studies found at least moderate levels of psychological harm from recent diagnosis. Qualitative studies found that men suffered shock, anxiety, fatalism, general distress, burden from protecting others from worrying, guilt, helplessness, and uncertainty (Petterson & Bergbom 2013; Gunasekera 2013; Hansson 2012) even though they were glad they were being monitored (Petterson & Bergbom 2013). Later qualitative studies have also found this heightened anxiety and described

how it impacts on men's health-related quality of life (HRQoL)(Brodersen 2018, Aber 2020a). These psychosocial issues also affect their partners' HRQoL (Ericsson 2020). A recently published narrative review focused on 11 quantitative studies of HRQoL for men being screened for AAA (Ericsson 2019). Those in surveillance had lower HRQoL compared to those with negative scans and the general population. A quantitative study in the UK showed that mental health was worse in those diagnosed with AAA compared with those with negative screens; this difference disappeared after 12 months (Bath 2018) although a generic rather than specific meaner of HRQoL was used. This means that each year approximately 2000 men enter surveillance and have reduced mental health at least in the first year. This has led researchers to conclude that counselling may be needed (Bath 2018).

Researchers propose that the psychological harms of screening are not considered enough and that the attention they receive depends on the screening programme (DeFrank 2014). Studies assessing psychosocial effects of AAA screening have used generic psychological health measures such as the SF36 which may not be sensitive to screening-related harms (DeFrank 2014). The exception to this is a recently published survey of 250 men detected with AAA through screening compared with 500 men with normal screens in Sweden (Damhus 2021). This research group used the Consequences of Screening in AAA tool (Brodersen 2018) and found that men with AAA had more negative consequences in 10/13 scales in Part 1 and 4/5 scales in Part 2 of the tool e.g. feeling more anxious. Damhus and colleagues highlighted that they did not consider how negative issues changed over time, or determine the characteristics of men with higher levels of negative consequences.

It is also the case that the current evidence base focuses on measuring and understanding psychosocial consequences of AAA screening rather than on developing or evaluating interventions to address these.

<u>Evidence about exiting the surveillance programme</u>

There is a limited 'Exit Strategy' for men in surveillance. There is a Standard Operating Procedure for men with small or non-progressing AAAs to be discharged after 15 years (when they reach 80 years of age). This is not in operation currently because men have only been 'in surveillance' for a maximum of 8 years due to the start date of the screening programme. It will be relevant in 2028 when it will start affecting thousands of men. Otherwise men in surveillance remain there unless they die, or decline screening, or develop a large AAA and are referred for surgery. While 'in surveillance' they may develop conditions (such as cancer and cardiovascular disease) that mean they are unfit for surgery if they develop large AAAs. That is, they remain in surveillance even though they cannot have treatment. Men's health is not checked in the screening programme. They are offered appointments with a Vascular Nurse Specialist for support and guidance when they enter surveillance and again if they change to three-monthly surveillance. There is no other input.

The issue of how best to deal with men who enter or stay in the surveillance programme when they are unfit for surgery is an important topic of debate amongst vascular surgeons. Some vascular surgeons have recommended an assessment of fitness for surgery rather than basing decisions on

age (Singh & Boyle 2021). Others have recommended that frailty might be a better determinant (Ambler & Twine 2021). Without a comprehensive Exit Strategy some men experience 'Turn Down' where men are referred for surgery but are not healthy enough to have it. Between 2009 and 2016, 8% of the 3000 referrals from NAAASP were unsuitable for surgery (Meecham 2021). This group is small but will continue to grow each year, leading to concerns that this could threaten the value of the programme (Meecham 2021). In 2019/20 858 men were appropriately referred for surgery and 124 (14%) of these men were unsuitable for surgery (NAAASP formal reports). Being unfit for surgery is not the only issue. Men's perception of risk may change as they get older or they may feel that a small non-progressing AAA does not warrant further surveillance earlier than 15 years.

There is a research gap in terms of understanding men's preferences for different exit options. For example, men may identify factors that are important to consider in any decision-making process e.g. age, frailty, co-morbidities. Or they may have preferences for different strategies and have preferences around how exit is identified. For example, they could have a health assessment after a number of years to see if they are fit for surgery, or have a formal review when their AAA reaches a specific size e.g. 5 cm, or have an age/size/growth rate exit strategy like the current situation.

2 RATIONALE

Researchers propose that the psychological harms of screening are not considered enough and that the attention they receive depends on the screening programme (DeFrank 2014). Studies assessing psychosocial effects of AAA screening have used generic psychological health measures such as the SF36 which may not be sensitive to screening-related harms (DeFrank 2014). The exception to this is a recently published survey of 250 men detected with AAA through screening compared with 500 men with normal screens in Sweden (Damhus 2021). This research group used the Consequences of Screening in AAA tool (Brodersen 2018) and found that men with AAA had more negative consequences in 10/13 scales in Part 1 and 4/5 scales in Part 2 of the tool e.g. feeling more anxious. Damhus and colleagues highlighted that they did not consider how negative issues changed over time, or determine the characteristics of men with higher levels of negative consequences.

It is also the case that the current evidence base focuses on measuring and understanding psychosocial consequences of AAA screening rather than on developing or evaluating interventions to address these.

There is a research gap in terms of understanding men's preferences for different exit options. For example, men may identify factors that are important to consider in any decision-making process e.g. age, frailty, co-morbidities. Or they may have preferences for different strategies and have preferences around how exit is identified. For example, they could have a health assessment after a number of years to see if they are fit for surgery, or have a formal review when their AAA reaches a specific size e.g. 5 cm, or have an age/size/growth rate exit strategy like the current situation.

3 THEORETICAL FRAMEWORKS

Harms associated with screening (WP1)

There are harms as well as benefits associated with screening people who have no symptoms of a disease. Harms include false positives, false negatives, overdiagnosis and overtreatment of harmless conditions, and physical and psychosocial consequences of screening (Johansson 2021). It is important to understand the frequency and severity of harms of any screening programme in order to make judgements about whether it is worthwhile having a screening programme, or who to include in any screening. It is also important to identify ways of reducing these harms in order to maximise the benefits of screening.

Person-centred care (WP1 and WP2)

The Health Foundation have offered a definition of person-centred care to include treating patients as individuals and as equal partners in the business of healing (Health Foundation 2014). Person-centred care can be achieved by involving patients, service users and carers in system redesign (Coulter & Oldham 2016). In our study, patients and their families will shape the intervention to reduce psychosocial consequences of screening in WP1 and identify their preferences for an Exit Strategy in WP2 so that any future strategy in NAAASP is informed by patient preferences.

4 RESEARCH QUESTION/AIM(S)

Aim

To improve the quality of care for men in the surveillance programme within NAAASP.

Research questions

How can we reduce the psychosocial consequences of being in surveillance in NAAASP?

What are men's preferences for exiting surveillance?

4.1 Objectives

1. Understand why and when men 'in surveillance', and their partners/family members, experience psychosocial consequences and the types of interventions that might help them.

2. Co-design an intervention to help men to manage the negative consequences of being in surveillance.

3. Assess the acceptability and feasibility of the co-designed intervention to reduce negative consequences.

4. Identify men's (and their partners'/family members') views about exiting surveillance and the options they think should be available for this.

5. Measure men's preferences for different aspects of a patient-centred Exit Strategy.

4.2 Outcomes for the study

1. An intervention to reduce psychological consequences that has been assessed for acceptability and feasibility. We may go on to evaluate this intervention in future study
2. A document that will list men's preferences for an Exit Strategy that can used by NAAASP to develop a patient-centred Exit Strategy

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

We will undertake two concurrent work packages.

WP1 will follow the MRC guidance/framework on developing and evaluating complex interventions (Craig 2008, Skivington 2021). In this guidance complex interventions are developed, their feasibility is considered, they are tested in a full evaluation which may include a randomised controlled trial (RCT), and then they are monitored when implemented in the real world. In this study we propose to undertake the first two phases of this guidance/framework. In this study we will develop an intervention to reduce surveillance-related anxiety and then consider its feasibility and acceptability. If we can produce a feasible intervention with potential for effectiveness and cost-effectiveness, we will work with NAAASP to evaluate it in a future study using an RCT.

WP2 will take a different approach from WP1. In the future NAAASP will need to develop a more comprehensive Exit Strategy as men in surveillance get older. This strategy will be informed by health benefits and risks for different types of men, and cost. We will undertake a sequential exploratory design of qualitative research followed by a survey to identify men's preferences for exiting surveillance to ensure that these preferences are central to NAAASP's considerations for an Exit Strategy. That is, we will feed into NAAASP's service development strategy for exiting surveillance rather than lead a study of the development and evaluation of an Exit Strategy.

<u>WORK PACKAGE 1 Reducing psychosocial consequences of being 'in surveillance'</u>

1.Survey of men 'in surveillance'

Design

We will undertake a cross-sectional postal survey.

The questionnaire

There are two validated instruments that measure screening-related consequences specific to AAA. The COS-AAA has approximately 100 items and was validated in Swedish (Broderson 2018, Damhus 2021). The e-PAQ-VAS questionnaire was developed in English to measure vascular outcomes for different conditions (Michaels et al 2021). It was based on evidence reviews, qualitative interviews and consensus, and underwent thorough psychometric testing (Aber 2020a). It includes e-PAQ-AAA which consists of: the EQ-5D-5L for generic quality of life; two AAA-specific scales measuring AAA-related

anxiety and impact of AAA on activities of daily living (14 items)(Aber 2020b); and the later addition of the Psychological Consequences of Screening Questionnaire (11 items) identified as suitable for AAA screening (Philips 2021). We will use e-PAQ-AAA because it has been developed and validated in English and is simple and short. It was developed by members of our current team who can advise on analysis and interpretation (SR, JM, LL). We will use it in paper format rather than electronically to promote a higher response rate in this older population, although we will offer an electronic link to the questionnaire in case some men prefer this mode of response. A recent pilot of the use of an electronic approach yielded a response rate of 20% of men in surveillance in NAAASP. This was not as high as a postal questionnaire of the other outcome measure undertaken in Sweden, which had a response rate of 63% after one reminder when sent to men with screening-detected AAAs (Damhus 2021).

The AAA-related anxiety scale asks how having AAA affects men at present: e.g. fear of sudden death, worry about increase in size. The AAA-impact on activities of daily living scale asks how much AAA affects physical activities, ability to undertake person roles and responsibilities, social activities etc. The response sets are four-point scales that are summed and a mean is calculated. The Psychological Consequences of Screening Questionnaire (PCSQ) asks about how men feel about being involved in the screening programme e.g. trouble sleeping, keeping things from those close to them. The EQ-5D-5L will allow comparison of the AAA-specific scale scores and PCSQ with a general HRQoL score. As well as using the e-PAQ-AAA we will also ask about the AAA size, whether the man perceives that the AAA is increasing in size based on each measurement he receives from NAAASP, when they had their last screen, and how long they have been in the screening programme. At screening, men are given a card with the size of their AAA so this information will be easily accessible to them. We will also collect socio-demographic information (age, general health, ethnicity, disability status). We can identify IMD scores using the men's postcodes. We will also ask respondents if they would be willing to be contacted about further involvement in the study such as an interview or taking part in a workshop.

Sample

There are 15,000 men in surveillance currently, with approximately 2000 new men joining the surveillance programme each year via screening. We will send the questionnaire to a sample of 1200 men (see sample size calculation below). We will work with 6-8 screening centres. One of them will be the Northeast of England Centre led by one of the joint lead investigators (GS). This centre covers the largest population in England, around three times larger than the average centre. In 2019-2020 they did 16,455 scans in a population of 3.1 million. They did 776 annual scans (small AAA) and 178 three-monthly scans (medium AAA). 85 of this latter group had AAAs measuring between 5.0 and 5.4 cm. This centre covers a population with high levels of social deprivation. We will approach other centres that offer diversity of population and practice e.g. Leicester with a large ethnic minority population, and centres with specialist nurse meetings when men enter surveillance or change from annual to three-monthly surveillance held face-to-face or by telephone.

We will draw three samples from the included centres: 400 men who joined surveillance in the previous year, a random sample of 400 men who have been in annual surveillance for 1-8 years, and 400 men in three-monthly surveillance. This sampling strategy ensures we include large numbers of men who are potentially most likely to be anxious. Discussions with PPI drew attention to the important group of men just below the threshold for surgery (5-5.4cm), and the Lead Nurse for NAAASP has identified this group as being in particular need of help. We will have no exclusion criteria.

We will start the process in a single centre as an informal pilot to gauge the response rate and identify ways to increase response rates in other centres if necessary. If we obtain a 60% response rate after one reminder, then we will have a sample of 720 responses (see sample size calculation below). A response rate of 50% would give us 600 responses. If all the questionnaires are sent at the same time, then men will be at different times post-screening, allowing us to compare rates of negative consequences at different times post-screening.

Identification of participants

Each screening centre will identify around 100 to 200 men from the 3 samples listed above (depends on the size of the Centre). Most men have given permission to be approached for research as part of the screening service. The Centre staff will remove men who have asked not to be approached for research and create a list of men who have given permission to be approached. The list will have the men's name and address (including postcode). The screening centre staff will send it using a secure data transfer process to the researchers at the University of Sheffield.

Each screening centre will require Caldicott approvals to send the data to the University of Sheffield. Caldicott permissions can only be applied for once NHS ethics and HRA approvals are in place.

