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Community and home-based exercise for the prevention and treatment of hypertension.

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A special case for Africa.

Introduction

Hypertension is a global public health concern. One of the key risk factors for cardiovascular disease, hypertension affects one billion people globally, and leads to heart attacks and strokes. The World Health Organisation estimates that complications of hypertension cause the deaths of 9.4 million people every year, accounting for at least 45% of deaths due to ischaemic heart disease and 51% of deaths due to cerebrovascular disease (WHO 2013).

Hypertension is most prevalent in the African region (46%), with some variation by country: South Africa 42.4%, slightly higher in men (43.4%) than women (41.4%); Botswana 40.8%, Namibia 43.4%, Tanzania 39.2%, Zambia 40.1% and Zimbabwe 39%.

In a South African survey an estimated 59% of black people visiting general practices had hypertension (Connor 2008), but these data are of limited use to determine actual care need, potential care costs, or burden of disease on the health care system because many South Africans report going without medical care due to living in resource limited communities (Kon 2008).

Lifestyle modifications, including increased physical activity, and dietary change to limit kilojoules and reduce body fat, are known to reduce elevated blood pressure.

- Regular aerobic physical activity such as brisk walking at least 30 min/day, most days of the week, for a minimum of 150 min/week has the potential to reduce systolic blood pressure by 4–9 mmHg (ACSM 2004);
- Maintaining normal body weight through limited kilojoule intake and adequate daily physical activity has the potential to reduce systolic blood pressure by 5–20 mmHg for every 10 kg body mass reduction (ACSM 2004).

Current guidelines include a strong recommendation that lifestyle advice be offered to all patients with hypertension (NHFA 2016). A review undertaken by a South African research team, commissioned by the WHO, identified “what works” by way of community interventions for promoting healthy diet and physical activity (Anderson 2009). Home and community based interventions are likely to be more available and affordable for people with hypertension in resource-limited communities than are supervised and practitioner led interventions.

Physical activity is key component of lifestyle modification, and is a widely available, affordable intervention to reduce hypertension, yet in Africa levels of inactivity remain very concerning. South Africa is the country with the highest level of inactivity in Africa; 51% of South Africans report insufficient levels of exercise (WHO 2014). Inactivity in other African countries varies markedly, with considerable disparity between urban and rural dwellers, and between men and women.

Hypertension is a silent, invisible killer that rarely causes symptoms.... Raised blood pressure is a serious warning sign that significant lifestyle changes are urgently needed. People need to know why raised blood pressure is dangerous, and how to take steps to control it.

It contributes to the burden of heart disease, stroke and kidney failure and premature mortality and disability. It disproportionately affects populations in low- and middle-income countries where health systems are weak.

Addressing behavioural risk factors, e.g. unhealthy diet, harmful use of alcohol and physical inactivity, can prevent hypertension. Tobacco use increases the risk of complications of hypertension. If no action is taken to reduce exposure to these factors, cardiovascular disease incidence, including hypertension, will increase.

Integrated noncommunicable disease programmes implemented through a primary health care approach are an affordable and sustainable way for countries to tackle hypertension. (WHO 2013).

Objective

The objective of this review is to assess the effects of community and home-based exercise interventions for the prevention and treatment of hypertension.

Methods

Studies: Randomised, controlled trials (RCTs), using either non-intervention or active controls, parallel and cross-over trials, and cluster RCTs examining the effects of exercise for the prevention or treatment of hypertension will be included.

We will seek trials comparing:

- community or home-based exercise (resistance or aerobic) versus no exercise or wait-list control
- community or home-based exercise versus supervised exercise
- community or home-based exercise versus active control (ie: pharmacological management or dietary modification).

Studies in which hypertension is part of a broader disease picture, such as type 2 diabetes or cardiovascular disease, will be included if the effect of interventions on blood pressure are reported.

Participants: Adults (18+ years) without regard to race or gender. Studies in children, and studies of hypertension or pre-eclampsia in pregnancy women will be excluded. Treatment trials will include participants with diagnosed hypertension of any severity and duration. We will use current Australian classification to grade hypertension as: Grade 1 (mild) 140–159/90–99 mmHg, Grade 2 (moderate) 160–179/100–109 mmHg, Grade 3 (severe) 180+/110+ mmHg, and isolated systolic hypertension 140+/90– mmHg (NHFA 2016). Prevention trials may include adults with high-normal blood pressure of 130–139/85–89 mmHg (NHFA 2016).

Outcomes

Primary:

- Systolic and diastolic blood pressure in millimetres of mercury (mmHg);
- Mean arterial pressure in millimetres of mercury (mmHg);
- Adverse events.

Note: These primary outcomes are criteria for inclusion. Studies that do not include a primary outcome measure of hypertension will be excluded.

Secondary:

- Anti-hypertensive medication use;
- Categorical classification of hypertension;
- Standardised measures of cardiovascular fitness (eg: VO₂ peak, VO₂ max);
- Body mass or composition (eg: BMI, waist circumference, waist to hip ratio);
- Other modifiable cardiovascular risk factors (eg: smoking);
- Medications known to alter cardiovascular function (eg: anti-retrovirals, glucocorticoids);
- Quality of life.

Data collection and extraction

Following a thorough search of all relevant electronic databases, titles and abstracts of potential trials will be reviewed, and a full manuscript retrieved for each study likely to meet review criteria. Data will be extracted from each eligible study. Because we anticipate a large number of studies will be included in this review, and the inclusion of studies in languages other than English, all investigators will contribute to data collection and extraction, and each task will be completed by at least two investigators acting independently. Any disagreements in data collection, extraction, and analyses will be resolved by consensus and reference to this protocol.

These data will be extracted from the included trials and entered into RevMan 5:

1. trial characteristics including size and location of the trial, and source of funding;
2. characteristics of the study population including age and clinical presentation (ie: risk of hypertension, stage of hypertension);
3. characteristics of the therapy in all trial arms including type and duration of intervention;
4. risk of bias domains;
5. primary and secondary outcomes, reported as mean and standard deviation for continuous outcomes, and number of events for dichotomous outcomes.

To avoid multiple outcome reporting, we will apply these rules to data extraction:

- Where outcomes are reported at several time points, we will extract the measure at the end of the intervention as the main outcome. Studies of similar duration will be analysed using end of intervention data only. We will also extract data at interim time points only when there is the opportunity to pool these data with trials of shorter durations, and we will clearly identify these data as being non-end-point data.
- Where trial authors report both final values and change from baseline values for the same outcome, we will extract final values.
- Where trial authors report analysis based on an intention-to-treat (ITT) sample and another sample (e.g. per-protocol), we will extract ITT-analysed data.
- If trial authors report an outcome using more than one standardised scale, we will extract data for that outcome once, according to an *a priori* determined hierarchy of scales.
- For crossover trials, we will extract data only to the point of crossover, given the potential for carry-over effects of interventions to bias results following crossover.

Adverse events will be measured as the number of patients experiencing any adverse event, patients who withdrew or dropped out because of adverse events, and patients who experienced any serious adverse events. Serious adverse events are defined as events resulting in in-patient hospitalisation, prolongation of hospitalisation, persistent or significant disability, life-threatening events, or death.

If additional data are required, we will contact the trial authors to obtain these data. Where missing data are imputed or calculated (eg: standard deviations calculated from standard errors; imputed from graphs; last measure carried forward) we will report these adjustments in the characteristics of included studies.

Analyses

We will assess included trials for homogeneity of participants, interventions, and comparators, and pool data from clinically homogenous trials in meta-analyses. For each trial, we will present outcome data as point estimates, mean and standard deviation for continuous outcomes, and risk ratio (RR) with corresponding 95% confidence interval (CI) for dichotomous outcomes.

Meta-analyses of continuous outcomes will be presented as weighted mean difference (WMD) of homogenous studies. When different scales are used to measure the same outcome, standardised mean difference (SMD) will be reported. Pooled dichotomous outcomes will be reported as omnibus RR.

We will quantify inconsistency (heterogeneity) across studies using the I² statistic, with a rough guide to interpretation as: 0% to 40% might not be important; 30% to 60% might represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity; 75% to 100% considerable heterogeneity. If moderate to substantial heterogeneity is present in any pooled studies, we will investigate possible subgroupings *post hoc*.

To identify possible publication bias, we will construct funnel plots if at least 10 studies are available for a meta-analysis of a primary outcome. We will assess the presence of small study bias in the meta-analyses by comparing random- and fixed-effects models.

Typically, sensitivity analyses would be conducted to investigate the robustness of the intervention effects on subjective outcomes (eg: quality of life) relative to allocation concealment and participant blinding. In exercise intervention trials, participant blinding is almost impossible (ie: participants know whether they are exercising or not), examiner blinding may be difficult (ie: examiners may observe exercise training effects in participants and be able to infer to which groups they were allocated), and allocation concealment is unlikely to reduce these study limitations. If there are substantial differences in trial design or quality within meta-analyses, we will attempt sensitivity analyses, such as removing the poorer quality trials from an analysis to see if this changes overall treatment effects.

Interpretation

Although hypertension is an independent predictor of cardiovascular disease risk, and lowering blood pressure reduces cardiovascular events and all-cause mortality, effective treatment targets have been ever changing and debated (NHFA 2016). Treatment effect sizes in this review will be discussed with reference to treatment targets in hypertension rather than any agreed minimum clinically important difference.

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