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Randomised controlled trial to test the impact of increased consumption of wholegrain foods on cardiovascular disease (CVD) risk

Submission date
22/06/2005

Recruitment status
No longer recruiting

Registration date
25/07/2005

Overall study status
Completed

Last Edited
03/02/2016

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
'Whole grains are good for you'. This is the message currently given by health professionals, nutritionists and, increasingly, food manufacturers worldwide. They make this statement after careful consideration of a large amount of evidence from studies of populations carried out over many years. These observational studies include information gathered from many thousands of people where diet is measured and later health outcomes are recorded. These studies are often used by governments and health agencies to develop health eating advice for the population. The results from these studies show strong associations between whole grain intake and health; those that eat the most whole grains are less likely to suffer from heart diseases, some cancers and to develop Type 2 diabetes compared with those who eat the least amount of whole grains. The government in America thinks that this evidence is so strong that it now advises its citizens to 'eat at least three servings of whole grain' every day. Some foods containing whole grain in America and Europe (including Britain) can show a health claim promoting the foods as being 'good for your heart'. The problem with observational studies is that they are good at showing relationships between diet and health, but they do not say why this effect is seen. Also, other factors such as whether subjects smoke, or do more exercise, or eat lots of other healthy foods can complicate the interpretation of the results. To really show whether a particular type of food or diet pattern is of benefit and why, we need to carry out interventional studies. These are studies where volunteers are asked to change their diet for a period of time (normally several weeks or months) and scientists look for changes in markers which are known to be related to disease risk. The role of the Food Standards Agency is to provide, interpret and disseminate information which can be used to help the UK population to live longer, healthier lives. Diet is very important in this context. If the Agency is to give advice on whether or not it should recommend we eat more whole grains it needs scientific evidence based on well designed dietary interventions. The aim of this study is to find out whether eating wholegrain foods results in reduced heart disease risk, to provide evidence for future dietary recommendations.

Who can participate?
Overweight but otherwise healthy people, aged 30-65.

What does the study involve?
Participants are randomly allocated to one of three groups. One group is asked not to change their diet and to carry on as normal. The second group is asked to eat three servings of wholegrain food (which we provided) every day for 16 weeks – this is the amount recommended by the American health agencies. The third group is asked to eat this amount for 8 weeks and then to double the amount to six servings of whole grain per day for the final 8 weeks. At the start of the study and after 8 and 16 weeks the participants are weighed and measured and provide blood and urine samples. At week 4 and 12 of the study the participants also give another small urine sample. We measure the diet of the participants at the same time points using a questionnaire. After the study has finished some of the participants attend a focus group meeting to discuss their experiences.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Newcastle upon Tyne (UK)

When is the study starting and how long is it expected to run for?
July 2005 to April 2007

Who is funding the study?
Food Standards Agency (UK)

Who is the main contact?
Dr Chris Seal
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Contact information

Type(s)
Scientific

Contact name
Dr Chris Seal

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
05/Q0905/75

Study information

Scientific Title
Randomised controlled trial to test the impact of increased consumption of wholegrain foods on cardiovascular disease (CVD) risk

Acronym
The WHOLEheart study

Study objectives
This study will test the hypothesis that increased consumption of wholegrain foods as substitutes for refined grain alternatives in the diet results in reduced CVD risk through improvements in fasting lipid profiles, insulin sensitivity, endothelial function and a reduction in inflammatory status.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
N/A - this study looks at pre-disease/condition state

Interventions
Treatment A: Control, no intervention
Treatment B: Consuming three portions of wholegrain food per day for four months
Treatment C: Consuming three portions of wholegrain food per day for two months increasing to six portions per day for a further two months

Intervention Type
Behavioural

Primary outcome measure
Low-density lipoprotein (LDL) cholesterol

Secondary outcome measures
1. Body Composition:
a. Body weight: in addition to the three main time-points weight will also be measured on volunteers collection of foods (i.e. four weekly intervals)
b. Height
c. Waist circumference
d. Body composition by bio-impedance

2. Fasting Lipid Profile:
a. Duplicate measures of total (high-density lipoprotein [HDL] and LDL cholesterol) triglycerides and non-esterified fatty acids. Distribution of lipoprotein sub-classes by nuclear magnetic resonance (NMR) (to be analysed by Dr Thies, University of Aberdeeen)

3. Insulin Sensitivity (HOMA, modified QUICKI):
a. Duplicate fasting measures of glucose and insulin
b. NEFA concentrations obtained during measurement of fasting lipid profile

4. Inflammatory Status and markers of endothelial function:
a. Serum markers of the acute protein phase response, including sialic acid and C-reactive protein (CRP), fibrinogen and PAI-1
b. The plasma cytokine interleukin-6 (IL-6) as the principal stimulus for the production of acute phase proteins 31, 32
c. Plasma ICAM-1, VCAM-1 and e-selectin as markers of endothelial function

5. Blood pressure:
a. Systolic and diastolic, at rest

6. Dietary change:
a. Dietary change will be assessed using the validated FFQ. Change in intake of other dietary factors which may influence plasma enterolactone concentrations (i.e. fruit and vegetable intake) will be recorded to assess the impact of the dietary intervention on intake of other food groups. Any changes will be included as a factor in subsequent statistical analyses.

Overall study start date
18/07/2005

Completion date
01/04/2007

Eligibility

Key inclusion criteria
Men and women, aged 30-65 years and with a body mass index (BMI) >25 kg/m^2

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
300 (150 at each centre)

Key exclusion criteria
Volunteers for the study will be excluded if they are:
1. Habitual consumers of wholegrain cereals and wholegrain bread
2. Individuals receiving clinical treatment for Type 2 diabetes, hyperlipidaemia or hypertension
3. Currently prescribed non-steroidal anti-inflammatory drugs (NSAIDS), aspirin, steroids or immunosuppressants
4. Allergic or intolerant to intervention foods
5. Planning to change dietary habits, increase physical activity, change body weight, move away from the study centre-locality or take a lengthy vacation during the time of the study
6. Heavy smokers (>20 cigarettes per day)
7. Individuals with a history of substance abuse or alcoholism
8. Currently planning pregnancy or have had a baby in the past 12 months
9. Individuals who have shown a recent weight change (>2 kg in past 1 month)

Date of first enrolment
18/07/2005

Date of final enrolment
01/04/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University of Newcastle upon Tyne
Newcastle upon Tyne
United Kingdom
NE1 7RU

Sponsor information

Organisation
Food Standards Agency (UK)

Sponsor details
Aviation House
125 Kingsway
London
United Kingdom
WC2B 6NH

Sponsor type
Government

ROR
https://ror.org/05p20a626

Funder(s)

Funder type
Government

Funder Name
Food Standards Agency (N02036)

Alternative Name(s)
The Food Standards Agency, FSA

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	01/07/2010		Yes	No
Results article	results	01/01/2012		Yes	No
Results article	results	01/02/2013		Yes	No