ISRCTN32114200 https://doi.org/10.1186/ISRCTN32114200

Evaluation of a programme of cardiovascular disease prevention in primary care

Submission date
22/04/2009

Recruitment status
No longer recruiting

Registration date
28/05/2009

Overall study status
Completed

Last Edited
17/08/2018

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.
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
T.P.Marshall@bham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Tom Marshall

Contact details
Unit of Public Health Epidemiology and Biostatistics
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT

Additional identifiers

Protocol serial number
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

Study type(s)
Prevention

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(s)
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.

Key secondary outcome(s))
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.

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 identifed 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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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)

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

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?
Results article	results	01/10/2016		Yes	No
Protocol article	protocol	26/10/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes