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SCALE UP: Sustainable model for Cardiovascular health by Adjusting Lifestyle and treatment with Economic perspective in settings of Urban Poverty - Development, implementation and evaluation of a comprehensive intervention package for primary prevention of cardiovascular diseases in the slums of Nairobi

Submission date
14/03/2013

Recruitment status
No longer recruiting

Registration date
25/04/2013

Overall study status
Completed

Last Edited
25/01/2016

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
Cardiovascular diseases (CVD) such as stroke and heart attack are the leading cause of death globally including in Sub Saharan Africa (SSA). In fact, 4 out of 5 deaths from CVD in the world occur in poor countries. Hypertension or raised blood pressure is the main risk factor for CVD and there is evidence that more and more people in SSA are becoming hypertensive. One of the main reasons why hypertension is becoming common in SSA is because of urbanization. People living in SSA are increasingly adopting western lifestyles such as smoking, alcohol misuse, lack of exercise and consumption of unhealthy diets (lots of salt and fat, and little or no fruits and/or vegetables). At the same time, there is a proliferation of slum settlements in large cities across SSA as people migrate from rural to urban areas. In Kenya for example, up to 70 per cent of the urban population resides in
slums. These slums are typically characterized by extreme poverty, high levels of crime and lack of social amenities such as water and sanitation services. Slum dwellers also tend to fare worse in terms of health than their non-slum counterparts. As regards hypertension in the slums, a recent study in two slums in Nairobi showed that 12% of adults aged 18 years and older were hypertensive. Further, only one out of five of those who were hypertensive were aware of their condition. Even among those who were aware, only a third reported being on any form of treatment over the preceding 12 months. These alarming findings are the reason for our study: a community based intervention that aims to implement and evaluate a comprehensive model for primary prevention of CVD in a low resource setting, and determine its health benefits in the population.

Who can participate?
All those aged 35 years and older and residing in the slum communities. Participants must not be pregnant, mentally incapacitated or already have an undiagnosed CVD such as stroke.

What does the study involve?
The study will compare the implementation of a community based intervention for prevention of CVD in one slum community in Nairobi while comparing it to the existing standard of care in another similar slum community. The community based intervention involves four main components: 1) increasing awareness about the problem of CVD in the slum community through community
gatherings and local radio messages; 2) increase access to screening for CVD risk through door-to-door screening of all adults aged 35 years and older in the slum community. The screening will be performed by trained community health workers (CHWs) selected from the slum community. The CHWs will take blood pressure measurements as well as other anthropometrics such as weight, height and waist circumference. The CHWs will also provide counseling on healthy lifestyle during the door-to-door visits; 3) increase access to treatment by referring to a local clinic all those found to be at high risk of CVD during the screening; and 4) improving adherence to treatment for CVD risk through establishing patient support groups, sending text (SMS) message reminders about clinic
appointments and an incentive system. The incentive system includes a reduction in cost of treatment for all patients who remain adherent to treatment for at least three consecutive months. CHWs will also receive a small cash incentive for successfully encouraging patients that they have screened to seek and remain adherent to treatment at the local clinic.

What are the possible benefits and risks of participating?
The possible benefits of participating in this study is that the participant will be aware about the risk for getting cardiovascular diseases and the person will be screened for this. The participant will get access to affordable treatment and will be assisted in the follow up of treatment. The possible risk from this is that the patient might get side-effects from the medication with symptoms being dizziness, muscle cramps, dry mouth, swollen legs, headaches, dry cough and nausea. As the study is following a strict treatment protocol based on international guidelines with well-established medication (hydrochlorothiazide, nifedipine, enalapril and metformin) we hope to limit this. We expect no harm to the respondents from the questionnaire and planned procedures i.e. blood pressure, weight, height, waist and hip circumference measurement. We will perform a finger prick to collect a blood glucose sample only if the patient has an increased risk of diabetes. The procedures to be employed will be done in accordance with established standards for collection, and handling of bio-hazardous materials.

Where is the study run from?
The study takes place in two slums in Nairobi: Korogocho and Viwandani (Kenya). The community based intervention will be implemented in Korogocho slum while Viwandani will be the comparison slum where the existing standard of care for CVD will be evaluated. Both slums, located about 10km from each other, are home to about 75,000 residents.

When is the study starting and how long is it expected to run for?
The study takes place from August 2012 to March 2014. The first and last three months of the study will involve before and after data collection of the CVD risk profile of residents in the two slum communities. The intervening 12 months of the study will be the period when the community based intervention will be tested in one slum community while comparing it with the standard of care in the other slum community.

Who is funding the study?
The study is funded by the Academic Medical Center (AMC) Foundation through the Amsterdam Institute for Global Health and Development (AIGHD).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A community-based intervention package for primary prevention of cardiovascular diseases among participants aged 35 years and older in a slum in Nairobi, evaluated in terms of cardiovascular risk outcomes and cost effectiveness, in comparison with the usual standard of care in a similar slum.

Acronym
SCALE UP

Study objectives

Cardiovascular diseases (CVD) are a group of disorders of the heart and blood vessels. Heart attacks and strokes are the two major CVD of interest in this study. According to the World Health Organization, both conditions are usually acute events and are mainly caused by a blockage that prevents blood from flowing to the heart or brain. The most common reason is a build-up of fatty deposits on the inner walls of the blood vessels. Strokes can be caused by bleeding from a blood vessel in the brain or by blood clots.Hypertension is the most important risk factor for CVD and it is characterized by raised blood pressure defined as systolic greater or equal to 140 mmHg and diastolic greater or
equal to 90 mmHg.

The null hypothesis is that a comprehensive intervention package for primary prevention of CVD that comprises raising awareness, improving access to screening, facilitating access to quality treatment, and promoting treatment adherence has no impact on cardiovascular disease risk and /or is not cost effective in a slum setting in Nairobi, Kenya after 12 months of implementation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval for this study was obtained from the Kenyan Medical Research Institute (KEMRI), reference KEMRI/RES/7/3/1 number 399, dated 11th of June 2012

Study design
Prospective quasi-experimental community-based single centre intervention study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
Cardiovascular diseases

Interventions
There is an intervention and control site assigned by convenience.The intervention site was selected because it had a centrally located primary health facility where part of the intervention could be administered. The control site did not have such a facility and the absence of an equivalent facility represents the usual standard of care in such settings.

The intervention involves a comprehensive package of primary prevention strategies for CVD in a low resource setting. The components of the intervention include:
1. Raising awareness
2. Improving access to screening
3. Facilitating access to quality treatment
4. Promoting long-term adherence.

The control is the standard of care usually available the slum setting. At present there is no known primary prevention strategy aimed at raising awareness, improving access to screening, facilitating access to quality treatment or promoting long term adherence for CVD in the control slum. There is only a public health facility that provides primary care for known high risk CVD patients from the community.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The change in the proportion of the study populations (intervention and control slums) that are at moderate or high risk of CVD (defined as >10% risk of developing cardiovascular event in the next five years)
2. The change in mean systolic blood pressure in the study populations (intervention and control slums)
3. The change in mean systolic blood pressure among patients attending the local clinic (intervention slum only)
4. The net cost of the intervention model per disability-adjusted life year gained (intervention slum only)

Secondary outcome measures
1. Prevalence of hypertension in the intervention and control slums
2. Proportion of hypertensive respondents who were aware of their condition in the intervention and control slums
3. Proportion of hypertensive respondents who were aware of their condition and on treatment in the intervention and control slums
4. Proportion of hypertensive respondents who were on treatment and whose blood pressure was under control in the intervention and control slums
5. Proportion of patients attending the local clinic in the intervention slum who blood pressure was under control
6. Proportion of high risk patients who sought first time treatment after screening and referral
7. Prevalence of behavioural CVD risk factors: smoking, physical exercise, diet and alcohol intake in the intervention and control slums

Overall study start date
09/08/2012

Completion date
09/03/2014

Eligibility

Key inclusion criteria
All adults aged 35 years and above living in the slums of Korogocho and Viwandani who give informed consent participate in the study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Intervention site targets 6780 participants Control site targets 1610 participants

Key exclusion criteria
1. Pregnant women
2. Persons with undiagnosed CVD such as stroke (including secondary hypertension)
3. All those unable to provide informed consent such as the mentally incapacitated

Date of first enrolment
09/08/2012

Date of final enrolment
09/03/2014

Locations

Countries of recruitment
Kenya

Study participating centre
African Population and Health Research Center
Nairobi
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Sponsor information

Organisation
Amsterdam Institute for Global Health and Development (Netherlands)

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Sponsor type
Research organisation

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http://aighd.org/

ROR
https://ror.org/037n2rm85

Funder(s)

Funder type
Research organisation

Funder Name
Academic Medical Center Foundation through the Amsterdam Institute for Global Health and Development (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	01/12/2013		Yes	No
Results article	results	27/06/2015		Yes	No