ISRCTN27657880 https://doi.org/10.1186/ISRCTN27657880

Effect of whole grain foods on cardiovascular risk

Submission date	Recruitment status	[_] Prospectively registered
04/12/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/01/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/08/2013	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Frank Thies

Contact details
University of Aberdeen Medical School
Polwarth Building
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NO2035

Study information

Scientific Title
Comparison of effects of increased whole grain foods on markers of cardiovascular risk: a single centre, single blind, randomised controlled longitudinal study

Study objectives
Dietary supplementation with three servings per day of whole-grain food provided as a mixture of wheat and oats or only wheat can decrease cardiovascular risk markers in healthy middle aged people.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Committee approved on the 23rd November 2005 (ref: 04 /S0801/66)

Study design
Single centre single blind randomised controlled longitudinal study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Overweight/moderately obese

Interventions
The dietary interventions proposed for this project are designed to compare a diet based on refined cereal products with:
1. The substitution of 3 servings of refined cereals foods with 3 servings of whole wheat foods, and
2. The substitution of 3 servings of refined cereals foods with one servings of whole wheat foods and two of oats
The interventions are designed to be practical and realistic for individuals to achieve.

These interventions represent a significant increase in current average intakes of non-starch polysaccharides (NSP). It is estimated that the substitution with 3 servings of whole wheat foods will provide approximately 6.4 g of NSP per day, of which 2.6 will be soluble fibre, while the whole wheat plus oats intervention will provide approximately 5.3 g NSP per day of which 3.6

will be soluble fibre. Data from the 2001/2 Expenditure and Food Survey (http://statistics.defra.gov.uk/esg/publications/efs/default.asp) indicate that the average intake of NSP in Scotland is 12.6 g per day. The proposed interventions are likely to bring intakes close to the Dietary Reference Value of 18 g per day but will not cause intakes to exceed the upper limit of 24 g per day set for individuals (Department of Health, 1991).

The total duration of the intervention is 16 weeks, with 4 weeks run-in in a refined diet prior to randomisation into one of the three groups (12 weeks).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
All outcome measures were determined four times during the intervention: prior run-in (T0), after run-in period (4 weeks, baseline), at week 10 and week 16 (end of intervention):
1. Serum total and low density lipoprotein (LDL) cholesterol concentrations
2. Insulin sensitivity

Secondary outcome measures
Measurement of vascular function and inflammation markers (vascular tonicity by pulse-wave velocity and pulse contour analysis, intercellular adhesion molecule 1 [ICAM-1], interleukin-6 [IL-6] and high sensitivity C-reactive protein [hsCRP]). All outcome measures were determined four times during the intervention: prior run-in (T0), after run-in period (4 weeks, baseline), at week 10 and week 16 (end of intervention).

Overall study start date
30/06/2005

Completion date
30/06/2009

Eligibility

Key inclusion criteria
1. Men and women aged 40 - 65 years
2. Body mass index (BMI in kg/m^2) between 25 and 35
3. Recruited from the surrounding community of Aberdeen
4. Sedentary or moderately active (less than two aerobic session per week)
5. Present signs of metabolic syndrome, e.g. if he/she has three or more of the following conditions:
5.1. Fasting plasma glucose greater than 6.1 mm/L
5.2. Triacylglycerol (TAG) level greater than 1.7 mmol/L
5.3. Low high density lipoprotein (HDL) cholesterol (less than 1.04 mmol/L for men, less than 1.29 mmol/L for women)
5.4. Hypertension (greater than 130/85 mmHg)
5.5. Central obesity (waist circumference greater than 102 cm for men, greater than 88 cm for women)
5.6. Moderate hypercholesterolemia

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
180 (60 per group)

Key exclusion criteria
1. Cardiovascular disease (CVD)
2. Diabetes or fasting blood glucose concentration greater than 7.0 mmol/L
3. Asthma
4. Systolic blood pressure greater than 160 mmHg or diastolic blood pressure greater than 99 mmHg
5. Thyroid gland disorders or eating disorders
6. Taking regular medication or supplements known to affect any dependant variable measured
7. Volunteers with high habitual intake of whole-grain foods (greater than 5 servings per week)
8. Taking regular nutritional supplements such as antioxidants or fish oil

Date of first enrolment
30/06/2005

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Aberdeen Medical School
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation
Food Standards Agency (UK)

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

Sponsor type
Government

Website
http://www.food.gov.uk

ROR
https://ror.org/05p20a626

Funder(s)

Funder type
Government

Funder Name
Food Standards Agency (UK) (ref: NO2035)

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	01/10/2010		Yes	No
Results article	results	05/08/2013		Yes	No