ISRCTN80995714 https://doi.org/10.1186/ISRCTN80995714

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

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 23/01/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 24/10/2019	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Paul McKeigue

Contact details
Conway Institute
University College Dublin
Belfield
Dublin
Ireland
4
+353 (0)1 716 6952
abc@email.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

WE1

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
4

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