

# Development of interventions to reduce the risk of coronary heart disease (CHD) in South Asians

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| <b>Submission date</b><br>23/01/2004   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>23/01/2004 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>24/10/2019       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

Development of interventions to reduce the risk of coronary heart disease (CHD) in South Asians

### Study objectives

People from South Asia have a 40% higher incidence of coronary heart disease, and a fivefold higher rate of non-insulin-dependant diabetes compared to other UK residents. These problems are linked to metabolic disturbances associated with insulin resistance and central obesity. The aims of this study were to see if these metabolic disturbances could be reversed by exercise or by dietary supplementation with omega-3 fatty acids.

### 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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

### Participant information sheet

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

Heart disease

### Interventions

There were three exercise categories

- i. Walking
- ii. Jogging
- iii. Running

comprising a 12 week programme with examinations 24 hours after the last session; a similar programme with examinations 5 days after the last session; and no change in activity. The exercise programmes involved three half hour sessions of walking/jogging/running, and one supervised aerobic circuit session per week.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

1. Insulin resistance was measured by a frequently-sampled intravenous glucose tolerance test after a 3-day high carbohydrate diet.
2. Cardio-respiratory function was assessed by measuring oxygen uptake during exercise on a treadmill using the Bruce protocol.
3. Before the programme height, weight, hip and waist circumference were measured. Information was sought on medical history, and on cigarette and alcohol consumption.

**Secondary outcome measures**

Not provided at time of registration.

**Overall study start date**

01/07/1994

**Completion date**

01/07/1997

**Eligibility****Key inclusion criteria**

92 subjects were recruited from general practices in West London. 87 subjects completed the trial made up of 28 South Asian men, 12 South Asian women, 27 European men, and 20 European women.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

87

**Key exclusion criteria**

Not provided at time of registration.

**Date of first enrolment**

01/07/1994

**Date of final enrolment**

01/07/1997

# Locations

## Countries of recruitment

Ireland

United Kingdom

## Study participating centre

### Conway Institute

Dublin

Ireland

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# Sponsor information

## Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

## Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

## Sponsor type

Government

## Website

<http://www.doh.gov.uk>

# Funder(s)

## Funder type

Government

## Funder Name

NHS Cardiovascular Disease and Stroke National Research and Development Programme

# 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