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The effect of a nutrition education intervention based on the dietary approaches to stop hypertension diet pattern on blood pressure among adults with mild-to-moderate hypertension in Asesewa, Ghana

Submission date
30/04/2016

Recruitment status
No longer recruiting

Registration date
07/06/2016

Overall study status
Completed

Last Edited
23/05/2016

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
High blood pressure is a worldwide public health problem with increasing prevalence in developing countries. Although data is limited, evidence suggests a trend towards increasing high blood pressure prevalence in both rural and urban populations in Ghana. Dietary modification based on the Dietary Approaches to Stop Hypertension (DASH) diet pattern has been shown to reduce high blood pressure in the United States and other countries. The effect of dietary modification based on the DASH diet pattern and emphasizing locally available foods has not yet been tested in Ghana. The aim of this study therefore is to find out whether a nutrition education intervention based on the DASH diet pattern is more effective at lowering blood pressure than standard care.

Who can participate?
Patients aged 25 and over, newly diagnosed with high blood pressure

What does the study involve?
Participants are randomly allocated to receive either standard care, or standard care plus nutrition education based on the DASH dietary pattern, emphasizing Ghanaian foods. At the start of the study, background information is collected through face-to face interviews and a dietary assessment is carried out using questionnaires. Weight, height, waist and hip measurements are also taken. Blood pressure is monitored bi-weekly for the first 6 weeks and then every 3 weeks for the next 6 weeks (total of five visits). Dietary assessments and measurements are repeated during the 12th week of the study. Changes in blood pressures and dietary intakes are compared between the two groups.

What are the possible benefits and risks of participating?
Participants benefit from knowing their blood pressure status and receiving treatment (standard

care). They also help the researchers to learn more about managing high blood pressure more effectively to benefit society at large. Participation in this study carries minimal or no risk. Treatment for high blood pressure may result in some minor discomforts associated with blood pressure medications.

Where is the study run from?
Asesewa Government Hospital (Ghana)

When is the study starting and how long is it expected to run for?
March 2015 to February 2016

Who is funding the study?
Office for Research Innovation and Development, University of Ghana

Who is the main contact?
Dr Esi Colecraft

Contact information

Type(s)
Scientific

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Protocol serial number
URF/6/ILG-007/2012-2013

Study information

Scientific Title
Can a nutrition education intervention based on the dietary approaches to stop hypertension (DASH) diet pattern in addition to the standard of care have a greater blood pressure lowering effect than the standard of care alone among adults diagnosed with hypertension in Asesewa, Ghana?

Acronym
Ghana DASH study

Study objectives
Adults diagnosed with hypertension who receive nutrition education based on the DASH diet principles in addition to the standard of care provided at Asesewa Government Hospital will have greater decreases in diastolic and systolic blood pressure compared to those who received the standard of care alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional review board at the Noguchi Memorial Institute for Medical research at the University of Ghana, 07/05/2014, protocol # 092/13-14

Primary study design
Interventional

Study design
Single-center single-blind (only study participants blinded) randomized control trial

Study type(s)
Treatment

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

Interventions
A total of 100 adults newly diagnosed with high blood pressure (defined as Systolic Blood Pressure [SBP] >140 and Diastolic Blood Pressure [DBP] >90 mmHG) at the Asesewa Government Hospital will be randomized to receive either the standard of care alone (control group) or the standard of care plus nutrition education based on the DASH dietary pattern and emphasizing meal planning based on Ghanaian foods (intervention group) . At the time of enrolment into the study (baseline), background sociodemographic information will be collected through face-to face interviews using a structured questionnaire, and dietary assessment completed using a 7-day food frequency questionnaire and the 24-hour dietary recall method. Additionally anthropometric measurements (weight, height, waist and hip circumferences) will be taken. Blood pressure will be monitored bi-weekly for the first 6 weeks and then every 3 weeks for the next 6 weeks (total of 5 visits). Total duration of the intervention will be 12 weeks (3 months). Dietary assessments and anthropometric measurements will be repeated during the 12th week of the study.

Intervention Type
Behavioural

Primary outcome(s)
Systolic and diastolic blood pressure. Mean change in blood pressure from enrolment to the end of the study will be compared between the control and intervention groups controlling for background socio-demographic, and anthropometric characteristics and baseline values.

Key secondary outcome(s)

Data were collected at 5 time points corresponding to : baseline (time or enrolment into the study); visit 1 (2 weeks post enrolment); visit 2 (4 weeks post enrolment); visit 3 (6 weeks post enrolment); visit 4 (9 weeks post enrolment): and visit 5 (12 weeks post enrolment)

1. Blood pressure taken with a digital blood pressure monitor at enrolment and each visit subsequently
2. Sociodemographic characteristics: semi-structured, pre-coded questionnaire administered at baseline (enrolment)
3. Dietary assessment: using 24-hour dietary recall method and 7-day food frequency questionnaire. Data collected at baseline and 12 weeks post enrolment
4. Anthropometric measurements: height (taken at baseline) and weight and visceral fat % (taken at baseline and every visit) measured with a digital weighing scale.

Completion date
05/02/2016

Eligibility

Key inclusion criteria
1. Adults ≥ 25 years
2. Newly diagnosed, or previously diagnosed but not currently on treatment, as having high blood pressure (HBP) (defined as systolic blood pressure (SBP) reading of greater than 140 mmHg and or diastolic blood pressure (DBP) >90 mgHg) through the hospital-based screening at the Asesewa Government Hospital during a 4-month participant recruitment period
3. Willing to participate and provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Persons with heart disease, diabetes mellitus, or diabetes requiring insulin
2. Persons with special dietary requirements
3. Persons unwilling to make dietary modifications

Date of first enrolment
09/03/2015

Date of final enrolment
05/02/2016

Locations

Countries of recruitment
Ghana

Study participating centre
Asesewa Government Hospital
Asesewa
Ghana
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Sponsor information

Organisation
University of Ghana

ROR
https://ror.org/01r22mr83

Funder(s)

Funder type
University/education

Funder Name
Office for Research Innovation and Development, University of Ghana

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request