Original Paper

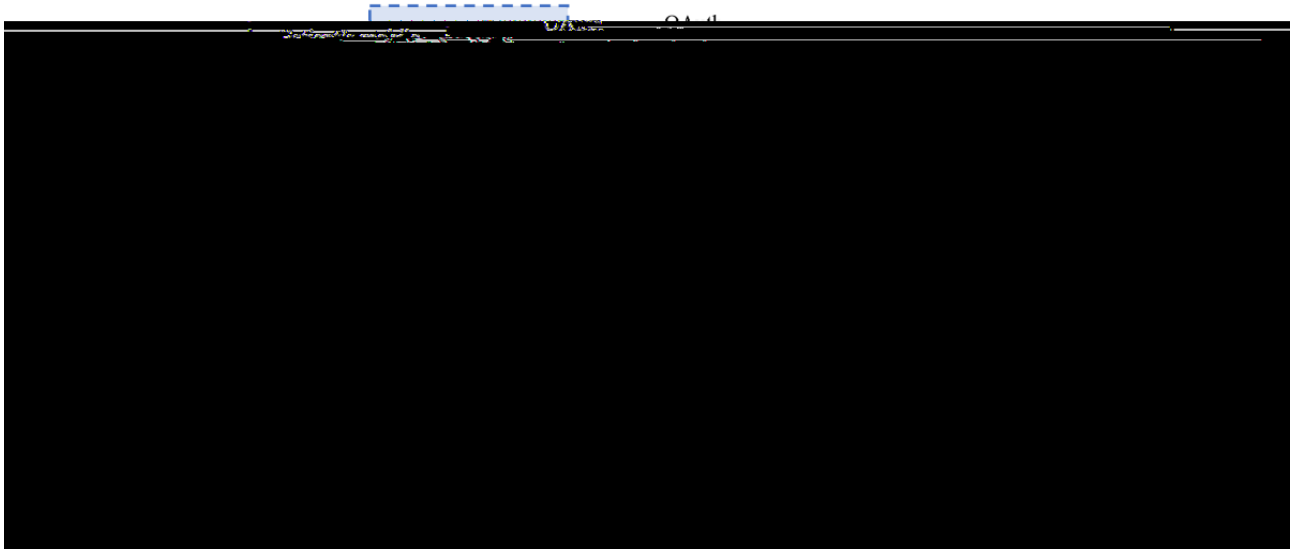
The Eff

KEYWORDS

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

such as a cane, wheelchair, or walker). In addition, participants were required to be aged ≥18 years at enrollment, be English speaking, and own an Android or iPhone (Apple Inc) 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 the Epic MyChart (Epic Systems Corporation) messenger. The flyer introduced

Figure 1. Architecture of data transmission. Participant data were collected from Bluetooth-enabled blood pressure (BP) monitors, wearable devices, and a mobile app–based questionnaire. Data were uploaded through the respective application programming interfaces (APIs) to our app server, where the individualized analysis was carried out before delivering recommendations to participants.



Description of the Intervention

The intervention is intended to support participants' 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 hypertension. The system integrates the data described in the previous section into a combined data set for each participant. Each participant's personal data set consists of lifestyle features (eg, step count, sleep duration, and salt consumption) that are time aligned with their BP measurements, which serve as the labels for training the ML model. Therefore, each participant's data set 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. On the basis of 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, such as increasing step count [29,30], improving sleep quality [31,32], managing stress [33], and reducing salt consumption [34,35], can result in BP reduction. The objective of these precise lifestyle recommendations is to encourage participants to concentrate on 1 aspect of their lifestyle at a time, focusing on the factor 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 study [23].

Figure 2. Lifestyle

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 2 critical BP readings in a row, as previously described.

Statistical Analysis

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

Change in SBP and DBP from baseline to 12 weeks and 24 weeks was analyzed using a 2-tailed paired Student *t* test with the level of statistical significance set to $P<.05$. Furthermore, 95% CIs were calculated for these changes. Baseline and follow-up BP data were normally distributed. The McNemar nonparametric test was used to examine the change in the proportion of participants in the

Figure 3. Flow of participants through the study. Adults with hypertension were enrolled from the University of California, San Diego Health between November 2021 and February 2023 into a single-arm nonrandomized trial. BP: blood pressure.

Table 1. Participant demographics and characteristics grouped by baseline BP[a] (N=141).

Characteristics	Baseline BP category			
	All (N=141)	Controlled (n=38)	Stage 1 (n=48)	Stage 2 (n=55)
Age (y), 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 (lb), mean (SD)	175.8 (48.4)	170.0 (41.6)	164.5 (52.3)	189.7 (45.7)
Baseline SBP[b] (mm Hg), mean (SD)	131.9 (11.5)	121.4 (6.1)	128.8 (7.1)	141.9 (9.3)
Baseline DBP[c] (mm Hg), mean (SD)	82.9 (9.0)	74.2 (4.4)	82.2 (6.4)	89.4 (8.0)
Taking hypertension medication, n (%)	118 (83.7)	32 (84)	39 (81)	47 (85)

[a]BP: blood pressure.

[b]SBP: systolic blood pressure.

[c]DBP: diastolic blood pressure.

Figure 4. Distribution showing the number of unique recommendations sent to each patient. Patients received an average

Table 3. Comparison of average BP[a] change at 24 weeks for different participant subgroups based on baseline BP (n=102)[b].

BP and subgroups	Participants, n (%)	Change in BP at 24 weeks, Δmean (SD; 95% CI)	*t* test (*df*)	*P* value	≥5–mm Hg reduction in SBP[c] at 24 weeks, n (%)
SBP					
Overall	102 (100)	−8.1 (10.1; −10.1 to −6.1)	8.1 (101)	<.001	60 (58.8)
Controlled	28 (27.5)	−3.9 (8.6; −7.1 to −0.8)	2.6 (27)	.02	14 (50)
Stage 1	37 (36.3)	−5.2 (8.0; −7.9 to −2.5)	3.9 (36)	<.001	17 (46)
Stage 2	37 (36.3)	−14.2 (10.6; −17.7 to −10.7)	8.2 (36)	<.001	29 (78)
DBP[d]					
Overall	102 (100)	−5.1 (6.0; −6.2 to −3.9)	8.4 (101)	<.001	N/A[e]
Controlled	28 (27.5)	−1.9 (4.3; −3.6 to −0.2)	2.3 (27)	.03	N/A
Stage 1	37 (36.3)	−4.4 (4.7; −6.0 to −2.8)	5.7 (36)	<.001	N/A
Stage 2	37 (36.3)	−8.1 (6.9; −10.4 to −5.7)	7.0 (36)	<.001	N/A

[a]BP: blood pressure.

[b]For participants with stage-2 hypertension at baseline, SBP and DBP changed by −14.2 mm Hg and −8.1 mm Hg, respectively, after 24 weeks.

[c]SBP: systolic blood pressure.

[d]DBP: diastolic blood pressure.

[e]N/A: not applicable.

Participants with a baseline BP classified as stage-2 hypertension had the greatest change in BP and the greatest percentage of participants achie

Table 5. Change in the percentage of participants in different BP[a] categories from baseline to 24 weeks (n=102)[b].

Subgroups	Population at baseline, n (%)	Population at 24 weeks, n (%)	24-week difference, n (%)	McNemar χ^2 (*df*)	*P* value
Controlled	28 (27.5)	55 (53.9)	27 (26.5)	2.0 (1)	<.001
Stage 1	37 (36.3)	37 (36.3)	0 (0)	N/A[c]	N/A
Stage 2	37 (36.3)	10 (9.8)	−27 (−26.5)	3.0 (1)	<.001

[a]BP: blood pressure.

[b]The percentage of participants with stage-2 hypertension decreased by 26.5% from 36.3% to 9.8% after 24 weeks.

[c]N/A: not applicable.

Participant Engagement

We assessed participant engagement based on the percentage of active participants completing the program tasks each week. Figures 5-7 show the weekly percentage of active patients measuring their BP, syncing their wearable device, and answering the questionnaire during the 24 weeks, respectively. We set an engagement goal of 90% for the study, which is represented by the red dashed lines in the figures. The average BP measurement engagement rate was 93% (SD 4.3%), and this rate was >90% for 19 (79%) out of 24 weeks. The average wearable syncing engagement rate was 94% (SD 2.4%), and this rate was >90% for 21 (88%) out of 24 weeks. The average questionnaire engagement rate was 88% (SD 4.9%), and this rate was >90% for 10 (42%) out of 24 weeks.

Figure 5. Percentage of active participants measuring their blood pressure (BP) during the 24 weeks.

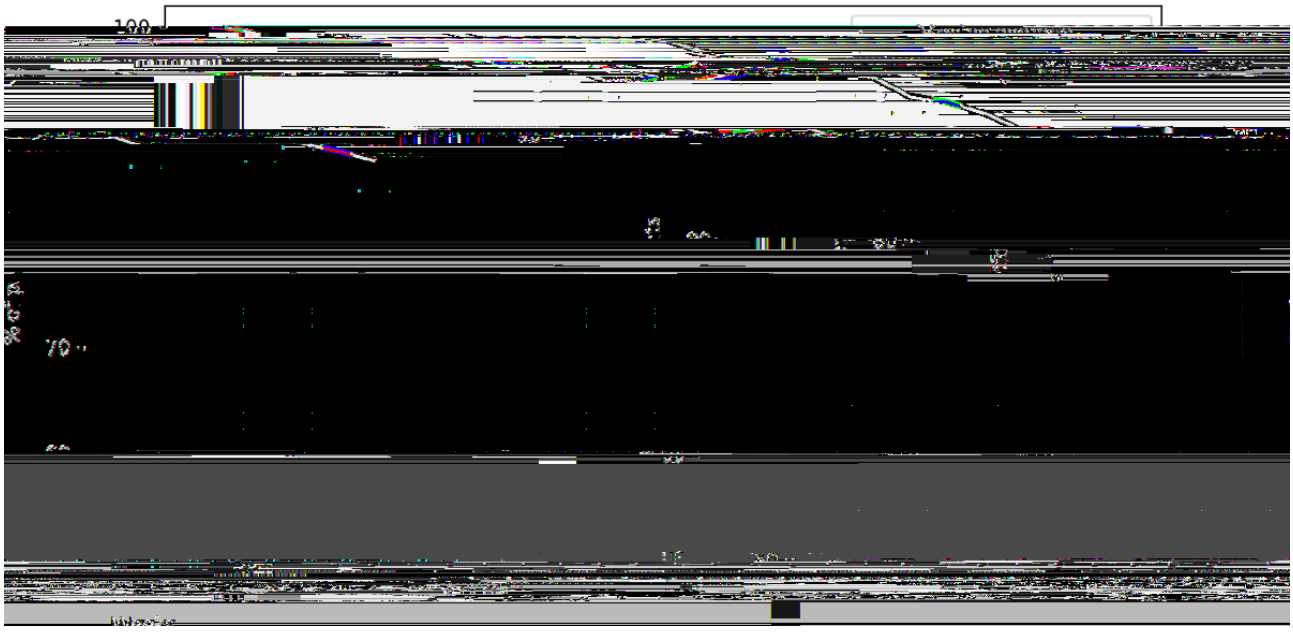


Figure 6. Percentage of active participants syncing their wearable device during the 24 weeks.

