

A pilot randomised trial in primary care to investigate and improve knowledge, awareness and self-management among South Asians with diabetes in Manchester

Submission date

23/01/2004

Recruitment status

No longer recruiting

Registration date

23/01/2004

Overall study status

Completed

Last Edited

30/11/2009

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Kennedy Cruickshank

Contact details

Clinical Epidemiology Unit

University of Manchester

Oxford Road

Manchester

United Kingdom

M13 9PT

+44 (0)161 275 5211

clinep@man.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

WE16

Study information

Scientific Title

Study objectives

Vascular disease and diabetes are major causes of morbidity and mortality in Manchester, especially among those of Afro-Caribbean and Indian sub-continent descent.

The aims of this study, which is part of a larger project, were to determine prevalence rates of some risk factors; to assess how such factors were detected and controlled in primary care; and to pilot an appropriate intervention programme to reduce obesity and high blood pressure.

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)

GP practice

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Peripheral arterial disease; Diabetes

Interventions

1. Advice on diet and exercise were given at the start, and reinforced at days 30 and 60
2. No advice

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

In the observational part of the study blood pressure, height, weight, and hip and waist measurements were taken by a trained observer. Subjects were asked about their knowledge of their blood pressure, whether they knew if they had diabetes, about their smoking (ever, current, number of cigarettes daily), their alcohol consumption (>12 units in a year), and details of their diet.

In the interventional study weight was recorded on Days 1, 30, 60, and 90, and blood pressure was recorded on Day 1 and Day 90. Information on the 18 foods making up 95% of energy and fat in the diets was obtained at day 1 and 90 for the AfC people in the sample.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/05/1994

Completion date

01/11/1997

Eligibility**Key inclusion criteria**

The research was undertaken in 7 general practices, in a part of Manchester with a high proportion of ethnic minority groups in their catchment areas.

Subjects aged 25-79 were selected from age-sex registers. Ethnicity was defined from grandparental origins. The final sample comprised 547 people of White European (WE) origin, 479 of African-Caribbean (AfC) origin, and 100 of Pakistani Muslim (PM) origin.

Of the initial sample 27% were no longer at the recorded address, and 16% were no longer in the practice. During the 4 years of the study 42% of people in the final sample changed address. The random sample in the intervention study comprised 61 people of AfC origin. However 25 declined to take part, and 22 had moved or could not be contacted. The final sample was 8 in the intervention group and 6 in the control group.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

547

Key exclusion criteria

Mental health illness that would preclude compliance

Date of first enrolment

01/05/1994

Date of final enrolment

01/11/1997

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Clinical Epidemiology Unit

Manchester

United Kingdom

M13 9PT

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

Diabetes (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2003		Yes	No