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Cluster randomised controlled trial of computer decision support for management of familial cancer in primary care

Submission date 16/10/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/10/2002	**Overall study status** Completed	
Last Edited 08/10/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
GRAIDS Trial

Study objectives
This project applies the Medical Research Council (MRC) framework for evaluation of complex interventions and encompasses an optimisation trial of computer decision support for familial cancer in primary care and an audit of current referral patterns for familial cancers to inform power calculations for a subsequent multi-centre trial. This optimisation trial will pilot procedures for the delivery and assessment of the intervention and will, in addition, seek to optimise and identify the most cost-effective intervention that should be evaluated in a full-scale trial by having a fixed and an adaptive intervention arm.

The underlying hypotheses are that the provision of computer decision support and a family history questionnaire in primary care will lead to more appropriate and cost-effective referrals for familial cancers (i.e. that are in line with regional referral criteria), and will enable patients to make better informed decisions about their familial risk of cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Familial breast or colorectal cancer

Interventions
Intervention arm subjects:
Patients approaching their GP or practice nurse with concerns about their family history of cancer will be given a family history questionnaire to take home to complete, and then return for a second appointment. At the second consultation the trained lead clinician will enter information supplied by the patient and the family history questionnaire into the GRAIDS software. The software will support discussions with the patient about their risk of cancer and subsequent management.

Control arm subjects:
Subjects in the control practices approaching their GP or practice nurse with concerns about familial cancer will have a normal consultation according to their GPs current practice.

All subjects:
Subjects who are referred to the Regional Genetics Clinic will be asked to complete the measure of Informed Decision Making (IDM) questionnaire. This request will come from the Clinic with their appointment letter. The subjects will be requested to return the completed questionnaire to the Study Team.

Subjects in the intervention practices who are not referred to the Regional Genetics Clinic will be sent a measure of IDM questionnaire by the Study Team. Six months after they have returned the measure of IDM, the subjects will be sent a second measure of IDM to complete and return to the Study Team.

Trial Principal Investigator: Professor Jon Emery

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. The number of times that the GRAIDS software is used in the GP practices
2. The total number of referrals to secondary care about familial cancer and the proportion that meet regional referral criteria
3. The cost per use of the software and the cost per appropriate referral

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2002

Completion date
30/09/2005

Eligibility

Key inclusion criteria
Patients approaching their General Prectitioner (GP) or practice nurse with concerns about their family history of cancer.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1300

Key exclusion criteria
1. Children under 18
2. People with learning difficulties
3. Severely ill
4. Other vulnerable groups e.g. mental illness, dementia

Date of first enrolment
01/04/2002

Date of final enrolment
30/09/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
GRAIDS Trial Coordinator
Cambridge
United Kingdom
CB2 2SR

Sponsor information

Organisation

Cancer Research UK (UK)

Sponsor details
P.O. Box 123
Lincoln's Inn Fields
London
United Kingdom
WC2A 3PX

Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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?
Results article	results	20/08/2007		Yes	No