ISRCTN10443908 https://doi.org/10.1186/ISRCTN10443908

Understanding the influence of NHS Health Check Cardiovascular Disease (CVD) Risk Assessment Tools

Submission date
01/02/2017

Recruitment status
No longer recruiting

Registration date
07/02/2017

Overall study status
Completed

Last Edited
24/04/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Cardiovascular disease (CVD) is a general term for conditions that affect the heart and blood vessels, such as heart disease and stroke. CVD accounts for over a quarter of all UK deaths. The risk of
developing CVD can be reduced through, for example, being more active, stopping smoking or some medications. In 2009 the NHS Health Check programme was launched to reduce CVD in England. This national programme invites people to have their CVD risk measured in general practice, usually by a practice nurse or health care worker. The clinician should then discuss the patients' CVD risk with them and, if required, advise them how to reduce it. Much of the value of Health Checks is likely to depend on how well clinicians understand CVD risk and if they are able explain it to patients in a way that encourages them to follow advice to reduce risk. The programme uses two main ways to measure risk. Firstly, QRISK2, which is a percentage risk of developing CVD in the next 10 years, which is currently used in most general practices. There is evidence that clinicians and patients often do not understand this kind of percentage score and have unanswered questions about their own CVD risk after a Health Check. Secondly, the JBS3 Risk Calculator, which is a new tool that measures 'lifetime' risk. It has different displays and functions to make it easier for clinicians to understand and explain why and how patients should reduce CVD risk. The aim of this study is to assess these risk assessment tools.

Who can participate?
Patients who are eligible for NHS Health Checks (aged 40-74 with no long-term diseases or taking cholesterol-lowering medication) and the staff who deliver these checks.

What does the study involve?
Participants are invited for a Health Check using the usual practice methods. At the appointment, they receive their Health Check as usual with the only differences being: in half of the Health Checks, the clinicians will use the usual CVD risk calculator which focuses on a 10-year % risk score and the other half use a risk calculator that includes lifetime risk; all consultations are video-recorded to allow the study team to see how CVD risk is communication and how patients respond. A sub-sample of participants then take part in interviews within two weeks

following their Health Check. During these interviews, they are shown clips of the Health Check and asked a series of open questions to ask them to which help them to recall and reflection on CVD risk communication during the Health Check, their personal perceptions and understanding of CVD risk as a result of the Health Check, and subsequent advice/treatment, and related patient intentions and behaviour

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
The study is run from Staffordshire University and takes place in 12 General Practices in the West Midlands, England (UK)

When is the study starting and how long is it expected to run for?
November 2016 to September 2019

Who is funding the study?
National Institute for Health and Care Excellence (UK)

Who is the main contact?
Dr Christopher Gidlow
c.gidlow@staffs.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Christopher Gidlow

ORCID ID
https://orcid.org/0000-0003-4990-4572

Contact details
Staffordshire University
Brindley Building
Leek Road
Stoke-on-Trent
United Kingdom
ST4 2DF
+44 (0)1782 294330
c.gidlow@staffs.ac.uk

Additional identifiers

Protocol serial number
HTA 15/170/02; 2016_11

Study information

Scientific Title
Qualitative video-stimulated recall study to explore cardiovascular disease risk communication in NHS Health checks using QRISK2 10-year risk and JBS3 lifetime risk calculators

Acronym
RICO (RIsk COmmunication in NHS Health Checks)

Study objectives
The aim of this study is to explore clinician and patient perception of CVD risk when using the JBS3 lifetime risk calculator or the QRISK2 10-year risk calculator, the associated advice or treatment offered by the clinician and the response of the patient.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/09/2017, London - Dulwich Research Ethics Committee, ref: 17/LO/1463

Primary study design
Observational

Study design
Observational cross-sectional study

Study type(s)
Other

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
Patients will attend their general practice for their NHS Health Check according to usual practice procedures. Patients will be sent study information sheets and have verbal explanations from practice staff when booking the Health Check.

On arrival, written informed consent would be sought to video-record the Health Check consultation (all participants), participation in a post-consultation interview (subsample within 2 weeks), and to allow searching of their medical records to gather information about possible actions following the Health Check (all participants). Patients would then have their Health Check (lasting 20-30 minutes), which would be will be video-recorded.

For a subsample of patients, a post-consultation semi-structured, video-stimulated recall (VSR) interview will be arranged within 2 weeks of their Health Check. VSR interviews will be held at a location of patient preferences (GP practice, participant's home. During interviews, participants will be shown the excerpts of the Health Check and then be asked a series of open questions. This Video-Simulated Recall (VSR) approach is designed to facilitate recall and reflection on CVD risk communication, individual perceptions and understanding, and subsequent advice /treatment, and related patient intentions and behaviour. VSR interviews are expected to last 30-60 minutes. The maximum time from participant consent to completion of the VS interview should be up to 2 weeks.

Intervention Type
Other

Primary outcome(s)
Patient understanding of CVD risk based on analysis of qualitative data from recorded NHS Health Check consultations and VSR interviews.

Key secondary outcome(s)
1. Clinician understanding of CVD risk based on analysis of qualitative data from VSR interviews
2. Patient response to the risk information based on analysis of qualitative data from recorded NHS Health Check consultations and VSR interviews
3. Patient intentions with respect to health-protective behaviours based on analysis of qualitative data from VSR interviews
4. Action following Health Checks as assessed by a review of patient records within four weeks of the Health Check (e.g., GP appointment, lifestyle referrals, physiotherapy referral, lifestyle referral, smoking cessation referral, alcohol advice, or statin prescription)

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Patient population:
1. Eligible for NHS Health Checks based on national criteria
2. Adults aged 40-74 years
2. Without chronic disease diagnosis or statin prescription

Clinician population:
Staff delivering NHS Health Checks (e.g., practice nurse, health care worker).

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 Years

Upper age limit
74 Years

Sex
All

Total final enrolment

173

Key exclusion criteria
Patient population:
1. Those not eligible for NHS Health Checks based on national criteria
2. Adults aged <40 or >74 years
3. With existing chronic disease diagnosis or statin prescription

Clinician population:
No exclusion criteria

Date of first enrolment
01/08/2017

Date of final enrolment
31/03/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Staffordshire University
College Road
Stoke-on-Trent
United Kingdom
ST4 2DF

Sponsor information

Organisation
Staffordshire University

ROR
https://ror.org/00d6k8y35

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The main dataset will be audio and video files and related transcripts, which will not be made available to protect participant identities.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Quantitative results	25/09/2020	28/09/2020	Yes	No
Results article	Qualitative results	03/12/2020	07/12/2020	Yes	No
Results article	Qualitative results	26/10/2021	15/03/2023	Yes	No
Results article	Qualitative results	23/04/2024	24/04/2024	Yes	No
Protocol article		14/01/2019	16/01/2019	Yes	No
Funder report results		25/08/2021	25/08/2021	No	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes