

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/10/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/10/2012	Condition category Cancer	<input type="checkbox"/> 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

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 Practitioner (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