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Effects of exercise on the heart, blood vessels and quality of life in individuals on two antihypertensive drugs

Submission date
21/12/2011

Recruitment status
No longer recruiting

Registration date
24/02/2012

Overall study status
Completed

Last Edited
19/01/2017

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
High blood pressure (hypertension) is a major public health problem affecting all populations of the world. Increasing age, obesity and lack of physical exercise are known predictors of hypertension. High blood pressure is strongly associated with stroke, disease of the heart blood vessels, heart enlargement, congestive heart failure, retina disease, and kidney insufficiency. Drug therapy remains the mainstay of hypertension treatment. Adequate blood pressure control is associated with delay or even regression of target organ damage and improvement in bodily pain and general quality of life. Patients who stop taking their medications therefore run the risk of developing cardiovascular complications of hypertension. Uncontrolled hypertension is the failure to achieve adequate blood pressure control after being on two antihypertensive drugs for at least 4 weeks. Uncontrolled hypertension has been reported to be common among Nigerian patients. Several studies have reported reductions of blood pressure in individuals with hypertension following moderate aerobic exercise training lasting 4-12 weeks. Furthermore, research indicates that aerobic exercise training has favourable effects on blood pressure, blood sugar regulation, blood lipids, body fat and blood vessel wall functions. Regular exercise is significantly associated with a reduction in major cardiovascular events in hypertensive elderly subjects with established coronary artery disease. Therefore, physical exercise may be recommended to complement the blood-pressure-lowering effects of drugs and thus reduce the dose and number of drugs required. The aim of this study was to investigate the effects of aerobic exercise training combined with two antihypertensive drugs on cardiovascular health and quality of life of patients with uncontrolled hypertension.

Who can participate?
Patients aged 18 to 65 years diagnosed as having high blood pressure.

What does the study involve?
If you take part in this study, first of all, you will ascertained to have had essential hypertension (hypertension with no identifiable cause) through some tests, which will include providing blood and urine samples. If you are found to have to have an underlying cause of your hypertension, you will be excluded from participating in the study. Otherwise you shall be placed on one tablet

of moduretic (50mg hydrochlorothiazide + 5mg amiloride hydrochloride) for 2 weeks. If your blood pressure is not less than 140/90mmHg after two weeks you shall be given an additional drug (5mg amlodipine). At the end of this second two-week period, if your blood pressure is still above 140/90 mmHg but below the severe hypertensive range (<180/110 mmHg) you shall be recruited into the study. However, if your blood pressure is still equal to or above 180/110 mmHg your amlodipine dose shall be increased to 10 mg for another two weeks. After the third two-week period, if your blood pressure is inadequately controlled but less than 180/110mmHg you shall be recruited into this study. Otherwise you are not eligible for the study. In essence, only those who have mild-moderate hypertension (>140/90mmHg to <180/110mmHg) after being on one tablet of moduretic in addition to either 5 mg or 10 mg amlodipine for 4 or 6 weeks respectively are recruited into this study. After you have been found eligible for the study, you shall be randomly assigned to either the exercise or the control group. All participants are treated with two antihypertensive drugs [1 tablet of moduretic (50 mg hydrochlorothiazide + 5 mg amiloride hydrochloride) plus 5 mg or 10 mg amlodipine] per day at recruitment. All the participants continue their antihypertensive medication throughout the 12-week study and 3-month follow up. If you are in the exercise group you shall undergo aerobic exercise training in addition to your antihypertensive medication. The consultants modify participants drugs as necessary. The medication is modified by increasing the dose of amlodipine per day (from 5 mg to 10 mg) such that the blood pressure reading of below 180/110mmHg is constantly achieved throughout the study. If a patient is on the maximum dose of amlodipine and their blood pressure increases into the severe antihypertensive range, the patient is withdrawn from the study. The aerobic exercise programme lasts for 12 weeks, at a frequency of three sessions per week (Monday, Wednesday and Friday). Before you are assigned to a group, we will collect information on age, sex, marital status, occupation, and alcohol consumption and cigarette smoking. Also, before and after the 12-week intervention, your blood pressure, physical work capacity, blood lipids, percent body fat, body mass index and waist circumference shall be assessed. Further, your quality of life, before and after the intervention, shall be assessed using a questionnaire. You shall be followed up for another three months after the 12-week intervention.

