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Impact of the amount and composition of dietary fat and carbohydrate on metabolic syndrome and cardiovascular disease risk

Submission date 16/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/09/2005	**Overall study status** Completed	
Last Edited 23/08/2013	**Condition category** Circulatory System	

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
NO2031

Study information

Scientific Title

Acronym
RISCK

Study objectives
To test whether the replacement of saturated fat (SFA) with monounsaturated fat (MUFA), compared with carbohydrate (CHO), will result in improved insulin sensitivity in adults with features of the metabolic syndrome; and whether CHO quality will influence the relative health impact of both the MUFA-rich and CHO-rich diet regimens.

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

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Metabolic syndrome and cardiovascular disease risk

Interventions
Comparison of four experimental diets (high MUFA, high glycemic index [GI]; high MUFA, low GI; low fat, high GI; low fat, low GI) with a control group (SFA intake typical of the UK habitual diet)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Saturated fat (SFA), monounsaturated fat (MUFA), carbohydrate (CHO)

Primary outcome(s)
Insulin sensitivity from measures of glucose and insulin during an intravenous glucose tolerance test.

Key secondary outcome(s))
1. Fasting lipid profile
2. Vascular reactivity and endothelial function
3. Haemostatic factors
4. Markers of the inflammatory response
5. Leptin and adiponectin

6. Urinary microalbumin to creatinine ratio
7. Plasma fatty acid composition
8. DNA for nutrient-gene interactions

Completion date
31/12/2007

Eligibility

Key inclusion criteria
Males and females, 30-70 years and at higher metabolic risk (based on a composite scoring system for metabolic syndrome features).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. History of the following conditions/treatments
1.1. myocardial infarction
1.2. cancer
1.3. diabetes mellitus
1.4. cholestatic liver disease or pancreatitis
1.5. chronic coronary, renal or bowel disease
1.6. gastrointestinal disorders
1.7. hypolipidemic therapy
1.8. systemic corticosteroids
1.9. androgens
1.10. phenytoin
1.11. erythromycin
1.12. heamostatic drugs (excluding aspirin)
2. Smokers >20/day
3. History of substance abuse or alcoholism
4. Pregnancy, planning pregnancy or 12-months post-partum
5. Allergy or intolerance to study foods
6. Recent weight change
7. Eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) >1 g/day

Date of first enrolment
01/01/2004

Date of final enrolment

31/12/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MRC Human Nutrition Research
Cambridge
United Kingdom
CB1 9NL

Sponsor information

Organisation
MRC Human Nutrition Research (UK)

ROR
https://ror.org/050pqs331

Funder(s)

Funder type
Not defined

Funder Name
Food Standards Agency (UK)

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

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	01/08/2009		Yes	No
Results article	results	01/10/2010		Yes	No
Results article	results	01/12/2011		Yes	No
Results article	results	01/02/2012		Yes	No
Results article	results	01/09/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes