

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

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Registration date 07/06/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/05/2016	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

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

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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

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 measure

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.

Secondary outcome measures

Data were collected at 5 time points corresponding to : baseline (time of 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.

Overall study start date

23/03/2015

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 mmHg) 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

Age group

Adult

Sex

Both

Target number of participants

100 (50 intervention and 50 control)

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

Sponsor details

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Sponsor type

University/education

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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**Publication and dissemination plan**

Currently, the plans are to publish two papers in two peer-reviewed journals (not identified yet):

1. Socio-demographic and lifestyle characteristics of adults diagnosed with hypertension in Aseewa, Ghana (based primarily on baseline data)
2. Effect of a DASH based nutrition education intervention on blood pressure among adults in Aseewa, Ghana (based on the longitudinal data)

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request