

# Effect of whole grain foods on cardiovascular risk

**Submission date**

04/12/2009

**Recruitment status**

No longer recruiting

**Registration date**

11/01/2010

**Overall study status**

Completed

**Last Edited**

14/08/2013

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Frank Thies

**Contact details**

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## 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<sup>2</sup>) 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?
<a href="#">Results article</a>	results	01/10/2010		Yes	No
<a href="#">Results article</a>	results	05/08/2013		Yes	No