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Educational session, salt intake, patients of African-Caribbean origin

Submission date	Recruitment status	[_] Prospectively registered
29/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/04/2012	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0236169544

Study information

Scientific Title

Study objectives
The target limiting salt intake to 6g per day is important for all adults, but in particularly so for people of African and Caribbean origin. These groups are more likely to develop - and are more susceptible to the effects of - raised blood pressure and hence heart attack, stroke and heart failure. Traditionally the biggest proportion of salt intake in people of African Caribbean descent in the UK is from salt added to cooking. However, components such as sauces used to prepare ethnic meals at home also have a high salt content.

A previous study for Salt Awareness Day 2005 stowed in individuals with high blood pressure that, in spite of claiming that they reduced salt intake by half, the 24 hour urine analysis of salt was still high - around 10g/day, illustrating that the public are very confused about where salt is in the diet and how sodium relates to salt. The same study showed that most people (69%) find nutrition labels incomprehensible.

Therefore, the aim of this study is to see whether education and advice for people of African-Caribbean descent in the form of a one-to-one training session addressing how to read a label and general education about how sodium relates to salt will result in a reduction in salt intake (as assessed by 24 hour urine collection). A control group comprising patients who claim to be making lifestyle changes, but who will not receive the educational session, will also be recruited.

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine

Interventions
All visits will be at the Blood Pressure Unit. At the first hospital visit patients will be asked if they want to take part in this study. They will be given at least 24 hours to make this decision. If they agree (we call them to confirm this) we will arrange their first visit where they will bring back their signed consent form.

Next patients will be randomised to either the experimental (n=20) or control (n=20) group by a person independent to the study. Both groups need to collect their urine for 48 hours from visit 1 (day 1) and from day 17 (visit 3) where they will be shown a wide variety of fresh and processed foods, taught how to read a label, taught what salt is and how sodium relates to salt etc. The patients will also be taught how to adapt recipes to include less salt.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The difference in 24 sodium content in the experimental group versus the control group

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2005

Completion date
01/09/2006

Eligibility

Key inclusion criteria
The recruits will be adults (aged 18 years and over) of African Caribbean origin. They will be patients with hypertension referred to the blood Pressure Unit at St Georges Hospital, Tooting, London. The participants can be on or off blood pressure treatment, but they must say they have been trying to make lifestyle changes with respect to reducing their blood pressure.

We have targeted people of African or Caribbean origin because these groups are more likely to develop - and are more susceptible to the effects of - raised blood pressure and hence heart attack, stroke and heart failure, than their Caucasian counterparts.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
40

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/2005

Date of final enrolment
01/09/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Blood Pressure unit
London
United Kingdom
SW17 0RE

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
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Sponsor type

Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
St George's Healthcare NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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	18/05/1996		Yes	No