Data collection

The research team will post a covering letter, the questionnaire and a reply-paid envelope to each man on the list. The letter will also include a web address (and possibly a QR code) to access the survey for any men that want to complete it online. We will send one reminder after two weeks.

Analysis

All data will be entered into SPSS for analysis and the scores calculated for the two AAA-specific scales, PCSQ and EQ5D-5L. Mean scores for each AAA-specific scale and PCSQ will be compared by size of AAA, perceived rate of growth of AAA, months since last screening, number of years in surveillance, socio-demographic characteristics and EQ5D-5L. It will be a simple analysis, first comparing unadjusted means by group using a t-test or ANOVA. Then we will undertake multiple linear regression on each AAA-specific scale and the PCSQ to identify the set of characteristics of the AAA or the man that predict negative consequences. Higher rates at particular time periods, or in particular groups of men, with help to focus the proposed intervention on where it can help the most. This information will also be useful to other research groups wanting to reduce the negative consequences of AAA surveillance. The analysis will be led by AOC who has a Masters in Social Statistics, with advice from SR who is experienced at analysing the e-PAQ suite of questionnaires.

We will check for non-response bias by age and level of social deprivation (using postcode to identify IMD quintile). We may weight the sample to compensate for differential non-response.

2. Qualitative interviews with men in surveillance with psychosocial consequences (and their partners/family members)

Sample

We will undertake a qualitative interview study with 20-24 men 'in surveillance' and reporting psychosocial consequences in the survey above. We will sample men with different sizes of AAA and feeling anxious at different times of the surveillance trajectory. We will attend to inclusivity by aiming for maximum diversity in terms of age, social deprivation, ethnicity, disability and multiple disadvantage. We will also interview partners (or key family members) with agreement of the men (n=12-20). We will explore causes of any anxiety in family members, the trajectory of anxiety over time, and views on different options for managing problems. We will interview men and their partners/family separately or together based on their preferences.

Identifying the sample

On the questionnaire in the survey of men, we will ask men if they are willing to be contacted about further aspects of the study, such as an interview or a workshop, and their preferred method of communication. If they tick 'yes' we will select men who fit our sampling criteria and contact them via their preferred method of communication to ask if they would like information about taking part in an interview, and how they would like to receive this information. We will then send those that are interested a letter of invitation, a PIS, consent form and response card with postage paid reply envelope. Men who would like to participate in an interview will be able to contact researchers using the contact details supplied in the PIS, or by returning the response card through the post in the envelope provided. We will also ask men if they want to identify someone who offers support to them when attending surveillance and see if they are happy for us to contact them for an interview.

Data collection

We will offer people the option of virtual, telephone or face-to-face interviews. People may have preferences depending on COVID-19 or how comfortable they feel using video-based meetings. We expect interviews to last about an hour. We will ask men about any problems caused by being in surveillance. We will ask them about what might help them to deal with those problems. We will also present men with different options for an intervention and ask them about their views of each option. If men become distressed during the interviews, we will stop the interviews if necessary. If men appear to be highly anxious about AAA we may also suggest that they contact their screening centre AAA nurse specialist, or their GP if it is felt that extra support might be required. We also signpost to the British Heart Foundation (BHF) who are also a charity that have lots of experience at supporting men with AAA, and provide both the telephone helpline for patients and the website address on our PIS.

The Qualitative Researcher (LL) has interviewed men with AAA and is experienced in dealing with this sensitively. We will audio-record the interviews and transcribe them verbatim.

Analysis

We will use the framework approach to analyse the interviews (Ritchie & Lewis 2003) because we have clear research questions, we are aware of some of the causes of negative consequences from previous research, and this approach also allows for what the framework approach authors call 'emergent themes' that we would identify inductively.

3. Co-design workshops

We will hold two workshops involving members of the research team and stakeholders. In the first one we will bring men, family members, regional screening centre leads, AAA nurse practitioners, screening technicians and NAAASP leaders together to co-design an intervention. Our Clinical Psychologist co-applicant (JH) will be key to these meetings because we will be discussing anxiety and how to address it. We will also try to include a GP because men and their partners may wish to approach primary care as part of any intervention. GPs are extremely busy, and it may be challenging to find a GP with an interest in this topic because NAAASP is not embedded within or linked to primary care. We will recruit men and family/partners to attend from our PPI group, survey respondents and interviews. We expect around 16 stakeholders to attend the workshops.

Identifying stakeholders to participate in the workshops

Clinicians: The PCAAAS study team includes vascular surgeons, a clinical director of a centre and a AAA specialist nurse. A sample of clinicians with expertise in AAA screening will be identified by our study AAA Nurse Specialist co-applicant and one of our principal investigators (a vascular consultant) from their clinical contacts at a number of clinics in England. The Nurse Specialist and PI will make initial contact with potential participants with a brief explanation of the study and ask for permission to pass their email contact details on to the wider research team. The research team will then contact those that agreed by email, and include a letter of invitation, a participant information sheet and consent form. These will contain the contact details of the researchers in case participants have any questions or require further information. We will send one email reminder.

GP: To identify a GP to attend the workshops the research team will approach the Academic GP group at the University of Sheffield to help us find a GP with an interest in AAA screening. The Academic GP group will make initial contact with potential participants with a brief explanation of the study and ask for permission to pass their contact details to the research team. The research team will then contact those that agreed by email, and include a letter of invitation, a participant information sheet and consent form. These will contain the contact details of the researchers in case participants have any questions or require further information. We will send one email reminder.

Men in Screening/family members: On the questionnaire detailed earlier we will ask men if they are willing to be contacted about further aspects of the study, such as an interview or a workshop, and

their preferred method of communication. If they tick 'yes' we will select men who fit our sampling criteria and contact them via their preferred method of communication to ask if they would like information about taking part in a workshop. We will then send those that are interested a letter of invitation, a PIS, consent form and response card with postage paid reply envelope. Men who would like to participate in a workshop will be able to contact researchers using the contact details supplied in the PIS, or by returning the response card through the post in the envelope provided.

The workshops

Co-design is 'in' at the moment and people can use the term to describe a multitude of approaches. Our approach to co-design is bringing people together as equal partners, where all experience and expertise is equally valued (Langley 2018). It involves using 'design thinking' such as the Design Council's double diamond process that encourages divergent and convergent thinking about problems and solutions (Design Council 2019). It encourages creative thinking by using activities such as storyboards, scenarios and personas to help overcome some of the barriers in designing an intervention such as power and differing use of language (Langley 2018). At first, we will focus on understanding the problem (we will present the findings of existing evidence, and our surveys and interviews, and use personas to explore experiences within small groups). Then we will identify solutions by generating ideas that are prioritised and agreed on together to inform the design of a prototype intervention (Langley 2018). The intervention could involve a mix of the following: improving the AAA website information, describing risks in different ways so that men find it easier to understand their own risk of a burst AAA, creating a new leaflet aimed at anxiety management, offering access to free self-delivered Cognitive Behavioural Therapy, offering guidance on when to seek help from a GP, or something we have not thought about.

