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The Nkateko trial

Submission date
31/10/2013

Recruitment status
No longer recruiting

Registration date
05/03/2014

Overall study status
Completed

Last Edited
25/09/2019

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In South Africa, it is very common for people to have hypertension (high blood pressure). We have found that over half of adults in the Agincourt Health and Demographic Surveillance System Site (HDSS) have hypertension and the blood pressure is well controlled using medication in less than one in ten of those people. Hypertension is a chronic condition thats needs long-term medication. However, until recently the primary care clinics in South Africa were only organised to deal with short-term conditions. The government has recognised the problem and is reorganising clinics to also deal with chronic conditions, such as HIV and hypertension. We aim to test whether providing extra lay health workers, to work alongside the nurses in the clinics focusing on the care of chronic conditions, will help to improve the care of people with hypertension.

Who can participate?
There will be nine clinics participating in the study, all of them publically-funded primary-care clinics serving the population living in the Agincourt HDSS site. Although the intervention is clinic-based we will also be collecting information from people visiting the clinics and people living in the area. The people we will be approaching will be permanent residents aged 18 or over, excluding pregnant women. Anyone who is approached to give information will first be told about the study and asked for consent.

What does the study involve?
We will randomly choose four clinics where we will provide the lay health workers for 15 months, plus one clinic which we will choose to be a pilot clinic. The pilot clinic will start ahead of the randomly allocated clinics and will give us a chance to test our plans out first on a small scale. The lay health workers will be trained and managed by an experienced nurse who will also consult with the staff in the clinics to make sure the lay health workers are doing things which are useful for the nurses. The other four clinics will not receive any intervention.

What are the benefits and risks of participating?
For the clinics involved the benefits will be the availability of extra help in the clinics which will release the nurses to spend more time with patients. The risk will be that the lay health workers will not prove to be helpful and will waste the nurses time. For most of the individuals who are asked to provide information there will be no direct benefit, although we believe that the results of the study will help to develop better health care for the community. The main risk will

be that individuals will spend time answering questions. Those individuals who are asked to take part in one of the population surveys will have their blood pressure measured and will be asked to give a drop of blood taken from a finger prick to measure their glucose (blood sugar) and cholesterol (blood fat). The benefit will be that they will be given the results of these tests and will be told if they need to go to the clinic to get advice. Taking blood from a finger prick may cause slight discomfort, pain or bruising at the puncture site. There is also a slight possibility of infection. However, all risks will be minimized because only well-trained personnel will perform the procedures under very clean conditions.

Where is the study managed from?
The study is managed from the Agincourt HDSS Unit in Agincourt village (South Africa)

When is the study starting and how long will it run for?
The study started in April 2013, when we began to visit clinics to find out how they worked and to consult the health-care staff. Between September and November 2013 we have carried out a population survey measuring blood pressures and asking questions about heath for a random sample of the population. From December 2013 to February 2014 we will be piloting the introduction of the lay health workers. The main study will start in February 2014 with the introduction of lay health workers in four randomly chosen clinics. It will run until April 2015. After that, we will carry out a second population survey.

Who is funding the study?
British Medical Research Council (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Treating hypertension in rural South Africa. A clinic-based lay health worker to enhance community-based outreach services for chronic care

Study objectives
The provision of trained lay health workers to support chronic care in rural clinics in South Africa will reduce the percentage of people in the population who have elevated blood pressure that is combined with other factors resulting in a risk profile that indicates moderate or greater added risk of cardiovascular disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
We have sought consent for the situational analysis, the baseline survey and the intervention and evaluation separately.

In the same order the consents from the University of the Witwatersrand Human Research Ethics Committee (Medical) are:
1. M130347 granted 05/04/2013, additional interviews approved 22/7/2013
2. M130754 granted 16/08/2013
3. M130964 granted 11/10/2013

From the University of Warwick Biomedical and Scientific Research Ethics Subcommittee:
1. REGO-2013-062 granted 04/03/2013, additional interviews approved 09/07/2013
2. REGO-2013-203 granted 10/6/2013
3. Consent for the intervention and evaluation is pending

From the Mpumalanga Provincial Government Research and Ethics Committee:
1. Consent for the situational analysis was granted on 07/06/2013
2. Consent for the baseline survey was granted on 18/09/2013
3. Consent for the intervention and evaluation is pending

Study design
Cluster randomised trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Cluster randomised trial of a complex health services intervention. A cluster is one clinic and the population that it serves.

This is a health services research trial and involves the provision of trained lay health workers (LHWs) in rural clinics to support the management of hypertension. The LHWs and the clinics they are in will be supported by an implementation manager who will work with clinic staff and LHWs to achieve change. We will randomly choose four clinics where we will provide the LHWs for 15 months (the intervention clinics). The four control arm clinics will not receive any intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The primary outcome of the trial is a population-level measure of hypertension control and will be derived from cross-sectional surveys carried out before and after the intervention. This primary outcome will be the change between the two surveys in the percentage of people in the population who have elevated blood pressure that is combined with other factors resulting in a risk profile that indicates moderate or greater added risk of cardiovascular disease.

Key secondary outcome(s))
1. Change in the proportion of the population with undiagnosed hypertension
2. Change in the proportion of the population reporting they had had their blood pressure measured
3. Change in the proportion of the population reporting that they are using medication for hypertension
4. Changes in the proportion of the population at different levels of blood-pressure-related cardiovascular risk by age group and sex
5. Change in the proportion of people in the population reporting that they have attended a clinic in the last year
6. The proportion of people with diagnosed hypertension using primary care clinics who are adherent to prescribed medication, defined by recorded collection of prescriptions
7. Retention in care of people with diagnosed hypertension defined by the proportion of appointments kept during the study period

All secondary outcomes will be measured after the intervention has finished.

Completion date
21/03/2017

Eligibility

Key inclusion criteria
Permanent residents of the Agincourt field site aged over 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Pregnancy

Date of first enrolment
22/04/2013

Date of final enrolment
31/01/2016

Locations

Countries of recruitment
South Africa

Study participating centre
School of Public Health in Johannesburg
Agincourt Health and Demographic Surveillance Site
27 St Andrews Road
Parktown
Johannesburg
South Africa
2193

Sponsor information

Organisation
University of Warwick

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type

Research council

Funder Name
Medical Research Council (UK) ref: MR/J016020/1

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
All data sets derived from this project will be made publicly available on Agincourt Health and Demographic Surveillance Site, within 1 year of the data collection, entry, and cleaning being completed (www.agincourt.co.za). Secondary data users will be asked to explain the purpose of intended analysis of the data, inform the Unit of any publications, and to provide any derivative dataset to the Unit.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/02/2018		Yes	No
Results article	health economics results	10/01/2019	25/09/2019	Yes	No
Protocol article	protocol	07/11/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes