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A systematic review of mobile health technologies to support self-management of concurrent diabetes and hypertension

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ABSTRACT

Objective: This article reports results from a systematic literature review of the current state of mobile health (mHealth) technologies that have potential to support self-management for people with diabetes and hypertension. The review aims to (a) characterize mHealth technologies used or described in the mHealth literature and (b) summarize their effects on self-management for people with diabetes and hypertension from the clinical and technical standpoints.

Materials and Methods: A systematic literature review was conducted following PRISMA guidelines. Online databases were searched in September 2018 to identify eligible studies for review that were published since 2007, the start of the smartphone era. Data were extracted from included studies based on the PICOS framework.

Results: Of the 11 studies included for in-depth review, five were clinical research examining patient health outcomes and six were technology-focused studies examining users' experiences with mHealth technologies under development. The most frequently used mHealth technology features involved self-management support (n = 11), followed by decision support (n = 6) and shared decision-making (n = 6). Most clinical studies reported benefits associated with mHealth interventions. These included reported improvements in objectively measured patient health outcomes (n = 3) and perceptual or behavioral outcomes (n = 4).

Discussion: Although most studies reported promising results in terms of the effects of mHealth interventions on patient health outcomes and experience, the strength of evidence was limited by the study designs.

Conclusion: More randomized clinical trials are needed to examine the promise and limitations of mHealth technologies as assistive tools to facilitate the self-management of highly prevalent comorbid of chronic conditions such as diabetes and hypertension.

INTRODUCTION

Chronic diseases such as heart disease, cancer, and diabetes are permanent, leave residual disability, and require long periods of supervision, observation, and care.[1,2] About 42% of the overall population of American adults and 81% of those 65 years old or older had two or more concurrent chronic conditions (i.e., multiple chronic conditions, or MCC) as of 2014.[3] Among prevalent chronic diseases, diabetes and hypertension often develop together because they are highly related pathogenetically.[4] In 2015, two thirds of diabetic patients had hypertension[5] and 33.1% of all Medicaid and Medicare beneficiaries had both conditions.[6] The negative synergy of this dyad precipitates significant microvascular (e.g., kidney diseases) and macrovascular (e.g., myocardial infarction, stroke) complications that may result in the need for dialysis or limb amputation.[5,7] Research evidence shows that people with MCC, such as those with diabetes and hypertension, use more health services (e.g., emergency and clinic visits, hospitalization, prescriptions), have more medical expenditures, and experience greater difficulties with activities of daily living (e.g., bathing, dressing, eating) and other social and cognitive functions (e.g., participating in social or family activities) compared to those with a single condition.[3,8]

Mobile health (mHealth) technology is defined as wireless devices and sensors intended to be worn, carried, or accessed by patients or health care providers for monitoring health status or improving health outcomes.[9] Given the increasing penetration rate of smartphones—81% of American adults owned a smartphone as of 2019,[10] which is a dramatic increase from 35% in 2011[11]—advanced mHealth technologies implemented in smartphones such as Bluetooth, motion-detecting sensors (e.g., accelerometer, gyroscope), global positioning system (GPS), and software applications (apps) have great potential to deliver health care services customized for

individuals in terms of timing, location, and needs. In the marketplace, more than 318,000 mHealth apps are available for download,[12] many of which have been developed for patients with prevalent chronic conditions such as diabetes and hypertension.[13] In the Google Play Store, for example, 241 apps for diabetes and 208 apps for hypertension were identified as of 2019.[14] Although the efficacy of mHealth interventions reported in the literature has been inconclusive, many studies have reported promising results of mHealth interventions in improving patient outcomes such as body measures (e.g., weight, waist circumference), metabolic and physiological measures (e.g., blood pressure, glucose), adherence to and safe use of medications, physical activity, diet management, and awareness of health conditions and treatment options.[15-17]

Previous reviews, however, focused mainly on mHealth interventions for a single condition (e.g., diabetes, weight loss, asthma)[18-20] or dealt with a group of diseases individually (e.g., respiratory disease, diabetes, hypertension),[13,17] not MCC. To address this gap in the literature, we systematically reviewed articles that used or developed mHealth technologies, or both, as an assistive tool to support self-management of MCC with a focus on diabetes and hypertension. In particular, we included both clinical studies that examined the effect of mHealth technology on patient outcomes (e.g., biomarkers, perceptions, behaviors) and nonclinical user studies focusing on the development and testing of mHealth technologies for diabetes and hypertension. The included articles, therefore, used different study designs such as randomized trials, cohort studies, and case reports that used or developed mHealth technologies, or both, for patients with both diabetes and hypertension. The goal of this systematic review is to advance our understanding of currently available mHealth technologies for diabetes and hypertension and the potential and limitations of mHealth interventions to improve various

aspects of patient outcomes. To our knowledge, this is the first systematic review of the efficacy of mHealth interventions targeting diabetes and hypertension.

MATERIALS AND METHODS

Literature search strategy and screening process

We developed a study protocol in compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[21] Eligibility criteria for publications were (a) original research articles published in peer-reviewed journals or conference proceedings; (b) reported findings from a study that developed or used mHealth technology, or both, to support patients' self-management of both diabetes and hypertension; (c) written in English; and (d) published in or after 2007, the year when the first smartphone, the iPhone, was introduced, after which mHealth apps could be developed. We excluded articles that (a) only focused on one condition, (b) broadly discussed chronic conditions without focusing on both diabetes and hypertension, or (c) covered both diseases yet ignored mHealth technology as an assistive tool in the interventions.

Based on Medical Subject Headings[22] and literature browsing, we identified two groups of search terms to retrieve an exhaustive collection of relevant articles meeting the eligibility criteria: (a) disease-related terms (e.g., diabetes, diabetics, hypertension, high blood pressure) and (b) mHealth technology-related terms (e.g., mobile health application, mHealth, smartphone). We searched five electronic databases (PubMed, Web of Science, ScienceDirect, Association for Computing Machinery Digital Library, and Institute of Electrical and Electronics Engineering Xplore Digital Library) and scanned reference lists of articles (for more details on search queries and results by database, see Supplementary Material). The last search was run on September 17, 2018. Two members of the review team, which included all authors of this paper,

screened the titles and abstracts of the retrieved articles to evaluate their relevance to the present review. When an article's relevance could not be determined by its title and abstract, the full text was reviewed by the two reviewers.

Data collection and analysis

Overall, relevant articles were recorded on a data extraction form based on the PICOS criteria. Specifically, the participant (P) criterion focused on describing the characteristics of the participants in each study (e.g., target audience, age); the intervention (I) criterion involved analyzing the procedure of clinical interventions and the types of mHealth technology features used in the studies; the comparator (C) criterion focused on identifying the subgroups of participants that were compared to evaluate the effects of interventions in each study (e.g., same group before and after a given intervention, similar groups with and without intervention); the outcome (O) criterion analyzed the effects of the interventions on self-management and treatment of diabetes and hypertension; and the study design (S) criterion described the methodological characteristics of the studies. A risk-of-bias assessment was completed for the clinical studies (n = 5), consisting of randomized controlled trials (RCTs), pre–post evaluation studies, and cohort studies, using the Cochrane Collaboration's tool for assessing risk of bias.[23] Review Manager 5.3[24] was used to record and generate a risk-of-bias graph.

The mHealth technology features implemented in the included studies were categorized into three groups based on an existing design framework for mHealth apps targeting chronic conditions[25]: (a) self-management module enabling patients to record their biomarkers (e.g., blood pressure, glucose) and other helpful activities (e.g., diet management, physical activities, medication adherence) and receive credible information about their health conditions (e.g., symptoms, treatment options); (b) decision support module helping patients assess their progress

and current status regarding self-management and detect abnormal or urgent situations requiring their providers' special attention (e.g., feedback on readings, alerting system); and (c) shared decision-making module allowing patients to share their data with clinicians and choose optimal treatment options together (e.g., data repository and transmission, connection with electronic health report systems, summary reports on trends of patients' conditions and self-management activities over time).

Two reviewers analyzed included articles to identify relevant information for the PICOS criteria. The other three authors addressed a subset of the criteria based on their expertise: One focused on analyzing the characteristics of the participants and design of the included studies; another analyzed the clinical aspects of the interventions and associated outcomes; and the other focused on the technical specifications of the mHealth technologies and associated outcomes. An online spreadsheet was shared among all authors to store information extracted from eligible publications. Disagreements were resolved by discussion among the relevant review authors (a subset or all of the authors).

RESULTS

Our search yielded 657 publications. After removing duplicates, 366 unique publications were identified. Of the 366 publications whose titles and abstracts were reviewed, 12 were identified as eligible for full-text review. Two additional publications meeting the eligibility criteria were identified from the references of the 12 full-text publications reviewed. Of the 14 publications, four were excluded due to not meeting the following criteria: One did not involve both diabetes and hypertension; two other studies did not involve the patient–mHealth technology interaction; and the other was not an original research paper—it was a review paper. Of the 10 eligible publications, one reported two distinct studies (phases I and II; see Logan,

2007, in the online Supplementary Material), resulting in 11 studies to be analyzed (see Figure 1 for the PRISMA flow diagram describing the overall search and selection process). Overall, five of the 11 included studies (45.5%) were clinical intervention studies focused mainly on examining the effects of mHealth technologies on health outcomes,[26-30] whereas the remaining six studies (54.5%) were user studies focused on the development and usability testing of mHealth technology under investigation.[31-36] We included both clinical and nonclinical types to understand the overall scope of mHealth-based studies in this field. More specifically, we aimed to survey currently available mHealth technologies used to deliver interventions to the target audience in clinical studies and technologies under development.

[Figure 1 goes here]

Characteristics of included studies

Of the 11 included studies, seven (63.6%)[26-28,31,33,34,36] were published in or after 2012; the remaining four (36.4%)[29,30,32,35] were published between 2007 and 2009. The majority of the studies were conducted in North America (*n* = 8; 72.7%)[26-28,30-32,34,36], followed by Asia (*n* = 1; 9.1%)[33] and Europe (*n* = 1; 9.1%)[29]; one report (*n* = 1; 9.1%)[35] did not specify the location of the study. Eight of the 11 studies (72.7%)[26-28,30,32-34,36] were published in peer-reviewed journals and three (27.3%)[29,31,35] were published in peer-reviewed conference proceedings (report characteristics are summarized in the online Supplementary Material).

Five studies (45.5%)[30,32,34-36] had a sample size smaller than 50; two (18.2%)[28,33] had a sample of 50–100; and four (36.4%)[26,27,29,31] had a sample size larger than 100. The ages of the participants ranged from 45 to 70 years old. Two (18.2%)[28,30] used a pre–post study design; two (18.2%)[27,29] were RCTs; one (9.1%)[26] was a retrospective cohort study;

five (45.5%)[31,33-36] were usability studies; and one (9.1%)[32] focused on gathering users' requirements for the app under development. In terms of interventions, three studies (27.3%)[27, 29,30] asked patients to take biomarkers (e.g., blood pressure, glucose) by themselves on a regular basis and two (18.2%)[26,28] delivered educational interventions to patients using mHealth technology. The six technology-focused user studies (50%)[31-36] did not involve an intervention. The duration of the interventions implemented in the clinical studies ranged from 3 to 20 months (study characteristics are summarized in the Supplementary Material).

mHealth technologies for self-management interventions targeting diabetes and hypertension

In terms of technology types used, three studies (27.3%)[31,35,36] used mHealth apps designed for mobile devices, especially smartphones; four (36.4%)[26,27,29,34] used generic mobile phone functions such as calling, texting, or reading a QR code; five (45.5%)[28,29,31,34,36] used web interfaces for visualization and sharing of patient data with providers; and five (45.5%)[27,29,30,32,35] incorporated Bluetooth-enabled devices for reading biomarkers such as blood pressure and glucose.

Features supporting patients' self-management

All of the 11 studies (100%)[26-36] used self-management-related features as follows. A reminder feature helped patients adhere to prescribed medications and encouraged them to enter data into the system. A data entry feature allowed users to log different types of data such as medical indicators (e.g., blood pressure, glucose), diet (e.g., nutrition information, calories), and physical activities (type and duration of exercise). A feedback feature generated feedback messages to inform users about their progress in the self-management of their chronic conditions. An education feature provided educational content to improve patients' understanding of their

conditions in general and address potential questions patients might have regarding the medications they were taking, new symptoms they had, and how to manage them.

Features supporting clinical decision

Six (54.5%) studies[29-32,34,36] used clinical decision support features, such as an assessment feature that interpreted readings based on guidelines and thresholds for important biomarkers such as blood pressure and an alerting feature that triggered messages requesting additional readings if the input exceeded threshold values and indicating the urgency of setting up an appointment with their physician if the readings remained persistently elevated or low.

Features supporting shared decision-making support

Six (54.5%) studies[29-32,34,36] used shared decision-making support features, such as a summary report feature that enabled patients and providers to share data using the data-entry feature and a communication feature that facilitated scheduling an office visit and exchanging messages to provide encouragement and suggestions to patients and answer questions.

Outcomes

Effects of mHealth-supported interventions on health outcomes

We identified six clinical interventions studies[26-31] as eligible for inclusion in the effectiveness analysis. Because the study designs, participants, interventions, and reported outcome measures varied markedly, we focused on describing the results of the studies and performing qualitative synthesis rather than meta-analysis. Overall, the clinical intervention studies that measured biomarkers (n = 3)[27,29,30] reported promising results. The reported effects included significant reductions in systolic blood pressure,[27,29] blood pressure in general,[30] and episodes of 24-hour ambulatory blood pressure.[30] Only one study[29] reported a statistically nonsignificant difference in diastolic blood pressure in the intervention

group (i.e., pre- and posttest evaluations) or between the intervention and control groups; this study also reported that the intervention did not have a significant effect on glucose level (HbA1c). In terms of behavioral and perceptual outcomes, three studies[26,28,30] reported that the intervention groups had a higher rate of adherence to the medication or measurement schedule and a lower rate of discontinuation. One study,[27] however, reported some adverse effects: The intervention group's depression worsened after the intervention program and was significantly worse than that of the control group.

A risk-of-bias assessment of these results[23] identified different domains of bias that could have decreased the validity of the studies. As presented in Figure 2, the unrandomized nature of sample selection and unconcealed allocation procedure were the main sources of bias risk in the clinical studies included. For more details about the assessments of risk of bias in individual studies, see the Supplementary Material.

[Figure 2 goes here]

User feedback on mHealth technology under investigation

The studies that examined patients' experiences with the mHealth technologies under investigation (n = 9; 81.8%)[29-36] reported that the usability and acceptability of the systems were generally high. Findings regarding areas for improvement included connectivity issues between medical devices and mobile terminals,[29,35] lack of compatibility and interoperability of the system with different mobile operating systems and terminals,[29] lack of integration with health electronic health records,[35] and low visibility of the content due to the small screens of mobile devices.[30,34] The PICOS classification of the included studies is provided in Table 1.

Table 1. Characteristics of the included studies (n = 12)

PICOS Category	Code	Description (Examples)	*n*	%
Participants				
Age	65+ years old	Mean age reported ≥ 65	2	18.2
	50–64 years old	Mean age reported = 50–64	6	54.5
	Unknown	Mean age not reported.	3	33.3
Sample size	1–49	Number of participants < 50	5	45.5
	50–99	Number of participants = 50–99	2	18.2
	100+	Number of participants ≥ 100	4	41.7
Interventions				
Procedure	Self-monitoring	Patients read and recorded biomarkers (e.g., blood pressure) by themselves	3	27.3
	Knowledge	Educational contents were delivered to patients	2	18.2
Duration	1–6 months	Intervention lasted for 1–6 months	3	27.3
	7–12 months	Intervention lasted for 7–12 months	2	18.2
Technologies used or tested	Self-management	Features allowing patients to monitor their disease progress and be better informed about their chronic health conditions and their symptoms and available treatments (e.g., reminder, data entry, educational content)	11	100.0
	Decision support	Features allowing patients assess their progress in the self-management (e.g., summary report, alerting system)	6	54.5
	Shared decision-making	Features allowing patients to share data with clinicians and choose ideal treatment together (e.g., data repository and transmission, connection with electronic health report systems, presenting summary reports on trends of patients' conditions and self-management activities over time)	6	54.5
Comparators				
Within subjects	Pre–post	Subjects measured before and after intervention	3	27.3
Between subjects	Similar controls	Similar subjects measured with and without intervention	4	36.4
None		No comparison	6	54.5
Outcomes				
Clinical	Biomarkers	Objectively measured patient health outcomes (e.g., blood pressure)	3	27.3
	Perceptions and behaviors	Self-reported perceptual outcomes (e.g., depression, satisfaction with the intervention); health behavior-related outcomes (e.g., adherence to	4	36.4

		medication and measurement schedule)		
Technical	User feedback on the mHealth technology	Perceptions of the system tested (e.g., perceived ease of use, intention to accept and continued use, requirements for future implementation); suggestions for improving the usability and usefulness of the system	9	81.8
Study design				
Experimental	Pre–post study	Measured outcome before and after intervention is implemented	2	18.2
	RCT	Measured outcome of two groups of homogenous study participants, one of which received an intervention and the other did not	2	18.2
Observational	Retrospective cohort study	Looked at data created prior to development of outcome to identify which participants developed outcomes of interest	1	9.1
User study	Usability testing	Evaluated overall quality of system in terms of users' performance and satisfaction (i.e., summative usability evaluation)	5	45.5
	Requirements gathering	Evaluated system to make improvements in design prior to release (i.e., formative usability evaluation)	1	9.1

DISCUSSION

Our systematic review provided an overview of the current development and application of mHealth technologies targeting diabetes and hypertension. We found a lack of research examining the effects of mHealth interventions on patients' self-management of diabetes and hypertension. Among the 11 studies identified, only five (45.5%) were clinical intervention studies examining the effects of mHealth technologies on patient health outcomes; the rest (n = 6; 54.5%) were user studies focused on the development or testing of mHealth technologies. In terms of types of mHealth technologies implemented in the included studies, the most common features supported patients' self-management activities such as recording data (e.g., blood pressure, glucose), keeping track of trends in the data, and taking medications (n = 11; 100%),

followed by features supporting clinical decisions such as assessing data based on established guidelines and thresholds (n = 6; 54.5%) and those supporting shared decision-making such as producing a summary report and facilitating communication between patients and providers (n = 6; 54.5%).

The results of the clinical intervention studies (n = 5) show that mHealth technologies can help patients (a) adhere to supposedly more complex drug and diet regimes (e.g., sending reminders when medications should be taken, notifying patients when refills are necessary, and assisting in the creation of medication histories) and (b) control biomarkers such as blood pressure and glucose. Regarding technical development and implementation of mHealth interventions, the user studies (n = 6) showed that patients generally perceive mHealth technologies as easy to use and useful for self-managing their health conditions. However, health care providers tend to have reservations about mHealth technology as a self-management tool, questioning the validity of patient-entered data and noting other unintended adverse effects such as increased anxiety among patients, liability issues, and disruption of workflow.

Although the clinical studies (n = 5) generally reported improved outcomes, our assessments were limited by the variability in study designs and outcome measures. Due to the heterogenous nature and limited number of studies deemed eligible for inclusion in the effects analysis, we could not conduct a meta-analysis of the effects of mHealth-supported intervention programs. We also note that two studies reported nonsignificant or adverse effects of the implementation of mHealth interventions.[25,28] Moreover, among these clinical studies, we could not necessarily find information on how these interventions were designed or supported efforts to overcome the complexity of managing both diabetes and hypertension. In other words, managing both conditions may not simply involve managing two separate conditions at the same

time, but also require the patient's deeper understanding of the nature of MCC to reduce any negative synergy of the two conditions. In this respect, future studies that focus on educating patients about the potential interactions among MCC and minimizing the complexity of managing multiple conditions using mHealth technologies may help improve health outcomes in this population. In addition, we suggest that the effects of such interventions on health outcomes, especially perceptual (e.g., depression, satisfaction with the intervention) and behavioral (e.g., adherence to medication and measurement schedule) outcomes, should be monitored as a whole at the MCC level rather than at the individual condition level. This is important because patients have to live with all the conditions they have all the time, not one at a time. For those living with diabetes and hypertension, for example, it would not be always clear to distinguish whether the changed depression level over a period is attributed to diabetes, hypertension, or both. As for behavioral outcomes, such as adherence to medications, it is important to help patients comply with their whole medication plan rather than medications for individual conditions..

Only two of the included studies (18.2%) were RCTs.[27,29] We suggest that this represents a limitation in relation to the meaningful evaluation of the effects of mHealth technology-supported interventions, and that future studies of mHealth interventions could improve the quality of evaluation results by employing an RCT study design. We also note that the nonrandomized nature of the study designs resulted in relatively high risk of bias in the study results (Figure 2; for more details, see Supplementary Material).

Notwithstanding these limitations, our assessment of the narrative review of the included studies suggests that mHealth technology interventions may represent promising areas for future research. The current interventions were intended to enable users to record personal health data, receive useful tips or suggestions to deal with diabetes and hypertension, and facilitate

communication between patients and their providers. Further investigation of the implementation of these technologies using robust study designs that minimize the risk of bias is needed. Future evaluations should carefully consider the outcome measures that they report to ensure they are likely to be of relevance to key stakeholders. Ideally, these outcome sets should include objectively measured patient health outcomes and adverse events to allow a full appraisal of the effects of the intervention being investigated. Last, considering the inevitably unique and complex nature of self-managing specific MCC, future research could focus first on diseases that are pathologically similar and often co-occur (e.g., diabetes and hypertension). Then, we could gradually target concurrent diseases that are pathologically different (e.g., diabetes and arthritis). Once more solid evidence has accumulated, a universal mHealth app that allows patients to self-manage as many and as varied chronic conditions as they want could be developed.

CONCLUSIONS

Future research with more randomized clinical trials is necessary to better understand the potential health benefits of mHealth technologies as assistive tools to facilitate the self-management of highly prevalent comorbid of chronic conditions such as diabetes and hypertension.

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COMPETING INTERESTS STATEMENT

The authors have no competing interests to declare.

CONTRIBUTORSHIP STATEMENT

Dr. Choi designed the search strategy and data collection instruments; reviewed the identified titles, abstracts, and full text (when needed) for inclusion in the review; completed the data collection process; carried out the analyses; and produced the initial manuscript. Mr. Wang contributed to the development of the study protocol; reviewed the titles, abstracts, and selected articles identified during the database searches to identify relevant studies for inclusion in the review; and contributed to the drafting of the initial manuscript. Dr. Lee helped prepare the review protocol; reviewed the full text of included articles to extract key information against the review protocol; conducted the risk-of-bias assessment; and critically reviewed and revised the manuscript for important intellectual content. Dr. Oh reviewed the full text of included studies to extract key information against the review protocol, especially the clinical aspects of the interventions and associated outcomes; conducted the risk-of-bias assessment; and critically reviewed and revised the manuscript for important intellectual content. Dr. Zheng reviewed the full text of included articles to extract information against the review protocol, especially the technical specifications of the mHealth technologies and associated outcomes; and critically reviewed and revised the manuscript for important intellectual content. All authors reviewed and approved the manuscript before submission.

SUPPLEMENTARY MATERIAL

Supplementary material is attached as a Word document and will be made available in the journal's online database.

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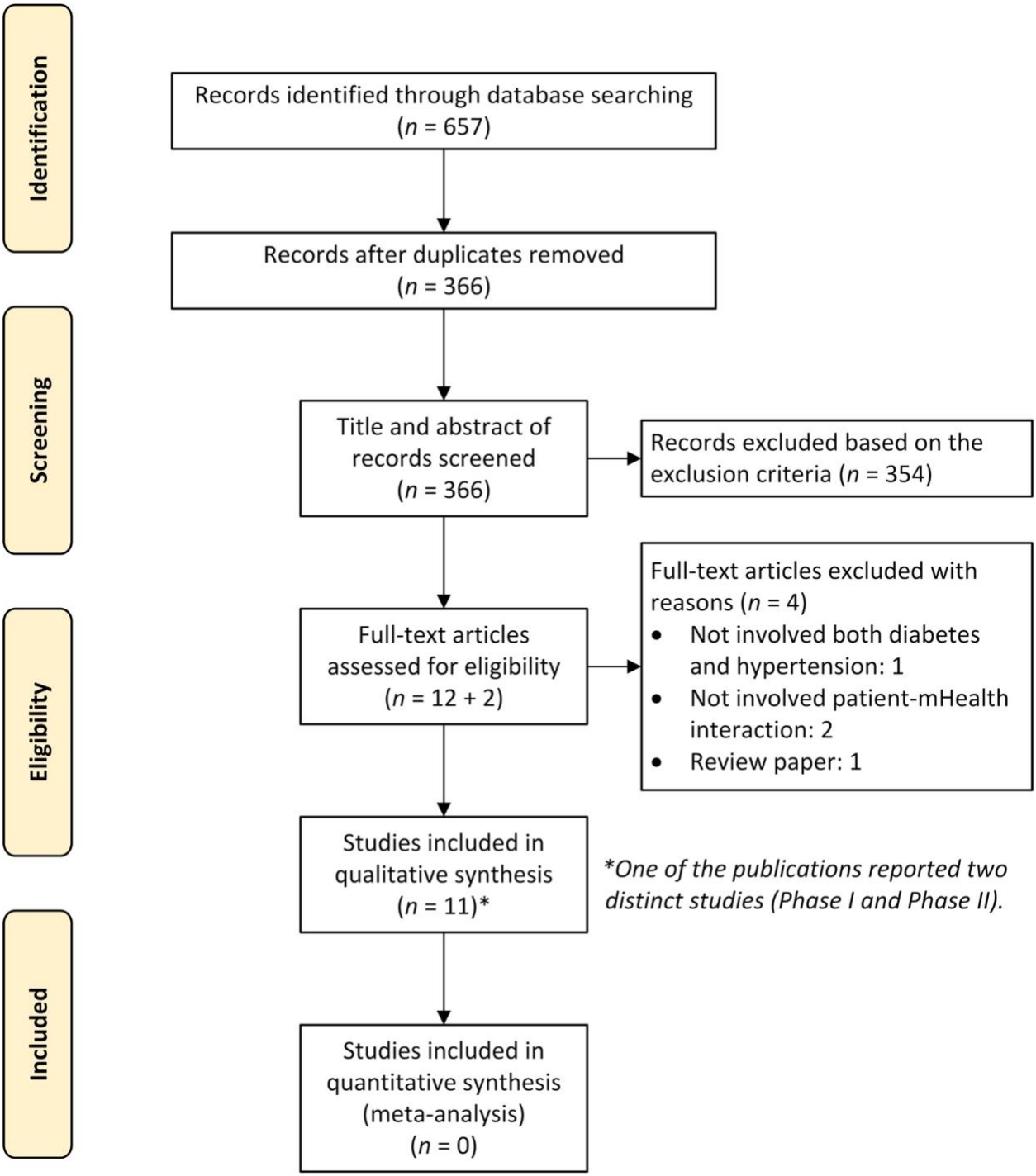

Figure 1. PRISMA flow diagram indicating results of identification and screening process for included and excluded papers.

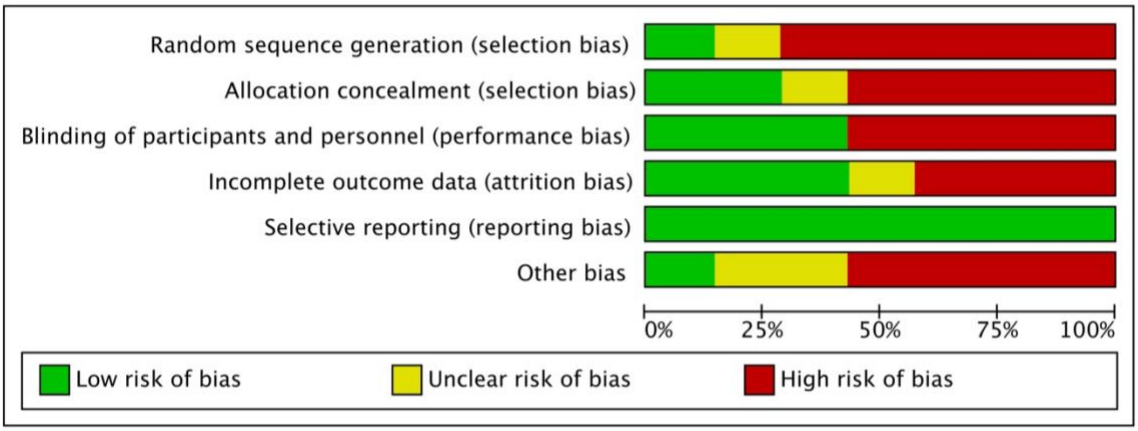

Figure 2. Risk of bias across clinical studies included (*n* = 5).