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Culturally sensitive hypertension counselling for Afro-Surinamese and Ghanaian hypertensive patients in Dutch general practices

Submission date 17/08/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/08/2009	**Overall study status** Completed	
Last Edited 10/03/2014	**Condition category** Circulatory System	

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

122000008

Study information

Scientific Title
A cluster randomised controlled trial evaluating the effect of an intervention to enhance culturally sensitive hypertension counselling on blood pressure control and adherence to prescribed medication and lifestyle changes among Afro-Surinamese and Ghanaian hypertensive patients in Dutch general practices

Acronym
OHD2

Study objectives
The project aims to test, in a cluster randomised trial, the effectiveness of multi-component intervention to improve culturally sensitive hypertension counselling for hypertensive Surinamese and Ghanaian patients who receive care in a Dutch primary care setting and who have an insufficiently controlled blood pressure: systolic blood pressure (SBP) greater than or equal to 140 mmHg and/or diastolic blood pressure (DBP) greater than or equal to 90 mmHg.

Specific hypothesis 1: patients randomised to the intervention (IC) will have, compared with those in usual care condition (UC), a significant reduction in SBP (greater than 10 mmHg) at eight months after the start of the intervention.
Specific hypothesises 2 and 3: patients randomised to the intervention (IC) will show, compared with those in usual care condition (UC), significant differences in compliance with respect to prescribed medication and prescribed lifestyle recommendations at 8 months after the start of the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee of the Academic Medical Centre of the University of Amsterdam approved in May 2009 (ref: IC MEC09/070)

Study design
Cluster-randomised controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

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
Patients in the IC practices will receive hypertension care as recommended by the guidelines from the Dutch College of General Practitioners, but instead of the recommended standard hypertension counselling, IC patients will receive:
1. Three culturally sensitive hypertension counselling sessions conducted by a trained nurse-practitioner
2. Written culturally specific educational materials
3. Referrals to neighbourhood facilities that may support Surinamese and Ghanaian patients in adopting a healthier lifestyle, if needed
4. Prior to each counselling session, an assessment of the blood pressure and self-reported medication and lifestyle adherence, made using standardised measures
The first culturally sensitive counselling session will take place 2 weeks after the baseline assessment interview and the next two sessions 3 and 6 months thereafter.

Patients in UC sites will receive hypertension counselling as usual, based on recommendations of the Dutch Hypertension Guidelines. After finishing the baseline assessment, patients will get appointments for two office visits to receive a new prescription for anti-hypertensive medication. These visits will take place at 3.5 and 6.5 months after the baseline assessment.

At both sites - UC and IC - an attending reserach assistant or nurse practitioner will assess the patients' blood pressure and adherence to medication and lifestyle changes, at baseline and at the 3.5- and 6.5-month office visits using the standardised measurement methods.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Proportion of patients with a significant reduction in the systolic blood pressure (10 mmHg [standard deviation = 15]), at 8 months after inclusion. We have chosen to use baseline SBP minus SBP after 8 months as the primary outcome measure because SBP is the most important factor in determining a patient's cardiovascular risk profile. In almost all cases the DBP will become lower if the SBP becomes lower.

Secondary outcome measures
1. The proportion of patients with adequate adherence to prescribed medication at 8 months after inclusion
2. The proportion of patients with adequate adherence to lifestyle recommendations at 8 months after inclusion

Data will also be collected with respect to factors that characterise the patient group (baseline demographics, baseline medical chart data) and factors that may influence patients'

hypertension management (perceptions of hypertension, perceptions of medications, self efficacy, experienced social support in hypertension management, satisfaction with care).

Overall study start date
01/01/2009

Completion date
01/01/2011

Eligibility

Key inclusion criteria
Primary Care Practitioners:
1. Have to provide hypertension care according to a practice protocol based on the guidelines for cardiovascular risk management from the Dutch Association for General Practitioners
2. Should not participate in any similar study to improve cardiovascular risk management

Patients:
1. Self-identified as Afro-Surinamese or Ghanaian
2. Aged 20 years and older, either sex
3. Diagnosis of hypertension with International Classification of Diseases, tenth edition (ICD-10) codes I10: Essential (primary) hypertension
4. Uncontrolled blood pressure (BP) (greater than or equal to 140/90 mmHg) at the last office visit. In addition all patients must have an uncontrolled BP at the time of the baseline assessment.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
148

Key exclusion criteria
Patients:
1. No diabetes type 1 or type 2
2. No current participation in other cardiovascular disease-related trials
3. The general practitioner who treats the patients judges him/her unfit for participation (e.g., due to co-morbidity)
4. Unable/unwilling to provide informed consent

Date of first enrolment
01/01/2009

Date of final enrolment

01/01/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Academisch Medicsch Centrum Amsterdam
Amsterdam
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Sponsor information

Organisation
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.zonmw.nl

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands) (ref: 12200008)

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?
Protocol article	protocol	22/10/2009		Yes	No
Results article	results	05/03/2014		Yes	No