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Quality Improvement Cardiovascular care Kwara I+II (QUICK-I + QUICK-II)

Submission date	Recruitment status	[_] Prospectively registered
23/07/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/10/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/04/2016	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
Protocol version 03-02-2010

Study information

Scientific Title
A prospective observational cohort project to assess the feasibility of a prevention program for cardiovascular diseases in the context of a private health insurance in rural Nigeria (QUICK-I) plus the development and evaluation of a patient centred cardiovascular health education program for patients in rural Nigeria: from an exploration of stakeholders perspectives towards practical tools (QUICK-II)

Acronym
QUICK-I + QUICK-II

Study objectives
Please note that under this record, two protocols are contained (but both part of the same trial). The first protocol, QUICK-I, is an observational cohort study to assess the feasibility of a prevention program for cardiovascular disease in rural Nigeria, whilst the second protocol, QUICK-II, is a two-part protocol that involves a qualitative study design for the development of a tailored cardiovascular health education program (CHEP) (part 1), and a prospective observational cohort study using repeated measurements for an evaluation of treatment adherence (part 2). The anticipated trial dates for each part of the trial are as follows:
QUICK-I:
Anticipated start date: 11/06/2010
Anticipated end date: 11/11/2011

QUICK-II:
Anticipated start date: 11/03/2011
Anticipated end date: 11/12/2012

Furthermore, the target number of participants for each protocol are as follows:
QUICK-I: 300 patients
QUICK-II: 150 patients

All other differences for each protocol can be found under the relevant section with the subtitles for each protocol (QUICK-I or QUICK-II).

QUICK-I:
The implementation of a cardiovascular disease (CVD) prevention program, based on international guidelines, is feasible in patients at risk for development of CVD in the context of a private health insurance in rural Nigeria.

QUICK-II:
The addition of a tailored cardiovascular health education program (CHEP) will lead to better treatment adherence in hypertensive patients who participate in a cardiovascular disease prevention program in rural Nigeria.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Review Committee University of Ilorin Teaching Hospital, 30/03/2010

Study design
QUICK-I: Prospective observational cohort study
QUICK-II: qualitative study design (part 1) + prospective observational cohort study (part 2)

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

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, cardiovascular diseases

Interventions
QUICK-I:
Observational research. In a rural clinic in Nigeria, participating in the Hygeia Community Health Plan insurance scheme, 300 patients at risk for development of CVD (patients with hypertension, diabetes, renal disease or established CVD) will be prospectively followed for one year. Patients will be treated for CVD risk factors (e.g. antihypertensive treatment, treatment for diabetes, treatment for dyslipidaemia) according to international guidelines. Data on test results, treatment regimes and treatment outcomes will be collected. Costs of the program will be estimated using costs data from the clinic and the insurance company with additional World Health Organization data. After one year of follow up for each patient, treatment will be continued (all treatment is standard CVD care) but data collection will end.

QUICK-II:
Patient centered cardiovascular health education program. The project consists of two parts:
1. The development of CHEP
2. The evaluation of CHEP

Part 1 will consist of four phases. First, interviews will be conducted to make a qualitative assessment of how key stakeholders perceive the nature and the management of risk factors for CVD. The interviews will be done with patients at risk for CVD visiting the participating clinic, health care professionals (HCP) and with the staff of the health insurance company. Second, the interview data from patients will be used for the development of CHEP. Third, the interview data from health care professionals will be used to identify supportive strategies that are needed for the implementation of CHEP. Fourth, these supportive strategies will be implemented (e.g. training health professionals).

The second part of the project will evaluate the effect of CHEP through a prospective hospital based project. Using a pre-post design, this project will assess the effect of CHEP on adherence

to therapy (primary outcome) and a number of secondary outcomes e.g. blood pressure (BP) control. Measurements will be conducted prior to CHEP (baseline) and 6 months thereafter in a subset of patients included in the CVD prevention project (QUICK 1) those with uncontrolled hypertension after eight months of treatment. Case file data, and interview data with health care professionals in the participating clinic will be used to evaluate the feasibility of the application of CHEP in practice.

Part 1 (development of CHEP) is planned for the first 8 months. After inclusion, patients will receive the intervention (CHEP): 3 sessions during 12 weeks. After the intervention, patients will be followed for a maximum of 6 months. The total duration of follow up per patient is therefore maximum 9 months.

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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
QUICK-I:
1. The adjusted cardiovascular care quality score based on the United Kingdom National Health Services Quality and Outcome framework (NHS QOF) after the implementation of the CVD prevention program
2. The range of possible costs of CVD prevention treatment per patient per year, divided per category (treatment, consultation etc):
2.1. For the insurance company considering the current benefit package
2.2. For the hospital
2.3. For the patient
2.4. Costs outside the scope of this particular insurance program (for example costs when using different benefit packages/treatment regimes)
3. The estimated resources required for CVD prevention per year related to the total yearly medical pay out of the insurance company
4. The estimated net health care costs of a CVD prevention program per quality adjusted life year gained in a community health insurance setting

All primary endpoints are assessed after completion of follow up of the entire cohort (the last patient is estimated to complete follow up 1.5 years after inclusion of the first patient). Assessment is estimated to be completed 6 months after completion of the cohort follow up time.

QUICK-II:
Part 1:
Development of CHEP. This will be completed after completion of the follow up period of the QUICK-I cohort (estimated 1.5 years after inclusion of the first patient in QUICK-I).

Part 2:
Level of adherence to medication at 6 months after the implementation of CHEP minus level of adherence to medication at baseline as measured by the 8 item Morisky adherence scale. The primary endpoint will be assessed after completion of the follow up period of the entire QUICK-II cohort. This is estimated to be one year after the inclusion of the first patient in the QUICK-II cohort.

Secondary outcome measures

QUICK-I:
1. The proportion of patients in whom CVD risk factor treatment is successful at one year of follow up. In addition, the proportion of patients successfully treated will be determined per risk factor.
2. Description of characteristics of responders to treatment and non responders to treatment after one year of follow up
3. The proportion of patients with target organ damage at baseline and at one year of follow up
4. The proportion of patients with CVD at baseline and at one year of follow up (new and recurrent CVD events)
5. Incidence of all cause mortality in the project population during one year of follow up
6. Score on the 12-item short form health survey (SF-12) quality of life questionnaire at baseline and after one year of follow up
7. Score on the 8-item Morisky Medication Adherence Scale at three, six, nine months and one year of follow up
8. The proportion of patients who report side effects during one year of follow up and description of the most frequent reported side effects of CVD preventive drugs during one year of follow up
9. The association between baseline serum creatine kinase (CK) and the reduction in blood pressure after drug treatment at 6 months and one year of follow up
10. The association between the changes in blood pressure after drug treatment and the changes in serum CK at 1 year of follow up compared to baseline

All secondary endpoints are assessed after completion of follow up of the entire QUICK-I cohort (the last patient is estimated to complete follow up 1.5 years after inclusion of the first patient). Assessment is estimated to be completed 6 months after completion of the cohort follow up time.

QUICK-II:
Part 2 only, measured at 6 months after baseline:
1. Changes with respect to physiological measures systolic blood pressure, diastolic blood pressure, and body mass index (BMI)
2. Changes in other factors that may influence patients' hypertension management
3. The presence of self-reported additional cardiovascular risk factors (physical activity, diet, smoking, alcohol, sodium intake)
4. Knowledge of hypertension and hypertension management
5. Perceptions of hypertension
6. Perceptions of medication
7. Self efficacy
8. Experienced stress

9. Patient satisfaction with the delivered care within QUICK-I (e.g. doctors' performance, supply of medication, frequency of follow up, satisfaction with CHEP)

All secondary endpoints will be assessed after completion of the follow up period of the entire QUICK-II cohort. This is estimated to be one year after the inclusion of the first patient in the QUICK-II cohort.

Overall study start date
11/06/2010

Completion date
11/12/2012

Eligibility

Key inclusion criteria
QUICK-I:
All of the following inclusion criteria:
1. Aged greater than or equal to 18 years of age, either sex
2. Visiting the outpatient site clinic/admitted to the site clinic
3. Hygeia Community Health Plan insurance
4. One of the following:
4.1. Diagnosis of hypertension
4.2. Diagnosis of diabetes mellitus
4.3. Established cardiovascular disease
4.4. Diagnosis of renal disease

QUICK-II:
Part 1 (development CHEP):
1. 30 patients with hypertension
2. 10 members of the hospital staff
3. 5 - 10 managers and doctors from the health insurance company

Part 2 (measurement patient adherence):
4. Enrolled in HCHP insurance plan
5. Having been included in QUICK-I for at least 8 months
6. Diagnosis hypertension
7. Either:
7.1. Uncontrolled blood pressure (greater than or equal to 140 mmHg systolic or greater than or equal to 90 mmHg diastolic), or
7.2. Non-adherent to any prescribed medication for cardiovascular risk factors and cardiovascular disease (CVD) according to Morisky scale

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
QUICK-I: 300; QUICK-II: 150 (derived from the QUICK-I cohort)

Key exclusion criteria
QUICK-I + QUICK-II:
1. Unwilling to provide consent for data-collection
2. All pregnant or lactating females
3. Suspected secondary hypertension
4. Any person who is incapable of giving informed consent
5. Patients who are not likely to complete the follow up period (for example nomads)

Date of first enrolment
11/06/2010

Date of final enrolment
11/12/2012

Locations

Countries of recruitment
Netherlands

Nigeria

Study participating centre
Amsterdam Institute for Global Health and Development
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Sponsor information

Organisation
Health Insurance Fund (Netherlands)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Health Insurance Fund (Netherlands)

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	25/03/2011		Yes	No
Results article	results	10/12/2014		Yes	No