Under Pressure II: evaluation of a culture sensitive educational programme for Afro Surinamese and Ghanaian patients with hypertension.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Vascular hypertensive disorders
Study type	Interventional

Summary

ID

NL-OMON33054

Source
ToetsingOnline

Brief title
Under Pressure II (UPII)

Condition

- Vascular hypertensive disorders

Synonym
high blood pressure, Hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: effect study, ethnicity, Hypertension, patient education

Outcome measures

Primary outcome

Baseline systolic BP minus systolic BP after 8 months (BP will be measured according to protocol: Average of two electronic BP measurements which are conducted with an interval of 15 minutes in sitting patients)

Secondary outcome

Changes after eight months with regard to the degree of medication compliance, compliance with life style recommendations, potentially mediating factors for hypertension management (beliefs, motivation, self efficacy) and satisfaction with care. These parameters will be measured through questionnaires

Study description

Background summary

In Western countries, hypertension (HTN) is more prevalent among ethnic-minority populations of African descent, and the HTN-related health outcomes of these groups are worse than those of Europeans. In the Netherlands high rates of HTN have been observed among two major immigrant groups of African descent: African-Surinamese from the former Dutch colony of Suriname (hereafter, Surinamese) and Ghanaians. Hypertension is a major risk factor for cardiovascular morbidity and mortality. This risk can be prevented through anti-hypertensive medication and lifestyle modification. However, compliance with these measures is often low, particularly within ethnic minority populations. Tailored forms of patient education and counselling can support patients with the implementation of medication and lifestyle changes and improve compliance. Based on in formation from a previous project (Heebroedoe) the research group has developed a protocol for culturally sensitive patient education (CSPE) for hypertensive patients for general practices. The protocol

was particularly focussed on patients from Ghanaian and Afro-Surinamese descent. A follow up project demonstrated that the protocol is applicable in practice, particularly by trained nurse practitioners (NP).

Study objective

The overall aim of the study is to evaluate the effect of CVPE in Afro-Surinamese and Ghanaian who are treated for HTN in general practice and who have an uncontrolled blood pressure. (systolic BP > 140 mmHG and/or diastolic BP > 90 mmHG)

The primary specific aim is;
To establish if patients who have received CVPE (intervention group) have a significant reduction in their systolic BP (> = 10 mmHG) as compared to a control group, at eight months after the start of the intervention.

Secondary specific aims are:
To evaluate if patients who have received CVPE (intervention group) show significant differences in compliance with respect to medication use as compared to a control group, at eight months after the start of the intervention.
To evaluate if patients who have received CVPE (intervention group) show significant differences in compliance with respect to life style recommendations as compared to a control group, at eight months after the start of the intervention.

Study design

Randomized controled trial, in which data will be collected at the level of the patients and radomization will take place at the level of health care centers (clusters). In addition to this a proces evaluation will be conducted to gain insight in contextual factors that may influence the effect of the intervention.

Intervention

Patients in the intervention group will receive three educational counselling sessions according to the protocol of culturally sensitive hypertension education with an interval of three months. Patients in the control group will receive care as usual.

Study burden and risks

1.
At baseline (T0) a research nurse will patients BP, weight length and waistline) and a research assistent will conduct an interview with them.

2.
Patients in the control group will receive care as ususal. Patients in the intervention group will receive three counselling consults with an interval of three months from a nurse practitioner.

3. At three moments in patients of the intervention group and at two moments in patients of the control group the BP will be measures and they will be asked to fill out a short questionnaire regarding medication use and life style changes (with an interval of three months).

4. At 8 months, base line measurements that were performed at (T0) will be repeated: a research nurse will measure patients BP, weight length and waistline and a research assistent will conduct an interview with them.

5. After 8 months, some patients (< =15) will be asked to provide a more extensive interview regarding their experiences for the process analysis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

African-Surinamese of Ghanaian (self-identification)
Aged 20 or more
Diagnosis hypertension
Uncontrolled blood pressure (>140/90)

Exclusion criteria

Diabetes Mellitus type I+II
Participation in other trials for cardiovascular disease
If GP decides a patient is not appropriate for participation (e.g. co-morbidity)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2009
Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission

Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL27507.018.09