The Effect of an Artificial Intelligence-based, Autonomous, Digital Health Intervention Using Precise Lifestyle Guidance on Blood Pressure in Adults with Hypertension: Single-Arm Nonrandomized Trial

Jared Leitner
Department of Electrical & Computer Enginnering
University of California, San Diego
San Diego, USA
jjleitne@ucsd.edu

Po-Han Chiang
Department of Electrical & Computer Enginnering
University of California, San Diego
San Diego, USA
pochiang@ucsd.edu

Parag Agnihotri
Department of Medicine
University of California, San Diego
San Diego, USA
pagnihotri@health.ucsd.edu

Sujit Dey
Department of Electrical & Computer Enginnering
University of California, San Diego
San Diego, USA
dey@ucsd.edu

ABSTRACT

Background: Home blood pressure (BP) monitoring in conjunction with lifestyle coaching is effective in managing hypertension (HTN) and reducing cardiovascular risk. However, traditional manual lifestyle coaching models significantly limit availability due to high operating costs and personnel requirements. Furthermore, the lack of patient lifestyle monitoring and time constraints experienced by clinicians can prevent personalized counsel on lifestyle modifications for patients.

Objective: This study aims to assess the effectiveness of a fully digital, autonomous, and artificial intelligence (AI)-based lifestyle coaching program on achieving BP control among adults with HTN.

Methods: Participants were enrolled in a single-arm nonrandomized trial in which they were provided with a BP monitor and wearable activity tracker. Data was collected from these devices and a questionnaire mobile application and used to train personalized machine learning (ML) models that enabled precision lifestyle coaching delivered to participants via SMS and a mobile application. The primary outcomes included: 1.) The change in systolic and diastolic BP from baseline to 12 and 24 weeks. 2.) The percent change of participants in the controlled, Stage 1, and Stage 2 HTN categories from baseline to 12 and 24 weeks. Secondary outcomes included: 1.) The participant engagement rate as measured by the consistency of data collection. 2.) The number of manual clinician outreaches based on the escalation rules set for the study.

Results: 141 participants were monitored over 24 weeks. At 12 weeks, systolic and diastolic BP decreased by 5.6 mmHg (P<.001; 95% CI -7.1 to -4.2) and 3.8 mmHg (P<.001; 95% CI -4.7 to -2.8), respectively. Particularly, for participants starting with Stage 2 HTN, systolic and diastolic BP decreased by 9.6 mmHg (P<.001; 95% CI -12.2 to -6.9) and 5.7 mmHg (P<.001; 95% CI -7.6 to -3.9), respectively. At 24 weeks, systolic and diastolic BP decreased by 8.1 mmHg (P<.001; 95% CI -10.1 to -6.1) and 5.1 mmHg (P<.001; 95% CI -6.2 to -3.9), respectively. For participants starting with Stage 2 HTN, systolic and diastolic BP decreased by 14.2 mmHg (P<.001; 95% CI -17.7 to -10.7) and 8.1 mmHg (P<.001; 95% CI -10.4 to -5.7), respectively, at 24 weeks. The percentage of participants with controlled BP increased by 17% (P<.001) and 26% (P<.001) from baseline to 12 and 24 weeks, respectively. The percentage of participants with Stage 2 HTN decreased by 25% (P<.001) and 26% (P<.001) from baseline to 12 and 24 weeks, respectively. The average weekly participant engagement rate was 92% and only 5.9% of participants required manual outreach over 24 weeks.

Conclusions: The study demonstrates the potential of fully digital, autonomous, and AI-based lifestyle coaching to achieve significant BP improvements and high engagement for patients with HTN, while significantly reducing the workload on clinicians and health coaches.

Keywords— blood pressure; hypertension; digital health; lifestyle change; lifestyle medicine; wearables; remote patient monitoring; artificial intelligence.

I. INTRODUCTION

High blood pressure (BP), or hypertension (HTN), is one of the most prevalent chronic diseases in the world [1]. HTN affects 48% of adults (120M) in the US and 78% of cases (93M) are uncontrolled (i.e., BP ⩾ 130/80 mmHg) [3]. HTN is a major risk factor for stroke and acute myocardial infarction (AMI) [4], and remains a large public health challenge with an extra cost of $2000/year per HTN patient, resulting in an additional $131B in annual healthcare costs in the US [5]. The American College of Cardiology and American Heart Association’s (ACC/AHA) clinical practice guidelines define HTN as systolic BP (SBP) ⩾ 130 mmHg or diastolic BP (DBP) ⩾ 80 mmHg, consistently over time [2]. Based on a large-scale analysis of 48 randomized clinical trials, a 5-mmHg reduction in SBP lowered the risk of major cardiovascular events by 10% [6], highlighting the importance of developing new strategies to achieve HTN control at scale.

HTN management typically begins with home monitoring of BP to gain a more accurate estimate of a patient’s BP within their usual, daily routine [7]. However, self-monitoring without additional support is not associated with lower BP or better control [8-10]. Lifestyle management in conjunction with self-monitoring is effective in controlling BP since lifestyle factors (e.g., activity, sleep, diet, stress) have a significant impact on BP [11-14]. Even for patients taking antihypertensive medication, lifestyle management can enhance medication efficacy leading to better BP control [15]. Traditionally, lifestyle management involves HTN patients visiting with their primary care physician and receiving guidance on lifestyle modifications that are generally known to improve BP. However, due to time constraints related to workload, physicians are often unable to optimally counsel patients on lifestyle modifications or personalize their guidance [16, 17]. Due to insufficient guidance and with lack of feedback in between clinic visits, patients may implement some of these changes; however, patient engagement and compliance are generally suboptimal for achieving control. To improve patient engagement, new digital health technologies and remote patient monitoring (RPM) programs have been developed for HTN care [18-21]. These programs typically provide patients with remote monitoring devices (e.g., BP cuffs and activity trackers) and match patients with health coaches. BP and lifestyle data collected from remote monitoring devices allow health coaches to view trends and make personalized recommendations to patients. However, these approaches do not consider the individual impact of lifestyle factors on BP, which may vary across individuals due to physiological differences. Furthermore, the reliance on health coaches is highly time and resource-intensive, resulting in a high operating cost which significantly limits scalability [22].

To address the challenges of poor patient engagement due to generic, insufficient guidance and limited scalability of care due to human coaching models, we propose an AI-driven, autonomous, precise lifestyle coaching program for patients with HTN. The intervention platform consists of a monitoring system that ingests lifestyle and BP data and builds personalized machine learning (ML) models to determine the individual impact of different lifestyle factors on BP. Based on the lifestyle impact analysis, the system autonomously provides precise lifestyle recommendations delivered to a patient's smartphone that enable patients to focus on specific aspects of their lifestyle that have the greatest associations with their BP. While the platform autonomously engages patients, it is clinician-supervised and notifies clinicians of critical BP readings. In our previous work [23], we enrolled 38 participants who were pre-hypertensive or had Stage I hypertension (SBP between 120-139 mmHg or DBP between 80-89 mmHg) and demonstrated that 75% of participants receiving the intervention were able to achieve a controlled BP (<130/80 mmHg) after 16 weeks of engagement. However, the limitations of [23] are 1.) the participants were not provided with an interactive mobile application for the delivery of our precise lifestyle recommendations, 2.) the small number of participants did not enable rigorous evaluation, and 3.) the study did not consider patients with Stage 2 HTN who can potentially benefit more from lifestyle management.

