

# An evaluation of behavioural methods for cardiovascular risk reduction in general practice

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/12/2010	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

[http://www.dh.gov.uk/en/Aboutus/Researchanddevelopment/AtoZ/Cardiovasculariseaseandstroke/DH\\_4001724](http://www.dh.gov.uk/en/Aboutus/Researchanddevelopment/AtoZ/Cardiovasculariseaseandstroke/DH_4001724)

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HB14

## Study information

Scientific Title

### Study objectives

Risk factors for cardiovascular disease include cigarette smoking, high blood pressure, high blood cholesterol, and being overweight. People with more than one risk factor are at even higher risk.

The aim of this study was to compare changes in behaviour and risk factors in patients in general practices using a specially trained practice nurse with those in practices where nurses used their usual procedures.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

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

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

Cardiovascular diseases

### Interventions

The behavioural intervention was based on the 'stages of change' model developed by Prochaska and Diclemente, an approach popular with those involved in health promotion in the 1990s. The trained nurses arranged assessment followed by two or three 20 minute counselling sessions, depending on the number of risk factors.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Initial assessment comprised a questionnaire covering demographic data, measures of smoking, diet, and physical activity, and measures of attitude and motivation; and physical measurements including height, weight, cholesterol, and blood pressure. These measurements were repeated at 4 and 12 months.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/09/1994

**Completion date**

03/08/1997

**Eligibility****Key inclusion criteria**

Patients with at least one out of three risk factors (raised cholesterol, smoking, raised body mass index [BMI] and physical inactivity) were to be recruited from each of 10 intervention practices and 10 control practices in and near London. Recruitment was difficult and eventually there were 316 patients in the intervention group and 567 in the control group (883 patients instead of 2000).

54% of patients were women, 96% were white, mean age was 47, 77% were married, and 78% employed. Risk factors were evenly balanced between the two groups.

Of 316 intervention patients 285, 230, and 176 attended the 1st, 2nd, and 3rd counselling session. 204 and 169 returned for the 4 and 12 month assessment. Comparable figures for the 567 patients in the control group were 423 and 251 for the follow-up assessments.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

883

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/09/1994

**Date of final enrolment**

03/08/1997

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Department of Epidemiology and Public Health

London

United Kingdom

WC1E 6BT

## Sponsor information

**Organisation**

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

**Sponsor details**

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

## Funder(s)

**Funder type**

Government

**Funder Name**

NHS Cardiovascular Disease and Stroke National Research and Development Programme (UK)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

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

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/1996		Yes	No
<a href="#">Results article</a>	change in behaviour results	01/06/1998		Yes	No
<a href="#">Results article</a>	promotion of health results	01/03/1999		Yes	No
<a href="#">Results article</a>	GP and nurse results	01/04/1999		Yes	No
<a href="#">Results article</a>	Behavioral counseling results	09/10/1999		Yes	No