What are the possible benefits and risks of participating?
Your hypertension shall be managed for free including providing you with antihypertensive medication free of charge. You will be able to know your blood lipid status free of charge. The underlying cause of your hypertension could be unravelled. This is an opportunity to partake in exercise training free of charge with no cost on your part except your time. With the exercise training, you will be exposed to no more risk than you exposed to in your daily activities except that you may have to sustain it for a longer time than usual for you but there shall be closed monitoring to forestall any untoward occurrence. Where it inevitably occurs, relevant personnel and facilities are on hand to take care of it.

Where is the study run from?
There two hospitals: University College Hospital, Ibadan & Adeoyo Maternity Teaching Hospital, Yemetu, Ibadan.

When is the study starting and how long is it expected to run?
September 2009 to February 2012

Who is funding the study?
African Population Health and Research Centre (APHRC), Kenya, in partnership with the International Development Research Centre (IDRC) and Ford Foundation through African Doctoral Dissertation Research Fellowship (ADDRF), and Neimeth Pharmaceutical Plc (Nigeria).

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UI/EC/09/0061

Study information

Scientific Title
Effects of regular physical exercise training on heart and blood vessels health indices and quality of life of individuals on two antihypertensive drugs without blood pressure control: a randomised control trial

Study objectives
1. The systolic BP of individuals with uncontrolled hypertension on two drugs combined with aerobic exercise would not differ significantly from systolic BP of matched controls on only antihypertensive drugs, after 12-week interventions.
2. The diastolic BP of individuals with uncontrolled hypertension on two drugs combined with aerobic exercise would not differ significantly from diastolic BP of matched controls on only antihypertensive drugs, after 12-week interventions.
3. The low-density lipoprotein of individuals with uncontrolled hypertension on two drugs combined with aerobic exercise would not differ significantly from low density lipoprotein of matched controls on only antihypertensive drugs, after 12-week interventions.

4. The high-density lipoprotein of individuals with uncontrolled hypertension on two drugs combined with aerobic exercise would not differ significantly from high density lipoprotein of matched controls on only antihypertensive drugs, after 12-week interventions.
5. The triglyceride of individuals with uncontrolled hypertension on drugs combined with aerobic exercise would not differ significantly from those of matched controls on only antihypertensive drugs, after 12-week interventions.
6. The total cholesterol of individuals with uncontrolled hypertension on two drugs combined with aerobic exercise would not differ significantly from total cholesterol of matched controls on only antihypertensive drugs, after 12-week interventions.
7. The number of antihypertensive drugs taken per day by individuals with uncontrolled hypertension on two drugs combined with aerobic exercise would not differ significantly from number of antihypertensive drugs taken per day of matched controls on only antihypertensive drugs, after 12-week interventions.
8. The dose of hydrochlorothiazide taken per day by individuals with uncontrolled hypertension on two drugs combined with aerobic exercise would not differ significantly from number of antihypertensive drugs taken per day of matched controls on only antihypertensive drugs, after 12-week interventions.
9. The dose of Amlodipine taken per day by individuals with uncontrolled hypertension on two drugs combined with aerobic exercise would not differ significantly from number of antihypertensive drugs taken per day of matched controls on only antihypertensive drugs, after 12-week interventions.
10. The body mass index (BMI) of individuals with uncontrolled hypertension on two drugs combined with aerobic exercise would not differ significantly from BMI of matched controls on only antihypertensive drugs, after 12-week interventions.
11. The percent body fat of individuals with uncontrolled hypertension on two drugs combined with aerobic exercise would not differ significantly from percent body fat of matched controls on only antihypertensive drugs, after 12-week interventions.
12. The waist circumference of individuals with uncontrolled hypertension on two drugs combined with aerobic exercise would not differ significantly from waist circumference of matched controls on only antihypertensive drugs, after 12-week interventions.
13. The physical work capacity of individuals with uncontrolled hypertension on two drugs combined with aerobic exercise would not differ significantly from physical work capacity of matched controls on only antihypertensive drugs, after 12-week interventions.
14. The score on physical health domain of individuals with uncontrolled hypertension on two drugs combined with aerobic exercise would not differ significantly from the score of matched controls on only antihypertensive drugs, after 12-week interventions.
15. The score on psychological health domain of individuals with uncontrolled hypertension on two drugs combined with aerobic exercise would not differ significantly from the score of matched controls on only antihypertensive drugs, after 12-week interventions.
16. The score on social relationship domain of individuals with uncontrolled hypertension on two drugs combined with aerobic exercise would not differ significantly from the score of matched controls on only antihypertensive drugs, after 12-week interventions.
17. The score on environment domain of individuals with uncontrolled hypertension on two drugs combined with aerobic exercise would not differ significantly from the score of matched controls on only antihypertensive drugs, after 12-week interventions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Ibadan Ethics Committee, 03/06/2009, ref: UI/EC/09/0061

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
The participants were randomly assigned to either exercise group or control group using a computer-generated randomized number.

