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A randomised controlled trial of the effect of a practice-based genetic screening facilitator.

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 04/12/2009	**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
PSI03-26

Study information

Scientific Title

Study objectives
To investigate the feasibility of improving screening for carriers of the recessively inherited haemoglobin disorders (thalassaemia and sickle cell disorders) in general practice, by using a nurse facilitator to work with primary care teams and the relevant haematology laboratories. To identify problems in communication between all those involved in delivering the service, and to implement solutions.

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)
Screening

Health condition(s) or problem(s) studied
Genetic screening for haemoglobin disorders

Interventions
The 13 intervention practices were given: posters, and leaflets to explain to the members of the relevant ethnic groups why carrier testing is advisable and how it can be obtained, an aide-memoire card for GPs¿ consulting rooms listing groups to whom screening should be offered, and a practice reference manual containing background information. Intervention practices were offered three formal practice-based 30-60 minute training sessions from the nurse facilitator during the intervention year. Screening requests from study, control and non-participating practices were recorded using computerised hospital haematology laboratory records.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The main outcome measure was the change in the number of requests for screening tests for haemoglobin disorders made by control and intervention practices in the baseline and intervention years. We also recorded the numbers of requests from the non-participating practices. For the 2 year follow-up trial the main outcome measure was the number of requests for screening tests from each intervention practice in 1997 and 1998.

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/04/1997

Eligibility

Key inclusion criteria
It took place in an area of North London where 29% of residents and 43% of births are in the ethnic groups at risk for haemoglobin disorders (mainly Camden, Islington, Haringey and Enfield). Twenty six of the 93 practices using the services of the Whittington haematology laboratory agreed to take part, and were divided into 13 control and 13 intervention practices.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/04/1995

Date of final enrolment
01/04/1997

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Primary Care & Population Sciences
London
United Kingdom
N19 3UA

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 Primary and Secondary Care Interface 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	19/09/1998		Yes	No