Our current study aims to evaluate the effectiveness of our AI-based, precise lifestyle guidance coaching program in helping patients with Stage 2 HTN achieve BP control and demonstrate the platform's scalability. The primary study objectives are to evaluate the change in BP and the percent change of participants in different BP categories (controlled, Stage 1 HTN, Stage 2 HTN) over time (baseline, 12 weeks, and 24 weeks). Secondary objectives include assessing participant engagement as measured by consistency of data collection and interactions with our mobile application, and determining the number of manual clinician interventions, as defined by the escalation rules set for the study, to assess the potential scalability of our approach..

II. METHODS

A. Recruitment

This study was in collaboration with UC San Diego Health's Population Health Services Organization (PHSO). Participants were enrolled on a rolling basis from November 2021 to February 2023. The inclusion criteria required participants to have Stage 2 hypertension (SBP ≥ 140 mmHg or DBP ≥ 90 mmHg per ACC/AHA 2017 guidelines [2]) based on their most recent clinical measurements and to be fully ambulatory (not requiring assistive device such as a cane, wheelchair, walker, etc.). In addition, participants were required to be ≥18 years of age at enrollment, English speaking, and own an Android or iPhone smartphone. The trial was designed in a fully remote manner so that participants could participate entirely from home. The PHSO care team aggregated a list of patients who met the inclusion criteria and sent a recruitment flyer via bulk message using Epic MyChart messenger. The flyer introduced the study and instructed patients to email the study team if they were interested in participating. After contacting the study team, eligible patients were asked to complete an electronic informed consent form. Patients who consented were sent a Fitbit Inspire 2 and a Bluetooth-enabled Omron Silver BP monitor to collect their lifestyle and BP data for up to 6 months. Each shipment included instructions for self-onboarding which described the steps to set up and connect the devices to the patient's mobile phone. Patients who already owned a Fitbit or Apple Watch had the option to use their device instead of receiving one from the study team. Patients who required an extra-large cuff were provided an iHealth Ease BP monitor instead of an Omron Silver.

B. Ethical Considerations

This study (protocol #181405) was reviewed and approved by UC San Diego's Human Research Protections Program, which operates Institutional Review Boards. All participants in this study provided informed consent.

C. Study Design and Data Collection

We collected data from each participant using a Fitbit or Apple Watch, Omron or iHealth wireless BP monitor, and the study's questionnaire mobile application. Participants were asked to wear their Fitbit or Apple Watch as often as possible, including during sleep, and take 1-2 BP measurements per day, in the morning (8-10 AM) and/or evening (7-9 PM). We provided participants with instructions on how to take accurate resting BP readings [24] and asked that they take 3 consecutive readings during each morning and/or evening session. This resulted in 1-2 sets of 3 measurements per day, and the average of the 3 measurements was used as the final value for each session. Participants synced their BP data to the Omron or iHealth mobile applications and their Fitbit data to the Fitbit mobile application after which the data was automatically uploaded to the Omron, iHealth, and Fitbit clouds. This data was retrieved remotely through the application programming

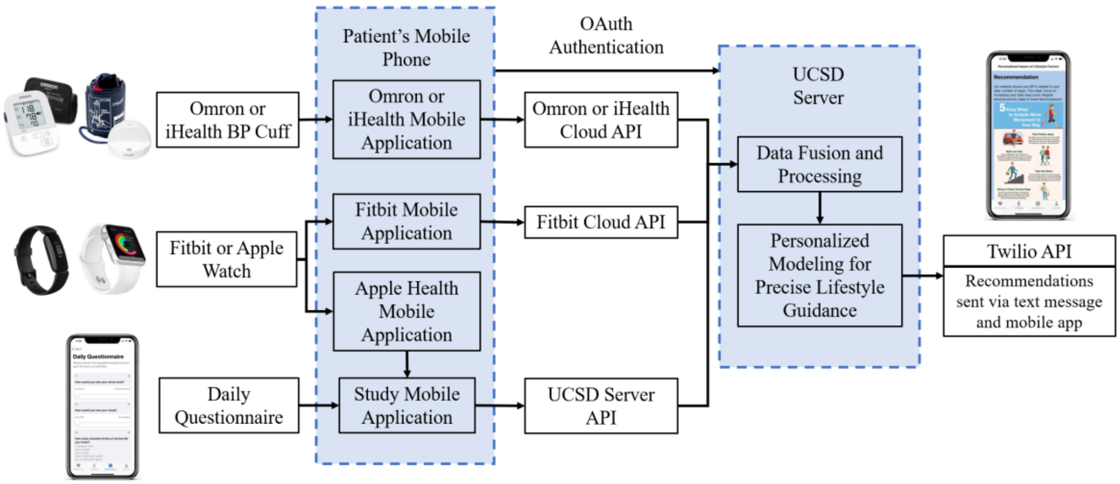


Figure 1. Architecture of data transmission.

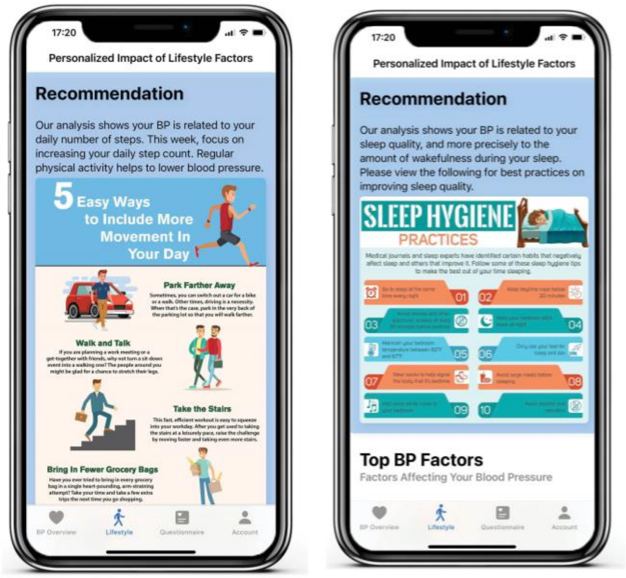
interfaces (APIs) provided by Omron, iHealth, and Fitbit. Data from the Apple Watch was synced with the study mobile application and uploaded via a custom API to our server. In addition, participants completed a daily questionnaire using our study mobile application that asked about their stress, mood, and dietary choices over the past 24 hours. These questions were developed in collaboration with physicians on our team. The diet questions are tailored to measure information relevant to HTN including alcohol, red meat, fruits/vegetables, and salt consumption [29]. The details of the questionnaire are described in our previous work [23]. Additionally, we asked participants to complete a study experience survey that asked them to rate the difficulty level of completing the study tasks, how useful they found the recommendations, and their experience using the app. These responses were collected through the mobile application and used to assess participant experience. Figure 1 describes the system architecture and data transmission.

Wrist-worn activity and sleep trackers have been widely used in health-related research studies [30] and devices like Fitbits and Apple Watches have been shown to accurately measure parameters such as step count, heart rate, and sleep duration [31-32]. Fitbits and Apple Watches include an optical heart-rate monitor and a 3-axis accelerometer. The devices use these sensors to calculate various health parameters, including lifestyle and vitals measurements. Lifestyle factors include activity (steps, walking/running speed, active time), sleep timing (sleep duration, bedtime, uptime), and sleep stages (deep, light, REM, awake). These lifestyle factors are used as part of the intervention, in which we use ML techniques to determine which of the factors have the greatest association with a participant’s BP and base our guidance on this analysis.

D. Description of Intervention

The intervention is intended to support the participant’s daily efforts to improve BP and overall cardiometabolic function by facilitating behavioral changes that target physical activity, sleep hygiene, stress management, and dietary choices most relevant to their BP. The intervention platform uses remotely collected lifestyle and BP data to provide personalized, precise, and proactive lifestyle coaching using AI to participants with HTN. The system integrates the data described in the previous section into a combined dataset for each participant. Each participant's personal dataset consists of lifestyle features (e.g., step count, sleep duration, salt consumption) that are time-aligned with their BP measurements, which serve as the labels for training the ML model. Therefore, each participant's dataset is used to train a personal ML model that can predict BP using the participant's lifestyle data as input. With this trained model, the intervention system can determine how different aspects of lifestyle affect the participant’s BP. Based on the model’s determination of the lifestyle factors’ impact, the system generates precise lifestyle recommendations. Each lifestyle factor is mapped to a corresponding lifestyle recommendation that was designed with physicians on our team to be consistent with evidence-based clinical guidelines. Furthermore, prior studies have demonstrated that these recommendations can result in BP reduction, including increasing step count [34, 35], improving sleep quality [36, 37], managing stress [38], and reducing salt consumption [39, 40]. The objective of these precise lifestyle recommendations is to encourage participants to focus on one aspect of their lifestyle at a time that has the greatest association with their BP based on the underlying relationship between their BP and lifestyle factors. We describe the AI-based intervention platform in more detail in our previous work [23].

Participants received weekly lifestyle recommendations based on their data and personalized analytics, which continuously evolved over time. These recommendations were delivered to participants via programmable text messages using the Twilio API service [25] and displayed in the study mobile application. Each text message included a summary of the participant’s BP progression for the current week in addition to the lifestyle recommendation. Figure 2 displays examples of these weekly lifestyle recommendations provided in the study application. Additionally, patients completed a mid-week check-in on the app, which asked whether they could follow each recommendation (yes/no) and to rate the recommendation difficulty on a scale from 1 to 5.



Recommendation

Our analysis shows your BP is related to your daily number of steps. This week, focus on increasing your daily step count. Regular physical activity helps to lower blood pressure.

5 Easy Ways to Include More Movement In Your Day

Park Farther Away

Sometimes, you can switch out a car for a bike or a walk. Other times, driving is a necessity. When that's the case, park in the very back of the parking lot so that you will walk farther.

Walk and Talk

If you are planning a work meeting or a get-together with friends, why not turn a sit-down event into a walking one? The people around you might be glad for a chance to stretch their legs.

Take the Stairs

This fast, efficient workout is easy to squeeze into your workday. After you get used to taking the stairs at a leisurely pace, raise the challenge by moving faster and taking even more stairs.

Bring In Fewer Grocery Bags

Have you ever tried to bring in every grocery bag in a single heart-pounding, arm-straining attempt? Take your time and take a few extra trips the next time you go shopping.

Recommendation

Our analysis shows your BP is related to your sleep quality, and more precisely to the amount of wakefulness during your sleep. Please view the following for best practices on improving sleep quality.

SLEEP HYGIENE PRACTICES

Medical journals and sleep experts have identified certain habits that negatively affect sleep and others that improve it. Follow some of these sleep hygiene tips to make the best out of your time sleeping.

Top BP Factors

Factors Affecting Your Blood Pressure

Figure 2. Lifestyle recommendations delivered in the study mobile app.

The system includes a safety mechanism to involve clinician intervention in the case of critically high or low BP readings. Critically high was defined as SBP >180 mmHg or DBP >110 mmHg and critically low was defined as SBP <90 mmHg or DBP <60 mmHg [2]. After a critical reading, participants received a text message asking them to remeasure their BP and prompting them to seek assistance or call their medical provider if they were experiencing certain symptoms (e.g., chest pain, severe headache, etc.). After 2 critical readings in a row, an escalation notification was sent to the PHSO care team via email for manual outreach. To avoid notification fatigue, we limited the number of critically high or low BP notifications sent to the care team to 1 notification per week for a patient.

E. Primary Outcomes: BP Change and Population HTN Control

The first primary outcome was the change in SBP and DBP from baseline to 12 and 24 weeks. A participant's baseline BP was calculated as the average of their readings during the first week of the study. The twelfth- and twenty-fourth-week BPs were a participant's average reading during that week of the study plus/minus one week. We included BP measurements from one week before and after to get a more representative result. For example, the week 12 value was the average of all readings from weeks 11-13. As previously mentioned, a 5-mmHg reduction in SBP can lower the risk of major cardiovascular events by 10% [6]. This motivated us to determine the percentage of participants who experienced >5-mmHg reduction in SBP at 12 and 24 weeks. To understand the effect on participants with different baseline BPs, we carried out subgroup analysis in which participants were sorted into 3 groups based on their baseline BP: 1. Controlled (SBP < 130 mmHg and DBP < 80 mmHg) 2. Stage 1 HTN (SBP 130-139 mmHg or DBP 80-89 mmHg) 3. Stage 2 HTN (SBP ≥140 mmHg or DBP ≥90 mmHg).

Another primary outcome was the percent change of participants in different BP categories from baseline to 12 and 24 weeks. To assess this, we calculated the percentage of participants who were in the controlled, Stage 1 HTN, and Stage 2 HTN categories at baseline, 12 weeks, and 24 weeks. Using these percentages, we determined the percentage change from baseline to 12 and 24 weeks.

F. Secondary Outcomes: Participant Engagement and Clinician Intervention

A secondary outcome measured participant engagement as determined by the consistency of data collection and interactions with our mobile application. The three main tasks participants were asked to complete included measuring BP, syncing their wearable, and answering the mobile application questionnaire. As a result, we used these 3 tasks as our measure of engagement and calculated the percentage of participants completing these tasks each week. A participant was marked as engaged for a given week if they provided a BP reading, synced their wearable data, and answered the questionnaire at least once during the week.

Another secondary outcome was the number of times participants were escalated to the PHSO care team for manual follow-up. The objective of this outcome was to determine the care team's time and resource requirements to implement the intervention and assess the scalability of our approach. The condition for care team intervention was two critical BP readings in a row as previously described.

G. Statistical Analysis

Descriptive statistics (e.g., mean, standard deviation, percentage) were calculated to describe the demographic and baseline clinical characteristics of the enrolled study population. We compared characteristics between subgroups based on their baseline BP classification.

Change in SBP and DBP from baseline to 12 and 24 weeks was analyzed using a two-tailed paired Student t-test with the level of statistical significance set to P<.05. 95% confidence intervals were calculated for these changes. Baseline and follow up BP data were normally distributed. The McNemar non-parametric test was used to examine the change in the proportion of participants in the controlled, Stage 1, and Stage 2 BP range from baseline to 12 and 24 weeks. McNemar's Test is used to determine if there is a statistically significant difference in proportions between paired data. We conducted all statistical analyses with Python 3.9 using the NumPy, Pandas, and SciPy libraries.

III. RESULTS

A. Feasibility Outcomes: Recruitment, Adherence, and Participant Experience

Participants were enrolled on a rolling basis from November 2021 to February 2023. Figure 3 details the recruitment numbers and participant flow through the study. 274 patients responded to the Epic MyChart recruitment message by contacting our team and expressing interest. In total, 164 patients consented to join the study out of which 141 were onboarded and started collecting data. There was a 9.2% drop rate from the start of the

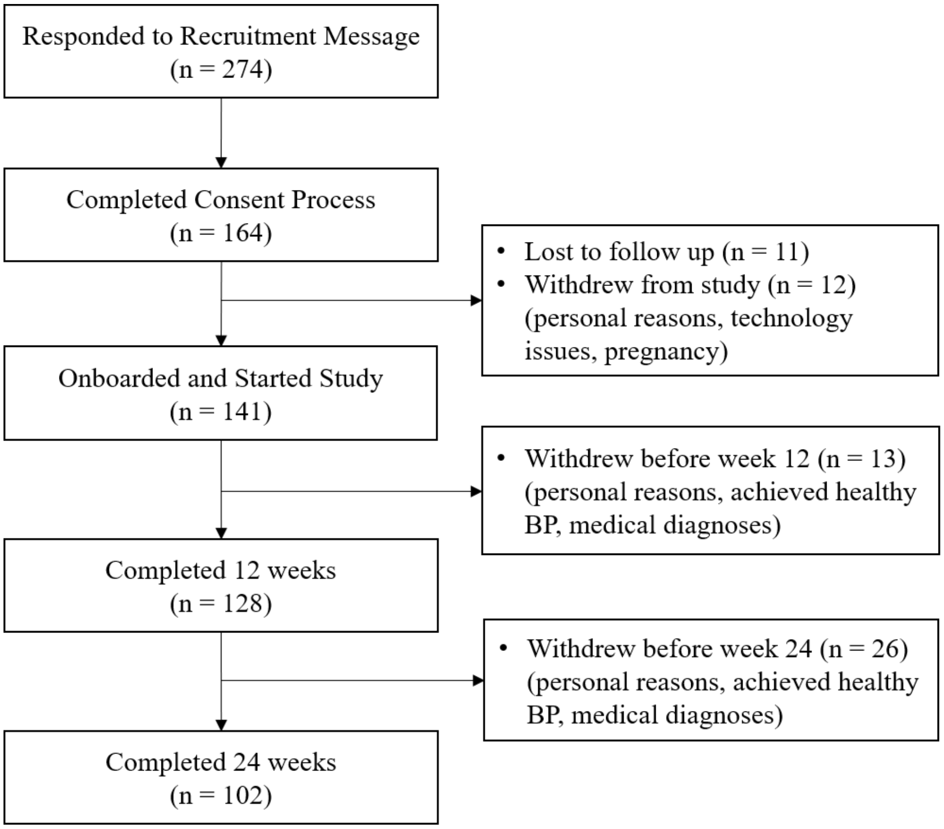


Figure 3. Flow of participants through the study.

Table I. Participant demographics and characteristics grouped by baseline BP.

	Baseline BP Category			
	All	Controlled	Stage 1	Stage 2
Participant Count	141	38	48	55
Age (years), mean (SD)	57.5 (13.9)	57.8 (16.0)	57.6 (12.6)	57.3 (13.5)
Female, n (%)	62 (44%)	14 (37%)	24 (50%)	24 (44%)
Weight (lbs.), mean (SD)	175.8 (48.4)	170.0 (41.6)	164.5 (52.3)	189.7 (45.7)
Baseline SBP (mmHg), mean (SD)	131.9 (11.5)	121.4 (6.1)	128.8 (7.1)	141.9 (9.3)
Baseline DBP (mmHg), mean (SD)	82.9 (9.0)	74.2 (4.4)	82.2 (6.4)	89.4 (8.0)
Taking HTN Meds, n (%)	118 (84%)	32 (84%)	39 (81%)	47 (85%)

study to 12 weeks and a 20.3% drop rate from 12 to 24 weeks. Reasons for participants withdrawing from the study included receiving new medical diagnoses (e.g., cancer diagnosis), achieving a healthy BP, family emergencies, and other personal reasons. For the 141 participants who onboarded, Table 1 compares characteristics between subgroups based on baseline BP classifications. The average age of participants was 57.5 years and 44% were female. For participants who had Stage 2 HTN at baseline, the average baseline BP was 141.9/89.4 mmHg. 84% of participants reported that they were taking antihypertensive medication at the beginning of the study.

As previously described, we asked participants each week to rate the difficulty of the recommendations they received on a scale from 1 to 5 and indicate whether they could follow each recommendation. This was done to assess compliance and the perceived difficulty of the recommendations. The histogram of difficulty ratings, divided into 'Yes' and 'No' responses, is shown in Figure 4. Recommendations were followed approximately 64% of the time and not followed 36% of the time. The average

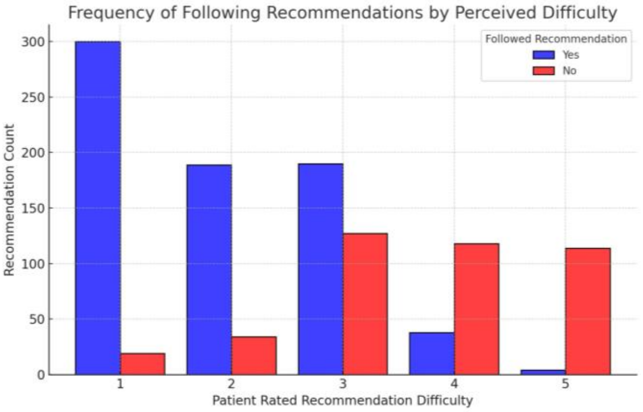


Figure 4. Histogram showing the number of recommendations adhered to based on their difficulty rating.

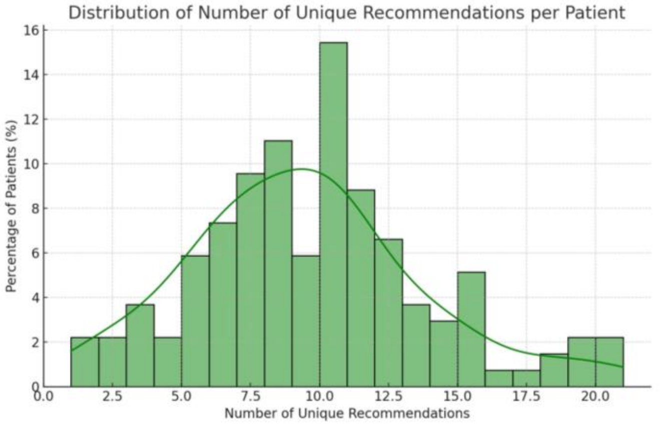


Figure 5. Distribution showing the number of unique recommendations sent to each patient. Patients received an average of 9.4 unique recommendations each.

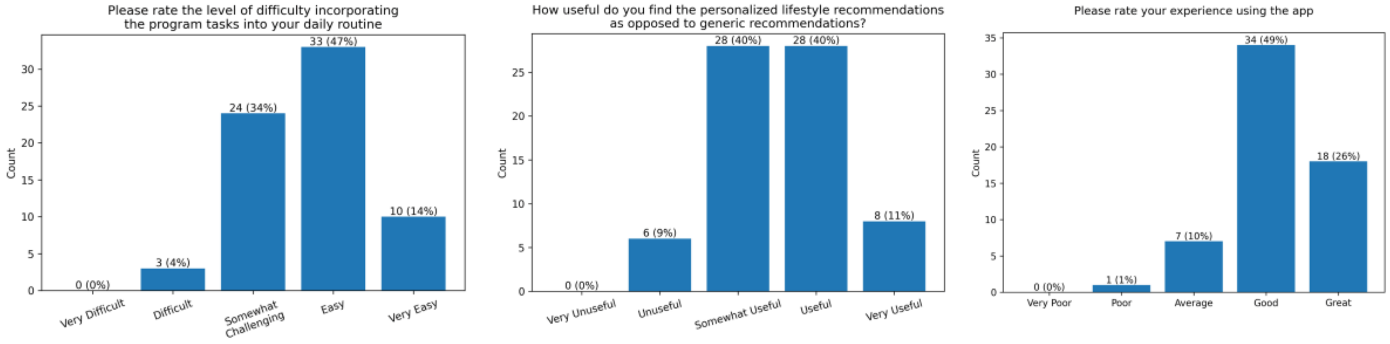


Figure 6. Participant responses to study experience survey.

difficulty rating for recommendations that were followed is 1.97, indicating lower difficulty, whereas the average for those not followed is 3.67, indicating higher difficulty. Evidently, there is a negative correlation between the perceived difficulty of a recommendation and its likelihood of being followed. We also tracked the number of unique recommendations each patient was sent. Out of 37 unique recommendations, patients received an average of 9.4 unique recommendations each. The distribution of the number of unique recommendations is shown in Figure 5. The 75th percentile, median, and 25th percentile suggest a distribution close to normal. The maximum number of unique recommendations received by a single patient was as high as 21. These statistics demonstrate a broad range of recommendations given to the patients, covering various aspects of lifestyle.

An additional feasibility outcome we evaluated was participant experience as measured by responses to a study experience survey. As previously mentioned, this survey asked patients to rate the difficulty level of completing the study tasks, how useful they found the recommendations, and their experience using the app. Figure 6 presents the distribution of participant responses to these three questions. In total, 70 participants responded to the survey. 61% responded the study tasks were "easy" or "very easy" to incorporate into their daily routine. 51% found the personalized recommendations to be "useful" or "very useful" compared to generic recommendations. 75% rated the app experience as "good" or "great".

B. Blood Pressure Outcomes

For assessing BP outcomes, we used data from the 128 and 102 participants who completed weeks 12 and 24, respectively. Table 2 details the change in BP from baseline to 12 weeks. Across all participants, there was a statistically significant change of -5.6 mmHg in SBP (t=7.6; P<.001; 95% CI -7.1 to -4.2) and -3.8 mmHg in DBP (t=7.7; P<.001; 95% CI -4.7 to -2.8) after 12 weeks. 45% (58/128) achieved a clinically meaningful SBP drop of ⩾5 mmHg after 12 weeks. Table 3 details the change in BP from baseline to 24 weeks. For those participants who completed 24 weeks, there was a statistically significant change of -8.1 mmHg in SBP (t=8.1; P<.001; 95% CI -10.1 to -6.1) and -5.1 mmHg in DBP (t=8.4; P<.001; 95% CI -6.2 to -3.9). 59% (60/102) achieved a clinically meaningful SBP drop of ⩾5 mmHg after 24 weeks.

Participants with a baseline BP classified as Stage 2 hypertension had the greatest change in BP and the greatest percentage of participants achieving a clinically meaningful SBP drop after 12 and 24 weeks. For these participants, SBP and DBP improved by -9.6 mmHg (t=7.3; P<.001; 95% CI -12.2 to -6.9) and -5.7 mmHg (t=6.2; P<.001; 95% CI -7.6 to -3.9) after 12 weeks, respectively, and -14.2 mmHg (t=8.2; P<.001; 95% CI -17.7 to -10.7) and -8.1 mmHg (t=7.0; P<.001; 95% CI -10.4 to -5.7) after 24 weeks, respectively. 65% (33/51) and 78% (29/37) achieved a clinically meaningful SBP drop of ⩾5 mmHg after 12 and 24 weeks, respectively.

Table II. Comparison of average blood pressure change at 12 weeks for different participant subgroups based on baseline BP.

	# of participants	Change in BP at 12 weeks, ∆ mean (95% CI)	t test (df)	P value	≥ 5 mmHg SBP drop at 12 weeks, N (%)
SBP					
Overall	128	-5.6 (-7.1 to -4.2)	7.6 (127)	<.001	58 (45%)
Controlled	31	-3.6 (-5.5 to -1.6)	3.7 (30)	.001	11 (35%)
Stage 1	46	-2.6 (-4.8 to -0.5)	2.5 (45)	.02	14 (30%)
Stage 2	51	-9.6 (-12.2 to -6.9)	7.3 (50)	<.001	33 (65%)
DBP					
Overall	128	-3.8 (-4.7 to -2.8)	7.7 (127)	<.001	N/A
Controlled	31	-1.6 (-3.0 to -0.2)	2.3 (30)	.03	N/A
Stage 1	46	-3.1 (-4.4 to -1.7)	4.7 (45)	<.001	N/A
Stage 2	51	-5.7 (-7.6 to -3.9)	6.2 (50)	<.001	N/A

Table III. Comparison of average blood pressure change at 24 weeks for different participant subgroups based on baseline BP.

	# of participants	Change in BP at 24 weeks, ∆ mean (95% CI)	t test (df)	P value	≥ 5 mmHg SBP drop at 24 weeks, N (%)
SBP					
Overall	102	-8.1 (-10.1 to -6.1)	8.1 (101)	<.001	60 (59%)
Controlled	28	-3.9 (-7.1 to -0.8)	2.6 (27)	.02	14 (50%)
Stage 1	37	-5.2 (-7.9 to -2.5)	3.9 (36)	<.001	17 (46%)
Stage 2	37	-14.2 (-17.7 to -10.7)	8.2 (36)	<.001	29 (78%)
DBP					
Overall	102	-5.1 (-6.2 to -3.9)	8.4 (101)	<.001	N/A
Controlled	28	-1.9 (-3.6 to -0.2)	2.3 (27)	.03	N/A
Stage 1	37	-4.4 (-6.0 to -2.8)	5.7 (36)	<.001	N/A
Stage 2	37	-8.1 (-10.4 to -5.7)	7.0 (36)	<.001	N/A

Another primary outcome we assessed was the percent change of participants in different BP categories from baseline to 12 and 24 weeks. Tables 4 and 5 detail this analysis. For participants completing 12 weeks, the percentage of participants in the controlled range increased by 17% from 24% to 41% (McNemar X^2=3.0, P<.001). The percentage of participants with Stage 2 HTN decreased by 25% from 40% to 15% (McNemar X^2=4.0, P<.001) after 12 weeks. This means that 71% (36/51) of patients with Stage 2 HTN at baseline moved into lower BP categories after 12 weeks. For those who completed 24 weeks, the percentage in the controlled range increased by 26% from 28% to 54% (McNemar X^2=2.0, P<.001), and the Stage 2 percentage decreased by 26% from 36% to 10% (McNemar X^2=3.0, P<.001). This means that 73% (27/37) of patients with Stage 2 HTN at baseline moved into lower BP categories after 24 weeks. Note that the percentage changes for the Stage 1 HTN category from baseline to 12 and 24 weeks were not statistically significant at the level P=.05. The smaller change in the Stage 1 HTN population is due to a cascading effect where the number of participants moving from Stage 2 into Stage 1 was offset by the number of patients moving out of Stage 1 and into the controlled BP category. For example, from baseline to 24 weeks, 18 participants moved from Stage 2 to Stage 1, and 17 participants moved from Stage 1 to controlled.

Table IV. Change in the percentage of participants in different BP categories from baseline to 12 weeks.

	Population at Baseline, % (n)	Population at 12 weeks, % (n)	12-week difference, %	McNeymar X^2	P value
Controlled	24% (31)	41% (53)	17%	3.0	<.001
Stage 1	36% (46)	44% (56)	8%	20.0	.20
Stage 2	40% (51)	15% (15)	-25%	4.0	<.001

Table V. Change in the percentage of participants in different BP categories from baseline to 24 weeks.

	Population at Baseline, % (n)	Population at 24 weeks, % (n)	24-week difference, %	McNeymar X^2	P value
Controlled	28% (28)	54% (55)	26%	2.0	<.001
Stage 1	36% (37)	36% (37)	0%	N/A	N/A
Stage 2	36% (37)	10% (10)	-26%	3.0	<.001

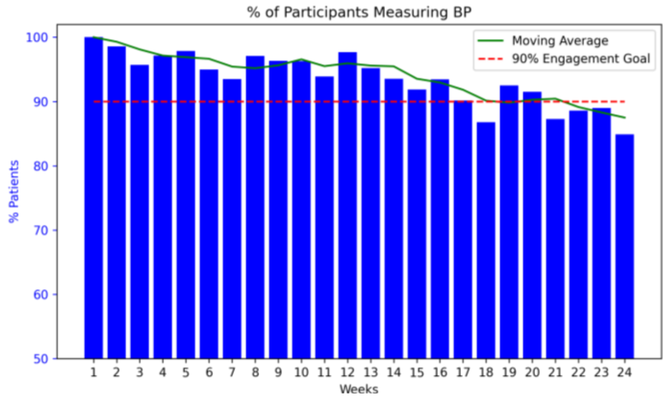

% of Participants Measuring BP

Figure 7. Percentage of active participants measuring their BP during the 24 weeks.

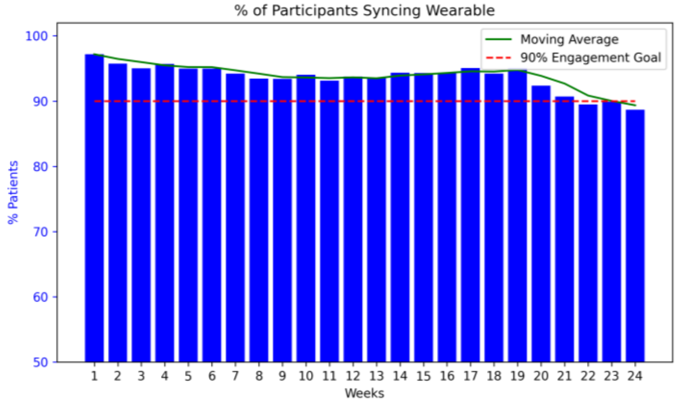

% of Participants Syncing Wearable

Figure 8. Percentage of active participants syncing their wearable during the 24 weeks.

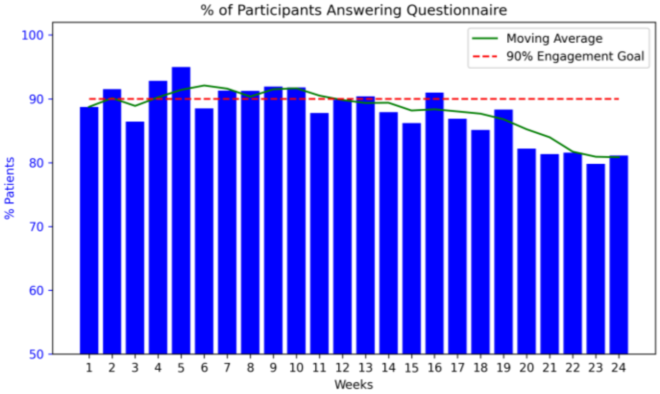

% of Participants Answering Questionnaire

Figure 9. Percentage of active participants answering the questionnaire during the 24 weeks.

C. *Participant Engagement*

We assessed participant engagement based on the percentage of active participants completing the program tasks each week. Figures 7, 8, and 9 show the weekly percentage of active patients measuring their BP, syncing their wearable, and answering the questionnaire during the 24 weeks, respectively. We had set an engagement goal of 90% for the study represented by the red dashed lines in the figures. The average BP measurement engagement rate was 93% and this rate was greater than 90% for 19 out of 24 weeks. The average wearable syncing engagement rate was 94% and this rate was greater than 90% for 21 out of 24 weeks. The average questionnaire engagement rate was 88% and this rate was greater than 90% for 10 out of 24 weeks.

D. *Clinician Intervention*

Table 6 details the clinician intervention required during the program. For 128 participants completing 12 weeks, an escalation notification was sent to the care team 8 times. There were 5 unique patients (3.9%) who required manual outreach during the first 12 weeks. For 102 patients completing 24 weeks, an escalation notification was sent to the PHSO care team 11 times. There were 6 unique patients (5.9%) who required manual outreach during the 24 weeks.

Table VI. Participant escalations leading to manual care team outreaches for critical BP readings.

	# of Participants	# of Escalations	# of Participants Escalated (%)
12 Weeks	128	8	5 (3.9%)
24 Weeks	102	11	6 (5.9%)

IV. DISCUSSION

A. *Principal Findings*

This study aims to assess the effectiveness of a fully digital, autonomous, and AI-based lifestyle coaching program in achieving BP control and high engagement among adults with HTN. The key components of this program included detailed lifestyle data collection via both wearables and questionnaires and weekly lifestyle recommendations based on personalized, AI-based analytics delivered via a mobile application. The guidance supported the participant's daily efforts to improve BP through behavioral changes that targeted physical activity, sleep hygiene, stress management, and dietary choices. Specifically, the program provided weekly guidance based on associations between lifestyle data and BP uncovered using ML, and asked the participant to focus on the lifestyle factor with the greatest association. The precise lifestyle recommendations enabled participants to focus on the most relevant aspect of their lifestyle as opposed to receiving general guidance. Our intervention approach aligns with the Fogg Behavioral Model which states that three elements (ability, motivation, prompts) are essential for behavior change [42]. By directing participants to focus on one lifestyle behavior at a time, the intervention simplified compliance and therefore increased the ability of the participants to adhere to the recommendations. This targeted strategy likely bolstered participants' motivation, as they could clearly see how specific lifestyle modifications directly influenced their blood pressure. Each recommendation was delivered via text message and prompted the user to take specific action. Furthermore, each recommendation was sent with a motivational message regarding their BP progress. We believe that this combination of personalized advice, ease of compliance, and motivational reinforcement contributed to our high engagement and improved BP outcomes.

We assessed multiple feasibility outcomes including enrollment rate, adherence, and participant experience. 60% (164/274) of patients who initially expressed interest in the joining the program ended up enrolling. Furthermore, although patients were recruited based on their last clinical BP reading which required an SBP $\geqslant$ 140 mmHg or DBP $\geqslant$ 90 mmHg (Stage 2 HTN), many participants were not in the Stage 2 range at baseline. Possible reasons for this include white coat hypertension [26] or that between the time of their last clinical BP reading and their enrollment in the study, they may have started taking BP medication or changed their diet. To improve the enrollment rate and ensure that patients who enroll have Stage 2 HTN, a new recruitment strategy is required. This new strategy could involve recruiting patients through primary care physician (PCP) referrals. We hypothesize this will increase the take-up rate due to increased trust from the more personal nature of the referral [33]. Furthermore, for those patients who are referred to the study, their PCPs would be instructed not to start the patients on any new BP medication or lifestyle intervention prior to the study, except in critical cases. This would help ensure patients joining the study are indeed in the Stage 2 HTN category. Another feasibility outcome we assessed was participant experience. While the majority of participants found the study tasks easy to incorporate into their daily routine, others encountered challenges. These included difficultly in measuring BP due to work schedules and travel, caregiving responsibilities, and equipment and syncing issues. To address these challenges, the intervention should be more context-aware and adapt the program tasks and recommendations based on patients' circumstances. For example, a patient who works a night shift should not be asked to measure their BP at the same time or be given the same sleep recommendations as a patient who works during the day. Context-aware interventions would enhance the patient experience and increase the engagement rate.

Participants experienced a statistically significant decrease of 8.1 and 5.1 mmHg in SBP and DBP, respectively, after 24 weeks. Furthermore, this improvement was more pronounced in participants who started the program with Stage 2 HTN, achieving a 14.2 and 8.1 mmHg reduction in SBP and DBP, respectively. Reducing blood pressure holds clinical significance not only for individuals with Stage 2 HTN but also for those with elevated BP or Stage 1 HTN. This is clinically meaningful as lower SBP values have been associated with progressively reduced risks of stroke, major cardiovascular events, and cardiovascular as well as all-cause mortalities [41]. In addition to BP improvement, the study demonstrates the intervention's ability to maintain sustained engagement. However, the engagement rate dropped during the last 4 weeks potentially because the participants whose BP had improved through the program may have reduced their engagement since they did not feel the urgent need. In this work, the required participant tasks are the same throughout; however, participants may find it useful if the requirements are adaptive based on their health condition and preferences. It is worthwhile to design a dynamic mechanism that can adjust the extent and frequency of patient requirements based on the intervention progress. Both the BP and engagement results are achieved with minimal clinician intervention, primarily due to the autonomous nature of the intervention, demonstrating the potential scalability of this approach for HTN management.

The observed BP improvement results from this study are comparable to those from clinician-led HTN management programs [18-21]. The 3-month intervention program presented in [18] combined lifestyle counseling with HTN education, guided home BP monitoring, support for taking medications, and was led by either a registered nurse or certified diabetes care and education specialist. Stage 2 patients who participated in this program experienced a 10.3 and 6.5 mmHg reduction in SBP and DBP, respectively, after 3 months. In [20], the 3-month digital intervention involved patients measuring their BP at least once per week and corresponding with pharmacists and health coaches to co-create their treatment plan by choosing among various lifestyle modifications (e.g., reducing dietary sodium) and medication options (e.g., switching to generics or lower cost options). Stage 2 patients participating in this program experienced a 14.0 and 5.0 mmHg reduction in SBP and DBP, respectively, after 3 months. Both interventions presented in [18] and [20] assigned participants a designated HTN coach who would provide lifestyle education and recommendations. These previous studies primarily attribute their BP outcomes to the program's support led by health professionals who interpreted BP data and supported lifestyle change. While health coach-based programs can produce meaningful BP improvements, the reliance on health coaches is highly time and resource-intensive. As a result, these approaches have limited scalability and accessibility since an individual health coach can only engage and care for a limited number of patients at a time. In contrast, our results demonstrate that a fully digital, AI-based lifestyle coaching program can produce clinically meaningful BP improvements comparable to those of programs led by health professionals. There is also potential for our approach to be used in conjunction with health coach-based programs. Under such a framework, our AI-based interactions and learnings from the patients can extend the reach of health coaches and provide them with more detailed insights about lifestyle factors impacting patients.

B. Study Limitations and Future Directions

Since this was a single-arm, nonrandomized study, it was not possible to conduct a causal analysis due to the lack of a control group. Additionally, regression to the mean is another limitation since participants with initially high BP values may naturally converge towards the average over time. Therefore, in order to conduct causal analysis and account for regression to the mean, a randomized controlled trial may be conducted to draw stronger conclusions in a future study. To gain additional insights into the effectiveness of the program, we can randomize patients into different treatment arms by providing different versions of the program. This could include varying the frequency or content of the lifestyle recommendations across the different treatment arms. Furthermore, we could investigate which lifestyle interventions, for example increasing steps or improving sleep hygiene, result in greater BP improvements. With careful design, we can create a multi-arm trial to investigate optimal engagement strategies and recommendations for different types of patients. Another limitation of this study is selection bias since the participants self-selected to enroll after receiving the recruitment flyer. To address this, we plan to recruit patients through PCP referrals. PCPs will refer their patients with high cardiovascular risk, who can benefit from our intervention. As previously mentioned, we hypothesize this will increase the take-up rate due to increased trust from the more personal nature of the referral [33]. Additionally, there is a need for a longer follow-up period since behavioral interventions can show improved outcomes during the first 6 months and then recidivism during the next 6 months. Finally, we did not collect socioeconomic data (e.g., occupation, education, income) from participants, preventing an analysis of how socioeconomic status impacts the program outcomes. In our future work, we will consider socioeconomic factors when analyzing the impact of the intervention. This analysis is imperative to ensure the use of digital technologies does not contribute to an increased digital divide in healthcare and that all patients have equal access to high-quality healthcare [27, 28].

C. Conclusions

To address the challenges of poor patient engagement due to generic, non-personalized lifestyle guidance and limited scalability of care due to human coaching models, we propose an AI-driven, autonomous, precise lifestyle coaching program for patients with HTN. Patients who enrolled in the program experienced a significant improvement in BP. The program maintained a high engagement rate while requiring minimal care team intervention. As the burden of hypertension increases globally, the necessity to develop new strategies to achieve HTN control at scale is greater than ever. An AI-based, autonomous approach to HTN-related lifestyle coaching can increase scalability and accessibility to effective BP management, ultimately improving the cardiovascular health of our community.

ACKNOWLEDGEMENTS

The research reported in this paper was supported by the Jacobs Family Endowed Chair fund for Professor Sujit Dey. We would like to thank Brian Khan, MD, MBA for his clinical guidance during the study. We would like to thank the following from UCSD Health Population Health Services Organization for their support during the study: Melissa Gellman, MSN, MBAc, BSN, BA, CDCES, Russell Shimada, RN, MSN, CDE/CDCES, and Victoria Harris, MPH.

REFERENCES

[1] Fryar C, Ostchega Y, Hales C, Zhang G, and Kruszon-Moran D, Hypertension prevalence and control among adults: United States, 2015–2016, NCHS data brief, no. 289, 2017.

[2] Whelton P, et al., Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, Journal of the American College of Cardiology, vol. 71, no. 19, pp. 2273-2275, 2018.

[3] Centers for Disease Control and Prevention. Hypertension Cascade: Hypertension Prevalence, Treatment and Control Estimates Among U.S. Adults Aged 18 Years and Older Applying the Criteria from the American College of Cardiology and American Heart Association's 2017 Hypertension Guideline. NHANES 2015–2018.

[4] Lebeau J, Cadwallader J, Aubin-Auger I, Mercier A, Pasquet T, Rusch E, et al. The concept and definition of therapeutic inertia in hypertension in primary care: a qualitative systematic review. BMC Fam Pract 2014 Jul 02; 15:130.

[5] Kirkland EB, et al., Trends in healthcare expenditures among US adults with hypertension: national estimates, 2003–2014. J Am Heart Assoc. 2018.

[6] Blood Pressure Lowering Treatment Trialists' Collaboration. Pharmacological blood pressure lowering for primary and secondary prevention of cardiovascular disease across different levels of blood pressure: an individual participant-level data meta-analysis. Lancet 2021 May 01;397(10285):1625-1636.

[7] Shimbo D, Artinian NT, Basile JN, Krakoff LR, Margolis KL, Rakotz MK, American Heart Association the American Medical Association. Self-measured blood pressure monitoring at home: a joint policy statement from the American Heart Association and American Medical Association. Circulation 2020 Jul 28;142(4): e42-e63.

[8] Muntner P, Shimbo D, Carey RM, et al. Measurement of blood pressure in humans: a scientific statement from the American Heart Association. Hypertension. 2019;73(5): e35-e66.

[9] Tucker KL, Sheppard JP, Stevens R, Bosworth HB, Bove A, Bray EP, et al. Self-monitoring of blood pressure in hypertension: A systematic

review and individual patient data meta-analysis. PLoS Med 2017 Sep;14(9): e1002389.

[10] Uhlig K, Patel K, Ip S, Kitsios GD, Balk EM. Self-measured blood pressure monitoring in the management of hypertension: a systematic review and meta-analysis. Ann Intern Med. 2013;159(3):185-194.

[11] Appel L, Champagne C, Harsha D, Cooper L, Obarzanek E, Elmer P, et al., Effects of comprehensive lifestyle modification on blood pressure control: main results of the PREMIER clinical trial, Journal of the American Medical Association, vol 289, pp. 2083–2093, 2003.

[12] Doughty K, Del Pilar N, Audette A, Katz D, Lifestyle Medicine and the Management of Cardiovascular Disease, Current cardiology reports, vol. 19, no. 11, pp. 116, 2017.

[13] Covassin N and Singh P, Sleep duration and cardiovascular disease risk: epidemiologic and experimental evidence, Sleep medicine clinics. vol. 11, no. 1, pp. 81-89, 2016.

[14] Cornelissen V and Smart N, Exercise Training for Blood Pressure: A Systematic Review and Meta-analysis, Journal of the American Heart Association, 2013.

[15] Eckel RH et al., 2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines, Circulation (2014).

[16] Bakris G, Ali W, Parati G, et al., ACC/AHA Versus ESC/ESH on Hypertension Guidelines, J Am Coll Cardiol. 2019 Jun, 73 (23) 3018–3026.

[17] Bell RA and Kravitz RL, Physician counseling for hypertension: What do doctors really do? Patient Educ Couns., 72 (2008), pp. 115-121

[18] Wilson-Anumudu F, Quan R, Cerrada C, Juusola J, Castro Sweet C, Bradner Jasik C, Turken M, Pilot Results of a Digital Hypertension Self-Management Program Among Adults with Excess Body Weight: Single-Arm Nonrandomized Trial, JMIR Form Res. 2022 Mar 30;6(3): e33057. doi: 10.2196/33057. PMID: 35353040; PMCID: PMC9008519.

[19] Toro-Ramos T, Kim Y, Wood M, et al., Efficacy of a mobile hypertension prevention delivery platform with human coaching. J Hum Hypertens 31, 795–800 (2017).

[20] Milani RV, Lavie CJ, Bober RM, Milani AR, Ventura HO. Improving Hypertension Control and Patient Engagement Using Digital Tools. Am J Med 2017 Jan;130(1):14-20.

[21] Mao AY, Chen C, Magana C, Caballero Barajas K, Olayiwola JN, A Mobile Phone-Based Health Coaching Intervention for Weight Loss and Blood Pressure Reduction in a National Payer Population: A Retrospective Study, JMIR Mhealth Uhealth 2017;5(6):e80

[22] Branch OH, Rikhy M, Auster-Gussman LA, Lockwood KG, Graham SA, Relationships Between Blood Pressure Reduction, Weight Loss, and Engagement in a Digital App-Based Hypertension Care Program: Observational Study, JMIR Form Res. 2022 Oct 27;6(10):e38215. doi: 10.2196/38215. PMID: 36301618; PMCID: PMC9650575.

[23] Leitner J, Chiang P, Khan B, Dey S, An mHealth Lifestyle Intervention Service for Improving Blood Pressure using Machine Learning and IoMTs, 2022 IEEE International Conference on Digital Health (ICDH), 2022, pp. 142-150, doi: 10.1109/ICDH55609.2022.00030.

[24] Monitoring Your Blood Pressure at Home. Heart Attack and Stroke Symptoms. URL: https://www.heart.org/en/health-topics/high-blood-pressure/understanding-blood-pressure-readings/monitoring-your-blood-pressure-at-home

[25] Alagappan R and Das S, Uncovering Twilio: Insights into Cloud Communication Services.

[26] Franklin SS, Thijs L, Hansen TW, O'Brien E, Staessen JA. White-coat hypertension: new insights from recent studies. Hypertension. 2013; 62:982–987.

[27] Ramsetty A and Adams C, Impact of the digital divide in the age of COVID-19, J. Amer. Med. Inform. Assoc., vol. 27, pp. 1147–1148, 2020.

[28] Rodriguez JA, Clark CR, Bates DW. Digital Health Equity as a Necessity in the 21st Century Cures Act Era. JAMA. 2020;323(23):2381–2382.

[29] Siervo M, Lara J, Chowdhury S, Ashor A, Oggioni C, Mathers JC. Effects of the Dietary Approach to Stop Hypertension (DASH) diet on cardiovascular risk factors: a systematic review and meta-analysis. British Journal of Nutrition. 2015;113(1):1-15.

[30] Henriksen A, Haugen Mikalsen M, Woldaregay A, Muzny M, Hartvigsen G, Hopstock L, Grimsgaard S. Using Fitness Trackers and Smartwatches to Measure Physical Activity in Research: Analysis of Consumer Wrist-Worn Wearables. J Med Internet Res 2018;20(3):e110

[31] Germini F, Noronha N, Borg Debono V, Abraham Philip B, Pete D, Navarro T, Keepanasseril A, Parpia S, de Wit K, Iorio A. Accuracy and Acceptability of Wrist-Wearable Activity-Tracking Devices: Systematic Review of the Literature. J Med Internet Res 2022;24(1):e30791

[32] Miller DJ, Sargent C, Roach GD. A Validation of Six Wearable Devices for Estimating Sleep, Heart Rate and Heart Rate Variability in Healthy Adults. Sensors. 2022; 22(16):6317.

[33] Pfaff E, Lee A, Bradford R, Pae J, Potter C, Blue P, et al. Recruiting for a pragmatic trial using the electronic health record and patient portal: Successes and lessons learned. J Am Med Inform Assoc 2019 Jan 01;26(1):44-49

[34] Yuenyongchaiwat K, Pipatsitipong D, Sangprasert P. Increasing walking steps daily can reduce blood pressure and diabetes in overweight participants. Diabetol Int 9, 75–79 (2018).

[35] Lefferts E, Saavedra J, Song B, Brellenthin A, Pescatello L, Lee D. Increasing Lifestyle Walking by 3000 Steps per Day Reduces Blood Pressure in Sedentary Older Adults with Hypertension: Results from an e-Health Pilot Study. Journal of Cardiovascular Development and Disease. 2023; 10(8):317.

[36] Bock J, Vungarala S, Covassin N, Somers V. Sleep Duration and Hypertension: Epidemiological Evidence and Underlying Mechanisms, American Journal of Hypertension, Volume 35, Issue 1, January 2022, Pages 3–11.

[37] Ali W, Gao G, Bakris G. Improved Sleep Quality Improves Blood Pressure Control among Patients with Chronic Kidney Disease: A Pilot Study. Am J Nephrol 11 March 2020; 51 (3): 249–254.

[38] Ponte Márquez P, Feliu-Soler A, Solé-Villa M, et al. Benefits of mindfulness meditation in reducing blood pressure and stress in patients with arterial hypertension. J Hum Hypertens 33, 237–247 (2019).

[39] Gupta D, Lewis C, Varady K, et al. Effect of Dietary Sodium on Blood Pressure: A Crossover Trial. JAMA. 2023;330(23):2258–2266. doi:10.1001/jama.2023.23651

[40] He F, Tan M, Ma Y, et al. Salt Reduction to Prevent Hypertension and Cardiovascular Disease: JACC State-of-the-Art Review. J Am Coll Cardiol. 2020 Feb, 75 (6) 632–647.

[41] Bundy JD, Li C, Stuchlik P, Bu X, Kelly TN, Mills KT, et al. Systolic blood pressure reduction and risk of cardiovascular disease and mortality: a systematic review and network meta-analysis. JAMA Cardiol 2017 Jul 01;2(7):775-781

[42] Fogg, B. Fogg behavior model. URL: https://behaviormodel.org.