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Screening strategies for hypertension (Protocol)

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Screening strategies for hypertension

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effectiveness of different screening strategies for hypertension (mass, targeted, or opportunistic) to reduce morbidity and mortality associated with hypertension.

BACKGROUND

Description of the condition

Hypertension, also known as raised or high blood pressure, is a long-term non-communicable medical condition where the blood pressure in the arteries is persistently elevated (Guwatudde 2015). Blood pressure can be expressed as two measurements: systolic blood pressure (SBP) and diastolic blood pressure (DBP), which are the minimum and maximum pressures. Table 1 compares previous (WHO 2013) versus current (ACCF 2018; Carey 2018; Whelton 2018) thresholds for high blood pressure.

Hypertension is a major public health problem and is the most common cardiovascular disorder, affecting approximately one billion people globally. It remains, since the early 2000s, the single leading contributor to the global burden of morbidity and mortality (Guwatudde 2015). In sub-Saharan Africa, an estimated 10 to 20 million people out of approximately 650 million people may

have hypertension (Lloyd-Sherlock 2014). This high prevalence of hypertension is attributed to population growth (migration from rural to urban areas), changes in dietary habits, ageing of the population, and social stress (Guwatudde 2015; WHO 2013). A large proportion of the population with hypertension remains undiagnosed, untreated, or inadequately treated, which contributes to the rising burden of cardiovascular disease (Ataklte 2015).

Over the long-term, hypertension is a major risk factor for cardiovascular events, such as heart disease, stroke, and kidney failure, and disability and premature mortality (WHO 2013). Factors that increase the risk of high blood pressure include genetic and lifestyle factors, such as excessive salt and fat consumption, physical inactivity, harmful alcohol consumption, and poor management of stress (WHO 2013). There is growing evidence that younger people, such as adolescents, are also at risk of hypertension because of these lifestyle factors (Cheung 2017; Kar 2015).

Description of the intervention

Screening programmes for hypertension could help reduce morbidity and mortality linked to it (Legorreta 2015; WHO 2013). Screening is generally defined as the detection of unknown disease among apparently healthy individuals by means of tests or examinations conducted to identify those at an increased risk for the condition (Screening Subcommittee 2008).

Various devices (electronic, mercury, and aneroid) can be used to measure blood pressure. Semi-automatic devices are the most reliable as readings can be taken even when batteries run low, which may be a common problem in resource-limited settings (WHO 2013). Two blood pressure measurements should be recorded daily for several days. These measurements should be taken at least a minute apart, ideally in the morning and again in the evening while the person is seated. For accuracy, measurements taken on the first day are discarded, and an average is taken of all the remaining measurements to confirm diagnosis of hypertension (WHO 2013). It is common practice that diagnosis of hypertension is confirmed if the resting blood pressure is persistently at a SBP \geq 130/140 millimetres mercury (mmHg) or a DBP \geq 80/90 mmHg (ACCF 2018; WHO 2013). This Cochrane Review will primarily focus

on screening strategies for hypertension and not on the thresholds used for diagnosis. However, we will note blood pressure thresholds as defined by the authors of included studies.

Key components of screening programmes for hypertension include not only equipment and trained health professionals, but also patient education and informed consent, and good relationships between health professions (which are beneficial for referral processes between different healthcare facilities or services) (WHO 2013). These components make screening for hypertension (across an entire population) a costly intervention because of the lengthy time to diagnosis and the human and financial resources required.

How the intervention might work

The logic model in Figure 1 outlines how hypertension screening may reduce the burden of disease considering participant, intervention, implementation, and contextual factors (Rohwer 2017). Early detection of hypertension through screening could increase awareness for those at risk of hypertension, and thus lead to preventative action or early management, which may ultimately curb the societal and economic burden of the disease (Ataklte 2015).

| Particular of the particular

Figure 1. Figure 1. Screening for hypertension

Why it is important to do this review

Interventions to prevent or manage hypertension should be feasible, affordable, sustainable, and effective. Thus, vertical programmes that focus solely on hypertension are not consistently recommended (WHO 2013). Early detection of hypertension may be a critical element for containing health-related costs, especially when screening for hypertension is offered as a point-of-care or integrated service. However, hypertension is primarily associated with behavioural and socioeconomic risk factors. Therefore, early detection of mild hypertension may not significantly impact health-related costs in the long-term or improve health outcomes. Additionally, the factors associated with hypertension are generally the problems of urban areas in resource-limited countries. Therefore, preventing hypertension may involve other stakeholders (e.g. policy-makers) beyond screening by health professionals (Hunter-Adams 2017; WHO 2013).

