# Cardiovascular risk reduction study: supported by an integrated dietary approach

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>			
04/08/2010		☐ Protocol			
Registration date	Overall study status Completed	Statistical analysis plan			
11/10/2010		[X] Results			
<b>Last Edited</b> 19/01/2017	Condition category Circulatory System	[] Individual participant data			
17/01/2011	Circulatory System				

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

### Type(s)

Scientific

#### Contact name

**Prof Thomas Sanders** 

#### Contact details

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## Additional identifiers

Protocol serial number N02047

# Study information

Scientific Title

The effectiveness of an integrated cardioprotective dietary intervention compared with an average UK diet in reducing cardiovascular disease risk factors in older men and women aged 40 - 70 years

#### Acronym

**CRESSIDA** 

#### **Study objectives**

An integrated dietary approach using a cardioprotective diet will significantly reduce cardiovascular disease (CVD) risk factors compared to the average UK diet.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

St. Thomas' Hospital Research Ethics Committee, April 2010, ref: 10/H0802/24

#### Study design

Randomised parallel-design single-centre controlled trial

#### Primary study design

Interventional

#### Study type(s)

Prevention

#### Health condition(s) or problem(s) studied

Cardiovascular disease

#### **Interventions**

This is a controlled dietary intervention trial comparing a cardioprotective diet (decreased salt and saturated fatty acids intake, and increased wholegrain cereals, fruit and vegetables and oily fish intake) with a control diet (average UK diet) for 3 months.

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome(s)

A change in systolic blood pressure (BP) measured by ambulatory blood pressure, a change in endothelial function measured by flow-mediated dilation, and a change in total/high density lipoprotein (HDL) cholesterol ratio measured at baseline and 3 months.

#### Key secondary outcome(s))

1. A change in arterial stiffness (pulse wave velocity and digital volume pulse), measured at baseline and 3 months

- 2. A change in insulin sensitivity (revised quantitative insulin sensitivity test [RQUICKI] and serum adiponectin), measured at baseline and 3 months
- 3. A change in C-reactive protein concentrations, measured at baseline and 3 months

#### Completion date

30/06/2012

# **Eligibility**

#### Key inclusion criteria

Healthy men and women, aged 40 - 70 years

#### Participant type(s)

Healthy volunteer

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

Αll

#### Key exclusion criteria

- 1. A reported history of angina, myocardial infarction, peripheral vascular disease, congenital heart disease or stroke
- 2. Asymptomatic atrial fibrillation
- 3. Type 1 or type 2 diabetes mellitus (fasting plasma glucose greater than 7 mmol/L)
- 4. Seated blood pressure greater than 160/105 mmHg
- 5. Current use of medication for lowering blood cholesterol (statins) or blood pressure
- 6. Body mass index less than 18.5 and greater than 35 kg/m2
- 7. An overall risk of cardiovascular disease over the next ten years of greater than 20% assessed according to current NICE guidelines in combination with untreated high blood pressure or raised cholesterol
- 8. Clinical history of cancer (excluding basal cell carcinoma) in the past five years
- 9. Chronic renal, liver or inflammatory bowel disease
- 10. Current cigarette smoker (confirmed by urinary cotinine analysis)
- 11. History of substance abuse or alcoholism (previous weekly alcohol intake greater than 60 units/men or 50 units/women)
- 12. Current self-reported weekly alcohol intake not exceeding 21 units for women and 28 for men
- 13. Currently pregnant, planning pregnancy or having had a baby in the last 12 months
- 14. Unwilling to follow the protocol and/or give informed consent
- 15. Unwilling to refrain from use of dietary supplements
- 16. Unwilling to restrict consumption of oily fish
- 17. Weight change of greater than 3 kg in preceding 2 months

#### Date of first enrolment

16/07/2010

#### Date of final enrolment

30/06/2012

## Locations

#### Countries of recruitment

United Kingdom

England

Study participating centre Nutritional Science Division London

United Kingdom SE1 9NH

# Sponsor information

## Organisation

King's College London (KCL) (UK)

#### **ROR**

https://ror.org/0220mzb33

# Funder(s)

# Funder type

Industry

#### **Funder Name**

Food Standards Agency (FSA) (UK) (ref: N02047)

#### Alternative Name(s)

The Food Standards Agency, FSA

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Other non-profit organizations

#### Location

# **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 Dat	e added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2015		Yes	No
Results article	results	01/04/2017		Yes	No
Results article	results	01/06/2017		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