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Web-based interventions to improve blood pressure control in patients with hypertension: a protocol for a systematic review

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ABSTRACT

Introduction Hypertension is the major cause of cardiovascular disease and mortality in the world. Blood pressure control (BPC) is recognised as a key measure in the management of hypertension. Several studies have been conducted assessing the impact of specific web-based interventions in improving BPC. Our systematic review intends to identify all the available web-based interventions and determine if and which are more effective than usual care in improving BPC.

Methods and analysis We will include randomised control trials completed until April 2023 including patients diagnosed with hypertension comparing the effect of receiving usual care versus web-based interventions in BPC. No language restriction will be applied. We will start with an extensive electronic database search, in the Cochrane Central Register of Controlled Trials, PubMed, Embase, Scopus, EU Clinical Trials Register, Pan-African Clinical Trials Registry and ClinicalTrials.gov. Eligibility criteria will be applied blindly and independently by two researchers to the title and abstract of the references, in the first stage, and to the full version of the ones selected. All divergences will be solved by a third researcher. We will conduct a narrative description and meta-analysis (if adequate) of the results of the included studies, structured according to the type of intervention, characteristics of the population and outcome measurement. We will extract features of the web-based interventions, selecting the ones with the best outcomes regarding BPC, to later propose an ideal web-based intervention to improve BPC in hypertensive patients and/or guide future research on this topic. The risk of bias will be assessed using Cochrane's RoB2 Tool.

Ethics and dissemination Ethical approval is not required since this is a protocol for a systematic review. The findings of this study will be disseminated through peer-reviewed publications and national or international conference presentations. Updates of the review will be conducted, as necessary.

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STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This article is a systematic review comparing the efficacy of usual care with web-based interventions in patients with hypertension.
⇒ This protocol follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses-P guidelines for reporting protocols of systematic reviews and meta-analysis, meeting the highest scientific quality standards.
⇒ We anticipate a shortage of randomised controlled trials, potentially limiting the interpretation of results.
⇒ Seven different databases will be searched to ensure that the number of studies included is the largest possible.
⇒ Since the search strategy is very broad, the heterogeneity of the studies might be very high.

INTRODUCTION

Hypertension is the major cause of cardiovascular disease and mortality worldwide.[1–3] This condition is responsible for 10.4 million deaths per year[2] and is now considered the major cardiovascular risk factor.[4 5] Hypertension is defined as office systolic blood pressure values ≥140 mm Hg and/or diastolic blood pressure values ≥90 mm Hg or equivalents. Equivalents can be home blood pressure monitoring (HBPM) ≥135/85 mm Hg or ambulatory blood pressure monitoring ≥130/80 mm Hg over 24 hours, with a daytime average of ≥135/85 mm Hg and a night-time average of ≥120/70 mm Hg.[6]

The epidemiology, pathophysiology and associated risk of hypertension are now widely known and it is demonstrated that lowering blood pressure can substantially reduce premature morbidity and mortality.[6–10] However, besides the fact that studies show high effectiveness in several strategies to control blood pressure,[5 6 10] the proportion of people with hypertension diagnosis and controlled blood pressure is still very low.[11–14] In a study addressing this topic, published in 2021, only 58.7% of the patients with diagnosed hypertension were aware of their

condition and, of those, 54.7% were medicated with at least one anti-hypertensive drug. Despite the wide variety of drugs available, only 57.8% of the medicated patients had their blood pressure under control.[13]

One of the described major barriers to improve blood pressure control (BPC) is poor adherence to therapy,[5 15] although it has been shown an increase in the quality of life[16] and a decrease of cardiovascular risk in patients with controlled blood pressure and high adherence to therapy.[15 17]

BPC can be improved using various tools, one of which is a daily HBPM.[1 18–20] Self-monitoring of blood pressure also helps decision making by healthcare providers.[6 20] Nevertheless, home self-monitoring of blood pressure faces problems in its practical implementation as, for example, blood pressure values handwritten by patients are often inaccurate or underreporting data leading to significant discrepancies compared with readings performed by healthcare professionals.[21 22] A recent meta-analysis provided evidence that the intensity of co-interventions (ie, additional support) added to self-monitoring of blood pressure (BP) leads to clinically significant BP reduction. Intensive co-interventions included telemonitoring and pharmacist management and web-based pharmacist management.[23] To overcome these limitations, research has been conducted assessing the effect of web-based interventions in BPC.[19 24]

For the above-mentioned reasons, we developed a protocol for a systematic review with meta-analysis having as the primary objective to conclude if web-based interventions have greater benefits than usual care in improving BPC in patients with hypertension and to identify the intervention with the most successful outcomes. As secondary outcomes, we aimed to understand if web-based interventions also have an impact on improving adherence to pharmacological therapy and quality of life in patients with hypertension.

METHODS

The date of commencement will be April 2023 and we predict this systematic review will last 12 months.

Study selection

We will have the following selection criteria: (1) Type of study: published or unpublished randomised controlled trials (RCTs), (2) Population: adults with diagnosed hypertension[6 25] or taking at least one medication for hypertension at the beginning of the study, non-regarding race, ethnicity or co-morbidity, (3) Intervention: web-based interventions, (4) Comparison: usual care and (5) Outcome: BPC. There will be no restrictions regarding date and language.

Studies will be excluded if they aim to prevent hypertension and/or if they are performed in hospitalised patients. Regarding the setting of the study, we will include studies that are performed in ambulatory, either from public or private hospitals and clinics, and either from hospital appointments or primary care.

We will consider as a web-based intervention any intervention using the internet to facilitate the dissemination of health-related information and to connect patients to healthcare support. These can include interventions involving medical devices (such as electronic monitorisation of medication, packaging with alarms, equipment to measure blood pressure at home or telehealth devices) as well as communication and information technologies (such as computers, telephones, cell phones, email or text messages).

Our primary outcome will be BPC in patients with hypertension, measuring the blood pressure changes in mm Hg. We will also consider two secondary outcomes: adherence to pharmacological therapy measured through 1–6 questionaries, pill count, electronic monitoring devices, biochemical urine analysis and algorithms; and quality of life in patients with hypertension, measured through validated questionaries, usually 0–100 scores and Likert scale.

Search methods and identification of studies

We will conduct electronic searches in the Cochrane Central Register of Controlled Trials, PubMed, Embase, Scopus, EU Clinical Trials Register, Pan-African Clinical Trials Registry and ClinicalTrials.gov. We will search the databases for studies published from inception to April 2023. The search strategy was deliberately broad favouring sensitivity.

The search strategy for Pubmed is presented in table 1.

Reference lists of all included studies will be hand-searched for additional records. Additionally, we will search for studies citing included studies and examine reference lists from key reviews to identify additional studies potentially not found in the electronic search.

For registered RCTs that were not published, we will contact the authors to ask for further information about the reason for not proceeding with publication and inquire if the results were presented in any form and can be shared.

The research team will sort the articles independently and blindly, identifying the ones that fit the inclusion criteria using the online tool Rayyan QCRI.[22] This process will be conducted in two phases: first, two of the researchers will run a pilot with 30 references applying the inclusion and exclusion criteria; then, they will apply the criteria to the titles and abstracts of the identified references and, second, we will apply them to the full-paper version of the references selected in the first phase. We will do a double screening to identify duplicates, first with a reference manager and after in Ryyan QCRI.[26] Any disagreement between the pair of reviewers over the eligibility of a particular study will be sorted by a third author. Reasons for exclusion and amount of disagreement will be registered.

Data extraction

Two researchers from the review team will extract data blindly and independently using a pre-specified form.

Table 1 Search strategy for PubMed

Population	(Hypertension[MeSH Terms] OR Hyperten*[Title/Abstract] OR (Blood Pressure[Title/Abstract] AND (High[Title/Abstract] OR Elevated[Title/Abstract] OR Uncontrolled[Title/Abstract] OR Marked[Title/Abstract] OR Essential[Title/Abstract] OR Escalated[Title/Abstract] OR Persistent[Title/Abstract] OR Abnormal[Title/Abstract])))
Intervention	(Mobile Applications[MeSH Terms] OR ((Mobile[Title/Abstract] OR Portable[Title/Abstract]) AND (Application*[Title/Abstract] OR Software[Title/Abstract] OR Electronic[Title/Abstract])) OR Multimed*[Text Word] OR Multimedia[MeSH Terms] OR Internet[Text Word] OR Internet[MeSH Terms] OR Email[Text Word] OR Web[Text Word] OR Cyberspace[Text Word] OR Online[Text Word] OR Multimedia[Text Word] OR Cell Phone[Text Word] OR Smart Phone[Text Word] OR Digital[Text Word] OR Computer[Text Word] OR Educational Technology[MeSH Terms] OR (Instruction[Title/Abstract] AND Tech*[Title/Abstract]) OR telemedicine[MeSH Terms] OR mobile[Title/Abstract] OR mHealth[Title/Abstract] OR telehealth[Title/Abstract] OR eHealth[Title/Abstract])
Types of study	(Randomized Controlled Trial[Publication Type] OR Controlled Clinical Trial[Publication Type] OR Randomized[Title/Abstract] OR Placebo[Title/Abstract] OR Drug Therapy[MeSH Subheading] OR Randomly[Title/Abstract] OR Trial[Title/Abstract] OR Groups[Title/Abstract]) NOT (Animals[MeSH Terms] NOT Humans[MeSH Terms]) AND (usual[Text Word] OR common[Text Word] OR traditional[Text Word] OR standard[Text Word])

The search strategies to the remaining databases were modified as necessary and can be found in online supplemental appendix 1.

Discrepancies will be solved by a third researcher. We will contact the authors every time there is critical information missing from the report.

Data will be extracted according to the following domains: (1) Study identification: title, publication year, study location, language and authors; (2) Population characteristics: setting; demographic and clinical characteristics (such as sex, race and anti-hypertension drugs prescribed, geographic location, socio-economic status, highest education level achieved, comorbidities) and hypertension diagnostic criteria; (3) Intervention characteristics: type and description of web-based intervention; frequency and duration of web-based intervention and follow-up; (4) Outcome: primary and secondary definitions; (5) Study results: the number of participants in each group; the number of lost to follow-up, results in each group; crude and/or adjusted association measures with respective 95% CI or p values.

Quality assessment

The assessment of the risk of bias will be made by two authors, independently, using the risk assessment tool in Cochrane ROB 2,[27] that considers the following domains: sequence generation, allocation concealment, blinding, outcome assessment, incomplete outcome data, selective outcome reporting and other sources of bias. Each item can be considered as high risk of bias, low risk of bias or unclear. This assessment will be conducted independently and blindly by two authors. Disagreements will be sorted by a third author.

The grade of evidence will be assessed using the Grading of Recommendations Assessment, Development and Evaluation approach.[28]

Data synthesis and statistical analysis

A narrative synthesis will be conducted for all included studies, structured according to population, type of intervention, results, effects risk of bias and conclusions. We will present effect measures of each study. If the search retrieves at least three studies, with low risk of bias (defined as having at least 4 out of the 7 items of RoB scored as low risk of bias), using a similar intervention in the same context and measuring primary or secondary outcomes with the same method, we will proceed for meta-analysis.

We will use a random-effects model for our meta-analysis since it is expected that the RCTs to be included in our study will be performed in populations with different characteristics. Heterogeneity between the studies will be quantified through the Q test and I2 heterogeneity index, where a value of 0%–40% will be considered unimportant heterogeneity, 30%–60% moderate, 50%–90% substantial and 75%–100% considerable. Additionally, the presence of publication bias will be evaluated using the funnel plot.

We expect to find mean differences for most of the effect measures of the studies. The analysis will be performed for all variables and results will be presented with a 95% CI. Standardised mean differences will be used as a measure of pooled results for each outcome.

Patient and public involvement statement

None.

Ethics and dissemination

Ethical approval is not required since this is a protocol for a systematic review. The findings of this study will be disseminated through peer-reviewed publications and national or international conference presentations. Updates of the review will be conducted, as necessary.

DISCUSSION

Summary

In this systematic review, we aim to assess whether web-based interventions have greater benefits than usual care in improving BPC in patients with hypertension. As hypertension becomes more prevalent worldwide, and its control remains very poor, these results will provide support to physicians when deciding which type of care they shall offer their patients.

This study will not only compare usual care with web-based interventions, but from its results, we will be able

to provide information about the type of web-based intervention with the best outcomes in hypertension control, analysing the RCTs with best hypertension control and best feasibility. From the type and description of the interventions used, we will analyse the ones with the best outcomes; and we will do the same for the duration of the intervention and the follow-up. This will provide physicians with valuable information and guidance on how to use these web-based interventions and which type of intervention to use.

Strengths and limitations

With this review, we expect to give a new perspective on the approach to hypertension and hope it will have a very positive impact on its control. Following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses-P guidelines for reporting protocols of systematic reviews and meta-analysis, we expect to meet the highest scientific quality.

We are searching several databases to guarantee that the largest possible number of studies meeting our inclusion criteria are included in the review, strengthening our results by minimising the risk of publication bias.

Nevertheless, since web-based interventions are still a new research topic, we anticipate a shortage of RCTs, and this might potentially limit the interpretation of results. Anticipating this, the search strategy is deliberately broad to gather all eligible studies. However, despite being a positive point, this may also lead to higher heterogeneity between study populations and constituting a potential limitation to our protocol.

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Competing interests None declared.

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