Since it is unclear whether screening for hypertension leads to healthier behaviours and better control of blood pressure levels, it is important to learn from studies that have assessed the impact of screening on hypertension outcomes. A 2014 systematic review supported the U.S. Preventive Services Task Force in updating its recommendation on screening for high blood pressure in adults (Piper 2014). The review focused on the role of confirming hypertension diagnoses, re-screening intervals, ambulatory blood pressure monitoring, and home blood pressure monitoring. The evidence from the systematic review does not provide guidance on different screening strategies.

A recent overview of systematic reviews on diabetes and hypertension screening programmes found that there is a need for a systematic review to assess the effectiveness and impact of various screening interventions (Durao 2014). This Cochrane Review aims to address this gap in the literature, with a specific focus on evidence from resource-limited countries, where the behavioural and socioeconomic risk factors of hypertension are similar to the broader problems of urban areas in these countries. This will provide clarity on whether screening of hypertension, in all age groups, will contain health-related costs and improve outcomes related to hypertension and associated life-threatening complications.

OBJECTIVES

To assess the effectiveness of different screening strategies for hypertension (mass, targeted, or opportunistic) to reduce morbidity and mortality associated with hypertension.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) and non-RCTs (NRCTs) (Cochrane EPOC 2017a), i.e. controlled before and after (CBA), interrupted time series (ITS) and prospective analytic cohort studies. We do not expect to find many RCTs, so we will also include NRCTs given the programmatic nature of screening for hypertension. RCTs are experimental studies in which people are randomly allocated to one of two or more groups receiving an intervention or control treatment or no treatment. CBA is a type of non-randomised study in which outcomes are measured before and after a treatment, both in a group that receives the treatment and in another comparison group. ITS is also a type of non-randomised study that measures an outcome at multiple time points before and after an intervention (the 'interruption'). The design attempts to detect whether the intervention has had an effect greater than any underlying trend over time. ITS studies should be controlled and they must have at least three data points before and after a clearly-defined intervention in terms of content and timing (Cochrane EPOC 2017a). The last type of non-randomised study that we will include is prospective analytic cohort studies, where participants are already either exposed or unexposed to an intervention, but had not developed the outcome of interest at the start of the study. This is because participants are followed forward in time, after which outcomes are measured. There should be at least two study arms for the cohort to provide a comparison of the exposure of interest.

We will include studies regardless of their language or publication status.

Types of participants

Healthy adolescents (15 to 24 years old), adults (25 to 64 years old) and elderly people (over 65 years old) without known hypertension. We will include studies where participants present with risk factors for hypertension.

Types of interventions

Studies on mass, targeted, or opportunistic hypertension screening will be eligible. The interventions must be compared to no screening and participants must be followed for at least one year. Mass screening involves screening apparently healthy populations regardless of risk factors (at public places, e.g. markets); targeted screening involves screening specific groups of people who are considered to be at higher risk of hypertension than the general population; and opportunistic screening involves screening individuals engaging with the health system or another environment where screening may be offered (e.g. HIV clinic, corporate health day).

Types of outcome measures

Primary outcomes

Clinical

- 1. Overall mortality (total deaths)
- 2. Hypertension-related mortality (deaths related to heart failure, coronary heart disease, stroke or end stage kidney disease)
- 3. Hypertension-related morbidity (incidence, prevalence and hospitalisation due to stroke, coronary heart disease, heart failure or end stage renal disease)
- 4. Incidence and prevalence of hypertension (ratio of detected hypertension to expected prevalence of hypertension)
- 5. Quality of life (physical and psychological well being and perceptions of the effects of treatment)

Secondary outcomes

Health system

- 6. Health care utilisation (time spent in care, duration on medication)
- 7. Linkage to care (attending clinic to initiate treatment following screening)
- 8. Retention in care after diagnosis and initiation of treatment
- 9. Costs and cost-effectiveness (as described in the included studies, or related sub-studies)

Adverse events of being screened

10. Psychological consequences of being screened, e.g. false positive or false negative and being correctly classified as positive (new diagnosis)

Search methods for identification of studies

Electronic searches

The Cochrane Hypertension Information Specialist will search the following databases without language, publication year, or publication status restrictions.

- 1. Cochrane Hypertension Specialised Register via the Cochrane Register of Studies (CRS-Web)
- 2. Cochrane Central Register of Controlled Trials (CENTRAL) via the Cochrane Register of Studies (CRS-Web)
- 3. MEDLINE Ovid (from 1946 onwards), MEDLINE Ovid Epub Ahead of Print, and MEDLINE Ovid In-Process & Other Non-Indexed Citations
 - 4. Embase Ovid (from 1974 onwards)
 - 5. LILACS Bireme (from 1982 onwards)
 - 6. ClinicalTrials.gov (www.clinicaltrials.gov)
- 7. World Health Organization International Clinical Trials Registry Platform (www.who.it.trialsearch)

The subject strategies for databases will be modelled on the search strategy designed for MEDLINE (Appendix 1). Where appropriate, these will be combined with subject strategy adaptations of the sensitivity- and precision-maximising search strategy designed by Cochrane for identifying RCTs (as described in Box 6.4.c of Higgins 2011). We have based the search terms for nonrandomised trials on the EPOC search filter for Ovid MEDLINE (Cochrane EPOC 2017b), and will provide the full search strategies for the listed databases in the review.

Searching other resources

The Information Specialist will search the Cochrane Hypertension Specialised Register segment (which includes searches of MED-LINE, Embase, the Cochrane Library, and Epistemonikos for systematic reviews) to retrieve published systematic reviews related to this review title, so that we can scan their reference lists to identify additional relevant trials. The Specialised Register also includes searches of the Allied and Complementary Medicine Database (AMED), CAB Abstracts & Global Health, CINAHL, ProQuest Dissertations & Theses, and Web of Science.

We will check the bibliographies of included studies and any relevant systematic reviews identified for further references to relevant trials.

We will contact experts and organisations in this research field to obtain additional information on relevant trials.

We may contact authors of the original studies for clarification and further data if trial reports are unclear.

Data collection and analysis

Selection of studies

At least two review authors will independently screen all titles or abstracts, or both, of all records retrieved to determine their eligibility for full-text screening. We will retrieve the full-texts of potentially eligible or unclear studies. Two review authors will independently assess these for inclusion and will resolve any disagreements by re-checking the full-text article, or by consulting a third review author, or both. We will illustrate the study selection process in a PRISMA flow diagram and will list all studies excluded after full-text assessment and their reasons for exclusion in a 'Characteristics of excluded studies' table (Liberati 2009).

Data extraction and management

We will pilot the data extraction form on two included studies to ensure information is captured in a standard manner. Two review authors will independently extract study data related to participants, intervention, comparison, and outcome (PICO) characteristics using the standard data extraction form. We will record any missing information in order to contact the author of the primary

study. Any disagreements will be resolved through discussion or by consulting a third review author.

Assessment of risk of bias in included studies

We will use the 'Risk of bias' assessment tool modified by the Cochrane Effective Practice and Organisation of Care (EPOC) Group (Durao 2014). It is widely used and validated for systematic reviews including a wide range of study designs. We will independently assess the risk of bias in included studies and will resolve any disagreements through discussion or by consulting a third review author. We will judge individual studies to have either 'low', 'unclear', or 'high' risk of bias. Low risk of bias is plausible bias that is unlikely to alter results, unclear risk of bias is plausible bias that raises some doubt about the results, and high risk of bias is plausible bias that seriously weakens confidence in results. We will follow the recommendations by Cochrane EPOC to score NRCTs as 'high' risk of bias (Cochrane EPOC 2017a).

We will apply the following criteria to the 'Risk of bias' assessments of RCTs and NRCTs.

- 1. Was the allocation sequence adequately generated? (RCTs)
- 2. Was the allocation adequately concealed? (RCTs)
- 3. Were baseline outcome measurements similar? (all)
- 4. Were baseline characteristics similar? (all)
- 5. Were incomplete outcome data adequately addressed? RCTs)
- 6. Was the knowledge of the allocated intervention adequately prevented during the study? (RCTs)
- 7. Was the study adequately protected against contamination? (RCTs)
- 8. Was the study free from selective outcome reporting? (RCTs)
- 9. Was the study free from other risks of bias? (all) For ITS, we will base the 'Risk of bias' assessments on the following criteria.
 - 1. Was the intervention independent of other changes?
 - 2. Was the shape of the intervention effect pre-specified?
 - 3. Was the intervention unlikely to affect data collection?
- 4. Was knowledge of the allocated interventions adequately prevented during the study?
 - 5. Were incomplete outcome data adequately addressed?
 - 6. Was the study free from selective outcome reporting?
 - 7. Was the study free from other risks of bias?

Measures of treatment effect

We will present dichotomous outcomes as risk ratios, and continuous outcomes as mean differences with standard deviations between the change in the intervention and control groups if the outcomes have been measured in the same way across all studies. In the case that included studies measured continuous outcomes in different ways, we will use the standardised mean differences between the intervention and control groups. We will present time-

to-event outcomes as hazard ratios. We will report 95% confidence intervals (CIs) for all outcomes.

Unit of analysis issues

We will consider the level at which randomisation occurred (e.g. in cluster-randomised trials, groups of individuals may be randomised together to the same intervention); and where repeated measurements are taken, there may be multiple observations for the same outcome (Higgins 2011). In the case that more than one comparison is available from the same study, we will combine groups into a single pairwise comparison. If included cluster-randomised trials have not appropriately adjusted for the clustering of participants in their analysis, then we will attempt to re-analyse them. The design effect (of cluster-randomised trials) may lead to inflated effect sizes of the intervention, so we will calculate the design effect, which involves an estimation of an intra-cluster correlation (ICC). We will impute estimates of the ICC value using estimates from other included studies that reported ICCs or using external estimates from empirical research. Also, we will examine the impact of the clustering using sensitivity analyses.

Dealing with missing data

Where necessary, we will contact the authors of included studies for data related to study methods, attrition rates, and outcomes that are unclear or missing. For example, we will request information on the number of participants screened, randomly assigned participants, intention-to-treat (ITT), as-treated or per protocol samples, drop-outs, losses to follow-up, or withdrawals. If the study authors do not provide estimates for the entire study sample (e.g. they only provide estimates for each sex group), then we will calculate it using available information, including imputing data, where appropriate. We will report all missing outcome data in the data extraction form and 'Risk of bias' table, and assess the impact of including studies with missing data in sensitivity analysis.

Assessment of heterogeneity

We will assess heterogeneity and variability amongst studies in relation to participant, intervention, comparison, and outcome information, as well as context and type of screening and its implementation. Where we undertake a meta-analysis, we will assess heterogeneity by visual inspection of overlap of CIs and statistical methods, i.e. Chi^2 test and I^2 statistic values. If the Chi^2 test has a small P value (P < 0.1) and the I^2 statistic is 60% and above, then this indicates moderate or substantial heterogeneity (Higgins 2011). We plan to explore reasons for heterogeneity through subgroup analyses.

Assessment of reporting biases

We will assess the likelihood of reporting bias for each outcome where a sufficient number of studies (more than 10) are included in a meta-analysis. We will use a funnel plot to visually check for asymmetry associated with small-study effects and publication bias. Through sensitivity analysis, we will assess how these factors affect the results and conclusions of the meta-analysis.

Data synthesis

We will conduct a meta-analysis if the included studies are sufficiently homogenous and if at least two studies of the same design assess the same intervention, comparison, and outcome. Outcomes should be at clinically relevant time points after hypertension screening to be analysed e.g. death within three months of screening may not be clinically relevant. If the characteristics of included studies are excessively heterogeneous, we will not pool results but will present a narrative synthesis of the results, potentially grouping findings by context measures.

We will assess the certainty of the overall evidence for each outcome according to the GRADE approach (Guyatt 2008). GRADE is for rating the certainty of evidence and grading the strength of recommendations in systematic reviews. It includes five criteria for downgrading the certainty of evidence: risk of bias, inconsistency, imprecision, publication bias, and indirectness; and three criteria for upgrading the certainty of evidence: large effect, dose response, and residual confounding opposing the observed effect. We will report the certainty of evidence as either 'high', 'moderate', 'low', or 'very low'. High certainty means that further research is very unlikely to change our confidence in the estimate of effect; moderate certainty means that further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate; low certainty means that further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate; and very low certainty means that we are very uncertain about the estimate. We will report the GRADE assessments in 'Summary of findings' table(s). The 'Summary of findings' table(s) will include the number of participants and studies included for each outcome, a summary of intervention effect, and a measure of the certainty of evidence against GRADE criteria. We will present results for the following outcomes: overall morality, hypertension-related mortality, hypertension-related morbidity, incidence and prevalence of hypertension, quality of life, health care utilisation and linkage to care. These are listed as 1 to 7 in the 'Types of outcome measures' section. The seven main outcomes to be presented prioritise clinically important outcomes, followed by adverse effect and health system outcomes. Given the complex nature of the interventions being studied, pre-specification of the outcomes is challenging (Cochrane EPOC 2017a).

Subgroup analysis and investigation of heterogeneity

We will consider subgroup analyses according to the following.

- 1. Sex: female or male
- 2. Age: adolescents (15 to 24 years old), adults (25 to 64 years old) and elderly people (over 65 years old)
- 3. Ethnicity: white, black, Asian or other
- 4. Setting: rural versus urban; or low- and middle-income countries versus high-income countries (which we will define according the World Bank's country classifications by income level (World Bank 2018)
 - 5. Screening tools: electronic, mercury, or aneroid
- 6. Cardiovascular risk factors: overweight or obesity, physical inactivity, dietary factors (e.g. sodium or salt intake), and comorbid condition

Sensitivity analysis

We will conduct sensitivity analyses to explore the influence of various factors, when applicable, on the effect size. We will stratify analyses per publication status and level of risk of bias to determine whether studies with high risk of bias skew the results.

ACKNOWLEDGEMENTS

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Schmidt B-M, Durao S, Toews I, Bavuma CM, Meerpohl JJ, Kredo T. Screening strategies for hypertension - a Cochrane Protocol. *BMJ Open* 2018;**x**(x):xx. DOI: x

ADDITIONAL TABLES

Table 1. Thresholds for hypertension screening

BP category	SBP (mmHg)	DBP (mmHg)	
Previous guidelines (WHO 2013)			
High	≥ 140 and	≥ 90	
Current guidelines (ACCF 2018; Carey 2018; Whelton 2018)			
Normal	< 120 and	< 80	
Elevated	120 to 129 and	< 80	
Hypertension	Stage 1: 130 to 139 or Stage 2: ≥ 140 or	80 to 89 ≥ 90	
Hypertensive crisis	> 180 and/or	> 120	

Abbreviations: BP: blood pressure; SBP: systolic blood pressure; DBP: diastolic blood pressure; mmHg: millimetres mercury

APPENDICES

Appendix I. MEDLINE search strategy

Database: Ovid MEDLINE(R) <1946 to October 10, 2018>
-----1 mass screening/

2 early diagnosis/

3 (screen? or screened or screening?).tw,kf.

4 (early adj3 (detect\$ or diagnos\$ or intervent\$)).tw,kf.

5 detect\$.ti.

6 or/1-5

7 hypertension/di, pc

8 essential hypertension/di, pc

9 (hypertens\$).ti,kf.

10 ((elevat\$ or increas\$ or lower or high or rais\$ or rising) adj2 (arterial pressure or blood pressure or diastolic pressure or systolic pressure)).tw,kf. 11 ((elevat\$ or increas\$ or lower or high or rais\$ or rising) adj2 (bp or dbp or hbp or sbp)).tw,kf. 12 or/7-11 13 randomized controlled trial.pt. 14 pragmatic clinical trial.pt. 15 controlled clinical trial.pt. 16 randomi\$.ab. 17 placebo.ab. 18 clinical trials as topic/ 19 randomly.ab. 20 trial.ti. 21 multicenter study.pt. 22 non-randomized controlled trials as topic/ 23 interrupted time series analysis/ 24 controlled before-after studies/ 25 groups.ab. 26 (multicenter or multi center or multicentre or multi centre).ti. 27 intervention?.ti. 28 (effect? or impact? or controlled or control group? or (before adj5 after) or (pre adj5 post) or ((pretest or pre test) and (posttest or post test)) or quasiexperiment\$ or quasi experiment\$ or evaluat\$ or time series or time point? or repeated measur\$).tw. 29 exp cohort studies/ 30 (cohort adj2 (analys\$ or design? or stud\$)).tw,kf. 31 epidemiologic methods/ 32 limit 31 to yr=1971-1988 33 or/13-30,32 34 animals/ not (humans/ and animals/)

36 6 and 12 and 35

CONTRIBUTIONS OF AUTHORS

BS drafted the protocol with methods input from SD, IT, and JJM, and content input from CMB. TK provided both methods and content oversight. All authors read and approved the final manuscript.

DECLARATIONS OF INTEREST

BS: nothing to declare.

SD: nothing to declare.

IT: nothing to declare.

CMB: nothing to declare.

JJM: nothing to declare.

TK: nothing to declare.

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Internal sources

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External sources

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