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Impact of home telemonitoring and management support on blood pressure control in non-dialysis CKD: a systematic review protocol

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ABSTRACT

Introduction Hypertension is a common public health problem and a key modifiable risk factor for cardiovascular (CV) and chronic kidney disease (CKD). Home blood pressure (BP) telemonitoring (HBPT) and management is associated with improved BP control, accelerated delivery of care and decision-making strategies that can reduce adverse outcomes associated with hypertension. The aim of this paper is to describe the protocol for a systematic review to assess the impact of HBPT interventions used for improving BP control and reducing CV and kidney outcomes in non-dialysis CKD patients.

Methods We developed this protocol using the Preferred Reporting Items for Systematic reviews and Meta-Analyses for Protocols 2015. We will search empirical databases such as MEDLINE, Embase, Cochrane Library, CINAHL, Web of Science and PsycINFO and grey literature for studies conducted in non-dialysis CKD patients on interventions using HBPT and reporting outcomes related to BP control and other outcomes such as CV events and kidney disease progression. All studies meeting these criteria, in adults and published from inception until 2020 with no language barrier will be included.

Ethics and dissemination Ethical approval will not be required for this review as the data used will be extracted from already published studies with publicly accessible data. As this study will assess the impact of HBPT on BP control in non-dialysis CKD patients, evidence gathered through it will be disseminated using traditional approaches that includes open-access peer-reviewed publication, scientific presentations and a report. We will also disseminate our findings to appropriate government agencies.

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Strengths and limitations of this study

- This study will assess the impact of home blood pressure telemonitoring on cardiovascular (CV) and kidney-related outcomes in non-dialysis chronic kidney disease (CKD) patients.
- Focus on non-dialysis CKD population is to reduce biases induced by recurrent haemodynamic changes with salt retention and volume status in CKD patients receiving dialysis, and lack of a standardised BP target in patients on dialysis.
- The key outcomes of interest include changes in blood pressure control, progression of CKD (estimated glomerular filtration rate, proteinuria criteria), hospitalisations, incident fatal and non-fatal CV events, all-cause mortality, cost effectiveness, patient-reported outcome measures and patient-reported experience measures.
- We will assess the quality of studies using a tool that incorporates assessments of risk of bias across core study domains: sampling, sampling technique and size, outcome measurement, response rate and statistical reporting.
- A potential limitation of this study could be heterogeneity and number of studies of low quality which could affect pooled estimates and our ability to conduct a meta-analysis.

INTRODUCTION

Hypertension, also known as raised or high blood pressure (BP), is a prevalent global public health problem and an important modifiable risk factor for cardiovascular disease (CVD) and chronic kidney disease (CKD). Hypertension is defined as office systolic BP (SBP) values≥140 mm Hg and/or diastolic BP (DBP) values≥90 mm Hg (table 1).[1] The prevalence of hypertension in the global adult population was estimated to be 31.1% (95% CI: 30.0% to 32.2%) in 2010, representing 1.38 billion people who were affected worldwide.[2] Notwithstanding the extensive availability of effective treatment options, BP control remains suboptimal, especially in low-income and middle-income countries for reasons that includes poor-adherence, clinical inertia and organisational failure.[2 3] A number of interventions have been targeted at improving medications adherence, as it is a major reason for poor BP control, including

Table 1 Definition and classification of hypertension (ESH)[1]

Category	SBP (mm Hg)		DBP (mm Hg)
Optimal	<120	and	<80
Normal	120–129	and/or	80–84
High normal	130–139	and/or	85–89
Grade 1 hypertension	140–159	and/or	90–99
Grade 2 hypertension	160–179	and/or	100–109
Grade 3 hypertension	≥180	and/or	≥110
Isolated systolic hypertension	≥140	and	<90
Office BP	≥140	and/or	≥90
Ambulatory BP			
Daytime (or awake) mean	≥135	and/or	≥85
Night-time (or asleep) mean	≥120	and/or	≥70
24-hour mean	≥130	and/or	≥80
Home BP mean	≥135	and/or	≥85

BP, blood pressure; DBP, diastolic blood pressure; ESH, European Society of Hypertension; SBP, systolic blood pressure.

those at physician level (eg, improving counselling and education), patient level (eg, self-monitoring of BP) and at healthcare system level (eg, support to the development of monitoring systems).[1]

Some of the major challenges with care in hypertension relates to the proportion of people who are aware (diagnosed), receiving treatment or those treated who have achieved control to target of their BP. Data from the International Society of Hypertension (ISH) screening programme (May Measurement Month (MMM)) in 2019 showed that of 1.5 million people who were screened for hypertension, 32.0% had never had a BP measurement before and 34.0% had hypertension. Of those identified to be hypertensives, 58.7% were aware, 54.7% were on treatment, 31.7% were controlled to <140/90 mm Hg and 23.3% had untreated or inadequately treated hypertension.[4] The results of previous ISH regional screening programmes for MMM support this global trend.[5 6] The low proportion of patients with hypertension who are controlled suggests a need for practical and sustainable models to improve BP control at the population level in order to reduce the excess risk of CVD and other target organ damage associated with hypertension.

Hypertension in CKD

Hypertension is a common cause of CKD and highly prevalent among patients with CKD with an increased incidence and prevalence as kidney function declines. Hypertension is present in as high as 87.5% of CKD patients compared with only 28.5% of patients in the general population.[7] The United States Renal Data System reports that hypertension is present in about 23.3% of the general population without CKD and in patients with CKD, occurs in 35.8% (stage 1), 48.1% (stage 2), 59.9% (stage 3) and 84.1% (stages 4 and 5).[8] Guideline recommendations for diagnosing, monitoring and treating hypertension in the general population and in patients with CKD are frequently revised and updated.[1 9 10] The Kidney Disease Improving Global Outcomes (KDIGO) guideline on management of BP in CKD recommends the use of lifestyle modifications and pharmacological treatments for lowering BP in non-dialysis CKD patients. These measures include individualising BP targets with the use of various BP lowering agents, achieving and maintaining a healthy weight (BMI: 20–25 kg/m^2), lowering salt intake to <2 g (<90 mmol of sodium) per day, undertaking exercise that is compatible with CV health and tolerance for at least 30 min five times per week and limiting intake of alcohol as options for BP control.[9]

BP exhibits a high level of short-term (24-hour ambulatory recordings) and long-term (office visit-to-visit) variability and both are associated with adverse outcomes independent of mean 24-hour or office-to-office BP values.[11 12] A number of studies have reported on the association between BP variability and risk CV events, progression of kidney failure or death in patients with CKD.[13–15] Although they mainly report no usefulness of short-term variability in predicting adverse events in CKD patients, they show an association with CV events and death using long-term BP variability. In one Italian study of 402 CKD patients with median follow-up of 4.8 years, although long-term BP variability was associated with composite end-point of CV event or death (HR: 1.24; 95% CI: 1.01 to 1.51 per 5 mm Hg higher systolic difference of office SBP), short-term SBP variability was not (HR: 0.92; 95% CI: 0.68 to 1.25 per 5 mm Hg higher SD of 24-hour ambulatory systolic BP).[13] In another large population-based cohort that included 225 759 Chinese hypertensive adults with median follow-up of 70.5 months, there were 25 714 CV events, 27 603 incident CKD and 16 778 deaths reported. SBP variability was continuously and positively associated with increased CV events (HR: 1.35, 95% CI: 1.30 to 1.39), incident CKD (HR: 1.39, 95% CI: 1.35 to 1.43) and mortality risk (HR: 1.40, 95% CI: 1.34 to 1.45).[16]

Home blood pressure telemonitoring (HBPT)

BP recorded out-of-office (either home BP monitoring (HBPM) or ambulatory BP monitoring (ABPM)) provide readings taken in conditions that are more representative of daily life than conventional office readings. Given that the goal of hypertension detection and treatment is to reduce mortality, and adverse CV and kidney outcomes, use of HBPM is encouraged as it is more accurate and superior to office BP monitoring (OBPM) in predicting CV events and all-cause mortality.[17 18] Also, OBPM does not always correctly identify patients with hypertension due to 'white-coat' or 'masking' effects, however, HBPM improves BP monitoring and provides more representative

BP data and better prediction of outcomes.[19] The ability to transmit, in real-time, data from HBPM device to a caregiver improve the chance of better BP control when combined to decision-making strategies can reduce adverse outcomes associated with hypertension.[20]

Home BP telemonitoring (HBPT) is based on the use of clinically validated electronic automated BP monitors storing BP values obtained at patient's home and promotes a more effective link between patients and their caregivers.[20 21] Increasingly, researchers have leveraged on telemonitoring technology for the monitoring and treatment of patients with various chronic conditions such as heart diseases,[22] respiratory diseases,[23] diabetes[24] and hypertension.[25 26]

The Telemonitoring and Self-Management in Hypertensions (TASMINH2) study has shown that self-management of hypertension is possible as most participants made at least one medication change, were confident about self-monitoring and many felt their multiple home readings were more valid than single office readings taken by their doctor.[27 28] In a subsequent study (TASMINH4), when compared with usual care, the adjusted mean SBP differences with self-monitoring was −3.5 mm Hg (95% CI: −5.8 to −1.2; p=0.0029) and −4.7 mm Hg (−7.0 to −2.4; p<0.0001)) for telemonitoring.[29] HBPT has also been shown to be cost-effective[30] and more effective in achieving BP control than usual care (RR: 1.16; 95% CI: 1.08 to 1.25; p<0.001).[31] However, when HBPT was combined with additional care (eg, counselling, education, behavioural management, etc.) and compared with HBPT alone, there were increased mean changes in SBP and DBP, suggesting that HBPT can be more efficacious when proactive additional support is provided.[31]

Other outcomes (eg, quality of life, QoL and cost) have also been evaluated. For example, in patients with kidney disease, telemonitoring has also been shown as a useful tool for improving QoL[32] and associated with reduced healthcare resource utilisation and costs in patients receiving automated peritoneal dialysis.[33] A recent systematic review and meta-analysis was conducted to evaluate the effects of telehealth on BP management in non-dialysis CKD patients.[34] From the two studies they included for meta-analysis, pooled estimates showed decreased SBP (mean difference (MD), −5.10; 95% CI: −11.34 to 1.14; p=0.11), increased DBP (MD: 0.45; 95% CI: −4.24 to 5.13; p=0.85), decreased serum creatinine (pooled MD: −0.38; 95% CI: −0.83 to 0.07; p=0.10) and maintained estimated glomerular filtration rate (eGFR) (pooled MD: 4.72; 95% CI: −1.85 to 11.29; p=0.16) in the telehealth group. However, Luo *et al*[34] used studies with telehealth interventions for BP control in only stages 3–5 CKD patients. Table 2 is a summary of the characteristics of their study design and the planned characteristics of our study.

Objective

Given that an increasing number of studies[25–29] have shown the efficacy of HBPT on hypertension control and outcomes with dearth of data for CKD, the aim of the current review is to specifically determine the impact of HBPT and management support on BP control and other prespecified CV and kidney-related outcomes in patients with non-dialysis CKD.

METHODS AND ANALYSIS

We used the Preferred Reporting Items for Systematic reviews and Meta-Analyses for Protocols 2015 (PRISMA-P 2015) to develop this protocol.[35]

Criteria for considering studies for the review

Types of studies

We plan to include all study designs including time series studies, before/after studies, observational studies, randomised controlled trials (RCTs) as well previously published reviews that evaluated telemonitoring for BP control or reports an outcome.

Types of participants

We will include studies that have participants over 18 years of age, regardless of sex and ethnicity with a diagnosis of CKD (stages 1–5, but not on dialysis and not transplanted).

Types of interventions

The intervention of interest will be the use of HBPT (with or without management support—nurses, pharmacist, physician, informed self-management of medications, health aids, exercise programmes, nutritional programmes, etc.) for BP assessment and monitoring. A telemonitoring intervention will be defined as any process or programme that involves transmission of BP records via information and communication technologies (ICT) using conduits leveraging a telephone or internet line (phones, computers, tablets, etc.). To be eligible, included studies will have reported on at least one outcome of interest. Comparators will include usual care and other interventions such as other BP device, education, counselling and behavioural management used to control BP. Studies that include only patients with CKD and no comparators will also be included if they meet other inclusion criteria.

Types of outcome assessments

The primary outcome will be any changes in mean SBP, mean DBP and/or mean arterial pressure (MAP) as well as proportion of controlled BP defined by each randomised trial's investigators. Secondary outcomes will include progression of CKD (eGFR, proteinuria criteria), hospitalisations, incident fatal and non-fatal CV events, all-cause mortality, cost effectiveness, patient-reported outcome measures and patient-reported experience measures.

Search methods for identification of studies

Electronic searches

We will electronically search the following databases: MEDLINE, Embase, Cochrane Library, CINAHL, ISI

Table 2 Comparison between a previous systematic review and this study

Features	Luo *et al*[34]	This study
Study design	Systematic review	Systematic review (with possible meta-analysis if there is sufficient homogeneity of included studies to allow this)
End of study search	2017	2020
Population	CKD (stages 3–5)	Non-dialysis CKD (stages 1–5)
Inclusion criteria		
	(1) CKD 3–5 patients over the age of 18	CKD 1–5 patients over the age of 18
	(2) Administered telemedicine to intervention groups	Will use home BP telemonitoring as intervention for BP control (including studies using additional non-telemonitoring management approaches for example, nurses, pharmacists, counselling, education or behavioural methods)
	(3) Randomised controlled trials (RCTs) or quasi-randomised controlled trials (qRCTs)	All study designs will be eligible for inclusion including time series studies, before/after studies, non-traditional comparison studies, clinical trials as well previously published reviews
	(4) Reported at least one main outcome including SBP, diastolic blood pressure (DBP) or mean arterial pressure (MAP)	Reported at least one outcome including achievement of guideline-concordant targets on BP control, progression of CKD (eGFR, proteinuria criteria), hospitalisations, cost reduction, incident CVD and quality of life (QoL)
Exclusion criteria		
	(1) Studies including patients on renal replacement therapy	CKD patient on KRT (dialysis or kidney transplantation)
	(2) Studies using additional non-telemedicine approaches such as face-to-face education or nutritional guidance in the multifactorial intervention for the intervention group	
	(3) Studies that were not reported in either English or Chinese	No language restriction
	(4) Studies with inaccessible or incomplete crucial information	Studies with inaccessible or incomplete information
Intervention	Telehealth/telemedicine	Home BP telemonitoring with or without management support (nurses, pharmacist, physician, health aids, etc.)
Comparator	Usual/standard of care	Usual/standard of care or other modes of eHealth used for comparison with HBPT
Outcome(s)	SBP, DBP, MAP, estimated glomerular filtration rate (eGFR), creatinine, blood pressure control rate	BP control (SBP, DBP, MAP), progression of CKD (eGFR, serum creatinine, proteinuria criteria), hospitalisations, incident CVD and QoL

CKD, chronic kidney disease; CVD, cardiovascular disease; DBP, diastolic blood pressure; eGFR, estimated glomerular filtration rate; HBPT, home blood pressure telemonitoring; KRT, kidney replacement therapy; SBP, systolic blood pressure.

Web of Science and PsycINFO. We will search for studies of interventions published from inception to 2020 with no language restriction and designed to compare the impact of telemonitoring of BP with management support (nurses, pharmacist, physician, health aids, etc.) compared with usual care in improving BP control and other outcomes in non-dialysis CKD patients. The search strategy will be developed after discussion among reviewers using guidance from the Cochrane handbook.[36] Using controlled vocabulary, we will adapt the MEDLINE search strategy for other databases. The search strategy for MEDLINE is shown in table 3.

Other sources

We will search the bibliographies of all relevant and selected publications for further studies and will also search grey literature using recommended resources in consultation with our medical Librarian. Thus, we will search ProQuest Dissertations and Theses Global, and Conference Proceedings Citation Index (Clarivate Analytics).

Data collection and analysis

Study selection

We will use a two-stage collaborative review process for screening and selection of studies to be included. In the first stage, two reviewers (SM and MMT) will independently assess the titles/abstracts of retrieved studies to be selected for full-text screening if conducted in a non-dialysis CKD population (stages 1–5). In the second stage, full texts, having met the above criteria will be obtained for further screening and will be included if HBPT (with or without management support—nurses, pharmacist, physician, health aids, etc.) is used as the intervention and the study reports one of the stated outcomes of interest. A third reviewer (IGO) will evaluate any discrepancies, if necessary, and will advise in case of disagreement. We will record all reasons for exclusion and exclude studies not using HBPT as the intervention to improve BP control. Figure 1 is a summary of the process that will be used for study selection. Thus, the inclusion and exclusion criteria for the study will be:

Inclusion criteria

- Studies conducted in a non-dialysis CKD population.
- Studies using HBPT (with or without management support, ie, nurses, pharmacist, physician, health aids, etc.) as the intervention.
- Studies reporting on at least one outcome measure (BP change/control, CV outcomes or CKD outcomes, patient-reported outcome measures and patient-reported experience measures).
- Studies that include only patients with CKD and no comparators will be included if they meet other inclusion criteria.
- Publication date (no restriction).
- Language restriction (none).

Exclusion criteria

- Studies reporting other forms of ehealth for hypertension control but not involving BP telemonitoring.
- Review articles, editorials, letters to the editor, commentaries, case studies, case reports, images and studies in which we are unable to get relevant data even after attempts to get these from the authors.
- Studies in which the specific outcomes of interest cannot be clearly identified or extrapolated (eg, studies reporting differences between groups but not providing information on the entire group).

Data extraction and management

Two reviewers (SM and MMT) will independently extract data and summarise the details of selected studies using a standard data extraction sheet. All extracted data will be reviewed for accuracy and completeness. The data items we will collect will include general study characteristics (eg, study type, publication year country, etc.), study design (RCT, observational, case–control study, cohort, etc.), type of intervention utilised (HBPT alone or with management support), duration of intervention, outcomes and conclusions. If more than one outcome time (eg, 12 and 24 months) is reported, the data on the longest follow-up will be extracted.

Assessment of risk of bias in included studies

Methodological quality will be evaluated using the checklist developed by Hoy *et al*[37] to assess the risk of bias in primary studies. This quality assessment tool incorporates assessments of risk of bias across core domains including sampling, the sampling technique and size, outcome measurement, response rate and statistical reporting. We will also present the overall risk of bias per study in a risk of bias summary table and we will examine for publication bias using a funnel plot. If the funnel plot is asymmetrical, we will explore possible causes including publication bias, poor methodological quality and true heterogeneity.

Measures of treatment effect

We will present the effects on BP between interventions at follow-up (SBP and DBP) according to the HBPT interventions proposed in each study. Dichotomous outcomes will be presented as risk ratios, while continuous outcomes will be presented as MD between the change in the intervention and control groups if the outcomes have been measured and reported in the same way across all studies. If the continuous outcomes have been measured in different ways across studies, then we will use the standardised MD between the intervention and control groups. We will present time-to-event outcomes as HR. We will report 95% CIs for all outcomes.

Dealing with missing data

In the case of missing or unclear data, we will contact the authors to request such information related to study methods, attrition rates and outcomes. Where possible, we will calculate missing data using available relevant information including imputing data, where appropriate.

Table 3 MEDLINE search terms and strategy

#	Search term	#	Search term
1	exp Hypertension/	34	(consult* and (skype or facetime or internet)).mp.
2	hypertens*.mp.	35	((distan* or remote* or video*) adj2 (consult* or deliver* or diagnos*)).mp.
3	exp Blood Pressure/	36	ehealth*.mp.
4	blood pressure*.mp	37	tele care.mp.
5	arter* pressure*.mp.	38	tele collaborat*.mp.
6	venous pressure*.mp.	39	tele consult*.mp.
7	vein pressure*.mp.	40	tele conference*.mp.
8	exp Blood Pressure Determination/	41	tele health.mp.
9	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8	42	tele guide*.mp.
10	exp Renal Insufficiency, Chronic/	43	tele diagnos*.mp.
11	Chronic Kidney disease*.mp.	44	tele med*.mp.
12	chronic kidney insufficienc*.mp.	45	tele monitor*.mp.
13	chronic renal disease*.mp.	46	tele presence*.mp.
14	chronic renal insufficienc*.mp.	47	tele robotic*.mp.
15	CKD.mp.	48	tele screen*.mp.
16	Renal fail*.mp.	49	tele transmi*.mp.
17	Kidney fail*.mp.	50	(teletherap* not (x-ray or radiat* or cobalt or gamma* or cesium)).mp.
18	10 or 11 or 12 or 13 or 14 or 15 or 16 or 17	51	telemetry/
19	exp Telemedicine/	52	telemetry.mp.
20	telecare.mp.	53	Telemetries.mp.
21	telecollaborat*.mp.	54	telenurs*.mp.
22	teleconsult*.mp.	55	telephone/
23	teleconference*.mp.	56	Telephon*.mp.
24	telehealth.mp.	57	smartphone/
25	teleguide*.mp.	58	smartphone*.mp.
26	telediagnos*.mp.	59	Cell phone/
27	telemed*.mp.	60	cellphone*.mp
28	telemonitor*.mp	61	cell* phone*.mp
29	telepresence*.mp.	62	internet/
30	telerehab*.mp.	63	internet*.mp.
31	telerobotic*.mp.	64	or/19–63
32	telescreen*.mp.	65	nine and 18 and 64
33	teletransmi*.mp.		

