

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

Submission date 23/01/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/01/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 01/12/2010	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

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)

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

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?
Results article	results	01/03/1996		Yes	No
Results article	change in behaviour results	01/06/1998		Yes	No
Results article	promotion of health results	01/03/1999		Yes	No
Results article	GP and nurse results	01/04/1999		Yes	No
Results article	Behavioral counseling results	09/10/1999		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes