

Evaluation of a programme of cardiovascular disease prevention in primary care

Submission date 22/04/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/05/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/08/2018	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims.

We know that many patients who are at high risk of heart disease or stroke do not receive treatment. Treatments include drugs to lower blood pressure and drugs to reduce cholesterol levels (statins). A new process was put in place in general practices in Sandwell (West Midlands) to help identify untreated patients at high risk of heart disease. The aim of this study was to find out whether this process resulted in more high risk patients being started on treatment. If successful the study may lead to similar systems being adopted in other parts of the UK, which should result in more successful prevention of heart disease and stroke.

Who can participate?

The participants in this trial were general practices in Sandwell (West Midlands). Individuals identified as being at high risk of heart disease in these participating general practices were invited for check ups.

What does the study involve?

In the participating general practices the general practice computer system was used to identify patients who are at high risk of heart disease or stroke but are currently not receiving any treatment. The study included only patients aged 35 to 74 who do not already have heart disease or diabetes: patients with heart disease or diabetes should already be receiving treatment. The patients identified by the computer system as high risk were sent letters inviting them for a check up in their own general practice by a Project Nurse. The letter indicated that they might be offered treatment. The plan was to introduce this system across all general practices in Sandwell. However, it was not possible to implement this in all practices at the same time. Practices were randomly allocated to have the computer search and Project Nurse earlier or later in the course of the project. In order to determine whether this is an effective way of identifying high risk patients for treatment, the study looked at how many high risk patients were started on treatment before the computer search was undertaken and how many were started on treatment after the computer search was carried out, the invitations were sent and the Project Nurse was undertaking check ups in the practice.

What are the possible benefits and risks of participating?

General practices that participated received help in identifying their high risk patients. Those

patients identified were offered lifestyle advice and drugs to prevent heart disease in accordance with good medical practice. There were no risks associated with participating in the research programme.

Where is the study run from?

The study was run from the School of Health and Population Sciences of the University of Birmingham.

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

The study began in 2009 and is now completed.

Who is funding the study?

It was funded by the National Institute of Health Research (UK).

Who is the main contact?

Dr Tom Marshall

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Contact information

Type(s)

Scientific

Contact name

Dr Tom Marshall

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Evaluation of a programme of cardiovascular disease prevention in primary care: a cluster randomised controlled trial

Study objectives

A programme of case finding targeted at high risk patients will result in more patients being started on preventive treatment than usual care.

On 10/07/2013 the target number of participants was changed from 1,254 to 6,250

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Birmingham ethics review committee, 07/06/2010, ERN_10-0429

Study design

Cluster randomised controlled 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Cardiovascular disease

Interventions

This is a step-wedge cluster randomised controlled trial. Targeted case finding is being implemented in general practices. Practices are randomised to early (intervention) or later implementation (control).

Interventions:

Systematic invitation and cardiovascular risk factor assessment of individuals aged 35 to 74 who are untreated but at high risk of cardiovascular disease. These individuals will then be referred for appropriate lifestyle advice or preventive treatment in accordance with good clinical practice and treatment guidelines.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Number of eligible patients started on preventive treatment (aspirin, antihypertensives and statins).

All primary and secondary outcomes will be assessed at 3 months, 6 months and 1 year after the start of the study.

Secondary outcome measures

1. Changes in blood pressure, total cholesterol, HDL cholesterol and smoking status

Process outcomes:

2. Numbers of persons attending for CVD risk factor assessment

3. Numbers of those assessed who are confirmed as being eligible for treatment

All primary and secondary outcomes will be assessed at 3 months, 6 months and 1 year after the start of the study.

Overall study start date

01/02/2008

Completion date

01/05/2010

Eligibility**Key inclusion criteria**

Participating practices are identified by the participating primary care trusts.

Patients for inclusion in the prevention programme are identified as follows. They must be registered at a participating practice. They must be aged between 35 and 74 and must not currently have coronary heart disease (CHD), not be on the diabetic register and not be currently receiving antihypertensive or statin treatment. From these patients are identified all those patients in whom a combination of risk factors indicates they are likely to be at greater than 20% ten-year risk of cardiovascular disease. These patients are considered eligible for inclusion in the cardiovascular prevention programme. These patients will be identified from primary care electronic medical records.

In summary:

1. Patients (both males and females) aged between 35 and 74
2. Patients who do not have CHD
3. Patients who are not diabetic
4. Patients who are not receiving antihypertensives or statins
5. Patients who are likely to be at greater than 20% ten-year CVD risk

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

At least 6,250 participants in at least 6 practices

Key exclusion criteria

Patients who in the opinion of the practice staff are unable to benefit from cardiovascular risk factor assessment. For example, patients who are terminally ill.

In practice this means that once a list has been created of individuals who are untreated high risk patients are eligible to be invited for cardiovascular risk factor assessment, practice staff will review the list and identify patients who are known to be terminally ill or otherwise unsuitable for inclusion.

Date of first enrolment

01/03/2008

Date of final enrolment

01/05/2010

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Unit of Public Health Epidemiology and Biostatistics

Birmingham

United Kingdom

B15 2TT

Study participating centre

Sandwell Primary Care Trust

United Kingdom

B70 9LD

Sponsor information**Organisation**

University Hospitals Birmingham NHS Foundation Trust (UK)

Sponsor details

PO Box 9551
Main Drive
Queen Elizabeth Medical Centre
Birmingham
England
United Kingdom
B15 2PR

Sponsor type

Hospital/treatment centre

Website

<http://www.uhb.nhs.uk>

ROR

<https://ror.org/014ja3n03>

Funder(s)**Funder type**

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Collaborations for Leadership in Applied Health Research and Care (CLAHRC): The Birmingham and Black Country collaboration

Results and Publications**Publication and dissemination plan**

No further publications planned

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/10/2012		Yes	No
Results article	results	01/10/2016		Yes	No

