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Diet and exercise and high risk adenomas

Submission date 24/06/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/06/2010	**Overall study status** Completed	
Last Edited 24/01/2022	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-lifestyle-changes-people-pre-cancerous-bowel-growths

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8451

Study information

Scientific Title
Diet and physical activity to prevent recurrence of high risk adenomas: a feasibility study

Study objectives
Colorectal cancer (cancer of the large bowel) is the third most common cancer and second most common cause of cancer death in the UK. One of the aims of the NHS Bowel Cancer Screening Programme is to detect early stage colorectal cancer and adenoma (pre-cancer) thus improve survival. Most colorectal cancers arise from polyps or adenomas, and high-risk adenomas are the most likely to become cancerous. The recurrence rate for high-risk adenomas is approximately 40% after three years. The recent World Cancer Research Fund report in 2007 concluded there was convincing evidence that high dietary red and processed meat and low levels of physical activity cause colorectal cancer.

The aims of the proposed study is to demonstrate the feasibility of altering the behaviour of patients recently diagnosed with high-risk adenoma. This study is intended to reduce the recurrence of high-risk adenoma and designed to:
1. Reduce consumption of red meat and eliminate processed meat from the diet
2. Increase physical activity levels

The first stage of the proposed study includes qualitative research to assess patients' preferences for feasible interventions aimed to bring about behaviour change, a postal questionnaire survey and a review of published evidence. Results of this stage will be assessed in the second phase to determine the most effective ways of delivering the interventions.

Added 24/03/2011: The first and second phases of the study are now complete. Phase three is a trial with 200 newly diagnosed high-risk adenoma patients.

Please note, as of 24/03/2011 the anticipated end date for this trial has been updated from 30 /09/2010 to 31/12/2012 and the target number of participants increased from 250 to 370.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Black Country Research Ethics Committee approved on the 17th December 2009 (ref: 09/H1202 /123)

Study design
Single centre observational prevention cross-sectional study

Primary study design
Observational

Secondary study design
Cross-section survey

Study setting(s)
Hospital

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
Topic: National Cancer Research Network; Subtopic: Colorectal Cancer; Disease: Colon, Rectum

Interventions
Focus Groups/interviews:
We will set up five focus groups (six to eight persons per group). The initial discussion will focus on knowledge and health beliefs about the proposed interventions and the aetiology of CRC. We will explore participants' perceptions of the value of the proposed behavioural changes given the possible health benefits of the interventions. Participants will be encouraged to discuss possible barriers (to behaviour modification and to participation in a randomised controlled trial [RCT]) and what may motivate them to change.

Questionnaires:
To build on the evidence review and qualitative work to determine the most promising ways of delivering these interventions patients will be mailed a questionnaire designed to assess participants' preferences for particular interventions and other issues, including the relative acceptability of the food frequency questionnaire (FFQ) or food diaries as potential data collection tools for part 2. The aim is to identify the methods of delivering the interventions that are acceptble to patients.

Added 24/03/2011:
Behavioural change interventions:
Groups will be asked to either reduce red meat intake and eliminate processed meat, increase physical activity levels, do both or change nothing. Behavioural change, compliance and acceptability will be assessed at six and 12 months. If the results of this study are successful, a future trial would aim to demonstrate that such behaviour change can reduce recurrence of high-risk adenomas.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To assess patients preferences for feasible interventions aimed to bring about behaviour change.

Secondary outcome measures
No secondary outcome measures

Overall study start date
28/05/2010

Completion date

31/12/2012

Eligibility

Key inclusion criteria
1. HRAs: greater than five small adenomas or greater than three with at least one greater than or equal to 1 cm
2. IRAs: 3 - 4 small adenomas or at least one greater than 1 cm
3. Aged 60 - 74 years at diagnosis, either sex
4. Diagnosis of I/HRA within one year of entry to study

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
370 (250 at time of registration)

Key exclusion criteria
1. Ongoing surveillance for CRC and high risk groups (familial history of CRC, familial adenomatous polyposis, hereditary non-polyposis CRC)
2. Any known contraindication to exercise
3. Current cancer treatment
4. Individuals who are vegetarian (greater than 3 months)
5. Individuals who are highly physically active (those meeting the current public health guidelines of 30 minutes of exercise 5 times per week)
6. Those who are both vegetarian and highly physically active (meeting criteria of 4 and 5 above)
7. Diagnosis of I/HRA greater than one year prior to entry to study

Date of first enrolment
28/05/2010

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

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Sponsor information

Organisation
University of Birmingham (UK)

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Sponsor type
University/education

Website
http://www.bham.ac.uk/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-0408-16026)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	18/06/2012		Yes	No
Plain English results			24/01/2022	No	Yes