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Improving the heart health of individuals with abdominal aortic aneurysms: the CRISP Study

Submission date
10/11/2020

Recruitment status
No longer recruiting

Registration date
18/11/2020

Overall study status
Completed

Last Edited
24/10/2024

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Abdominal Aortic Aneurysm or AAA is an abnormal swelling of the aorta, the biggest artery in the body. It usually occurs in men aged over 65. An AAA can occasionally burst, leading to life-threatening bleeding. An AAA can be easily detected using a simple ultrasound scan. AAA screening programmes are now available across the UK through the NHS. These programmes invite all men at the age of 65 to have an ultrasound scan to check for AAA. Most of the men found to have an AAA in screening do not need surgery as their AAA is small in size. These men are, however, offered regular ultrasound scans to check the growth of the AAA. We already know that if someone has even a small AAA, they are far more likely to develop heart attacks and strokes compared to people without AAA. In fact, most people who have a small AAA will not die because of their AAA but because of a heart attack or a stroke. Despite this, individuals with AAAs in the UK AAA screening programmes do not receive adequate help and support to prevent these problems. This is an important missed opportunity. Simple things like taking an aspirin, lowering cholesterol, lowering blood pressure and improving one's diet can greatly decrease the chances of heart attacks and strokes. Unfortunately there hasn't been much research in this area and we do not know how to best support people with AAA to help them take advantage of these treatments.

The existing NHS AAA screening programmes can be used to improve the treatment of people with small AAAs by offering them medication, diet support, and other help to prevent heart attacks and strokes. The aim of this research is to develop and then test a health intervention specifically for men with AAA, which will improve their health and reduce their chances of heart attacks and strokes.

Who can participate?
Adult men with an abdominal aortic aneurysm identified through the existing NHS Abdominal Aortic Aneurysm (AAA) Screening Programme (NAAASP)

What does the study involve?
This research will consist of two stages:
1) In the first stage, patients with AAA, their relatives, and experts in this area will work together to develop the health intervention aimed to improve the heart health of those with AAA. First,

patients with AAAs and their families will be approached and invited to take part in the research. Experts including General Practitioners (GPs), public health doctors, surgeons who treat AAA, NHS staff from NHS AAA screening programmes and psychologists will also be invited. The first step will be to identify the barriers that prevent good heart care in people with AAA. Then, the patients and experts will discuss how these barriers can be overcome. The health intervention will eventually be designed using the information from those discussions
2) In the second stage, the intervention will be tested in the Leicestershire AAA screening unit to assess how many men with AAA will take it up. Eventually, a national study will confirm whether it works and whether it offers value-for-money in the NHS

What are the possible benefits and risks of participating?
If this study is successful, the existing NHS AAA screening programmes will be used as a platform to offer people with small AAAs better medical care and reduce the chance of heart attacks and strokes. This will benefit thousands of patients across the UK and prevent hundreds of admissions and deaths every year. It will bring significant cost savings to the NHS as the treatment of these health problems is very expensive.
No risks.

Where is the study run from?
NHS Abdominal Aortic Aneurysm Screening Programme, Public Health England (UK)

When is the study starting and how long is it expected to run for?
August 2019 to October 2024

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

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
273793

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
0746, IRAS 273793

Study information

Scientific Title
Cardiovascular Risk reduction In the NHS abdominal aortic aneurysm (AAA) Screening Programme: a co-developed cardiovascular prevention intervention (CRISP)

Acronym
CRISP

Study objectives
All 65 year-old men in the UK are invited for an ultrasound (US) to screen for AAA. The vast majority of those with AAA enter a disease-surveillance programme, undergoing regular repeat US. There are 11,601 men in AAA-surveillance, spending an average 4-7 years in follow-up.

Screening has minimal effect on all-cause mortality. The principal preventable cause of mortality in AAA-surveillance is cardiovascular disease. Regular attendance at surveillance clinics represents an excellent opportunity to address cardiovascular-risk. Unfortunately, AAA-surveillance was not designed to deliver cardiovascular-risk modification. Consequently, uptake of cardiovascular-risk management in AAA-surveillance is poor and does not follow National Institute for Health and Care Excellence (NICE) guidance in most instances. In this study we are therefore going to develop and test a cardiovascular-risk reduction intervention for the specific needs of individuals with AAA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/01/2020, East Midlands - Leicester Central Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 0207 972 2568; nrescommittee.eastmidlands-leicestercentral@nhs.net), ref: 19/EM/0366.

