

# HEalth Check TRial (HECTR): Risk-tailored invitations to improve uptake of NHS Health Checks

<b>Submission date</b> 03/10/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/10/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/06/2019	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Cardiovascular disease (CVD) (heart disease) is the leading cause of death, accounting for 27% of all UK deaths. NHS Health Check is a national CVD risk assessment programme for adults in England aged 40-74 without a chronic disease. Typically, general practice records are used to identify those eligible and invite them for a Health Check, where the practitioner assesses their risk of CVD in the next 10 years. This forms the basis of discussions around how to manage and reduce this risk. Nationally, uptake of Health Checks remains around 50%, as just half of those invited for a Health Check attend. This is way below the 75% needed for the programme to be cost-effective. There is some evidence that how people are invited for a Health Check is a strong predictor of whether or not they will attend (i.e., a predictor of uptake). Telephone invitations seem to increase the likelihood that patients will attend their Health Check. Yet, most general practices use standard letters to invite patients as making calls takes more time and is therefore more expensive. Changes to the standard letter could make it more relevant to patients to increase the likelihood that they will attend. This study aims to design and test a NHS Health Check invitation letter personalised to the patient's level of CVD risk, and to compare the likelihood of patients attending when invited with the personalised letter compared with the standard letter and telephone invitation.

### Who can participate?

Patients aged 40-74 who are eligible for and due to have a NHS Health Check at 10 general practices in North Staffordshire

### What does the study involve?

Participants are randomly allocated to be invited to attend a Health Check using one of the three methods: standard letter, telephone call, or personalised letter. Participants are invited up to three times before being classified as a non-responder (or if they responded and declined the invitations). The study explores whether the way in which patients are invited predicts whether or not they attend the Health Check, taking other factors such as age and gender into account.

What are the possible benefits and risks of participating?

Patients may benefit from an increased likelihood of attending the Health Check. The potential risks include patients in the personalised letter group finding the risk-tailored messages distressing or difficult to understand. However, considerable development work and public consultation was undertaken to mitigate this risk.

Where is the study run from?

Staffordshire University (UK)

When is the study starting and how long is it expected to run for?

July 2015 to December 2017

Who is funding the study?

Stoke-on-Trent City Council, Public Health (UK)

Who is the main contact?

Dr Christopher Gidlow

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

NCT03524131

**Secondary identifying numbers**

# Study information

## Scientific Title

HEalth Check TRIal (HECTR): randomised controlled trial comparing uptake of NHS Health Check in response to standard letters, CVD risk-personalised letters and telephone invitations

## Acronym

HECTR

## Study objectives

To test the reach and uptake of Health Checks using standard letter versus telephone invitation versus letter that is personalised based on individual % cardiovascular disease (CVD) risk.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

NHS National Research Ethics Service Committee East of England – Cambridge, 25/08/2015, ref 15/EE/0340

## Study design

Three-arm randomised controlled trial; single-centred; 12-month data collection period

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

GP practice

## Study type(s)

Screening

## Participant information sheet

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

## Health condition(s) or problem(s) studied

Cardiovascular disease

## Interventions

The three trial arms are the different methods of invitation to attend a NHS Health Check (with attendance/non-attendance as the outcome):

1. Standard letter (control) - patients receive a letter with the same content (the most recent national letter template), with accompanying Health Check information leaflet.
2. Telephone - patients are invited by telephone, usually by the reception staff (a guide was provided to practices to standardise the type of information relayed to patient).
3. Personalised letter - risk-personalised letter templates developed to include messages

appropriate to different levels of CVD risk based on the QRISK 10-year score (templates for 3 risk categories - High  $\geq 20\%$ ; Medium 10-19.9%; low  $< 10\%$ ).

Random allocation of individual patients within practices was completed within EMIS using bespoke searches: an eligible cohort search was run using the existing search based on the national NHS Health Check criteria; search was run to randomly select 33.3% of the cohort and allocate them to Arm 1; search was run to randomly select 50% of the remaining cohort and allocate them to Arm 2; the remaining 33.3% of the cohort were allocated to Arm 3. For each arm, patients are invited up to three times before being recorded as a non-responder (and non-attender).

### **Intervention Type**

Other

### **Primary outcome measure**

Uptake of NHS Health Check, measured at 12 months from baseline or earlier if the practice had invited the entire cohort before 12 months

### **Secondary outcome measures**

Response to NHS Health Check invitation, measured at 12 months from baseline or earlier if the practice had invited the entire cohort before 12 months

### **Overall study start date**

01/07/2015

### **Completion date**

31/12/2017

## **Eligibility**

### **Key inclusion criteria**

Patients will be included if they are:

1. Registered at one of the participating practices
2. Aged 40-74 years
3. Are eligible and due for a NHS Health based on the national programme criteria (see exclusion criteria)

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

2500

### **Key exclusion criteria**

National NHS Health Check eligibility criteria will exclude patients from receiving an invitation if any of the following apply:

1. Coronary heart disease
2. Chronic kidney disease (CKD) which has been classified as stage 3, 4 or 5 within the meaning of the National Institute for Health and Care Excellence (NICE) clinical guideline 182 on Chronic Kidney Disease
3. Diabetes
4. Hypertension
5. Atrial fibrillation
6. Transient ischaemic attack
7. Hypercholesterolemia
8. Heart failure
9. Peripheral arterial disease
10. Stroke
11. Prescribed statins
12. People who have previously had an NHS Health Check, or any other check undertaken through the health service in England, and found to have a 20% or higher risk of developing cardiovascular disease over the next ten years

**Date of first enrolment**

14/10/2015

**Date of final enrolment**

28/02/2017

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Staffordshire University**

School of Life Sciences and Education

Brindley Building

Leek Road

Stoke-on-Trent

United Kingdom

ST4 2DF

## **Sponsor information**

**Organisation**

Staffordshire University

**Sponsor details**

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**Sponsor type**

University/education

**ROR**

<https://ror.org/00d6k8y35>

**Funder(s)****Funder type**

Government

**Funder Name**

Stoke-on-Trent City Council, Public Health

**Funder Name**

Staffordshire County Council, Public Health

**Funder Name**

Public Health England

**Alternative Name(s)**

PHE

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Results and Publications**

## Publication and dissemination plan

The study protocol has not been published, but can be requested from the study team. The main result paper should be submitted by December 2017. The trialists hope to present findings at conferences in 2018 (e.g., Annual NHS Health Check conference in February 2018, if accepted to present).

## Intention to publish date

01/12/2017

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available because the third party data sharing agreement between Staffordshire University and general practices did not include statements regarding further sharing of data. The data will remain stored at Staffordshire University.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	21/02/2019	04/03/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No