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[Intervention Protocol]

Self-monitoring for improving control of blood pressure in patients with hypertension

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ABSTRACT

Objectives

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

The objective of this review is to determine the effectiveness of SBPM in adults with hypertension on blood pressure control as compared to OBPM or usual care (i.e. usual care that does not include systematic use of SBPM).

- Is SBPM more efficacious in reducing blood pressure, compared with OBPM or usual care?
- Is SBPM with additional supports more efficacious in reducing blood pressure, compared with no additional support?
- Are there any adverse events associated with SBPM, compared with OBPM or usual care?

BACKGROUND

Description of the condition

Hypertension, or high blood pressure, has been recognised for many years as a major risk factor for cardiovascular events such as heart disease, stroke, kidney failure, disability and premature mortality (Lim 2012). It is a major public health problem, affecting approximately one billion people worldwide, with a predicted increase to over 1.5 billion people by 2025 (Kearney 2005, Mills 2016). Despite this, blood pressure control among hypertensive patients remains poor, with only a minority of people treated to satisfactory levels (Patel 2016).

Hypertension in adults is defined by the World Health Organization (WHO) as follows:

- an untreated persistent office blood pressure that is greater than or equal to 140 mmHg systolic pressure; and/or greater than or equal to 90 mmHg diastolic pressure; or
- greater than or equal to 135/85 mmHg home blood pressure average (WHO 2013).

Definitions and classifications of hypertension vary among countries, with European guidelines adopting the WHO definition (Williams 2018). However, in 2017, revised American guidelines lowered their threshold for the diagnosis of hypertension to 130/80 mmHg (Whelton 2018).

Only 25% to 40% of the patients who take antihypertensive drug treatment achieve blood pressure goals (Wang 2007), a situation which may worsen with the recent publication of new lower blood pressure targets (Whelton 2018). This is particularly concerning, as hypertension is the leading risk factor for global disease burden (Lim 2012).

Description of the intervention

Due to the low cost and broad availability of validated electronic blood pressure monitoring devices (O'Brien 2010), self-blood pressure monitoring (SBPM) by patients is increasingly common and is regarded as a more reliable and reproducible representation of blood pressure control. This is due to minimisation of the "white coat effect" (a normal blood pressure reading in a non-clinical setting, compared with an elevated reading in a clinical setting) (Stergiou 2002). It has been recommended for the diagnosis (Williams 2018) and evaluation of hypertension (NICE 2011) as well as for use as a tool to increase the likelihood of therapeutic intensification, in response to above-target blood pressure readings (Agarwal 2011). SBPM can be carried out at the clinic, at the pharmacy or at home by patients using a validated upper arm manual, automatic or semi-automatic blood pressure monitor. It can be done with or without the assistance of a family member or carer. Blood pressure readings can be recorded manually by patients or transferred electronically to their health care providers. SBPM may be accompanied by co-interventions such as telemonitoring (McManus 2010), education (Ogedegbe 2014), lifestyle interventions (Margolis 2013) and systematic medication titration by doctors, pharmacists or patients (McManus 2010).

How the intervention might work

SBPM may lead to improved blood pressure control for patients with hypertension, leading to a reduction in the burden of cardiovascular disease by reducing the risk of heart disease, stroke and heart failure (Lim 2012). Better management and control could ultimately lead to a reduction in the global societal and economical burden of this disease (Williams 2018).

Why it is important to do this review

The most recent Cochrane Review on interventions to improve hypertension management (Glynn 2010) proved too large for timely updates. It classified 72 trials of interventions, based on searches up to 2008, into six categories: self-monitoring, patient education, health professional education, health professional-led care (nurse and/or pharmacist), appointment reminder systems and organisational interventions. The review concluded that self-monitoring and appointment reminders may be useful adjuncts to antihypertensive drug therapy, implemented by means of a vigorous stepped care approach, but required further evaluation.

Since the publication of that review, there has been an increasing body of literature pertaining to the beneficial effect of SBPM on blood pressure control in hypertensive patients (Bray 2010 - 25 trials) (Agarwal 2011 - 37 trials) (Uhlir 2012 - 49 trials). SBPM empowers patients; it is cost effective (McManus 2005), well-tolerated, and has been shown to be a better predictor of end organ damage than traditional office blood pressure monitoring (OBPM) (Bobrie 2004). However, a recent review showed that self-monitoring alone does not improve blood pressure control, but may be of benefit when combined with co-interventions that provide tailored support for patients (Tucker 2017 - 25 trials).

The aim of this Cochrane Review is to provide an up-to-date assessment on the effectiveness of self-monitoring in the management of hypertension. Our review will add to the existing body of knowledge and will help to determine if self-monitoring of blood pressure, with or without co-interventions, is effective in lowering blood pressure.

OBJECTIVES

The objective of this review is to determine the effectiveness of SBPM in adults with hypertension on blood pressure control as compared to OBPM or usual care (i.e. usual care that does not include systematic use of SBPM).

- Is SBPM more efficacious in reducing blood pressure, compared with OBPM or usual care?
- Is SBPM with additional supports more efficacious in reducing blood pressure, compared with no additional support?
- Are there any adverse events associated with SBPM, compared with OBPM or usual care?

METHODS

Criteria for considering studies for this review

Types of studies

All published and unpublished randomised controlled trials (RCTs) that examine the effect of SBPM, compared with OBPM or usual care, will be included. Cluster-randomised controlled

designs and cross-over randomised controlled designs are eligible for inclusion if pre-cross over data are available, to ensure there is no carry-over effect from the intervention. Quasi-randomised trials will be assessed independently by two reviewers and will only be eligible for inclusion if the reviewers are certain that random allocation was used to form the study groups. Non-randomised designs will be excluded. Due to the nature of SBPM, we will not require that trials be blinded.

Types of participants

All adult patients (18 years or over) with a diagnosis of primary hypertension (either treated or not treated with antihypertensive medications) assessed in a primary care, outpatient or community setting will be included. Hypertension will be defined according to the published diagnostic criteria identified in the trial, i.e. persistent office blood pressure that is greater than or equal to 140 mmHg systolic pressure, and/or greater than or equal to 90 mmHg diastolic pressure (WHO 2013, Williams 2018); or greater than or equal to 130/80 mmHg (Whelton 2018). We will not include studies that use SBPM as part of a comprehensive disease management intervention (e.g. for heart failure or weight loss), in patients who have not been diagnosed with hypertension. SBPM in patients on dialysis or with gestational hypertension will not be included due to the unique pathophysiology and different outcomes of interest in these groups.

Types of interventions

The intervention of interest is SBPM (without health professional assistance) in patients with hypertension. Studies can include SBPM as a sole intervention (Halme 2005, Godwin 2010) or they can include co-interventions, e.g. telemonitoring (McManus 2010, Bove 2013), nurse/pharmacist support (Kerry 2013), lifestyle and behaviour interventions (Ogedegbe 2014) or systematic medication titration (McManus 2018). Studies that use validated upper arm blood pressure monitors (manual, semi-automated or automated) will be included, whether commercially available or not. Studies with wrist monitors or unvalidated blood pressure monitors will not be included. Self measurement of blood pressure may take place at home (with or without help from a carer) or in the clinic, office or pharmacy without input from a health care professional. RCTs with a minimum of 24 weeks follow-up will be included, with no minimum sample size threshold (Uhlig 2012). RCTs that involve home visits by medical professionals, or intensified clinic or telecommunication follow-up, will only be included if SBPM is included in the intervention.

Types of outcome measures

Outcome measures will not influence the eligibility criteria.

Primary outcomes

- Change in mean office systolic blood pressure (SBP) and/or mean office diastolic blood pressure (DBP)
- Change in mean systolic and diastolic ambulatory blood pressure (ABP) including overall mean, day time mean or night time mean
- The proportion of participants achieving target blood pressure in each group (control as defined by each randomised trial's investigators)
- Adverse events in the self-monitoring and control groups including any evidence of mortality or cardiovascular morbidity

or adverse events related to treatment with antihypertensive agents e.g. hypotensive episodes or orthostatic falls. This will be measured by examining the number of patients in each arm of the study with any adverse events.

If blood pressure measurements are available at more than one time during the 24-hour period, we will use the trough measurement. We defined the peak level as within 12 hours of the antihypertensive dose and the trough level as between 12 and 24 hours after the dose. If several blood pressure measurements are available within the acceptable window, we will use the weighted mean of all blood pressure measurements reported by the study authors during the 1 to 12-week range as the best estimate of treatment effect.

Secondary outcomes

- Intensification of treatment measured by examining the change in the number of antihypertensive medications and the dose of antihypertensive medications, from baseline to end of trial
- Adherence to intervention (dropout rate), including reasons
- Adherence to medication (compliance rate) measured using an objective tool (e.g. pharmacy fill, electronic monitoring or urine testing).
- Changes in health related quality of life data related to self-monitoring of blood pressure, measured using validated scales. All validated scales will be accepted. A hierarchy of scales will be considered by the authors in relation to its design, applicability to primary care, ease of administration and if it covers physical, psychological and social domains (Hand 2016).
- Left ventricular hypertrophy (LVH) or LV mass, measured by echocardiography
- Costs (information on costs related to the intervention and resources required)

Search methods for identification of studies

Electronic searches

The Cochrane Hypertension Information Specialist (CIS) will search the following databases without language or publication status restrictions:

- the Cochrane Hypertension Specialised Register via the Cochrane Register of Studies;
- the Cochrane Central Register of Controlled Trials (CENTRAL) via the Cochrane Register of Studies;
- MEDLINE Ovid (from 2008 onwards), MEDLINE Ovid Epub Ahead of Print, and MEDLINE Ovid In-Process & Other Non-Indexed Citations;
- Ovid Embase (from 2008 onwards);
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov);
- World Health Organization International Clinical Trials Registry Platform (www.who.int/trialsearch).

The information specialist will model the subject strategies for databases on the search strategy designed for MEDLINE. Where appropriate, the CIS will combine them with subject strategy adaptations of the highly sensitive search strategy designed by Cochrane for identifying randomised controlled trials (as described in the *Cochrane Handbook for Systematic Reviews*

of *Interventions* Chapter 4 (Lefebvre 2019). The most recent Cochrane Review by Glynn 2010 includes trials published up to 2008. Therefore, the CIS will run MEDLINE and Embase searches from 2008 to present. We present the MEDLINE search strategy in Appendix 1.

Searching other resources

The CIS will search the Hypertension Specialised Register segment (which includes searches of MEDLINE, Embase, and Epistemonikos for systematic reviews) to retrieve published systematic reviews related to this review title. We will examine reference lists of these reviews to identify additional relevant trials. The Specialised Register also includes results of weekly searches of MEDLINE and Embase, as well as yearly searches of 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 search Epistemonikos for related reviews.
- We will contact experts and organisations in the field to obtain additional information on relevant trials.
- We will search clinical study reports for additional information on relevant trials.
- We will contact original authors for clarification and further data if trial reports are unclear.
- We will seek information from grey literature sources, such as internal reports and conference proceedings.
- With the splitting of Glynn 2010 into several more focused Cochrane Reviews, we will maintain dialogue and share results with the review authors of collaborating teams.

Data collection and analysis

Two separate authors will independently assess the list of citations and abstracts generated from the searches for eligibility.

Selection of studies

All titles or abstracts or both will be screened for eligibility for full text review. If possible, we will exclude studies that are clearly irrelevant on the basis of their titles alone. We will review the remaining abstracts and denote them as potentially relevant, not relevant or uncertain. We will retrieve the full texts of potentially relevant and uncertain articles. Two independent reviewers will then make final decisions on their eligibility. A third review author will help to arbitrate and discuss any disagreements on study classification. We will apply no additional methodological quality criteria, e.g. in regard to study size or language of publication. We will list all studies excluded after the full text has been examined, with the reasons for their exclusion.

Data extraction and management

Two review authors will independently extract the following data from the included trials and enter the data into Review Manager Web (RevMan Web 2020).

- Trial characteristics, including study design, size, setting, source of funding

- Study population characteristics, including age, co-morbidities, number of antihypertensive medications prescribed, inclusion and exclusion criteria
- Method of blood pressure baseline and outcome measurement, including monitor used, number of readings used in analysis, measurement criteria used
- Randomisation methods, including group allocation, generation of randomisation list, concealment of randomisation
- Characteristics of intervention in all trial arms, including type and duration of intervention, education or training given to control and intervention groups, additional allocated intervention
- Information related to titration of medication
- Adverse events measured as the number of participants experiencing an adverse event or who withdrew because of an adverse event

We will contact the trial authors if additional data are required. If the data are not provided, we will calculate data where possible, e.g. with standard deviations (SD) calculated from standard errors (SE), P values, confidence intervals (CI) or results imputed from graphs. We will report these adjustments in the 'Characteristics of included studies'.

Where studies report outcomes at more than one time point, we will extract data from every reported time point. The primary endpoint will be 12 months. Outcome data from other endpoints will be also be reported. Any unresolved differences in the extraction and interpretation of the data will be resolved by discussion and arbitration with a third review author.

Two review authors will pilot-test the data collection form on two studies, to ensure accuracy and clarity of data collection. The two review authors will then independently complete the data extraction form for all included studies.

Assessment of risk of bias in included studies

To assess study quality and reporting bias, we will use the Cochrane Collaboration 'Risk of Bias' assessment tool (Higgins 2017). We will assess seven domains: randomisation and allocation concealment to assess selection bias; blinding of the participants and physician to assess performance bias; blinding of the outcome assessor to assess detection bias; incomplete outcome reporting to assess attrition bias; selective reporting of outcomes to assess selective reporting bias; and we will add an additional category - other bias, to assess any other sources of bias. We will produce 'Risk of bias' tables as outlined in the *Cochrane Handbook*, Chapter 8 (Higgins 2017). We will consider a study to be a low risk of bias study if we assess all key domains as being at low risk of bias. We will assess it to be a study at unclear risk of bias if we assess one or more key domains as having an unclear risk of bias. If we assess one or more key domains as high risk of bias, we will consider it to be a high risk of bias study (Higgins 2017).

This process of assessing bias will be carried out independently by two separate review authors. Disagreements will be arbitrated by a third review author. We will include studies in the meta-analysis, if their 'Risk of bias' assessments do not lead to high statistical heterogeneity. These studies will be narratively described instead.

Measures of treatment effect

Analysis will be based on intention-to-treat (ITT) data from individual trials. We will present means and SDs for data with continuous outcomes and risk ratios (RR) with corresponding 95% CIs for dichotomous outcomes.

We will calculate weighted mean differences (WMD) for the overall change in systolic and diastolic blood pressure (both for office and ABP monitoring) between intervention and control groups. We will report other primary and secondary outcomes in terms of RR, with corresponding 95% CIs. We will use risk difference (RD) with 95% CIs to measure the effect of exposure to the intervention, compared with the control group. This will be important when comparing the effect of SBPM alone or SBPM with co-interventions.

We will extract data as change-from-baseline, where possible, rather than as absolute figures at the end of treatment.

Unit of analysis issues

We will take care to avoid problematic unit of analysis issues if the same group of participants is included twice in the same meta-analysis. Where studies including more than one intervention group with a single comparator arm are used, both intervention groups will be included and the number of patients split across the intervention arms.

Dealing with missing data

Any potential missing data will be discussed by the review authors, and if necessary, clarified by corresponding with the relevant study authors. All participants not receiving assigned interventions according to the study protocols, as well as those dropping out or lost to follow-up, will be included in the analysis on an ITT basis. This will be performed, with sensitivity analysis, by either available-case analysis or by imputation (see section 10.14 of *Cochrane Handbook*, [Deeks 2019](#)). In examining the primary outcomes, where the SD of the change in blood pressure is not reported, we will compute SD from standard errors and confidence intervals for group mean (see section 6.5.2.2 of *Cochrane Handbook*, [Higgins 2020](#)).

Assessment of heterogeneity

We will assess clinical heterogeneity qualitatively by comparing the study characteristics of included trials and quantitatively using the I^2 statistic. Pooled data with I^2 of 50% or higher will be considered to have high heterogeneity, and will be explored using subgroup or meta-regression analyses. We will carry out meta-regression if we have 10 or more studies in any meta-analysis.

Where there are sufficient data from two or more studies, we will perform subgroup analysis to determine the sources of clinical and statistical heterogeneity. Subgroup analysis will be conducted according to age, gender, baseline antihypertensive treatment (treated versus untreated) and type and length of intervention, in order to explain the heterogeneity. Data will not be pooled if heterogeneity is statistically significant ($P > 0.05$) but will instead be described narratively in the findings instead.

Assessment of reporting biases

We will consider the possibility of reporting bias where studies do not report absolute blood pressure measures at follow-up, in favour

of indirect measures (e.g. change from baseline, achievement of target). We will use publication bias funnel plots if ten or more studies per outcome are available for meta-analysis, producing funnel plots of effect size and of sample size against WMD to provide a visual review of any potential bias. We will use a funnel plot to visually check for asymmetry associated with small-study effects.

Data synthesis

We will describe results from all included studies. We will only pool data if studies are sufficiently similar in terms of heterogeneity (i.e. those with the same interventions, comparators and outcomes). Pooling and analysis of data will be carried out with RevMan Web ([RevMan Web 2020](#)). Separate analyses will be conducted for each intervention and outcome measure, compared to OBPM or usual care. We will calculate intervention effects as RRs with 95% CIs for dichotomous data. In the absence of significant heterogeneity ($P > 0.05$ or $I^2 < 50\%$) we will calculate mean differences (MDs) and WMDs with 95% CIs for continuous data, using a conservative fixed-effect meta-analytic model. Where there is significant heterogeneity, we will use a random-effects model.

Subgroup analysis and investigation of heterogeneity

The primary analysis will include all trials. We will use meta-regression to investigate the effects of different study characteristics on treatment effects. Planned subgroups will include terms for age (grouped in 10-year age bands), sex of participants (male or female), length of follow up (grouped in six month intervals, i.e. at 6, 12, 18, and 24 months), and the number of treated or untreated patients (all treated, all untreated or mix of treated and untreated). We will examine these in terms of overall intensification of treatment (change in number and/or dose of antihypertensive medications from baseline), mean baseline SBP and use of additional co-interventions (where these are part of the intervention in addition to self-monitoring).

Sensitivity analysis

Sensitivity analysis will be performed by excluding single outlying results. The impact of each study will be assessed on the overall outcome with recalculation of both WMDs and meta-regression with the removal of each study one at a time from the analysis. Analysis will be restricted to studies at low risk of bias if possible, however, due to the nature of self-monitoring interventions, it is impossible to have participant blinding. This can have an effect on the risk of bias. We will consider other sensitivity analyses during the review, as other design and methodological issues become apparent.

Summary of findings and assessment of the certainty of the evidence

We will assess the certainty of the body of evidence for each outcome according to the GRADE system ([Guyatt 2008](#)), as set out in Chapter 14 of the *Cochrane Handbook* ([Schünemann 2019](#)). We will produce a 'Summary of findings' table, using the GRADE software ([GRADEpro GDT](#)). Our GRADE analyses will take into account the risk of bias, the directness of evidence, heterogeneity, the precision of effect estimates and the risk of publication bias. We have pre-selected the following outcomes for inclusion in the 'Summary of findings' tables ([Table 1](#)):

- Change in mean office systolic blood pressure

- Change in mean office diastolic blood pressure
- Change in mean systolic ambulatory blood pressure
- Change in mean diastolic ambulatory blood pressure
- The proportion of patients achieving target blood pressure
- Therapeutic intensification
- Adverse events
- Compliance rate

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ADDITIONAL TABLES

Table 1. Sample GRADE 'Summary of findings' table

SBPM compared with OBPM for control of hypertension						
Patient or population: Patients with hypertension						
Settings: office/home						
Intervention: SBPM						
Comparison: OBPM						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	OBPM	SBPM				
Change in mean office SBP [range of scale or scale description] [follow-up]	The mean [BP] ranged across control groups from [value][measure]	The mean [outcome] in the intervention groups was [value] [lower/higher] [(value to value lower/higher)]		[value] ([value])	[to be deleted as appropriate] ⊕⊕⊕⊕ very low ⊕⊕⊕⊕ low ⊕⊕⊕⊕ moderate ⊕⊕⊕⊕ high	
Change in mean office DBP [range of scale or scale description] [follow-up]	The mean [outcome] ranged across control groups from [value][measure]	The mean [outcome] in the intervention groups was [value] [lower/higher] [(value to value lower/higher)]		[value] ([value])	[to be deleted as appropriate] ⊕⊕⊕⊕ very low ⊕⊕⊕⊕ low ⊕⊕⊕⊕ moderate ⊕⊕⊕⊕ high	

Table 1. Sample GRADE 'Summary of findings' table (Continued)

Change in mean systolic ambulatory BP [range of scale or scale description] [follow-up]	The mean [outcome] ranged across control groups from [value][measure]	The mean [outcome] in the intervention groups was [value] [lower/higher] [(value to value lower/higher)]	[value] ([value])	[to be deleted as appropriate] ⊕⊕⊕⊕ very low ⊕⊕⊕⊕ low ⊕⊕⊕⊕ moderate ⊕⊕⊕⊕ high
Change in mean diastolic Ambulatory BP [range of scale or scale description] [follow-up]	The mean [outcome] ranged across control groups from [value][measure]	The mean [outcome] in the intervention groups was [value] [lower/higher] [(value to value lower/higher)]	[value] ([value])	[to be deleted as appropriate] ⊕⊕⊕⊕ very low ⊕⊕⊕⊕ low ⊕⊕⊕⊕ moderate ⊕⊕⊕⊕ high
Proportion achieving target BP [range of scale or scale description] [follow-up]	The mean [outcome] ranged across control groups from [value][measure]	The mean [outcome] in the intervention groups was [value] [lower/higher] [(value to value lower/higher)]	[value] ([value])	[to be deleted as appropriate] ⊕⊕⊕⊕ very low ⊕⊕⊕⊕ low ⊕⊕⊕⊕ moderate ⊕⊕⊕⊕ high
Therapeutic intensification [range of scale or scale description] [follow-up]	The mean [outcome] ranged across control groups from [value][measure] treated vs untreated subgroups	The mean [outcome] in the intervention groups was [value] [lower/higher] [(value to value lower/higher)] treated vs untreated subgroups	[value] ([value])	[to be deleted as appropriate] ⊕⊕⊕⊕ very low ⊕⊕⊕⊕ low ⊕⊕⊕⊕ moderate ⊕⊕⊕⊕ high
Adverse events	The mean [outcome] ranged across control groups from	The mean [outcome] in the intervention groups was	[value]	[to be deleted as appropriate]

Table 1. Sample GRADE 'Summary of findings' table (Continued)

[range of scale or scale description] [follow-up]	[value][measure]	[value] [lower/higher] [(value to value lower/higher)]	[(value)]	⊕⊕⊕⊕ very low ⊕⊕⊕⊕ low ⊕⊕⊕⊕ moderate ⊕⊕⊕⊕ high
Compliance rate [range of scale or scale description] [follow-up]	The mean [outcome] ranged across control groups from [value][measure]	The mean [outcome] in the intervention groups was [value] [lower/higher] [(value to value lower/higher)]	[value] [(value)]	[to be deleted as appropriate] ⊕⊕⊕⊕ very low ⊕⊕⊕⊕ low ⊕⊕⊕⊕ moderate ⊕⊕⊕⊕ high

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

BP: Blood pressure; **CI:** Confidence interval; **DBP:** Diastolic blood pressure; **OBPM:** Office-based blood pressure monitoring; **RR:** Risk ratio; **SBP:** Systolic blood pressure; **SBPM:** Self-blood pressure monitoring.

APPENDICES

Appendix 1. MEDLINE search strategy

- 1 blood pressure monitoring, ambulatory/
- 2 (blood pressur\$ adj3 (24h or 24hr? or 24-h or 24-hr? or 24 hour? or ambulatory or determin\$ or measur\$ or monitor\$ or self-measur\$ or self-monitor\$)).mp.
- 3 (bp adj3 (24h or 24hr? or 24-h or 24-hr? or 24 hour? or ambulatory or determin\$ or measur\$ or monitor\$ or self-measur\$ or self-monitor\$ or self-record\$)).tw,kf.
- 4 (abpm or sbpm).tw,kf.
- 5 or/1-4
- 6 (home\$ adj25 (base\$ or bp or blood pressur\$ or measur\$ or monitor\$)).tw,kf.
- 7 (own\$ adj5 (manag\$ or measur\$ or monitor\$ or record\$)).tw,kf.
- 8 (self\$ adj5 (manag\$ or measur\$ or monitor\$ or record\$)).tw,kf.
- 9 (m-health or mobile health or mobile healthcare).tw,kf.

10 (telemedicine or tele-medicine or telemonitor\$ or tele-monitor\$).mp.
 11 or/6-10
 12 randomized controlled trial.pt.
 13 controlled clinical trial.pt.
 14 randomi?ed.ab.
 15 placebo.ab.
 16 clinical trials as topic/
 17 randomly.ab.
 18 trial.ti.
 19 or/12-18
 20 animals/ not (humans/ and animals/)
 21 19 not 20
 22 5 and 11 and 21

Appendix 2. Data Extraction Template

Data Extraction Template

- Study year
- Country
- Setting (primary or secondary care)
- Study Design
- Population (inclusion and exclusion criteria)
 - * Total number of patients included in trial
 - * Number of patients at each trial point and completing trial
 - * Number of patients excluded and reason
- Method of BP baseline and outcome measurement
 - * Was office or ambulatory measurement used at baseline, during and at the end of trial?
 - * Was the monitor used validated?
 - * Number of readings used in the analysis
 - * Measurement criteria used
- Randomisation
 - * Number in control group and intervention group
 - * Randomisation method
 - * Stratification of groups
- Intervention data
 - * Details of training and education given to control and intervention groups
 - * Frequency and method of self-monitoring
 - * BP targets used and number of patients reaching targets
 - * Co-interventions used (e.g. tele-monitoring, lifestyle and behavioural modification, healthcare professional input)
 - * Titration of medication (? Doctor, nurse, pharmacist, patient)
 - * Frequency and timing of trial follow-up
- Comparator data
 - * Usual care-how is it defined?
 - * Was there any organised self-measurement of BP in the control group?
 - * Number of patients in control group

- Outcome data
 - * Mean systolic and diastolic BP measurements at baseline and trial endpoint
 - * Change in mean office systolic blood pressure (SBP) and/or mean office diastolic blood pressure (DBP)
 - * Change in mean systolic and diastolic ambulatory blood pressure (ABP) including overall mean, day time mean or night time mean
 - * The proportion of participants achieving target BP in each group (target as defined by each trial, or if not specified, we will use the concurrent national target)
 - * The number of patients in each arm of the study with any adverse events
 - * The number of new incidence of cardiovascular events or death
 - * Change in the number of antihypertensive medications and the dose of antihypertensive medications, from baseline to end of trial
 - * Dropout rate
 - * Rate of adherence to medication, measured using an objective tool (e.g. pharmacy fill, electronic monitoring or urine testing)
 - * Changes in health related quality of life data
 - * Left ventricular hypertrophy or LV mass, measured by echocardiography
- The primary outcome will be 12 months but outcomes will also be assessed at 6 and 18 months (if available).
- Risk of bias
 - * The Cochrane 'Risk of bias' assessment tool will be used to assess each study

WHAT'S NEW

Date	Event	Description
11 January 2021	New citation required but no major changes	The protocol has been amended to include a change in authors on the review team. The primary and secondary outcomes have been revised and changes made. The search methods, data collection and analysis sections have been amended to meet MECIR standards. Changes to the protocol reflect the latest guidance from the Cochrane Handbook, including assessment of risk of bias and GRADE assessment of the certainty of evidence.

HISTORY

Protocol first published: Issue 1, 2013

CONTRIBUTIONS OF AUTHORS

- R Doogue: drafted the updated protocol. For the review will undertake study selection, data extraction, analysis and interpretation, and draft the manuscript.
- P Hayes: contributed to the updated protocol. For the review will undertake study selection, data extraction and contribute to the manuscript.
- K Tucker: contributed to the protocol. For the review will be involved in interpretation, and contribute to the manuscript.
- T Fahey: contributed to the protocol. For the review will be involved in interpretation, and contribute to the manuscript.
- A Sheikhi: contributed to the protocol. For the review will be involved in interpretation, and contribute to the manuscript.
- C Koshiaris: contributed to the protocol. For the review will be involved in interpretation, and contribute to the manuscript.
- L G Glynn: contributed to the protocol. For the review will be involved in study selection, data extraction, interpretation, and contribute to the manuscript. Will act as guarantor for the final output.

DECLARATIONS OF INTEREST

R Doogue: None known.

P Hayes: None known.

K Tucker: None known. K Tucker has received funding for projects through the NIHR: SPCR, Programme grants and the Oxford CLAHRC for research in the area of hypertension.

T Fahey: None known.

A Sheikhi: None known.

C Koshiares: None known.

L G Glynn: None known.

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- University of Limerick, Ireland
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External sources

- University of Limerick, Education and Health Science (EHS) scholarship, Ireland
R Doogue has received an EHS scholarship