Study design
Qualitative study with additional quantitative feasibility study (mixed methodology)

Primary study design
Other

Secondary study design

Study setting(s)
Community

Study type(s)
Prevention, Quality of life, Screening

Participant information sheet
https://www.dropbox.com/s/5n0s9g68jqynof3/273793%20PIS%20patients%20CRISP%20v1.1%2021.12.2019.docx?dl=0

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

Interventions
There are two phases to this study, this registration concerns phase 2.
In Phase 1, we will develop an intervention that will help patients with an abdominal aortic aneurysm improve their heart health. Invited participants who have provided written informed consent will take part in remote focus groups (up to 90 minutes each, up to 4 focus group sessions) and, if necessary, in one hour long interviews (telephone or via a computer). Both patients with aneurysms (or carers/partners) will be invited to take part in these focus groups as well as healthcare professionals. This process will take a year. Once we have the necessary data from the participants, we will finalise the structure of the intervention.

Phase 2
In the second phase (Phase 2) of the research, we will test whether the intervention can be used in current NHS care and within aneurysm screening programmes. We will invite patients from

phase 1 and additional patients with aneurysms to use the intervention for six months. We will record their cardiovascular health when they are invited to take part and after six months. We will also assess how easy it was to use the intervention.

The CRISP intervention aims to address the following areas of best medical care/therapy in individuals who have an abdominal aortic aneurysm (small or moderate size) and are having surveillance using ultrasound scans:
1. Smoking cessation: A clear and easy to follow pathway, including patient-centred discussion of barriers and referral to existing NHS smoking cessation services available locally and regionally.
2. Lifestyle modifications: physical activity and diet assessed when one is diagnosed with an aneurysm in screening programmes and then the individual (if needed) is supported in setting and achieving specific targets for change (lose weight, eat healthy based on current guidance).
3. Antiplatelet agents: Aspirin 75mg (or Clopidogrel 75mg if Aspirin is contra-indicated) offered to all individuals and their primary care doctor is updated via direct communication.
4. Lipid control: Atorvastatin 80mg offered to all individuals regardless of baseline lipid levels and their primary care doctor is updated via direct communication.
5. Blood pressure control: A target of 140/90mmHg should be achieved; the primary care doctor is contacted via direct communication in order to achieve that target with appropriate pharmacotherapy

The intervention will include:
1. One initial face-to-face consultation (to assess and discuss risk-factors, address motivation and barriers and decide what actions and specific risk-factors to initially target)
2. Telephone-based remote follow-up (potentially with further face to face catch-up meetings)

Intervention Type
Mixed

Primary outcome measure
1. Proportion of patients agreeing to take part out of all patients invited at six months (recruitment rate) measured using case report forms
2. Proportion of people recruited who provide data at the end of the intervention period i.e. at six months (retention rate) measured using case report forms
3. Percentage of intervention sessions that participants complete at six months (intervention uptake) measured using case report forms
4. Intervention acceptability to patients (assessed qualitatively using semi-structured interviews and a satisfaction questionnaire) and service providers (assessed qualitatively)

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/08/2019

Completion date
01/10/2024

Eligibility

Key inclusion criteria

1. Men with an abdominal aortic aneurysm identified through the existing NHS Abdominal Aortic Aneurysm (AAA) Screening Programme (NAAASP)
2. Any healthcare professional involved in the care of individuals with an abdominal aortic aneurysm

Participant type(s)
Patient, Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
15 patients, 30 stakeholders

Total final enrolment
153

Key exclusion criteria
Age <18 years

Date of first enrolment
01/04/2020

Date of final enrolment
01/04/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NHS Abdominal Aortic Aneurysm Screening Programme
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University/education

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https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of the study will be published in medical journals, media, posted to patients and presented to those in charge of AAA screening as well as health-policy makers.

Intention to publish date
01/11/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Data will become available on 01/10/2022 and for five years.
Data will only be shared for qualitative analyses with qualified researchers, once a request has been made to the chief investigator and once the request has been reviewed and approved by the study Sponsor; all data will be anonymised and non-identifiable. No patient quotes will be shared. No individual patient level data will be shared at any time. Data will only be shared via an NHS computer or NHS email.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other publications	intervention development	29/01/2024	01/02/2024	Yes	No
Protocol file	version 1.4	11/01/2023	28/08/2024	No	No
Results article		03/09/2024	03/09/2024	Yes	No