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The ADDFAM study: Realising the potential of the family history in risk assessment and primary prevention of Coronary Heart Disease (CHD) in primary care

Submission date 21/08/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 08/10/2007	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 16/01/2018	**Condition category** Circulatory System	[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.rdnottspct.nhs.uk/npcrp/clinical-genetics-in-primary-c

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HSR/36A

Study information

Scientific Title
The ADDFAM study: Realising the potential of the family history in risk assessment and primary prevention of Coronary Heart Disease (CHD) in primary care

Acronym
ADDFAM - Added Value of ADDing FAMily history to CVD risk calculations

Study objectives
The project will assess the clinical value and utility of a systematic approach to incorporate family history information into Coronary Heart Disease (CHD) risk assessment in primary care, from the perspective of the users of this service; the health care practitioners providing this service, and the National Health Service. Principal research questions:
1. What is the extra proportion of patients who will be defined as being at higher risk of CHD and who would benefit from intensive lifestyle advice and medications, when systematically collected family history is incorporated into CHD risk assessment?
2. Will changes in self-reported behaviour, anxiety and social/contextual experience be different in those whose CHD risk assessment is assessed using standard risk assessment complemented with systematic collection of family history compared with those whose risk is assessed using standard CHD risk assessment alone?
3. What is the cost-effectiveness of systematic family history collection as part of CHD risk assessment?

Study hypotheses:
1. The increase in the number of patients defined as being at high risk of CHD by inclusion of systematic family history collection will identify a cost-effective approach to target limited primary care CHD prevention resources.
2. Patients in whom family history is systematically collected will be more likely to change their behaviour than those who do not have this information collected.

To evaluate these hypotheses, the project will include:
1. An exploratory randomised study (including validated quantitative measures, qualitative semi-structured interviews and focus groups) to evaluate the impact of systematic family history recording on patients' and primary care professionals' experience, and
2. Develop an economic model of the costs and benefits of incorporating family history into CHD risk assessment.

Please note that as of 21/09/10 the start and end dates of this trial have been updated from 01/04/2006 and 01/12/2008 to 01/03/2007 and 02/04/2009 respectively.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ethics approval granted by Multi-centre Research Ethics Committee (MREC) for Scotland on 15 /05/2006. REC reference number 06/MRE10/9

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Coronary Heart Disease (CHD)

Interventions
A pragmatic exploratory cluster randomised controlled trial with a nested qualitative semi-structured interview and focus group study, in two centres (Nottingham and Exeter). 1400 patients will be invited to participate. Estimate 1000 will complete CHD risk assessment and 600 complete the final postal survey at 6 months, 300 in each arm of the study.

For the cluster RCT, pairs of practices will be matched according to deprivation and ethnic minority population. One practice within each pair will be randomly allocated to either the family history arm of the study or standard CHD risk assessment arm.

Participants in the intervention arm of the RCT will receive standard CHD risk assessment complemented by systematic collection of family history, whilst participants in the control arm will only receive standard CHD risk assessment (as recommended by Joint Cardiac Societies: JBS2).

All study participants receive a health heart advice leaflet with information on smoking, exercise and diet.

All study participants at "high" risk (i.e. 20% or more risk of CardioVascular Disease (CVD) over the next 10 years) have a follow-up consultation with the nominated clinician at the surgery. In the consultation, patients have their CHD risk explained and given lifestyle advice and, when clinically indicated, statins will be offered. Patients in the intervention arm will also have the impact of premature CHD family history on the CVD risk score explained.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The increase in the proportion of patients falling in the "high" risk group resulting from the inclusion of family history in the CHD risk assessment.

Secondary outcome measures
The secondary outcome measures given below will be compared between patients recruited to the intervention (family history) and control (standard assessment) arms of the study.
Quantitative data will be taken at initial visit and by postal survey at 2 weeks and 6 months from all respondents. The principal measures include:
1. Proportion of people who have stopped smoking
2. Proportion of patients in action/maintenance exercise stage
3. Fat intake score measured using Dietary Instrument for Nutrition Education (DINE) questionnaire
4. Anxiety score measured using 6-item Spielberger State-Trait Anxiety Inventory (STAI)
5. Changes in short-term health status (SF-6D)

Overall study start date
01/03/2007

Completion date
02/04/2009

Eligibility

Key inclusion criteria
Practices: To be within either Trent Primary Care Trusts (PCTs) in East Midlands or PCTs in Central Cornwall, Plymouth and Exeter
Participants: To be registered patients at the above practices and be between 30 and 65 years of age

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1,400

Key exclusion criteria
General Practices outside of these defined areas will be excluded

Participants exclusion criteria:
1. Patients noted to have a previous history of atherosclerotic disease (this includes CHD, CerebroVascular Accident [CVA] and peripheral vascular disease)
2. Previous history of diabetes mellitus
3. Patients already on statin therapy or other lipid lowering medication
4. Patients considered by the General Practitioners to be inappropriate to recruit due to psychosocial reasons

Date of first enrolment
01/03/2007

Date of final enrolment
02/04/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
Department of Health, the Research into Genetics Based Health Services programme (ref: HSR /36A) (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?
Protocol article	study protocol	12/10/2009		Yes	No
Results article	results	21/02/2012		Yes	No