We will create a prototype of the intervention. In the second workshop we will bring the same group together to consider: assumptions about how the intervention will improve men's quality of life (we will present the developing logic model for discussion); ways of improving the prototype; when the intervention would be offered, for how long it would be used, and by whom; what outcomes we should be measuring at what point and for whom; how easy it would be to implement in the real world; how best to evaluate it. We will then improve the prototype based on this feedback and develop instructions on how best to use it.

We will aim for workshops to last around four hours each (with time costed for some preparation). Ideally we would like to do them face-to-face but there are ways of doing them online if COVID-19 prevent in-person meetings (https://lab4living.org.uk/projects/co-design-during-covid/, accessed 11/1/22). If we have to do the workshops online, we will offer IT support to men and their families. Older patients with vascular problems were able to participate successfully in online priority setting workshops undertaken by the Vascular Society on behalf of the James Lind Alliance so it is possible but not preferable.

4.Integrating components to create an intervention

Integration of all the development components will occur within the first co-design workshop. We have set aside funds to work with a design expert to facilitate the production of the prototype.

5. Assessing the acceptability and feasibility of the intervention

Sample recruitment

We will recruit 20 men from three sources: participants from our interviews and co-design workshops, and volunteers from the survey (on the questionnaire in the survey we will ask men if they want to be involved in other aspects of the study). We will aim for diversity in this sample.

Data collection

Men (and perhaps their partners/family) will use the intervention for the required amount of time and complete a telephone-administered questionnaire about whether they used it, how they used it, what they liked and did not like about the intervention, whether they perceived they benefited from it and what they feel helped this, and the improvements they would like to see. We do not expect that men would need to use it for long in order to gain benefit so this part of the study will last 2-3 months only. Based on the findings, we will make further changes to the intervention.

The questionnaire has not yet been developed as it will be based on earlier work.

<u>WORK PACKAGE 2: Identifying men's preferences for exiting surveillance</u>

*1.*Qualitative interview study with men and their partners

Sample

We will undertake qualitative interviews with 20-24 men 'in surveillance' and their partners/key family member (n=12-20). We will undertake maximum diversity sampling to include men of different ages, with different health profiles, who have different sizes of AAA, different rates of growth, and different lengths of time in surveillance.

Recruitment

After Caldicott permissions are in place, we will ask for 100 names and addresses of men in surveillance from the Northeast & Cumbria Screening Centre to be sent to the research team at the University of Sheffield. The research team will send a postal request for men to participate in an interview to talk about how long men should stay in surveillance and why men might be asked to leave surveillance. If they say yes, we will ask them to complete a short form so we can sample a diverse range of men. The form will consist of the 'about you' questions on the survey of men used to identify problems caused by screening. Then we will select men and ask them for consent and ask if they are happy for us to approach a key family member.

Data collection

We will offer people the option of virtual, telephone or face-to-face interviews. People may have preferences depending on COVID-19 or how comfortable they feel using video-based meetings. We expect interviews to last about an hour. We will ask men about issues important to them when considering whether to leave surveillance before focusing on some potential Exit Strategies and their characteristics. If men become distressed during the interviews, we will stop the interviews if necessary If men appear to be highly anxious about AAA we may also suggest that they contact their screening centre AAA nurse specialist, or their GP if it is felt that extra support might be required. We also signpost to the British Heart Foundation (BHF) who are also a charity that have lots of experience at supporting men with AAA, and provide both the telephone helpline for patients and the website address on our PIS. The Qualitative Researcher (LL) has interviewed men with AAA and is experienced in dealing with this sensitively. We will audio-record the interviews and transcribe them verbatim.

Analysis

We will use the framework approach to analyse the interviews (Ritchie & Lewis 2003) because we have clear research questions and this approach also allows for what the framework approach authors call ‘emergent themes’ that we would identify inductively.

2 Survey to measure men’s preferences

Design

We will undertake a telephone survey of a random sample of men in surveillance.

Based on the findings of the qualitative interviews above, we will develop a questionnaire to elicit the preferences of men in surveillance for possible Exit Strategies. Without knowing the outcomes of the interviews, it is not possible at this stage to specify the method we will use. If it is possible to describe all the Exit Strategies in terms of a set of common attributes, then a discrete choice experiment (DCE) method will be used to elicit preferences. Each of the attributes will be assigned at least two levels (the levels will be decided from a combination of interview outcomes and expert opinion). Once levels have been assigned, a range of hypothetical Exit Strategies can be defined in terms of the attributes and levels (the final number of strategies is a function of the numbers of attributes and levels). The DCE will present men with a series of pairwise choices between two hypothetical strategies, and for each choice, they will be asked which they would prefer. The resulting choices will be analysed to reveal preferences for Exit Strategies and willingness to trade between them (Ryan 2007).

If it is not possible to define all the Exit Strategies in terms of a set of common attributes, then preferences will need to be elicited for each possible Exit Strategy individually. In this case, it is proposed to elicit preferences using the contingent valuation (CV) method. With this method, men will be presented with descriptions of the strategies and asked first to rank them from least preferred to most preferred. Maximum willingness to pay (WTP) for each strategy will then be elicited using a marginal approach (Shackley & Donaldson 2002). With this method, individuals are asked their WTP

for their least preferred programme and then subsequently asked how much more they would be prepared to pay for their next most preferred strategy.

As this questionnaire will be developed on the basis of the results from the earlier work packages, the precise content is not currently known and will require an amendment to ethics and HRA nearer the time.

Sample

The generation of the sample for the survey will be the same, irrespective of which method is used. The sample will be men in surveillance.

Identifying men

We will ask two screening centres (Northeast & Cumbria and one other) centres to provide names, addresses of a random sample of men in surveillance to the research team using processes described in the previous survey section. The research team will send written information (covering letter, PIS, consent form, reply paid envelope) and then arrange for a telephone call to those who reply to administer the questionnaire.

Sample size

Based on previous experience with telephone surveys with vascular patients, where an approximate 60% response rate was achieved, we expect we will need to contact 500 men to achieve 300 responses (Michaels et al 2021). The sample size is based on precedence, where the literature shows that the majority of DCE sample sizes range between 100 and 300 (de Bekker-Grob 2015). Precedence is used because sample size calculations are difficult to estimate *a priori* without knowing the number of attributes and levels that will be included in the DCE. Based upon the CV literature and previous experience with the technique (Lin 2013, Shackley and Dixon 2014), a sample of 300 will be sufficient for meaningful analysis of WTP data.

Data collection

The telephone survey will be administered by the Research Associate with support from the Qualitative Researcher if necessary. Men will be asked to give verbal consent prior to the questionnaire being administered. We expect each telephone call to last no more than 20 minutes, based on our previous study where the average interview time was 13 minutes (Wickramasekera 2019).

Analysis

For the DCE, choice data will be modelled using a conditional logic model. Regression coefficients will be used to estimate the relative importance of attributes and the marginal rates of substitution will be calculated (i.e. trade off preferences for Exit Strategy characteristics) (de Bekker-Grob 2012). Latent class models will be used to analyse individual heterogeneity and to identify subsets of patients with

varying preferences (Hole 2016). For CV, the relative strength of men's preferences for the strategies will be estimated from calculating mean and median WTP values and testing for differences by using t-tests and Mann–Whitney U tests. Multivariate regression analyses will be performed to examine possible determinants of stated WTP and determine how WTP varies by different group characteristics. We will consider the use of a weighted sample here to address non-response bias.

PS has considerable experience of both DCE and CV studies, as well as preference elicitation studies more generally (Shackley & Dixon 2014, Rowen 2016). Whichever method is used, the results will identify whether preferences differ by factors such as age, size of AAA, rate of AAA growth (men are given the size of their AAA in writing at each screening attendance), social deprivation, general health, ethnicity, and disability. This will help NAAASP to develop an Exit Strategy and/or a decision aid for exit that is patient focused. The results can also feed into future cost-effectiveness modelling of Exit Strategies by considering men's preferences alongside costs and effectiveness.

3. Integration of qualitative interviews and survey

This is a sequential study where findings from one phase inform the content of the next phase. That is, integration is built into the design. However, it is still beneficial to bring the findings of the components together to identify an integrated set of findings. We will use adapted Triangulation Protocol to compare and contrast findings from each component, considering where they agree, disagree, or offer explanation of findings from different phases (Farmer 2006). We have used this successfully in a number of NIHR studies e.g. to bring together findings from a realist review, qualitative interview study and population survey undertaken sequentially (O'Cathain 2020).

6 STUDY SETTING

The 38 NHS screening providers in England that offer surveillance to men with AAA will be the setting for the study, although only a few of the centres will sent names and addresses of men for the surveys.

The University of Sheffield will be the research site. Additionally, there will be 6-8 participant identification centres (PICS) they will all be NHS screening centres in England.

PICS and the NHS sites are appropriate as they help us identify eligible participants quickly and efficiently. The University site is where the research will be coordinated, surveys will be sent from, data will be stored and analysis will take place.

PICS will require Caldicott permission to transfer identifiable data to transfer data to the University.

PICS will identify potential participants only. They will send the list of potential participants to The research team at the University of Sheffield. Only men who have agreed to be contacted for research purposes will be included in this list.

The University will send out surveys and contact people for interviews, focus groups and telephone surveys.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

Inclusion criteria for the study are men currently in the AAA surveillance programme, provided by the NHS in England. Only men (people with their gender listed as male on their GP record) are included in the screening and surveillance programme.

Men are invited for their initial screening at 65 so all patient participants will be 65 or over.

All ethnicities and socio-economic groups will be included.

The surveillance programme in England only will be included.

We will endeavour to ensure our 6-8 PICS cover a range of North/South, East/West and urban/rural

Different parts of the study require men in different stages of the programme, this has been described in the work packages above.

For family members of men, the only inclusion criteria is that they are identified by the men as someone who offers them support related to AAA screening. They may be of any gender, age, ethnicity or socio-economic group.

7.1.2 Exclusion criteria

There are no exclusion criteria

7.2 Sampling

7.2.1 Size of sample

Size of samples are described earlier in the methods section of each study component. In addition, we have undertaken a sample size calculation to ensure our survey of men's screening problems is large enough. A 'rule of thumb' approach to sample size for linear regression is 104 cases plus the number of predictors for testing coefficients. We have 9 predictors so the sample size could be small: 104+9=113. The sample size for testing the whole model would be 50+(8x9 predictors)=124. We want to be convinced that some sub-groups have clinically and statistically significantly higher scores (that is, more negative consequences) so we have undertaken a sample size calculation based on a comparison of the mean of a scale in two groups of small vs medium AAAs. With a mean score of 23.74 and a standard deviation of 21.84 on the AAA-related anxiety scale (Aber 2020b), a difference of 5 points (classed as a 'small effect size' of 0.23 and one that our medical co-applicant JM has identified as clinically meaningfully) would be identified at the 5% level with 80% power with 300 in each group. That is, we would need 600 respondents in total.

7.2.2 Sampling technique

The sampling technique is described earlier in the methods of each study component. Purposive sampling is used in each qualitative component.

7.3 Recruitment

7.3.1 Sample identification

The sampling technique is described earlier in the methods of each study component.

Each component will recruit differently and should not be taken out of context

No one will be contacted without consent or via public recruitment means.

Men who attend the workshops in work package one will be offered a £30 voucher and travel costs for attending the workshop. No other costs will be paid.

7.3.2 Consent

All potential participants will be assumed to have capacity.

All potential participants will have given consent to be contacted for research purposes.

Consent process are described earlier in the methods of each study component.

8 ETHICAL AND REGULATORY CONSIDERATIONS

Any component of the project that involves men from the screening programme will require NHS ethics and HRA governance approvals.

There are two study components (not described here) that involve health professionals only and we have sought University ethics approval for these components.

Transfer of data from the PIC to the University will require Caldicott approval. This will be applied for once the NHS ethics and HRA approvals have been completed.

Later parts of the project (the feasibility of the new intervention) and the survey on Exit Strategies will require an amendment to be submitted to IRAS as we develop full details of these components.

8.1 Assessment and management of risk

We would like to undertake interviews and workshops in-person, but COVID-19 restrictions may mean that these need to be undertaken virtually or by telephone. We will plan for in-person and then move to virtual if necessary or if preferred by participants.

We will be talking to men about anxiety. We anticipate that some participants may be highly anxious. The Research Associate and Qualitative Researcher have worked with men with AAA before and are used to dealing with this situation sensitively. The Project Manager has not worked with AAA before but is a mental health nurse and has worked with many cases of extreme anxiety linked to physical health conditions. There will also be a specific plan for what to do if a participant gets anxious during the interview. The interview may be stopped (temporarily or permanently), and they may be directed to speak to their GP or AAA nurse. In extreme circumstances they will be given the phone number for the Samaritans. Due to the nature of the questions, we will be asking, it is unlikely that safeguarding issues will arise. However, if they do, we will let the participant know we have a duty to report their situation and we will contact the safeguarding service at their local council. In an immediate life-threatening situation we would call the police.

In the unlikely scenario that a man discloses suicidal thoughts, we will contact the NHS Screening Centre and ask them to notify the man's GP. We will also include in the PIS that men can contact their GP at any time if they feel they are struggling with depression or anxiety.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from a REC for the study protocol, informed consent forms and other relevant documents e.g. advertisements. Parts of the study will require NHS REC and HRA, others will go before our University REC.

