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

Submission date
16/06/2016

Recruitment status
No longer recruiting

Registration date
27/06/2016

Overall study status
Completed

Last Edited
27/06/2016

Condition category
Circulatory System

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

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-

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Committe, 23/05/2013, ref: KEMRI/RES/7/3/1 number: 2514

Study design
Prospective quasi-experimental community based study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

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
Hypertension

Interventions
Kibera slum is one of the largest slums in Nairobi, Kenya. The slum is further subdivided 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 measure
Mean Systolic Blood Pressure (SBP) is measured using an automated OMRON Digital Blood Pressure Monitor at baseline, 3 and 6 months.

Secondary outcome measures
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

Overall study start date

03/01/2012

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 ≥120 mmHg and Diastolic Blood Pressure ≥80mmHg)
4. Willing and able to participate fully in all aspects of the intervention

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Total 342 participants shall be recruited with each arm having 171 participants.

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
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Sponsor information

Organisation
Kenya Medical Research Institute

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Sponsor type
Research organisation

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

Publication and dissemination plan
Planned publication of at least two peer-reviewed papers based on the study results.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date