

# Effectiveness of a community based lifestyle modification program to reduce risk factors associated with hypertension

|  |   |  |
|--|---|--|
| <b>Submission date</b><br>16/06/2016   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>27/06/2016 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>27/06/2016       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Hypertension (high blood pressure) is a long term medical condition in which the pressure in the arteries is higher than it should be. It is major risk factor for cardiovascular disease (disease of the heart and blood vessels), which is the case of around 17 million deaths worldwide, 80% of which occur in low and middle income countries (LMICs). In Kenya, the growth of cities has led to the emergence of slums. Those who live there often adopt less healthy lifestyles (e.g. sedentary lifestyles and diets high in saturated fat, salt and sugar) and have poor access to healthcare, leading to an increase in hypertension and associated diseases. The best strategy for preventing cardiovascular disease (CVD) is to treat and control blood pressure early on. The World Health Organization (WHO) has stated that 80% of deaths relating to hypertension can be prevented by lifestyle modification, namely, increasing physical activity, healthy eating and stopping smoking. The aim of this study is to investigate the effectiveness of a community based lifestyle modification program delivered by community health workers (CHWs) in reducing blood pressure and other risk factors for developing CVD.

### Who can participate?

Adults aged 35 and over with high blood pressure, who live in participating villages of the Kibera slum in Nairobi (Kenya).

### What does the study involve?

Two villages (areas) from the Kibera slum in Nairobi are selected to take part. Participants living in the first village take part in the lifestyle modification programme in their community. This involves attending 14 weekly group classes over 16 week, followed by home-based biweekly sessions for eight weeks. The weekly group sessions are run by a CHW and each session lasts for around 1-1.5 hours. During the sessions, participants receive information about reducing the risks linked with high blood pressure by eating more healthily and exercising more. Participants living in the second village receive standard care which involves being provided with written information about diet and lifestyle changes which could help to reduce their blood pressure, as well as continuing with their usual healthcare arrangements (such as visiting the local health centre). At the start of the study and then after three and six months, participants have their

blood pressure, weight and health taken as well as completing questionnaires to measure their exercise levels, dietary intake and stress levels.

What are the possible benefits and risks of participating?

Participants will benefit from increase awareness of risk factors associated with high blood pressure. Additionally, adoption of a healthy lifestyle will have a positive impact of participant's blood pressure and health in general. There are no notable risks involved with participating in this study

Where is the study run from?

The study is run from the Kenya Medical Research Institute and takes place two villages in the Kibera slum in Nairobi (Kenya)

When is the study starting and how long is it expected to run for?

January 2012 to January 2015

Who is funding the study?

Wellcome Trust (UK)

Who is the main contact?

Ms Beatrice Olack

## Contact information

**Type(s)**

Public

**Contact name**

Ms Beatrice Olack

**Contact details**

Kenya Medical Research institute  
Center for Global Health Research  
Off Mbagathi Road  
Nairobi  
Kenya  
-

## Additional identifiers

**Protocol serial number**

N/A

## Study information

**Scientific Title**

Effectiveness of a community based healthy lifestyle promotion on risk factors for hypertension in an urban slum population: a quasi experimental study

**Study objectives**

Six months after the program, participants allocated to the intervention (community based lifestyle modification program), will exhibit a reduction in blood pressure, increased levels of physical activity, increased intake of fruits and vegetables and reduced sodium intake compared to participants allocated to the usual standard of care.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Kenya Medical Research Institute Scientific Steering Committee, 23/05/2013, ref: KEMRI/RES/7/3 /1 number: 2514

### **Study design**

Prospective quasi-experimental community based study

### **Primary study design**

Interventional

### **Study type(s)**

Prevention

### **Health condition(s) or problem(s) studied**

Hypertension

### **Interventions**

Kibera slum is one of the largest slums in Nairobi, Kenya. The slum is further subdivided into 13 geographic demarcations called villages. The intervention and comparator villages are allocated by convenience and separated by three other villages. The intervention village is selected as it is involved in active population based surveillance and has a designated referral health facility. The comparator village lacks a surveillance system and primary health facility thus represents the usual standard of care.