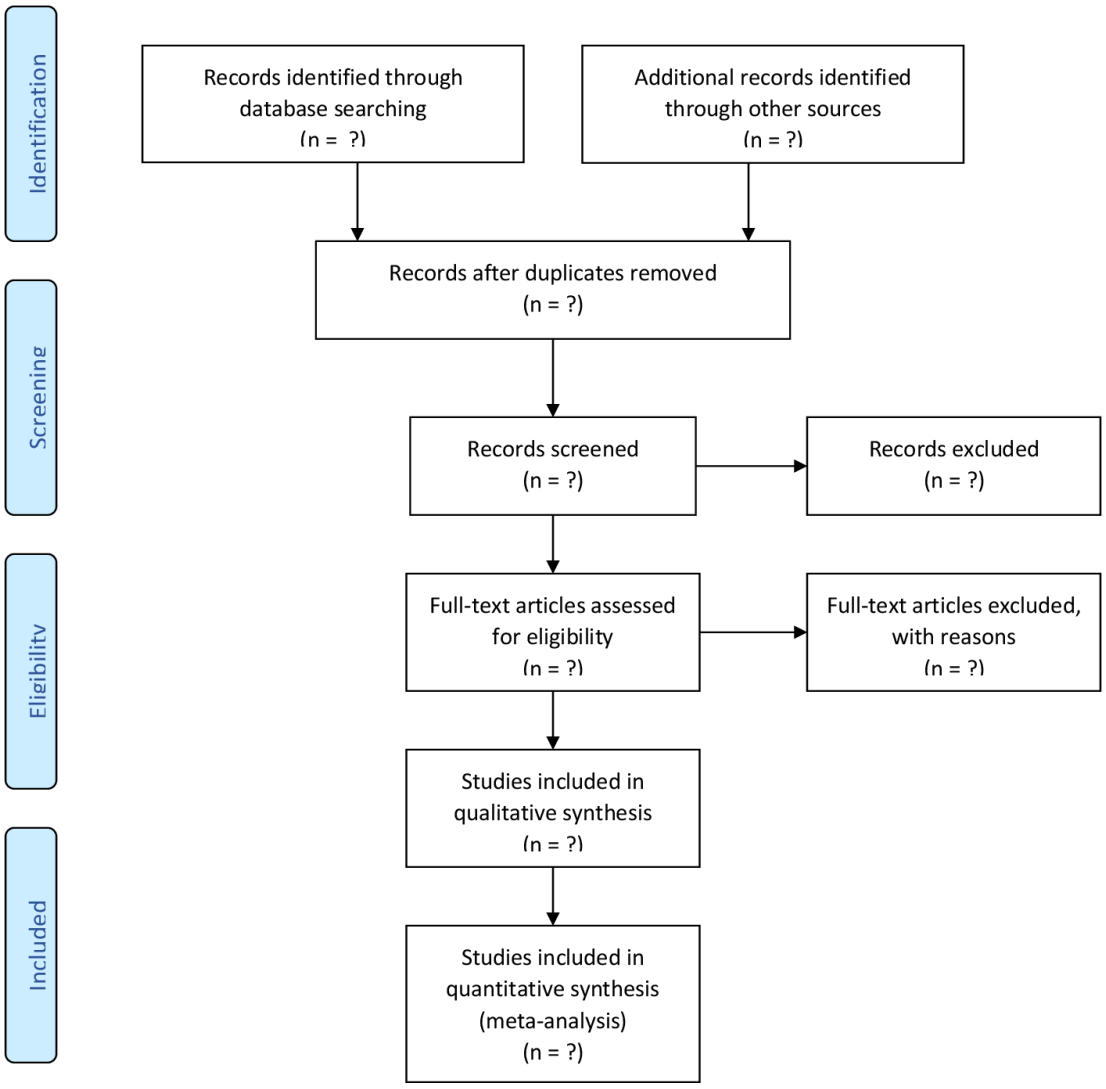

Figure 1 PRISMA flow chart for process of study selection. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

All missing outcome data will also be reported in the data extraction form and risk of bias table.

Assessment of heterogeneity

We will assess heterogeneity among studies in relation to participant characteristics (diabetic CKD and others), intervention type (HBPT alone or HBPT plus management), duration and outcome (BP control, CKD progression, death or QoL). We will test statistical heterogeneity using the χ^2 test (considering a value of $p<0.1$ to indicate heterogeneity) and estimate the amount of heterogeneity using the I^2 statistic (I^2 values of <25%, 25%–50% and >50% represent low, medium and high heterogeneity, respectively).[36] We will assess reasons for heterogeneity through subgroup analysis.

Data synthesis

We will summarise the characteristics of included studies in a table and we will assess if there is possibility to conduct a meta-analysis. If the characteristics of included studies are excessively heterogeneous, we will not pool results, but we will only present a narrative synthesis of the results of group findings by context measures. If a meta-analysis is conducted, intervention effects will be calculated as relative risks (RR) with 95% CIs for dichotomous data and we will calculate MD with 95% CIs for continuous variables. Whether a fixed-effects model or a random-effects model will be used depends on the results of the χ^2 test and I^2 test for heterogeneity. If there is substantial statistical heterogeneity, we will adopt a random-effects model, whereas a fixed-effects model will be used if there is no substantial statistical heterogeneity ($I^2<50\%$).

Subgroup analysis

Subgroup analysis will be considered according to the following variables: age, gender, CKD stage, study setting (rural vs urban or low-income and middle-income vs high-income using the World Bank country classifications by income level)[38] study duration (<6 months vs >6 months) and hypertension status (controlled vs uncontrolled).

Patient and public involvement

Patients and the public will not be involved in this study.

Ethics and dissemination

Ethical approval will not be needed for this study as data used will be extracted from already published studies. Our dissemination strategy will use traditional approaches, including open-access peer-reviewed publication(s), scientific presentations and a report.

DISCUSSION

Hypertension is the leading prognostic marker for risk of adverse health outcomes in patients with CKD, and effective BP control to mitigate this risk remains a challenge. There is limited data on the use of HBPT for assessing and monitoring BP control in patients with CKD. This work will therefore provide new information on the potential role of HBPT in the management of hypertension and reducing adverse health outcomes in comparison with usual care. As telehealth practices and telemonitoring technologies continue to evolve worldwide, this study will demonstrate the impact of HBPT for hypertension monitoring and control as well as its impact on fatal and non-fatal CV events, progression of kidney function, QoL and death in non-dialysis CKD patients. Strengths and limitations of this study will be highlighted in the process of identified evidence.

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Contributors IGO and AKB conceived the study design. The first version of the protocol was drafted by IGO and AKB, and was revised by SM, MMT, DZ, LNH, BB, KJ, SK, RSP, SS and ST. The search strategy was developed and performed by LNH. SM, MMT and DZ will perform the screening, study selection and collect data from all included studies. All authors drafted and critically reviewed this manuscript and approved the final version.

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Competing interests RSP is CEO of mmHg, a digital health company creating guideline-concordant innovations to improve the efficiency of remote patient monitoring. All other authors declare no conflict of interest.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication Not required.

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