Exercise group = aerobic dance with antihypertensive drug therapy

The intervention involves antihypertensive drug therapy and aerobic dance. All participants are on two antihypertensive drugs [1 tablet of Moduretic (50mg hydrochlorothiazide + 5mg amiloride hydrochloride) plus 5mg or 10 mg amlodipine] per day at recruitment. The dose of amlodipine per day depends on how soon the participant blood pressure gets below 180 /110mmHg at recruitment. All the participants continue their antihypertensive medication throughout the 12-week study and 3-month follow up. If you are in the exercise group you shall undergo aerobic exercise training in addition to your antihypertensive medication. Thus the difference between the exercise and control groups is the exercise training. The consultants modify participants drugs as necessary. The medication is modified by increasing the dose of amlodipine per day (from 5mg to 10mg) such that the BP reading of below 180/110mmHg is constantly achieved throughout the study. When a patient is on the maximal dose of amlodipine per day and the BP increases into the severe antihypertensive range, the patient is withdrawn from the study.

The aerobic exercise programme lasts for 12 weeks, at a frequency of 3 sessions per week (Monday, Wednesday and Friday). There are 5-10 participants in a session of aerobic exercise class at a time. The aerobic class is conducted using an exercise video disc. The video disc contains a 45-minute exercise dance. Exercise intensity is monitored by recording the heart rate (number of beats for 15 seconds multiplied by 4) of randomly selected participants three times during the aerobic exercise class. The target exercise intensity was set at 60-70% heart rate reserve.

Before you are assigned to a group, the information on age, sex, marital status, occupation, and alcohol consumption and cigarette smoking shall be collected about you. Also, before and after the 12-week intervention, your blood pressure, physical work capacity, blood lipids, percent body fat, body mass index and waist circumference shall be assessed. Further, your quality of life, before and after the intervention, shall be assessed using a World Health Organization questionnaire (WHOQOL-BREF). All these is with a view to determining the possible differential impacts of antihypertensive drug therapy alone, on one hand, and its combination with exercise, on the other hand, on these outcome variables. You shall be followed up for another three months after the 12-week intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Systolic blood pressure
2. Diastolic blood pressure
3. Number of antihypertensive drug
4. Quality of life

Secondary outcome measures
1. Physical work capacity
2. Body mass index
3. Percent body fat
4. Waist circumference
5. Total cholesterol
6. Low-Density Lipoprotein (LDL) cholesterol
7. High-Density Lipoprotein (HDL) cholesterol
8. Triglyceride

Overall study start date
01/09/2009

Completion date
15/02/2012

Eligibility

Key inclusion criteria
1. 18 years of age
2. Essential uncontrolled hypertension on 1 or 2 antihypertensive drugs
3. Resting BP from 140/90 to less than180/110mmHg

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Currently pregnant or breast-feeding individuals
2. Cardiovascular diseases such as:
2.1. Unstable angina and arrhythmia
2.2. Class IV heart failure
2.3. Uncontrolled sustained tachyarrhythmias or bradyarrhythmias
2.4. Severe and symptomatic aortic or mitral stenosis
2.5. Hypertrophic obstructive cardiomyopathy
2.6. Active or suspected myocarditis or pericarditis
2.7. Thrombophlebitis
2.8. Recent significant systemic or pulmonary embolus
3. Syncopal disorder or orthostatic hypotension of defined by greater or equal to 20 mmHg decrease in standing systolic blood pressure (SBP) as compared to sitting SBP at screening or greater or equal to10 mmHg decrease in standing diastolic blood pressure (DBP) as compared to sitting DPB at screening
4. Participants with BP not less than180/110mmHg
5. Individuals with hyperglycaemia (diabetes)

Date of first enrolment
01/09/2009

Date of final enrolment
15/02/2012

Locations

Countries of recruitment
Nigeria

Study participating centre
University of Ibadan
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Funder type
Government

Funder Name
African Population Health and Research Centre (Kenya)

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?
Results article	results	01/07/2013		Yes	No
Results article	results	01/04/2016		Yes	No