For NHS REC reviewed research components

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place.

All participants will be enrolled from the NHS, from 6-8 participant identification centres (PICs). All of the NHS R&D teams will be contacted as close to the start of the IRAS process as possible to apply for NHS REC and HRA approvals to ensure they have capacity and capability to support the study.

Organisational Information Documents will be completed for each site/PIC

Amendments affecting the PICs will be communicated to their R&D teams as soon as possible and the research team will work with the R&D teams to implement the changes once approved by REC/HRA.

End of Study Definition

The end of the study will be the last post-test visit for the intervention feasibility study. We expect that this will be Month 23 (August 2024)

Amendments

NHS REC

Amendments for parts of the study requiring NHS REC/HRA approvals will be undertaken by the senior project manager.

The HRA amendment form will be used to determine if that is substantial or not.

NHS REC /IRAS guidance will be followed for making decisions about amendments to the REC.

University REC

Amendments for parts of the study requiring University REC approval will be undertaken by the senior project manager.

The University has a standard form for applying for an amendment. This standard process will be used and guidance followed.

Amendment history will be recorded in the protocol and, where it affects patients, online.

8.3 Peer review

The study has been externally peer reviewed as part of the NIHR funding application process.

8.4 Patient & Public Involvement

Design of the Research:

There is not an existing AAA surveillance specific PPI group. Therefore, we have established the first one. However, there has been PPI input right from the outset of the research development.

The PPI member on the NAAASP research committee (NMS) was approached to become a co-applicant on the research bid and was involved in the development of the planned research.

During the initial development of the research bid, the views of four men who had also been through the screening process were sought. The men described the impact that screening had had on them, including the anxiety associated with it, and the importance of trying to find ways to reduce this. Two of the original group of four men have also joined the PPI group in order to help take the project forward. The group now consists of six men, who have been through AAA screening or had AAAs that have been surgically repaired. Three members of the group have PPI experience and three do not; training and support has been offered to all.

As the project progresses, we hope to recruit other members to the PPI group who have not been through AAA screening themselves but who may provide support for men that have, such as partners or family members. This will help ensure a wider representation of views within the group.

The PPI group will meet approximately ten times during the study duration. The group will meet at points that are most relevant, and meaningful, to the study so the durations between meetings will be flexible to meet the study needs. For example, at the beginning of the project whilst we are developing study documentation with the input of the PPI group we may need to meet more often.

Acceptability of the research:

We are consulting with the PPI group about the most suitable ways of recruiting participants for each work package, to ensure that we can be as inclusive as possible.

We are asking the PPI group to be involved with development of study materials such as invitation letters, consent forms, interview topic guides and survey development to ensure that they are clear and concise.

Management of the Research:

The PPI Lead (LL) and PPI co-applicant (NMS) worked together to develop the agenda for the first PPI meeting that was held two weeks after the project officially commenced. They will continue to so for further meetings.

Undertaking the Research:

PPI members will attend the two workshops that are planned as part of work package one to help with the co-design of the intervention to reduce screening related anxiety, and to facilitate the inclusion of men and their families/partners in the workshops.

Analysis of the Research:

We do not intend to merely present findings from completed analysis to the group. Rather we would like them to be involved in the analysis in a more meaningful way. This could be through looking at, and discussing, the results of the questionnaires, discussions around coding frameworks for interviews, and through helping with interpretation of findings from the interviews.

Dissemination of Findings:

We would like the group to help establish the best way to disseminate the study findings, including to those that have participated in the research. Some of the PPI group are active on social media and have identified that this may be a way of helping to reach a wide audience as the study progresses. As the group who attend for screening is aged 65 or older we need to ensure that we have a wide range of dissemination approaches.

8.5 Protocol compliance

The research team will ask NIHR for approval for changes to the protocol.

8.6 Data protection and patient confidentiality

The University of Sheffield is the data custodian and data is collected only for research purposes. Data will be stored on the University's secure server. Only researchers from the PCAAAS team will have access to the drive (along with some IT administration staff for IT security and audit purposes only).

Data for the different work packages will be treated differently as some needs to remain identifiable so we can contact specific individuals

Wherever possible we will de-identify as soon as possible

Data transfer will be conducted within Caldicott and University Information Governance guidelines. Data will be stored for 5 years

8.7 Indemnity

The University of Sheffield is the sponsor and has all the required insurance and indemnities in place for this research project.

8.8 Access to the final study dataset

The Research Team will have access to anonymised datasets.

We will share anonymised data from the surveys. Qualitative data will not be shared.

Anonymised data sets from the surveys will be stored on ORDA, the University of Sheffield research archive. Other researchers can request access to the data set. Any requests would be rigorously evaluated, and research ethics committee approvals and data sharing agreements would be required. All PIS make this clear.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

Dissemination

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 (e.g. HSRUK, Vascular Society of Great Britain & Ireland Annual Scientific Meeting, European Society of Vascular Surgery annual conference, NAAASP Research Day and Networking event). An international vascular conference will be important to reach AAA screening programmes in other countries as well as countries considering introducing a programme. For example, Nair et al (2019) shows that screening would be cost-effective in New Zealand so this country may be considering introducing a programme.

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. Social media is likely

to be less useful than on other projects because the patient group is older but we will use our team member Twitter accounts to disseminate our findings.

Outputs

Conference presentations, presentations to NAAASP, presentations to patient information days.

Peer-reviewed publications reporting the findings of the whole project and each work package.

An intervention to reduce psychosocial consequences of being in AAA surveillance.

Guidance on patient preferences so that AAA programmes can develop a patient-centred AAA Exit Strategy.

Impact

NAAASP, as of October 2021, sits operationally with NHS England (NHSE). A co-applicant Akhtar Nasim (the Clinical Lead for NAAASP) will feed the findings directly to the NHSEAAA Screening Programme Operational Delivery Group and the NHS E Screening Programme Board. He will present the intervention to reduce psychosocial consequences, and the guidance on men's preferences for exit from surveillance and identify what actions these groups/boards would like to take within NAAASP or see taken in future research. Currently a health optimisation strategy is being developed in NAAASP (under the direction of the NAAASP Nurse Lead Alan Elstone who is a co-applicant) for men in surveillance and the findings of our study will inform the strategy for dealing with AAA-related anxiety/impact on quality of life. The preferences work on an exit strategy could inform the development of a decision aid that would help men and their partners decide when to leave the surveillance programme.

Akhtar Nasim will also present our findings to the National Screening Committee in relation to reconsideration of modification of current surveillance intervals (previously proposed to the committee in 2019) in NAAASP. Our findings on the % of men with small AAA (measuring 3-4.4cm) who have psychosocial consequences will help in deciding whether men with sub-aneurysmal aortas (measuring 2.5-2.9cm) should be offered surveillance in NAAASP. Currently this group are not followed up but a proportion of them develop large AAAs requiring treatment. The decision to include these men in surveillance will be influenced by the potential impact of surveillance on their quality of life. If we find only small levels of impact on quality of life for men with 3-4.4cm AAAs then this will reduce concerns about screening-related harms.

NAAASP also has close links with the Vascular Society of Great Britain and Ireland, and Akhtar Nasim will discuss findings at the annual scientific meeting via a dedicated session on AAA Screening. This is important as some patients with non-screening-detected small and medium sized AAAs are undergoing surveillance outside NAAASP and our findings will apply equally to them.

Akhtar Nasim will liaise with other AAA screening programmes in Wales, Scotland, and Sweden to help them understand and apply learning from our work.

The University of Sheffield will own the data arising from the study.

The NIHR will be acknowledged in all publications.

9.2 Authorship eligibility guidelines and any intended use of professional writers

All of the research team will be authors on the final synopsis report published by NIHR.

10 REFERENCES

Aber A, Phillips P, Lumley E, Radley S, et al (2020a). Mixed methods study to develop the content validity and the conceptual framework of the electronic patient-reported outcome measure for vascular conditions. BMJ Open 10(8), e034154. doi:10.1136/bmjopen-2019-034154

Aber A, Phillips P, Hughes J, Keetharuth AD, Rooney G, Radley S, Walters S, Nawaz S, Jones G, Michaels J (2020b). Electronic personal assessment questionnaire for vascular conditions (ePAQ-VAS): development and validity. Br J Surg. 2020 Jul;107(8):1004-1012. doi: 10.1002/bjs.11531.

Ambler G, & Twine C (2021). Abdominal Aortic Aneurysm Repair in Advanced Age: Is Age Really the Problem? Eur J Vasc Endovasc Surg 61(6), 929. doi:10.1016/j.ejvs.2021.02.031

Bath M, Sidloff D, Saratzis A, Bown M et al (2018). Impact of abdominal aortic aneurysm screening on quality of life. Br J Surg 105(3), 203-208. doi:10.1002/bjs.10721

Baxter SK et al (2014). Using logic model methods in systematic review synthesis: describing complex pathways in referral management interventions. BMC Med Res Methodol 14, 62.

Brodersen J, Hansson A, Johansson M, Siersma V et al (2018). Consequences of screening in abdominal aortic aneurysm: development and dimensionality of a questionnaire. J Patient Rep Outcomes 2, 37. doi:10.1186/s41687-018-0066-1

Cockburn J, De Luise T, Hurley S, & Clover K (1992). Development and validation of the PCQ: a questionnaire to measure the psychological consequences of screening mammography. Soc Sci Med 34(10), 1129-1134. doi: 10.1016/0277-9536(92)90286-y

Cotter A, Vuong K, Mustelin L, Yang Y, et al (2017). Do psychological harms result from being labelled with an unexpected diagnosis of abdominal aortic aneurysm or prostate cancer through screening? A systematic review. BMJ Open 7(12), e017565. doi:10.1136/bmjopen-2017-017565

Coulter A, & Oldham J (2016). Person-centred care: what is it and how do we get there? Future Hosp J 3(2), 114-116. doi:10.7861/futurehosp.3-2-114

Craig P, Dieppe P, Macintyre S, Michie S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance BMJ 2008; 337 :a1655 doi:10.1136/bmj.a1655

Damhus CS, Siersma V, Hansson C, Winther Bang C & Brodersen J (2021): Psychosocial consequences of screening-detected abdominal aortic aneurisms: a cross-sectional study, Scandinavian Journal of Primary Health Care, DOI: 10.1080/02813432.2021.2004713

de Bekker-Grob E et al (2015). Sample Size Requirements for Discrete-Choice Experiments in Healthcare: a Practical Guide. Patient 8(5), 373-384. doi:10.1007/s40271-015-0118-z

de Bekker-Grob E, Ryan M, & Gerard K (2012). Discrete choice experiments in health economics: a review of the literature. Health Econ 21(2), 145-172. doi:10.1002/hec.1697

DeFrank JT, Barclay C, et al (2015). The psychological harms of screening: the evidence we have versus the evidence we need. J Gen Intern Med 30(2):242-248. doi:10.1007/s11606-014-2996-5

Design Council (2019) What is the framework for innovation? Design Council's evolved Double Diamond. Retrieved from https://www.designcouncil.org.uk/news-opinion/what-framework-innovation-design-councils-evolved-double-diamond

Ericsson A, Carlson E, Siu-Yin Ching S, Molassiotis A, & Kumlien C (2020). Partners' experiences of living with men who have screening-detected abdominal aortic aneurysms: A qualitative descriptive study. J Clin Nurs 29(19-20), 3711-3720. doi:10.1111/jocn.15399

Ericsson A, Holst J, Gottsäter A, Zarrouk M, & Kumlien C (2017). Psychosocial consequences in men taking part in a national screening program for abdominal aortic aneurysm. J Vasc Nurs 35(4), 211-220. doi:10.1016/j.jvn.2017.06.001

Ericsson A, Kumlien C, Ching S, Carlson E, & Molassiotis A (2019). Impact on Quality of Life of Men with Screening-Detected Abdominal Aortic Aneurysms Attending Regular Follow ups: A Narrative Literature Review. Eur J Vasc Endovasc Surg 57(4), 589-596. doi:10.1016/j.ejvs.2018.10.012

Farmer T, Robinson K, Elliott S, & Eyles J (2006). Developing and implementing a triangulation protocol for qualitative health research. Qual Health Res 16(3), 377-394. doi:10.1177/1049732305285708

Gunasekera R, Moss J, Crank H, Mitchell P, Nawaz S, & Tew G (2014). Patient recruitment and experiences in a randomised trial of supervised exercise training for individuals with abdominal aortic aneurysm. J Vasc Nurs 32(1), 4-9. doi:10.1016/j.jvn.2013.05.002

Hansson A, Brodersen J, Reventlow S, & Pettersson M (2012). Opening Pandora's box: The experiences of having an asymptomatic aortic aneurysm under surveillance. Health Risk Soc 14(4), 341-359. doi:10.1080/13698575.2012.680953

Health Foundation (2014) Person-centred care made simple. Retrieved from https://www.health.org.uk/publications/person-centred-care-made-simple Accessed 23/1/22

Hole A et al (2016). Response Patterns in Health State Valuation Using Endogenous Attribute Attendance and Latent Class Analysis. Health Econ 25(2), 212-224. doi:10.1002/hec.3134

Johansson M, Borys F, Peterson H et al (2021). Addressing harms of screening – A review of outcomes in Cochrane reviews and suggestions for next steps. Journal of Clinical Epidemiology 129, 68-73. doi.org/10.1016/j.jclinepi.2020.09.030

Langley J, Wolstenholme D, & Cooke J (2018). 'Collective making' as knowledge mobilisation: the contribution of participatory design in the co-creation of knowledge in healthcare. BMC Health Serv Res 18(1), 585. doi:10.1186/s12913-018-3397-y

Lin P et al (2013). Willingness to pay for diagnostic technologies: a review of the contingent valuation literature. Value Health 16(5), 797-805. doi:10.1016/j.jval.2013.04.005

Maheswaran R, Tong T, Michaels J, Brindley P, et al. Socioeconomic disparities in abdominal aortic aneurysm repair rates and survival in England – a population-based study. Currently under review.

Meecham L, Jacomelli J, Davis M, Pherwani A, Lees T, & Earnshaw J (2021). Outcomes in Men From the NHS Abdominal Aortic Aneurysm Screening Programme With a Large Aneurysm Referred for Intervention. Eur J Vasc Endovasc Surg 61(2), 192-199. doi:10.1016/j.ejvs.2020.09.009

Michaels J (2021). Value assessment frameworks: who is valuing the care in healthcare? J Med Ethics. doi:10.1136/medethics-2020-106503

Michaels J, Wilson E, Maheswaran R, Radley S, Jones G, Tong T, . . . Shackley P (2021). Configuration of vascular services: a multiple methods research programme. Programme Grants Appl Res 9(5). doi:10.3310/pgfar09050

Nair N, Kvizhinadze G, Jones GT, Rush R, et al. Health gains, costs and cost-effectiveness of a population-based screening programme for abdominal aortic aneurysms. Br J Surg. 2019 Jul;106(8):1043-1054. doi: 10.1002/bjs.11169.

O'Cathain A, Croot L, Duncan E, et al (2019). Guidance on how to develop complex interventions to improve health and healthcare. BMJ Open 9:e029954. doi:10.1136/bmjopen-2019-029954

O'Cathain A, & Thomas K (2004). "Any other comments?" Open questions on questionnaires - a bane or a bonus to research? BMC Med Res Methodol 4, 25. doi:10.1186/1471-2288-4-25

O'Cathain A, Knowles E, Long J, Connell J, et al (2020). Drivers of 'clinically unnecessary' use of emergency and urgent care: the DEUCE mixed-methods study. Health Serv Deliv Res 8(15). doi:10.3310/hsdr08150

Papaioannou D et al (2010). Literature searching for social science systematic reviews: consideration of a range of search techniques. Health Information & Libraries Journal, 27: 114-122.

Pettersson M & Bergbom I (2013). To be under control: a qualitative study of patients' experiences living with the diagnosis of abdominal aortic aneurysm. J Cardiovasc Nurs 28(4), 387-395. doi:10.1097/JCN.0b013e31824bd965

Phillips P, Rooney G, Wilson E, & Michaels J (2021). A systematic review to identify anxiety measures for use in populations undergoing abdominal aortic aneurysm screening. J Vasc Nurs 39(4), 120-125. doi:10.1016/j.jvn.2021.09.001

Ramer SL (2005). Site-ation pearl growing: methods and librarianship history and theory. J Med Libr Assoc 93(3):397–400.

Richards M (2019). Report of the independent review of adult screening programmes in England. Retrieved from https://www.england.nhs.uk/wp-content/uploads/2019/02/report-of-the-independent-review-of-adult-screening-programme-in-england.pdf

Ritchie J, & Lewis J (2003) Qualitative research practice: a guide for social science students and researchers. London: Sage.

Rowen D, Brazier J, Mukuria C, Keetharuth A, Hole A, Tsuchiya A, . . . Shackley P (2016). Eliciting Societal Preferences for Weighting QALYs for Burden of Illness and End of Life. Med Decis Making 36(2), 210-222. doi:10.1177/0272989X15619389

Ryan M, Gerard K, & Amaya-Amaya M (Eds.). (2007). *Using discrete choice experiments to value health and health care*: Springer Science & Business Media

Damhus CS, Siersma V, Hansson A, Winther Bang C, & Brodersen J (2021). Psychosocial consequences of screening-detected abdominal aortic aneurisms: a cross-sectional study. Scand J Prim Health Care 39(4), 459-465. doi:10.1080/02813432.2021.2004713

Shackley P & Dixon S (2014). The random card sort method and respondent certainty in contingent valuation: an exploratory investigation of range bias. Health Econ 23(10), 1213-1223. doi:10.1002/hec.2980

Shackley P & Donaldson C (2002). Should we use willingness to pay to elicit community preferences for health care? New evidence from using a 'marginal' approach. J Health Econ 21(6), 971-991. doi:10.1016/s0167-6296(02)00052-8

Singh A & Boyle J (2021). Small Aneurysm Surveillance Over 80: Is it Worthwhile? Eur J Vasc Endovasc Surg 62(1), 54. doi:10.1016/j.ejvs.2021.03.018

Skivington K, Matthews L, Simpson S A, Craig P, et al (2021). A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance BMJ 374 :n2061 doi:10.1136/bmj.n2061

Thompson S, Ashton H, Gao L, Scott R, & Multicentre Aneurysm Screening Study Group (2009). Screening men for abdominal aortic aneurysm: 10 year mortality and cost effectiveness results from the randomised Multicentre Aneurysm Screening Study. BMJ 338, b2307. doi:10.1136/bmj.b2307

Wickramasekera N, Howard A, Philips P, Rooney G, Hughes J, Wilson E, . . . Shackley P (2019). Strength of public preferences for endovascular or open aortic aneurysm repair. Br J Surg 106(13), 1775-1783. doi:10.1002/bjs.11265

Wickramasekera N, Barr A, Shackley P, Lee M, et al (2022). A mixed methods study of patient preferences and current practice for adults with steroid resistant ulcerative colitis (PoPSTER). Health Technol Assess In Press.

11. APPENDICIES

11.1 Appendix 1- Required documentation

CVs of the local research team and CI
PIS and consent form (headed paper)
Protocol for how participants will be identified
Caldicott approvals
Ethics committee and HRA approvals
Contact details for University research team

11.2 Appendix 2 – Schedule of Procedures (Example)

Procedures (WP1)	**Contacts**					
	WP1 survey (month 6)	**Month 11**	**Month 17**	**Month 20**	**Month 21**	**Month 23**
Informed consent	x					
Demographics	x					
Medical history	x					
experience of anxiety questionnaire (1200 men)	x					
WP1 interviews (20-24 men plus partners)		x				
Workshop 1 (16 men)			x			
Workshop 2 (16 men)				x		
Feasibility study pre tests (20 men)					x	
Feasibility study post tests (20 men)						x

Procedures (WP2)	**Contacts**	
	Month 5	**Month 10**

Informed consent	x	
Demographics	x	
Medical history	x	
WP2 interviews (20-24 men plus partners)	x	
Survey (up to 500 men)		x

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made