

Literature Review: Hypertension Management & Prevention Program Considerations for Vermont

April 2020

Introduction

The Vermont Department of Health has been charged with conducting a literature review on behalf of the Vermont Blueprint for Health and OneCare Vermont with the goal of identifying effective and scalable self-management or community-based programs to address the underlying health behaviors associated with hypertension.

The criteria for the review include:

(1) Strength of the evidence for self-management and/or community-based interventions for prehypertension management/ hypertension prevention and hypertension self-management;

(2) Size of the population reached by the intervention and impact on clinical outcomes;

(3) When possible, cost efficiency ratio (impact for investment) including scale of delivery model and administration of programs; and

List of Programs <u>Reviewed</u> for Hypertension Prevention

- Brigham Protocol-based Hypertension Optimization Program (BP-HOP)
- Check. Change. Control. (CCC)
- Check it, Change it (CICI)
- Health Coaches for Hypertension Control (HCHC)
- Ola Hou i ka Hula (Ola Hou) "renewed life through hula"

(4) Findings that may inform feasibility to scale the intervention state-wide will be noted.

Evidence-based programs identified during this review are provided in the box to the right of this section with further descriptions provided programs below.

Review Context

It is important to note that this is a rapid review. Due to time constraints, not all articles selected for review were included in this summary and as such, this should not be considered a comprehensive literature review. It is critical to note that there is no uniform definition as to what constitutes a *program* or agreement on specific elements necessary to include in such an intervention for chronic disease self-management or prevention. Therefore, to establish consistency in this review,

the term **program** is used here to refer to an intervention that has a structured, evidence-based curriculum or process that was used on a community scale.

Any other intervention will be referred to as a study protocol used to prevent or manage disease.

Article Selection

Due to constraints on time and resources, articles included in this review focused on:

1. Systematic reviews and meta-analyses published between January 2000 and March 2020

 Peer-reviewed articles describing established, structured programs with a standardized intervention protocol for preventing or managing hypertension or blood pressure reduction from January 2010 – January 2020 with blood pressure or heart disease risk score as reported outcomes.

With few exceptions, the majority of peer-reviewed literature in this review were obtained from PubMed searches. It is possible that the inclusion of searches in other databases (e.g. the Chochran Library, Medline, etc.) may yield novel research that was not available through PubMed. Where full text articles were not available, an inter-library loan through the University of Vermont, Larner College of Medicine, Dana Medical Library was used to obtain full text articles. Librarians from the Dana Medical Library aided reviewers with creating PubMed searches and establishing a literature review framework.

Search Terms

The search terms used to identify records for consideration in PubMed are shown in the table below. These terms were used as OR statements in their respective searches with medical subject headings (MeSH) to allow for synonyms to be included as well. Variations in hyphenation were also included (e.g. self care and self-care). This provides for a wide net in returned results. Articles shared by subject matter experts were also considered for inclusion.

Table. Tubineb Search Terms for Initial Article Search	
Hypertension Management AND	
Hypertension OR	
Evaluation studies as topic OR	
Validation studies as topic OR	
Program evaluation OR	
Cost efficiency OR	
Protocol or program OR	
Community based OR	
Self-management OR	
Self care OR	
Blood pressure OR	
Aged or middle aged or adult OR	
English	