Participants in the intervention village are invited to participate in lifestyle modification sessions at a community venue, conveniently located for study participants. Participants in the intervention village are invited to attend 14 weekly group classes (sessions) over 16 weeks (intensive phase) followed by home based biweekly individual sessions for 8 weeks (maintenance phase). Two sessions (5 and 13) within the 16 weeks are used as make up sessions. Structure and content of the weekly classes are adapted from established non pharmacologic Interventions like Healthy Eating and Lifestyle Program (HELP) with additional home based individual sessions. The weekly group sessions are conducted by trained community health workers (CHWs) and each session lasts one to one half hours. The key components of the intervention are creating awareness on the risk factors associated with hypertension, motivating the participants to engage in healthy eating, increased physical activity via brisk walking and identifying symptoms of stress and the ways to cope with it. The content of the lifestyle program is underpinned in behaviour change approaches focusing on patients motivation, social support and self efficacy for gradual adoption and maintenance of healthy lifestyle. The trained CHWs talk about hypertension and its risk factors, optimal diet based on Dietary approaches to Stop Hypertension (DASH) diet. Contents of food pyramid, role of different foods, reading food labels, recipes, and food serving portions on hypertension are also discussed. Participants are encouraged to increase fruit and vegetable consumption while reducing consumption of saturated fats and foods high sodium content. The guided physical activity instructions are in

accordance with the World Health Organization Global recommendations on physical activity for health. Participants will be taught deep breathing as a technique for stress management. Maintenance period lifestyle classes will emphasize continuity of positive lifestyle changes made during the intervention period. Community health workers focus on individual needs, assist them to overcome challenges and prevent relapse to unhealthy life styles.

Participants in the comparison village will receive standard of care which includes standard written information on diet and lifestyle changes recommended for reducing blood pressure and continue with their regular health care arrangements visiting the health facility when necessary.

Study assessments measures for intervention and comparison groups are completed at baseline, 3 months and at six months. The measures include:

1. Blood pressure and anthropometric measurements
2. Self reported measures of perceived stress, dietary intake and physical activity
3. Data extraction from patients diaries

All assessments are performed by trained research assistants independent of the intervention.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Mean Systolic Blood Pressure (SBP) is measured using an automated OMRON Digital Blood Pressure Monitor at baseline, 3 and 6 months.

### **Key secondary outcome(s)**

1. Targeted dietary intake (intake of fruits and vegetables, sodium and saturated fats) is measured through self-reporting in a 24 hour dietary recall at baseline, 3 and 6 months
2. Physical activity is measured using the International Physical Activity Questionnaire (IPAQ) at baseline, 3 and 6 months
3. Mean body mass index calculated from individual weight and height measures obtained by trained field staff following standard procedures at baseline, 3 and 6 months
4. Perceived Stress measured by a questionnaire on perceived stress using Cohens scale at baseline, 3 and 6 months

### **Completion date**

31/01/2015

## **Eligibility**

### **Key inclusion criteria**

1. Aged 35 years and over
2. Living in the selected villages within the slum
3. Above optimal blood pressure (Systolic Blood Pressure  $\geq 120$  mmHg and Diastolic Blood Pressure  $\geq 80$  mmHg)
4. Willing and able to participate fully in all aspects of the intervention

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Medical condition or disability that hinders engagement
2. Females who are pregnant (self reported)
3. Participants planning to leave the area prior to the anticipated study end date
4. Unwillingness to give informed consent

**Date of first enrolment**

30/05/2013

**Date of final enrolment**

01/08/2014

**Locations****Countries of recruitment**

Kenya

**Study participating centre**

**Kenya Medical Research Institute**  
Center for Global Health Research  
Off Mbagathi Road  
Nairobi  
Kenya  
254

**Sponsor information****Organisation**

Kenya Medical Research Institute

**ROR**

<https://ror.org/04r1cxt79>

**Funder(s)**

**Funder type**

Charity

**Funder Name**

Wellcome Trust

**Alternative Name(s)**

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

International organizations

**Location**

United Kingdom

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Data sharing statement to be made available at a later date