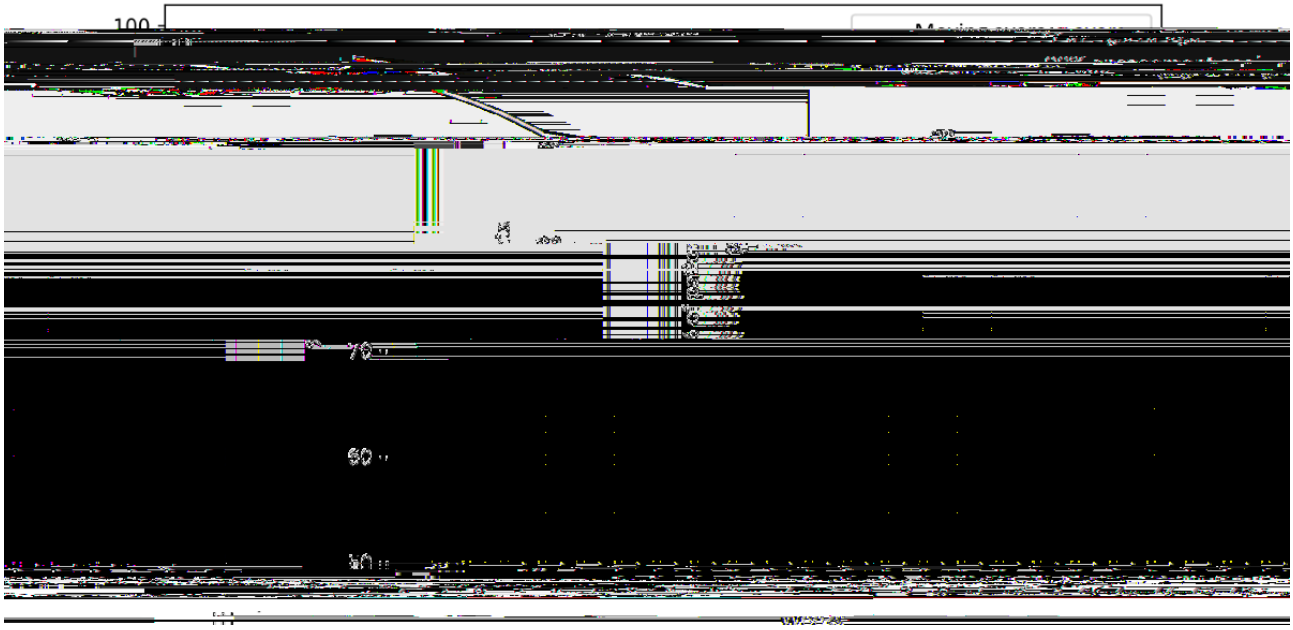
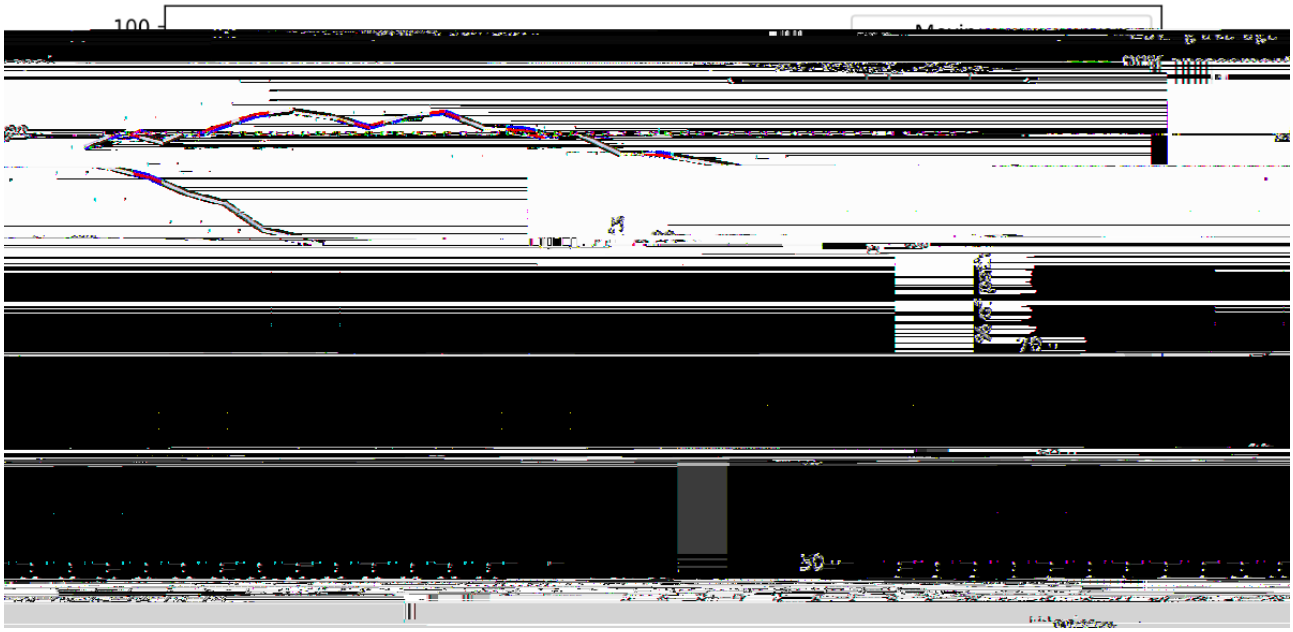


Figure 7. Percentage of active participants answering the questionnaire during the 24 weeks.



