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Communicating cardiovascular disease risk in UK primary care

Submission date
09/02/2018

Recruitment status
No longer recruiting

Registration date
12/02/2018

Overall study status
Completed

Last Edited
15/03/2023

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims:
Cardiovascular disease (CVD) is an umbrella term that encompasses heart disease and strokes. It is a leading cause of death in the UK. General practitioners (GPs) in the UK use risk scoring tools to calculate patients' chances of having a heart attack or stroke in the future. This percentage risk score (called QRISK2) is based on patients' characteristics, family history, and other risk factors for CVD including high blood pressure, high cholesterol, smoking and obesity. However, some research suggests that many people do not fully understand risk using numbers. A new tool has been developed called 'heart age'. This calculates the approximate age of an 'ideal' person with normal risk factors but the same current risks of CVD as the patient. Therefore, having a heart age higher than your real age means you have a higher risk of CVD. This may be easier to understand for patients. Research in Spain has shown people who were given their heart age make more positive lifestyle changes resulting in a greater improvement in their risk of CVD compared with those given a percentage risk score. The aim of this study is to investigate the effects of GPs using heart age to communicate the risk of CVD to patients. It is a feasibility or pilot study, meaning that only a few patients are involved, and depending on the results it may lead to a larger study in the future.

Who can participate?
Patients aged 30-84 with no prior history of CVD and QRISK2 score of ≥10%

What does the study involve?
Participants are randomly allocated into two groups to see a GP. One group receive their QRISK2 score (usual care) and the other group (whose consultation is audio-recorded) also receive their heart age. All participants receive a follow-up health check and blood test after 3 months.

What are the possible benefits and risks of participating?
Participants get the opportunity to have their risk of CVD re-assessed after a period of 3 months. Therefore, if they make any healthy lifestyle changes, they are able to see if this has made any difference to their risk of CVD and test results at 3 months. No significant risks are expected. Participants are required to have a repeat blood test after 3 months. However, as part of usual medical practice, they may in any case have been offered a repeat blood test. The GP may offer participants a cholesterol-lowering medication (statin) and s/he will explain any side

effects during the consultation. However, participants will not be obliged to take this or any other medication for this study.

Where is the study run from?
Leach Heath Medical Centre (UK)

When is study starting and how long is it expected to run for?
June 2017 to August 2018

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

Who is the main contact?
Dr Varun Anand

Contact information

Type(s)
Scientific

Contact name
Dr Varun Anand

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RG_17-155

Study information

Scientific Title
The effect of using the heart age tool to communicate cardiovascular disease risk to primary care patients in the UK: a feasibility study

Study objectives
To determine the feasibility of undertaking a definitive trial of the effectiveness of using the heart age tool for cardiovascular disease (CVD) risk communication in a UK primary care setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Solihull Research Ethics Committee, 23/01/2018, ref: 18/WM/0010

Study design
Single-centre single-blind randomised feasibility trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Primary prevention of cardiovascular disease

Interventions
Participants will be randomised 1:1 by the researcher using opaque sealed randomisation envelopes containing randomisation cards with a two-letter code to represent the allocation. The randomisation envelopes will have been independently pre-prepared and participants will be blinded to their allocation.

1. The intervention is the delivery of the participant's heart age and its meaning by the GP, in addition to the QRISK2 score
2. The control will be usual care (delivery of QRISK2 score only)

The intervention will be delivered during a routine GP consultation after the patient's NHS health check or CVD risk assessment. The additional time to deliver heart age to participants will be approximately 5 minutes. All participants will receive a follow-up health check and blood test after 3 months.

Intervention Type
Behavioural

Primary outcome measure
The feasibility of using heart age for CVD risk communication, including:
1. Acceptability of heart age to patients and GPs: measured by an internally developed score (5-point Likert scale) towards the end of the study (June-July 2018)

2. Recruitment and retention of participants: to be measured throughout the study using a tally chart and the percentage of participants that were lost to follow-up
3. Completeness and range of data: to be measured throughout the study using percentages
4. Fidelity of the delivery of the heart age intervention: to be measured using a digital audio recorder at the GP consultation during the first part of the study (Feb-April 2018)
5. Feasibility of the trial procedures: no single measurement or time point but will be assessed throughout the study and at the end

Secondary outcome measures
1. CVD risk factors (blood tests and clinical measurements) measured at baseline and at the end of the study (June-July 2018)
2. Health behaviours (smoking, alcohol, diet, physical activity) measured at baseline and at the end of the study (June-July 2018)
3. QRISK2 and heart age scores measured at baseline and at the end of the study (June-July 2018)
4. Statin medication use assessed at baseline and at the end of the study (June-July 2018)
5. GP consulted, assessed towards the beginning of the study (Feb-April 2018)

Overall study start date
01/06/2017

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Patients aged between 30 and 84 years inclusive. This is because the heart age tool can only be accessed by people aged 30 and above and NICE recommend CVD risk assessment up to the age of 84
2. QRISK2 score ≥ 10%, as it is these patients who are referred to the doctor for further assessment as per NICE guidelines
3. Able to attend the GP practice for appointments
4. Able to give informed consent

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Prior history of CVD
2. Known high risk of CVD where NICE does not recommend CVD risk assessment: type 1

diabetes, chronic kidney disease stage 3 or higher and familial hypercholesterolaemia
3. Palliative care patients on the gold standards framework register
4. Unable to speak and understand written and verbal English
5. Pregnant women
6. Currently or recently (last 6 months) been involved in other research

Date of first enrolment
15/02/2018

Date of final enrolment
17/04/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leach Heath Medical Centre
Leach Heath Lane
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Sponsor information

Organisation
University of Birmingham

Sponsor details
Research Support Group, Room 119, Aston Webb Building
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Sponsor type
University/education

ROR
https://ror.org/03angcq70

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
An abstract of the protocol has been accepted for elevator pitch presentation at the National GP ACF Annual Conference in Oxford. Planned publication of the study results in a high-impact peer reviewed journal.

Intention to publish date
01/07/2019

Individual participant data (IPD) sharing plan
Deidentified data will be made available after publication. Data will be held in a research office in the Institute of Applied Health Research department of the University of Birmingham.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			15/03/2023	No	No
HRA research summary			28/06/2023	No	No