Table. PubMeb Search Terms for Initial Article Search

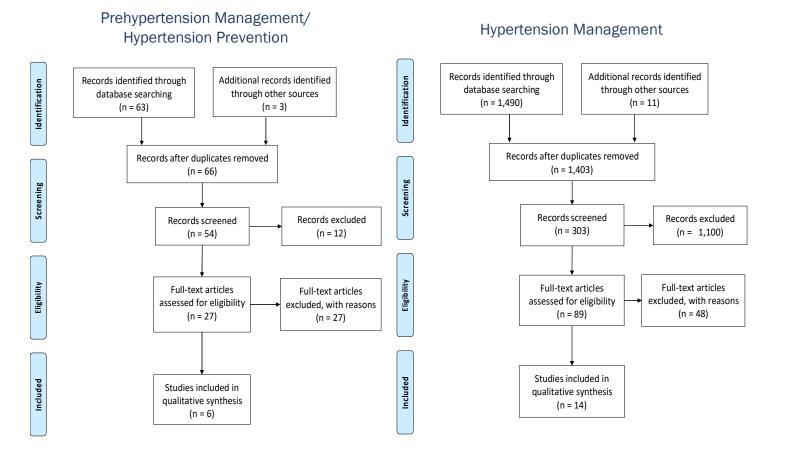
Inclusion Criteria

- Article published in English
- Study was conducted in the U.S.
- Study sample was 50+ adults
- Focus of study was prehypertension or hypertension
- Measured outcomes included blood pressure or established disease risk scores (e.g. Framingham cardiovascular disease risk score)
- Published 2000 and later (systematic reviews and meta-analyses) or 2010 and later (all other articles)

Exclusion Criteria

- Population too specific to be scalable or generalizable
- Statistical power <80%, if reported
- Duplicate study

Article Inclusion Flow Charts



Prehypertension Management/Hypertension Management

There is a lack of targeted research for programs or study protocols with prehypertension as the study focus. This is likely because prehypertension is not a disease category but a diagnosis of risk (National High Blood Pressure Education Program, 2004), which only in recent years has been a targeted area of focus. For reasons that likely seem related to funding for this topic primarily being given to communities and health departments which have very limited publishing capacity compared to academic and laboratory settings, most studies reporting prehypertension, hypertension, or overall heart disease risk reduction as outcomes **focus on risk factor reduction through lifestyle change programs** (e.g. those focused on physical activity and nutrition). Such programs or study protocols focused mainly on obesity prevention and improving physical activity and/or nutrition. Only one article, an evaluation of exercise training on resting blood pressure in young adults, had prehypertension as the topic of focus. This article evaluated an eight-week exercise training protocol. Researchers found a clinically and statistically significant 7 to 12 mmHg reduction in blood pressure after program completion (Beck et al., 2013).

Given **only one article fit inclusion criteria** for prehypertension for this review, a small selection of four additional studies were included that addressed heart disease outcomes. All other articles were generic chronic disease prevention programs or study protocols to improve health that happened to have blood pressure and/or cardiovascular risk scores as a measured outcome. These studies focused on physical activity and nutrition and showed favorable to significant reduction in blood pressure following intervention (Fornari et al., 2013; Folta et al. 2019, Jurik and Stastny, 2019; Remy et al., 2017). Supporting these findings, the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC), describes that people with prehypertension are not candidates for drug therapy and should "be firmly and unambiguously advised to practice lifestyle modification in order to reduce their risk" (National High Blood Pressure Education Program, 2004, p. 12).

A systematic review of the effect of strength training on blood pressure reduction identified weight loss as essential for hypertension control (Jurik and Stastny, 2019). The authors also found that nutrition-based interventions are recommended as first-line prevention therapy and strength training study protocols as standalone interventions can be recommended as effective prevention methods for both prehypertension and hypertension; perhaps most importantly they identified that

overall lifestyle modification is more important than modifying a single behavior.

A randomized controlled trial of changes in diet and physical activity as a result of participation in the **Strong Hearts, Healthy Communities (SHHC) program** found that as a result of program participation there was a significant increase in participant physical activity through walking compared to the control group (Folta et al., 2019). The authors also found significant differences in fruit and vegetable consumption between the intervention and control group however, they note that this finding should be treated with caution as it is likely related to decreased consumption in the control group rather than increased consumption in the intervention group. Positive blood pressure reduction outcomes have also been seen through an evaluation of an employer-funded workplace implementation of the **Complete Health Improvement Program (CHIP)**. While physical activity and participant education are components of the CHIP, the current study used the CHIP with a strong focus on the nutrition component. At the end of the CHIP, participants showed a clinically and statistically significant 3 to 5 mmHg reduction in blood pressure (Remy et al., 2017).

A prospective case-control **study targeted a heart disease intervention intentionally designed for adults towards children** stood out unique in its approach whereby both children and adults participated in the program. The program used a multidisciplinary team including nurses, physical education teachers, nutritionists, physiotherapists, psychologists, and the children's teachers to develop educational materials for participants and in the case of children, using multiple modalities for children (videos, acting, and games). Additionally, group (family) activities were planned for physical activity. The authors saw 91% of parents reduced their Framingham cardiovascular disease risk score after completion of children's educational program; the reduction in the Framingham risk score is attributed mainly to changes in cholesterol and blood pressure (Fornari et al., 2012).

There was insufficient information on economic analyses in articles to provide a summary of cost efficiency.

Hypertension Management

While there are a number of hypertension management programs, the body of literature for hypertension management programs is small. Further, the number of programs with widespread implementation or recognition is very limited and only two programs were identified: the American Heart Association's (AHA's) Check. Change. Control. (CCC) programs and Health Coaches for Hypertension Control (HCHC) (Anderson et al., 2017; Dye et al., 2015). A meta-analysis of 13 studies on chronic disease self-management programs in older adults with reported blood pressure outcomes found an overall clinically significant reduction in blood pressure with program participation (Chodosh et al., 2005). In a systematic review of 56 randomized controlled trials of study protocols used to control hypertension and increase follow-up for patients, Fahey et al. (2005) noted education alone (of either patient or provider) is unlikely to influence blood pressure control as a single intervention. Most programs or study protocols included several key elements that the study authors linked to program success. These include self-monitoring blood pressure (SMBP), programming taking place in the community and/or serving as a clinical extension of usual care, incorporation of team-based care, and inclusion of online or mobile based technology.

Ambulatory Blood Pressure Monitoring is Essential

Many programs and study protocols used to manage hypertension employed SMBP. SMBP is frequently cited as having been a critical component in program/protocol success. The effect known as "white coat syndrome" resulting in higher than usual blood pressure taken in the health care setting is well established. Ambulatory blood pressures are much more reliable measurements of an individuals' true blood pressure than those taken in the healthcare setting. In their systematic review Fahey et al. (2005) found that protocols using SMBP were associated with significant decreases in diastolic blood pressure. In an outcome evaluation of the CCC program, conducted simultaneously in 18 similar U.S. cities, SMBP with electronic upload into the Heart360 online platform found overall, 33% of program participants moved from either hypertensive or prehypertensive to prehypertensive or normotensive blood pressure. Those participants also had a 3 to 8 mmHg reduction in blood pressure over the course of the program (Anderson et al., 2017). Both Fahey et al. (2005) and Anderson et al. (2017) identified that participant reminders, electronic or postal, were associated with an increase in blood pressure reporting.

In a 2019 study, Fisher et al. evaluate a pilot program of the Brigham Protocol-based Hypertension Optimization Program (BP-HOP), an entirely remote visit-based intervention of 130 people recruited from primary care. SMBP was performed using automated blood pressure cuffs that contained Bluetooth and Wi-Fi technology that automatically transmitted readings to the participants electronic medical record. BP-HOP participants saw a 20 to 31 mmHg reduction in blood pressure at program conclusion with lower blood pressures sustained at one-year follow-up.

Community Programs as Clinical Extensions

Interventions usually involve a multiple component intervention design that incorporates some form of patient education, SMBP (with a bi-directional feedback mechanism), and physical activity. Another program design element credited with program success is with the CCC program where localities conducting the program had some freedom to tailor the program to meet the logistic or programmatic needs of the community (Anderson et al., 2017).

Successful programs do not employ one single intervention strategy Some programs while conducted in the community are **more appropriately looked at as clinical extensions** as they engage the provider and patient while reducing the burden on the provider. BP-HOP used what they termed patient navigators who volunteered for the duties and were uniformly trained by pharmacists and nurses to review patients blood pressures and engage in rapid assessment/treatment cycles. Pharmacists developed, tested and approved an algorithm that patient navigators could use to titrate medications. This was deemed appropriate by the hospital review board as the patient navigator was not making clinical decisions. Rather they were only following the pharmacist designed algorithm (Fisher et al., 2017).

The Check it, Change it (CICI) program engaged in the use of community health coaches (CHCs) and physician assistants (PAs) to augment the primary care provider and reduce their burden (Thomas et al., 2014). The CICI program is a 6-month intervention (Shah et al., 2013) that provides longitudinal blood pressure monitoring (home monitoring or monitoring kiosks placed in community areas) using the web-based Heart360 portal. Participants are **provided with bi-directional feedback** on blood pressure entries, hypertension education, and support and technical assistance from PAs and CHCs. As needed, PAs were in contact with the participants provider (Thomas et al., 2014; Shah et al., 2013). After the 6-month CICI program, participants saw a 3 to 5 mmHg decline in blood pressure, a result that was even more pronounced among those with hypertension at the beginning of the program. A variable that patients felt most contributed to their success in CICI was the time they spent with PAs and CHCs outlining a blood pressure control plan (Thomas et al., 2014).

At least **two programs have applied the CICI programs success in more scalable formats**. These include the previously described CCC program and the HCHC program. HCHC employed volunteer Health Coaches (similar to the CHCs in the CCC program). These volunteer Health Coaches followed a concept of a community health worker with added skills of behavior change motivation used by wellness coaches. Health Coaches provided an eight-week core educational program intervention plus eight additional weekly classes focused on physical activity and nutrition. The results of an evaluation of the HCHC community based self-management program in a rural Appalachian community found statistically significant positive changes in systolic blood pressure, weight, and fasting glucose upon program completion along with significant increases in participant hypertension knowledge that was positively linked to program duration. Participant providers were pleased with how their patients became more efficacious self-managers as a result of the HCHC (Dye et al., 2015). Similar significantly positive clinical outcomes for blood pressure, body mass index (BMI), and HDL cholesterol were reproduced in an evaluation of participants in an expanded version of the HCHC in a different community from the original study (Dye et al., 2016).

Modalities that account for the unique spiritual and cultural values delivered in a familiar community setting should be considered for communities where cultural traditions and beliefs are important to individual/community identity, preferences, trust, and decision making. One such example is Native Hawaiians/Pacific Islanders (NHPI). A multidisciplinary team in Hawaii (including a hula expert) created the Ola Hou i ka Hula (Ola Hou) program, which translates to "renewed life through hula." Ola Hou is a 12-week educational and physical activity intervention targeted toward NHPI with provider diagnosed hypertension. This randomized control trial found a significant 18 mmHg reduction in systolic blood pressure among program participants where 72% of participants saw more than a 10 mmHg reduction (Kaholokula et al., 2017). This was statistically significant compared to the control group.

Another cultural approach to hypertension management is Tai Chi, an activity whose blood pressure reduction effects have been well documented. In a systematic review of randomized controlled trials of Tai Chi as a hypertension management strategy compared to health education/no treatment (9 studies), other exercise (5 studies), and antihypertensive medication alone (15 studies) found that Tai Chi was more effective than medication in those under 50 years old. A significant 7 to 15 mmHg reduction in blood pressure was identified among those using Tai Chi compared to health education/no treatment and a 4 to 8 mmHg compared to other. A Tai Chi intervention lasting 12-24 weeks was shown to significantly reduce blood pressure compared to those lasting less than 12 weeks or greater than 24 weeks (Zhong et al., 2020). While the review methodology included consideration of U.S. and Chinese studies, only studies performed in China were selected. It is therefore possible that results from studies performed in the U.S. may differ.

Of note, blood pressure reduction using hula was found to be comparable to reductions seen in other physical activity protocols including Tai Chi (Kaholokula et al., 2017). While these articles focused on specific communities, these culturally based interventions are likely to be more widely applicable as Tai Chi and hula are commonly accepted activities among a wide array of people. Another effective blood pressure control modality is stress reduction. In their meta-analysis Chodosh et al. (2005) found that stress reduction and anxiety management programs had similar success to other programs in reducing blood pressure.

Boulware et al. (2005) reported a **distinction between counseling and education** with education describing didactic learning without other lifestyle change support that would otherwise be included as part of counseling. The authors found that counseling provided by various provider types was favored over usual care, though not statistically significant, and education with counseling compared to usual care being statistically significant.

Incorporation of Team-Based Care

Several articles cited the use of team-based care as part of the program/protocol intervention or design. BP-HOP, CCC, and Ola Hou (Fischer et al., 2019, Anderson et al., 2017; Kaholokula et al., 2017) discuss the development of program materials with a multidisciplinary team of experts. All articles for established **programs used a patient care team of varying make-up** including providers, physician assistants, nurses, pharmacists, community health coaches, community health workers, or patient navigators as part of the program intervention or design.

In their systematic review Fahey et al. (2005) found that the use of registered nurses and pharmacists as patient educators was significantly linked with improved blood pressure control compared to providers. Similarly, another systematic review of 15 studies on patient-centered behavioral interventions for hypertension identified significant improvements in blood pressure when pharmacists (4 to 12mmHg reduction) or registered nurses (up to 6mmHg reduction) led counseling interventions over provider-led counseling (Boulware et al., 2001). The comparison from this article should be treated with some caution as there were only a limited number of studies included where providers conducted patient education compared to pharmacists or nurses. However, additional evidence exists to support the use of pharmacists as patient educators over providers. In a retrospective review of a pharmacist-based intervention protocol, the involvement of a pharmacist significantly improved goal-directed therapy for blood pressure control even 18-months following the discontinuation of the intervention compared to usual care (Wentzlaff et al., 2011). In this study protocol the pharmacist education was directed both at patients and providers.

Program or protocol **skepticism on the part of the participant's provider can be a barrier to overcome but was achieved in a few studies in different ways**. The CICI program included the participant's provider as part of the intervention team (Thomas et al., 2014). It also targeted the patient's provider for education to gain their support (Shah et al., 2013), while BP-HOP allowed program success to speak for itself thus gaining provider support through recognition of patient improvement. In the BP-HOP pilot study, providers initially didn't want patient management taken away from them however, when they saw their patient's positive health outcomes and experienced reduced clinic burden, providers became supportive of the program (Fisher et al., 2019).

Inclusion of Mobile/Online Programming Solutions

In recent years, technological applications have been incorporated into self-management programs with good success. The **use of Bluetooth/Wi-Fi technology bridges the technology gap** allowing programs to become more accessible to those unfamiliar with technology. However, the program is dependent on the availability of broadband internet, which may limit feasibility in rural areas where broadband is limited or unavailable. A lack of familiarity with technology could also serve as a barrier to participation in programs dependent on technology. In a meta-analysis of 11 randomized controlled trials of evidence for interactive mobile health interventions and hypertension management defined mobile health (mhealth) as the ability of technology to compute and communicate health findings, Lu et al. (2019) found that compared to usual care, mobile health interventions favored a blood pressure reduction of 2 to 4 mmHg.

Several previously described articles employed mobile health or online strategies as part of the intervention. The BP-HOP bridges the technology gap by removing the participant from blood pressure uploads by using a Bluetooth enabled automated blood pressure cuff to automatically upload readings. (Fisher et al., 2019). The CICI program **directly attributed program success** to their finding of a positive association in systolic blood pressure reduction with increased use of the web portal used to track blood pressures (Thomas et al., 2014). Participants in the CCC program used the Heart360 online tracking platform where the authors found a significant association between increased number of uploads to Heart360 and blood pressure decline (Anderson et al., 2016).

A prospective workplace trial of a six-month automated, web-based hypertension self-management protocol at six different worksites for 600 employees in the same company found a clinically relevant 5 to 10 mmHg reduction in blood pressure, significantly higher than that seen in the control group. Intervention group participants also reported improved communication with their provider as a result of participation (Watson et al., 2012). While this study protocol removed the technology gap through the use of an automated blood pressure cuff that automatically uploaded results to a custom designed self-management website, the protocol was implemented in a tech savvy workplace which could have influenced the effect of technological based interventions.

Cost Efficiency

Few articles included any information on the cost of the implementation of interventions. Therefore, the following information on programmatic costs should be interpreted with caution due to the limited amount of evidence available and the lack of comparability due to differing methods in reporting of economic results. The CICI program, while successful, is not financially feasible on a large scale with a flat implementation cost of \$1.5 million dollars for a single run (Anderson et al., 2016). Two programs used the success of CICI to build more feasible and scalable programs. These included CCC and HCHC. Implemented for about \$20,000, the CCC program used more moderate monetary resources compared to the CICI (Anderson et al., 2017). In an evaluation of an expanded version of the HCHC Dye et al. (2016) identified that the program cost around \$380 per person compared to \$1,131 per person for usual care. See referenced articles for further detail.

Conclusions

While several programs and study protocols have been described for both prehypertension management/hypertension prevention and hypertension management in this rapid review, all programs and protocols focus on risk factor reduction, primarily physical activity and nutrition. Specific to blood pressure control, SMBP is a critical component in program success. However, SMBP without some form of community or clinical support is less likely to be effective. Similarly, education or counseling alone are likely insufficient for overall blood pressure reduction. Teambased care specifically involving pharmacists, nurses, or community health coaches, has been an effective delivery mechanism for education and counseling. While provider buy-in to a program's value can be a barrier, utilizing these provider types as an extension of clinical care serves has the benefit of reducing the burden on clinics and ultimately, providers have expressed positive feelings about self-management programs upon seeing positive outcomes for their patients.

Given the limited timeframe for this review, it is possible that this review does not include a complete list of evidence-based programs, particularly those developed in studies outside of the U.S. With few exceptions, articles represented study populations of a hundred or more individuals. The findings of these studies would therefore be scalable to the population of residents that Vermont is currently serving for self-management programs at any one time, if not more. Further, as all articles had the key elements of focusing on risk factor reduction through physical activity and nutrition, SMBP, team-based care, conducted in the community setting, and possibly the incorporation of mobile/online strategies as part of the intervention, any program incorporating these elements in a multicomponent approach may merit consideration.

Suggested Resources

- Rural Health Information Hub
 - Health Coaches for Hypertension Control (HCHC) program development website with <u>summaries of program</u> successes and program descriptions.
- National Association of Chronic Disease Directors (NACDD)
 - Resources describing <u>how to implement</u> a self-monitoring blood pressure (SMBP) program including coverage and reimbursement procedures from such a program.
- YMCA of the USA (YUSA)
 Information about their blood pressure self-monitoring program.
- American Heart Association Check. Change. Control. (CCC) Program
 - Provides <u>community resources</u> for program implementation. The program relies on an <u>online tracking portal</u> for blood pressure self-monitoring, the use of which largely attributed to the programs' success.
- The Joint National Committee on Detection, Prevention, Evaluation, and Treatment of Hypertension (JNC), the seventh and eighth reports both contain relevant information on treating prehypertension and hypertension treatment and management with the eighth report providing updates and some modifications to the seventh report.
 - <u>Seventh Report</u> of the JNC
 - <u>Eighth Report</u> of the JNC
 - o <u>Summary of updates</u> in the eighth report

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