Clinician Intervention

For the 128 participants completing 12 weeks in the study, an escalation notification was sent to the care team 8 times. There were 3.9% (5/128) unique patients who required manual outreach during the first 12 weeks. For the 102 patients completing 24 weeks in the study, an escalation notification was

are essential for behavior change [37]. By directing participants to focus on 1 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 BP. Each recommendation was delivered via a 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

mont2mgroup. In addition, regression to the mean is another limitation as participants with initially high BP values may naturally converge toward the average over time. Therefore, 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 multiarm trial to investigate optimal engagement strategies and recommendations for different types of patients. Another limitation of this study is selection bias as 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 that this will increase the take-up rate due to increased trust from the more personal nature of the referral [39]. In addition, there is a need for a longer follow-up period as 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 (eg, occupation, education, and income) from participants,2.1 69.611 48Tj1 g 0 0

guideline- NHANES 2017–2020. Centers for Disease Control and Prevention. 2017. URL: https://millionhearts.hhs.gov/data-reports/hypertension-prevalence.html [accessed 2023-05-12]
3. 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. Jul 02, 2014;15:130. [FREE Full text] [doi: 10.1186/1471-2296-15-130] [Medline: 24989986]
4. Kirkland EB, Heincelman M, Bishu KG, Schumann SO, Schreiner A, Axon RN, et al. Trends in healthcare expenditures among US adults with hypertension: national estimates, 2003-2014. J Am Heart Assoc. May 30, 2018;7(11):e008731. [FREE Full text] [doi: 10.1161/JAHA.118.008731] [Medline: 29848493]
5. WhelA48m9Jin

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. Oct 27, 2022;6(10):e38215. [FREE Full text] [doi: 10.2196/38215] [Medline: 36301618]
23. Leitner J, Chiang P, Khan B, Dey S. An mHealth lifestyle intervention service for improving blood pressure using machine learning and IoMTs. In: Proceedings of the 2022 IEEE International Conference on Digital Health. 2022. Presented at: ICDH '22; July 10-16, 2022:142-150; Barcelona, Spain. URL: https://ieeexplore.ieee.org/document/9861082 [doi: 10.1109/icdh55609.2022.00030]
24. Monitoring your blood pressure at home. American Heart Association. URL: https://www.heart.org/en/health-topics/high-blood-pressure/understanding-blood-pressure-readings/monitoring-your-blood-pressure-at-home [accessed 2024-04-05]
25. 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. Br J Nutr. Jan 14, 2015;113(1):1-15. [doi: 10.1017/S0007114514003341] [Medline: 25430608]
26. Henriksen A, Haugen Mikalsen M, Woldaregay AZ, Muzny M, Hartvigsen G, Hopstock LA, et al. Using fitness trackers and smartwatches to measure physical activity in research: analysis of consumer wrist-worn wearables. J Med Internet Res. Mar 22, 2018;20(3):e110. [FREE Full text] [doi: 10.2196/jmir.9157] [Medline: 29567635]
27. Germini F, Noronha N, Borg Debono V, Abraham Phibraham

BP: blood pressure
DBP: diastolic blood pressure
ML: machine learning
PCP: primary care physician
PHSO: Population Health Services Organization
SBP: systolic blood pressure

Edited by A Mavragani; submitted 24.08.23; peer-reviewed by Y Jeem, J Cheng, P Washington; comments to author 14.11.23; revised version received 29.01.24; accepted 09.04.24; published 28.05.24

Please cite as:
Leitner J, Chiang PH, Agnihotri P, Dey S
The Effect of an AI-Based, Autonomous, Digital Health Intervention Using Precise Lifestyle Guidance on Blood Pressure in Adults With Hypertension: Single-Arm Nonrandomized Trial
JMIR Cardio 2024;8:e51916
URL: https://cardio.jmir.org/2024/1/e51916
doi: 10.2196/51916
PMID: