

## Supplemental Online Content

Pletcher MJ, Fontil V, Modrow MF, et al. Effectiveness of standard vs enhanced self-measurement of blood pressure paired with a connected smartphone application: a randomized clinical trial. *JAMA Intern Med*. Published online August 15, 2022. doi:10.1001/jamainternmed.2022.3355

**eFigure 1.** Subgroup analyses

**eTable 1.** Complete case analysis of blood pressure control outcomes, by study arm, among only participants without missing electronic health record data

**eTable 2.** Complete case analysis of patient-reported outcomes by study arm, among only participants without missing survey data

**eTable 3.** As-treated analysis of blood pressure control outcomes, by study arm, among only participants confirming receipt of the study device

**eTable 4.** As-treated analysis of patient-reported outcomes by study arm, among only participants without missing survey data

**eTable 5.** EHR data only analysis of the primary blood pressure control outcome, by study arm

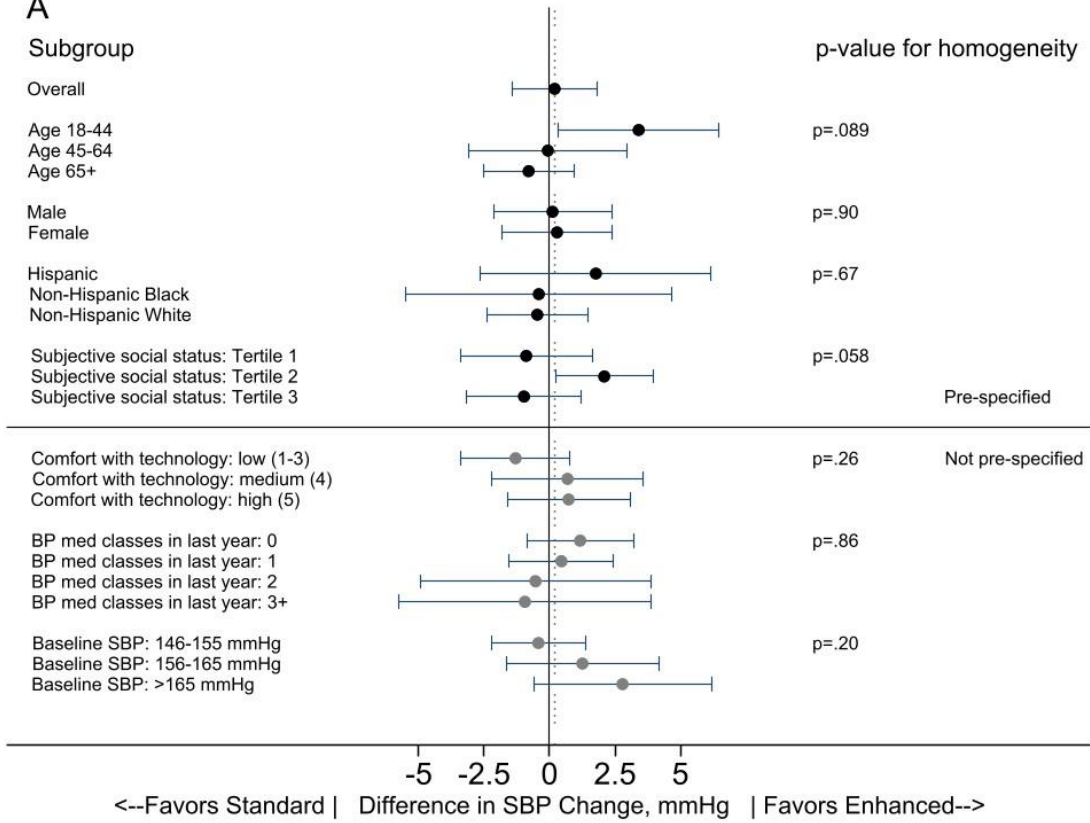
**eTable 6.** Linear mixed modeling approach using EHR data only of the primary blood pressure control outcome, by study arm

**eFigure 2.** Average clinic BP and SMBP measurements, by week, in a subset of the enhanced group

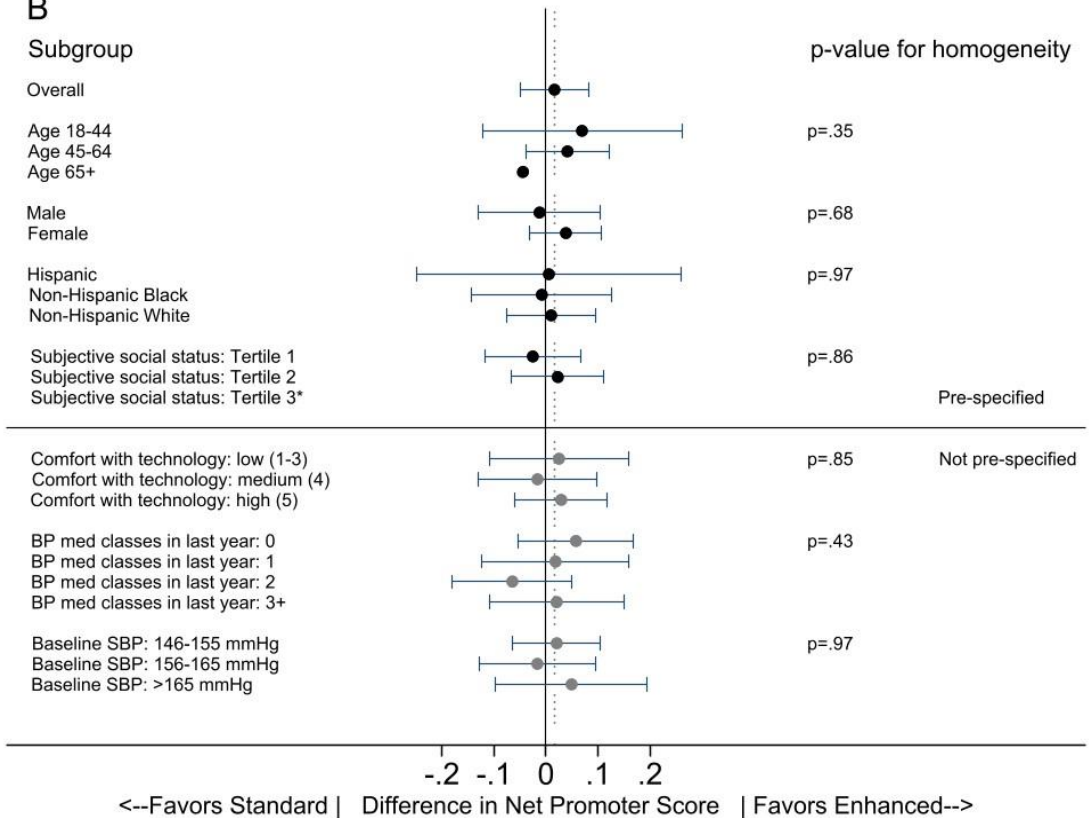
This supplemental material has been provided by the authors to give readers additional information about their work.

**eFigure 1 Subgroup analyses** For difference in SBP change (Panel A, primary BP outcome) and difference in Net Promoter Score (Panel B, primary patient satisfaction outcome), we present point estimates and confidence intervals for each subgroup, and p-values for homogeneity comparing estimates across each set of subgroups. Estimates from pre-specified subgroups are black, those from subgroups that were not pre-specified are grey. \* - No estimate is provided in Panel B for tertile 3 of subjective social status because the model did not converge. BP – Blood Pressure; SBP – Systolic blood pressure

**A**



**B**



<b>eTable 1. COMPLETE CASE ANALYSIS<sup>1</sup> of blood pressure control outcomes, by study arm, among only participants without missing electronic health record data</b>				
Outcome	Standard SMBP N=1034	Enhanced SMBP with smartphone application N=1028	Difference or odds ratio (95% CI) comparing Enhanced to Standard <sup>3</sup>	p-value <sup>3</sup>
<i>Primary Outcome:</i> SBP change at 6 months <sup>2</sup> , mean +/- SD	-10.6 +/- 18	-10.8 +/- 18	Difference = -0.12 (-1.70-1.47)	.88
DBP change at 6 months <sup>2</sup> , mean +/- SD	-4.2 +/- 10	-4.3 +/- 10	Difference = -.09 (-1.02-0.84)	.85
SBP reduction > 10 mmHg at 6 months <sup>2</sup> , n (%)	41%	40%	Odds ratio = 0.97 (.88-1.07)	.56
BP control to <140/<90 mmHg at 6 months, n (%)	29%	32%	Odds ratio = 1.16 (1.00-1.34)	.037
BP control to <130/<80 mmHg at 6 months, n (%)	12%	13%	Odds ratio = 1.05 (.75-1.47)	.78

<sup>1</sup> – For this sensitivity analysis, we used only data collected by the study without imputing missing outcomes for patients without linked EHR data (see Methods)

<sup>2</sup> – Difference in BP between self-reported most recent BP measurements at baseline (at the time of randomization) and the most recent office BP measurement from EHR data (encounter type = AV) within 6 months (183 days) of randomization. If no clinic BP measurements were made during follow up, the documented reduction is zero.

<sup>3</sup> – Summary measures of association and p-values are calculated using regression models that include a fixed effect for a clinic's participation and randomization assignment in a concurrent clinic-level quality improvement intervention<sup>18</sup>, and accounting for clustering by clinical site with robust standard errors (see Methods). For continuous measurements, a linear model was used and differences calculated; for dichotomous outcomes, a logistic model was used and odds ratios calculated.

BP – Blood pressure; SBP – Systolic blood pressure; DBP – Diastolic blood pressure; SD – Standard deviation; CI – Confidence interval; EHR – Electronic health records

<b>eTable 2. COMPLETE CASE ANALYSIS<sup>1</sup> of patient-reported outcomes by study arm, among only participants without missing survey data<sup>1</sup></b>				
Outcome	Standard SMBP	Enhanced SMBP with smartphone application	Difference or odds ratio (95% CI) comparing Enhanced to Standard <sup>7</sup>	p-value <sup>7</sup>
How likely are you to recommend [device] to a friend (0-10), n (%)	N=640	N=596		
- 0-6 (Detractor)	13%	11%		
- 7-8 (Passive)	19%	19%		
- 9-10 (Promoter)	69%	70%		
Net Promoter Score <sup>2</sup> (primary patient satisfaction outcome)	.56	.59	Difference = .03 (-.03 - .08)	.38
Use of device in last month, n (%)	N=545	N=497		
- Never	5%	6%		
- Less than once a week	13%	13%		
- About once a week	28%	18%		
- 2-3 times a week	25%	20%		
- 4 or more times a week	29%	42%	OR of being in a higher category = 1.43 (1.02-2.02)	.036
Shared measurements with your doctor in last month	N=546	N=498		
- n (%) shared	47%	42%	OR = 0.85 (0.69-1.05)	.14
How satisfied are you with (1-5 scale) <sup>3</sup> , mean +/- SD	N=537	N=486		
...your overall treatment	4.3 +/- 1.0	4.3 +/- 1.0	Difference = -.08 (-.16 - .01)	.073
...your healthcare provider	4.4 +/- 1.1	4.3 +/- 1.1	Difference = -.05 (-.16 - .07)	.41
...your blood pressure medication(s)	4.2 +/- 1.2	4.1 +/- 1.1	Difference = -.05 (-.15-.06)	.36
How much do you agree with the following statements about your home BP monitoring device (1-7 scale), mean +/- SD:	N=544	N=495		
- My device is easy to use	6.4 +/- 1.3	6.4 +/- 1.3	Difference = .02 (-.10 - .13)	.74
- Using my device improves my ability to manage my BP	6.1 +/- 1.5	5.9 +/- 1.5	Difference = -.12 (-.26 - .01)	.072
- I find my device useful for managing my blood pressure	6.0 +/- 1.5	5.9 +/- 1.6	Difference = -.15 (-.26 - -.05)	.006
- My healthcare provider thinks I should regularly use my device <sup>4</sup>	5.7 +/- 1.9	5.7 +/- 1.8	Difference = -.02 (-.23 - .20)	.87
- Overall, I am satisfied with my experience using my device	6.3 +/- 1.5	6.3 +/- 1.4	Difference = -.02 (-.20 - .15)	.77
Quality of shared decision-making score (CollaboRATE-5 <sup>5</sup> )	N=274	N=233		
- Mean +/- SD	3.4 +/- 1.2	3.6 +/- 1.1	Difference = .17 (-.11 - .45)	.21
- N (%) with the top score	15%	20%	OR = 1.42 (1.03 - 1.97)	.035

<sup>1</sup> – For this sensitivity analysis, we used only collected survey data without imputation (see Methods)

<sup>2</sup> – The Net Promoter Score is calculated as the proportion Promoters minus the proportion Detractors<sup>26,27</sup>.

<sup>3</sup> – Satisfaction scores additionally exclude persons answering “N/A” (7% for “overall treatment”, 9% for “your healthcare provider”, and 20% for “your blood pressure medications)

<sup>4</sup> – Additionally excludes persons answering “Don’t know” (23%)

<sup>5</sup> – Quality of shared decision-making uses responses to 3 questions (1-5 each) adapted from the CollaboRATE-5<sup>23</sup>. We calculate the mean score, and the proportion with the top score (answering the top of the scale on all three items) according to published methods.

<sup>6</sup> – Summary measures of association and p-values are calculated using regression models that include a fixed effect for clinic’s participation in a concurrent clinic-level quality improvement intervention, and accounting for clustering by clinical site with robust standard errors (see Methods). For continuous measurements, a linear model is used and differences calculated; for dichotomous outcomes, a logistic model is used and odds ratios calculated; for ordinal variables, ordinal logistic regression is used, and odds ratio for being in the next higher category calculated.

BP – Blood pressure; SBP – Systolic blood pressure; DBP – Diastolic blood pressure; SD – Standard deviation; OR – Odds ratio

<b>eTable 3. AS-TREATED ANALYSIS<sup>1</sup> of blood pressure control outcomes, by study arm, among only participants confirming receipt of the study device</b>				
Outcome	Standard SMBP N=702	Enhanced SMBP with smartphone application N=688	Difference or odds ratio (95% CI) comparing Enhanced to Standard <sup>3</sup>	p-value <sup>3</sup>
<i>Primary Outcome:</i> SBP change at 6 months <sup>2</sup> , mean +/- SD	-10.7 +/- 18	-10.9 +/- 17	Difference = -0.17 (-1.87-1.53)	.84
DBP change at 6 months <sup>2</sup> , mean +/- SD	-3.9 +/- 10	-4.6 +/- 10	Difference = -.68 (-1.65-0.29)	.16
SBP reduction > 10 mmHg at 6 months <sup>2</sup> , n (%)	41%	40%	Odds ratio = 0.98 (.86-1.13)	.81
BP control to <140/<90 mmHg at 6 months, n (%)	30%	34%	Odds ratio = 1.21 (1.02-1.43)	.030
BP control to <130/<80 mmHg at 6 months, n (%)	13%	15%	Odds ratio = 1.13 (.82-1.55)	.46

<sup>1</sup> – For this sensitivity analysis, we only analyzed participants who confirmed receipt of their study device. Multiple imputation was used, as in our base case analysis (see Methods and Table 3 footnote)

<sup>2</sup> – Difference in BP between self-reported most recent BP measurements at baseline (at the time of randomization) and the most recent office BP measurement from EHR data (encounter type = AV) within 6 months (183 days) of randomization. If no clinic BP measurements were made during follow up, the documented reduction is zero.

<sup>3</sup> – Summary measures of association and p-values are calculated using regression models that include a fixed effect for a clinic's participation and randomization assignment in a concurrent clinic-level quality improvement intervention<sup>18</sup>, and accounting for clustering by clinical site with robust standard errors (see Methods). For continuous measurements, a linear model was used and differences calculated; for dichotomous outcomes, a logistic model was used and odds ratios calculated.

BP – Blood pressure; SBP – Systolic blood pressure; DBP – Diastolic blood pressure; SD – Standard deviation; CI – Confidence interval; EHR – Electronic health records

<b>eTable 4. AS-TREATED ANALYSIS<sup>1</sup> of patient-reported outcomes by study arm, among only participants confirming receipt of the study device and without missing survey data<sup>1</sup></b>				
Outcome	Standard SMBP N=702	Enhanced SMBP with smartphone application N=688	Difference or odds ratio (95% CI) comparing Enhanced to Standard <sup>7</sup>	p-value <sup>7</sup>
How likely are you to recommend [device] to a friend (0-10), n (%)				
- 0-6 (Detractor)	13%	12%		
- 7-8 (Passive)	20%	20%		
- 9-10 (Promoter)	67%	67%		
Net Promoter Score <sup>2</sup> (primary patient satisfaction outcome)	.54	.55	Difference = .01 (-.07 - .09)	.82
Use of device in last month, n (%)				
- Never	5%	6%		
- Less than once a week	14%	13%		
- About once a week	29%	20%		
- 2-3 times a week	24%	21%		
- 4 or more times a week	28%	40%	OR of being in a higher category = 1.44 (1.03-2.01)	.034
Shared measurements with your doctor in last month, n (%) shared	46%	41%	OR = 0.84 (0.67-1.05)	.12
How satisfied are you with (1-5 scale) <sup>3</sup> , mean +/- SD				
...your overall treatment	4.3 +/- 1.0	4.2 +/- 1.0	Difference = -.08 (-.20 - .04)	.17
...your healthcare provider	4.3 +/- 1.1	4.3 +/- 1.1	Difference = -.04 (-.18 - .10)	.56
...your blood pressure medication(s)	4.1 +/- 1.2	4.1 +/- 1.1	Difference = -.04 (-.16-.08)	.47
How much do you agree with the following statements about your BP monitoring device (1-7 scale), mean +/- SD:				
- My device is easy to use	6.4 +/- 1.4	6.4 +/- 1.3	Difference = .01 (-.17 - .19)	.90
- Using my device improves my ability to manage my BP	6.1 +/- 1.5	6.0 +/- 1.5	Difference = -.10 (-.26 - .07)	.24
- I find my device useful for managing my blood pressure	6.0 +/- 1.6	5.9 +/- 1.6	Difference = -.13 (-.29 - .02)	.087
- My healthcare provider thinks I should regularly use my device <sup>4</sup>	5.7 +/- 1.9	5.7 +/- 1.9	Difference = -.00 (-.29 - .30)	.99
- Overall, I am satisfied with my experience using my device	6.3 +/- 1.5	6.3 +/- 1.5	Difference = -.02 (-.19 - .15)	.83
Quality of shared decision-making score (CollaboRATE-5 <sup>5</sup> )				
- Mean +/- SD	3.4 +/- 1.0	3.5 +/- .9	Difference = .10 (-.07 - .27)	.23
- N (%) with the top score	6.3%	7.8%	OR = 1.25 (.80 - 1.96)	.32

<sup>1</sup> – For this sensitivity analysis, we only analyzed participants who confirmed receipt of their study device. Multiple imputation was used, as in our base case analysis (see Methods and Table 3 footnotes)

<sup>2</sup> – The Net Promoter Score is calculated as the proportion Promoters minus the proportion Detractors<sup>26,27</sup>.

<sup>3</sup> – Satisfaction scores additionally exclude persons answering “N/A” (7% for “overall treatment”, 9% for “your healthcare provider”, and 20% for “your blood pressure medications)



<sup>4</sup> – Additionally excludes persons answering “Don’t know” (23%)

<sup>5</sup> – Quality of shared decision-making uses responses to 3 questions (1-5 each) adapted from the CollaboRATE-5<sup>23</sup>. We calculate the mean score, and the proportion with the top score (answering the top of the scale on all three items) according to published methods.

<sup>6</sup> – Summary measures of association and p-values are calculated using regression models that include a fixed effect for clinic’s participation in a concurrent clinic-level quality improvement intervention, and accounting for clustering by clinical site with robust standard errors (see Methods). For continuous measurements, a linear model is used and differences calculated; for dichotomous outcomes, a logistic model is used and odds ratios calculated; for ordinal variables, ordinal logistic regression is used, and odds ratio for being in the next higher category calculated.

BP – Blood pressure; SBP – Systolic blood pressure; DBP – Diastolic blood pressure; SD – Standard deviation; OR – Odds ratio

<b>eTable 5. EHR DATA ONLY ANALYSIS<sup>1</sup> of the primary blood pressure control outcome, by study arm</b>				
Outcome	Standard SMBP	Enhanced SMBP with smartphone application	Difference or odds ratio (95% CI) comparing Enhanced to Standard <sup>3</sup>	p-value <sup>3</sup>
<b>Subset 1: Among all participants with EHR data and a visit with a valid SBP measurement prior to baseline</b>				
	N=1010	N=1002		
<i>Primary Outcome: SBP change at 6 months<sup>2</sup>, mean +/- SD</i>	-6.0 +/- 17	-6.0 +/- 18	Difference = -.02 (-1.45-1.40)	.98
<b>Subset 2: Subset 1 and confirmed receipt of their study device</b>				
	N=676	N=657		
<i>Primary Outcome: SBP change at 6 months<sup>2</sup>, mean +/- SD</i>	-5.8 +/- 18	-6.5 +/- 17	Difference = -0.60 (-2.8-1.60)	.58
<b>Subset 3: Subset 1 and had a visit with a valid SBP measurement during follow-up</b>				
	N=629	N=632		
<i>Primary Outcome: SBP change at 6 months<sup>2</sup>, mean +/- SD</i>	-9.7 +/- 21	-9.6 +/- 22	Difference = 0.06 (-1.90-2.03)	.94
<b>Subset 4: Among all participants with EHR data and a visit with a valid SBP measurement prior to baseline, confirming receipt of their study device, and with a valid SBP measurement during follow-up (i.e., meets criteria for Subsets 1, 2 and 3 above)</b>				
	N=414	N=402		
<i>Primary Outcome: SBP change at 6 months<sup>2</sup>, mean +/- SD</i>	-9.5 +/- 22	-10.5 +/- 20	Difference = -1.00 (-4.26-2.26)	.53

<sup>1</sup> – For this sensitivity analysis, we only analyzed electronic health record (EHR) data (using EHR data only for the baseline SBP measurement instead of the value reported by the participant during enrollment), with complete case analysis, for the subsets of participants as described.

<sup>2</sup> – Difference in BP between most recent BP measurements DERIVED ONLY FROM EHR DATA at baseline (at the time of randomization) and the most recent office BP measurement from EHR data (encounter type = AV) within 6 months (183 days) of randomization. If no clinic BP measurements were made during follow up, the documented reduction is zero.

<sup>3</sup> – Summary measures of association and p-values are calculated using regression models that include a fixed effect for a clinic's participation and randomization assignment in a concurrent clinic-level quality improvement intervention<sup>18</sup>, and accounting for clustering by clinical site with robust standard errors (see Methods).

BP – Blood pressure; SBP – Systolic blood pressure; DBP – Diastolic blood pressure; SD – Standard deviation; CI – Confidence interval; EHR – Electronic health records

<b>eTable 6. LINEAR MIXED MODELING analysis<sup>1</sup> of the primary blood pressure outcome using EHR DATA ONLY</b>				
Outcome	Standard SMBP	Enhanced SMBP with smartphone application	Difference (95% CI) comparing Enhanced to Standard <sup>1</sup>	p-value <sup>1</sup>
<b>Subset 1: Among all participants with EHR data and at least one valid SBP measurement ever in EHR</b>				
	N=1024	N=1016		
<i>Primary Outcome: SBP change at 6 months<sup>2</sup>, mean (95% CI)</i>	-4.1 (-4.8 to -3.4)	-4.3 (-5.0 to -3.6)	-0.2 (-1.2 to 0.83)	.72
<b>Subset 2: At least one measurement within 6 months of baseline, and limiting the analysis to measurements within 6 months of baseline<sup>2</sup></b>				
	N=878	N=884		
<i>Primary Outcome: SBP change at 6 months<sup>2</sup>, mean (95% CI)</i>	-11.7 (-16 to -7.9)	-13.3 (-17 to -9.4)	-1.6 (-7.1 to 3.9)	.57

<sup>1</sup> – For this sensitivity analysis, we only analyzed electronic health record (EHR) data, with complete case analysis, for the subsets of participants as described. And instead of the pre-specified analysis plan, we used a linear mixed modeling approach including a random intercept and slope over time for each participant. We included fixed effects for group, pre-post randomization, slope over time, and the 2- and 3-way interactions between these covariates, and then used a post-estimation linear combination of fixed effect components of the model to estimate the difference in SBP from baseline to 6 months post-randomization for each group, and the difference between these estimates. The p-value represents a test of the null hypothesis that the difference between the estimates is equal to zero.

<sup>2</sup> – In many participants, blood pressure measurements were available long before randomization or long after the 6-month follow-up was complete. For Subset 2, we limited the analysis to only measurements within 6 months before or after baseline (during which time an underlying linear time trend is more credible), and to participants with at least 1 measurement within this time period.

BP – Blood pressure; SBP – Systolic blood pressure; DBP – Diastolic blood pressure; SD – Standard deviation; CI – Confidence interval; EHR – Electronic health records

**eFigure 2 Average clinic BP and SMBP measurements, by week, in a subset of the Enhanced group.** Participants randomized to the Enhanced arm of the study received a device that connects with a smartphone application. We do not know how many participants successfully downloaded the smartphone application and successfully synced their device to their application. We asked participants in the Enhanced arm to also donate their SMBP measurements to the study for analysis, and a subset of participants in the Enhanced arm were successful in this. Through this mechanism, we received 78,287 individual SMBP measurements from n=429 participants in the Enhanced group. For this subset of the Enhanced group, we have plotted both the average clinic BP by week (equivalent to Figure 2, but in only this subset of the Enhanced group) and also their average SMBP measurements by week.

