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FLAVonoids: University of Reading Study

Submission date 12/11/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/12/2007	**Overall study status** Completed	
Last Edited 13/01/2015	**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
N02R0001

Study information

Scientific Title
Impact of increasing doses of flavonoid-rich and flavonoid-poor fruit and vegetables on cardiovascular risk factors in an at risk group

Acronym
FLAVURS

Study objectives
To determine the impact of different amounts and types (flavonoid-rich versus flavonoid-poor) of fruit and vegetables on heart disease risk factors in an 'at risk' group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Isle of Wight, Portsmouth and South East Hampshire Research Ethics Committee on 6th November 2007 (REC no.: 07/H0501/81).

Study design
A single-blind, single-centre, randomised, controlled dietary intervention study with three parallel treatment arms (one control and two intervention groups)

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
After a three week run-in period following a habitual (low fruit and vegetable) diet, 180 participants, selected on the basis of their increased risk of developing cardiovascular disease, will be randomly assigned to either the habitual diet (control) or one of two intervention groups, which involves the increased intake of flavonoid-rich or flavonoid-poor fruits and vegetables. In both intervention groups, participants will be asked to sequentially increase their fruit and vegetable intake by 2, 4 and 6 portions, with a 6-week duration for each dose increase. The intervention phase will last for 18-weeks. Due to the duration of the study, a parallel design is adopted to minimise burden on the participants. The control group is necessary to control for the impact of study participation and seasonal effects on the outcomes of the study.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Each subject has to attend four intervention visits in total for the study. The following primary outcome measures will be taken at each visit:
1. Changes in endothelial function measured by vascular reactivity and arterial stiffness using Laser Doppler Imaging with iontophoresis and Pulse Wave Analysis measurement respectively

2. Plasma biomarkers of endothelial function (e.g. nitric oxide, Vascular Cell Adhesion Molecule [VCAM], Intercellular Adhesion Molecule [ICAM], E-selectin, von Willebrand factor, microalbumin) - fasting bloods will be taken at each visit to measure these outcomes

Key secondary outcome(s))
1. Fasting bloods will be taken during each intervention visit to measure the following outcomes:
1.1. Fasting lipids (total, Low Density Lipoprotein [LDL] cholesterol, HDL cholesterol, triglycerides and non-esterified fatty acids)
1.2. Indices of insulin resistance
1.3. Haemostatic factors (Plasminogen Activator Inhibitor 1 [PAI-1], fibrinogen)
1.4. Inflammatory biomarkers (C-Reactive Protein [CRP], Tumour Necrotising Factor [TNF]-alpha and Interleukin-6 [IL6])
2. The following will be measured during the 6-week intervention periods between visits:
2.1. 24-hour ambulatory blood pressure
2.2. Dietary intake assessed by 24 hour dietary recalls and biomarkers of fruit and vegetable intake (24 hour urinary flavonoid metabolites, urinary potassium, plasma ascorbic acid)
3. Faecal samples will be collected at each intervention visit to perform quantitative and qualitative analysis of faecal microflora and estimation of faecal water genotoxicity and mucosal integrity
4. Changes in cognitive performance will be measured during each intervention visits using computer tests

Completion date
30/10/2009

Eligibility

Key inclusion criteria
1. Men and women between the ages of 30 - 70 years
2. At above average risk of developing heart disease
3. Meet one or more of the following criteria:
3.1. Overweight
3.2. High total cholesterol (but not on medication)
3.3. Low High Density Lipoprotein (HDL) cholesterol
3.4. High blood pressure (but not on medication)
3.5. Cigarette smoker

For the specific range of inclusion for each risk factor, we have come up with a scoring system, adapted mainly from the Framingham study. Volunteers who have an above average risk of developing heart disease (RR 1.5) would be included in the study. Volunteers who have risk factor/s at a very high risk level would be excluded. Participants should also have a low intake of fruit and vegetable (i.e. less than or equal to 3 portions per day).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
People:
1. Who have diabetes, heart disease (previous stroke/myocardial infarction), renal or bowel or liver diseases and hormone abnormalities
2. On drug treatment for hyperlipidemia, hypertension, inflammation or hypercoagulation
3. Taking dietary supplements (e.g. vitamins and minerals, fish oils)
4. Who drink more than 15 units of alcohol per week
5. Who are pregnant, lactating or if of reproductive age and not using a reliable form of contraception (including abstinence)
6. Who are regularly undertaking vigorous exercise or fitness training
7. Who are on a weight-reducing regime
8. Who consume over 3 portions of fruit and vegetables per day

Date of first enrolment
19/11/2007

Date of final enrolment
30/10/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hugh Sinclair Human Nutrition Unit
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Sponsor information

Organisation
Foods Standards Agency (UK)

ROR
https://ror.org/05p20a626

Funder(s)

Funder type
Government

Funder Name
Foods Standards Agency (UK) (ref: N02R0001)

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	01/02/2013		Yes	No
Results article	results	01/03/2014		Yes	No
Results article	results	01/11/2014		Yes	No