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Effects of wholegrain components on metabolic biomarkers: a four-week intervention study in 'at risk' subjects

Submission date 03/09/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/12/2008	**Overall study status** Completed	
Last Edited 05/07/2012	**Condition category** Other	

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
N/A

Study information

Scientific Title

Study objectives
Long-term consumption of bran-rich cereal products impacts favourably on risk factors for heart disease and metabolic syndrome in apparently healthy, 'at risk' men and women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the University of Ulster Research Ethics Committee in March 2007 (ref: REC/07/0016).

Study design
Single centre randomised single blind parallel controlled study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Chronic diseases, particularly cardiovascular disease and cancers

Interventions
Volunteers were stratified by age and sex and randomly assigned into the test or control group:
1. Test group: 3 x high-bran products per day for 4 weeks (1 x ready-to-eat cereal + 2 x bread products)
2. Control group: 3 x refined high-fibre products per day for 4 weeks (1 x ready-to-eat cereal + 2 x bread products)

Test and control products were balanced for energy, fibre and macronutrients and incorporated by volunteers into their normal diet.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Bran-rich cereal products

Primary outcome(s)
Changes in plasma homocysteine (a risk marker for CHD) attributable to treatment during the intervention, measured at baseline and 4 weeks.

Key secondary outcome(s))

Changes in other risk markers for disease attributable to treatments during the intervention:
1. Inflammatory markers and endothelial function
2. Antioxidant status
3. Lipid profile
4. Relevant micronutrient levels
5. Insulin and glucose levels

Outcomes measured at baseline and 4 weeks.

Completion date
04/06/2008

Eligibility

Key inclusion criteria
1. Healthy men and women aged between 45 - 65 years
2. Body Mass Index (BMI) greater than 25 kg/m^2

This inclusion criteria were selected as such individuals are thought to be at a slightly greater risk of chronic disease.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Smokers
2. People on special diets (e.g. vegetarians, coeliac patients)
3. People with diabetes
4. Pre-existing chronic disease
5. Regular use of prescription medicine, including statins and blood pressure medication
6. People who regularly take any vitamin or mineral supplement or have done so in the last 6 months
7. Women who are pregnant or lactating
8. People who have given blood to the blood transfusion service (BTS) within the past 4 months

Date of first enrolment
15/12/2007

Date of final enrolment
04/06/2008

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Northern Ireland Centre for Food and Health (NICHE)
Coleraine
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BT52 1SA

Sponsor information

Organisation
European Commission (Belgium)

ROR
https://ror.org/00k4n6c32

Funder(s)

Funder type
Government

Funder Name
HEALTHGRAIN (Europe) - an integrated 6th framework European Union (EU) project (ref: FOOD-CT-2005-514008)

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	14/11/2012		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes