

BMJ Open Links between blood pressure and medication intake, well-being, stress, physical activity and symptoms reported via a mobile phone-based self-management support system: a cohort study in primary care

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ABSTRACT

Objectives To explore relationships between patients' self-monitoring of blood pressure (BP) and their concurrent self-reports of medication intake, well-being, stress, physical activity and symptoms.

Design This study is a secondary analysis of a prospective study exploring the 8-week effectiveness of a mobile phone-based self-management support system for patients with hypertension.

Setting Four primary healthcare centres situated in urban and suburban communities in Sweden.

Participants 50 patients undergoing treatment for hypertension.

Primary and secondary outcome

measures Associations between systolic (SBP) and diastolic blood pressure (DBP) and 10 self-report lifestyle-related variables were analysed using linear mixed effects modelling.

Results Medication intake, better well-being, less stress and greater physical activity were associated variously with lower same-day SBP and DBP. The single strongest association was found between medication intake and SBP, where failure to take medications was associated with an estimated 7.44 mm Hg higher SBP. To a lesser degree, medication intake was also associated with DBP, where DBP was 4.70 mm Hg higher in cases where medications were not taken. Well-being and stress were consistently associated with SBP and DBP, whereas physical activity was associated with only SBP. None of the symptoms—dizziness, headache, restlessness, fatigue or palpitations—were significantly associated with BP.

Conclusions Our findings that BP was associated with patients' BP management behaviours and experiences of well-being and stress, but not symptoms suggest that enabling persons with hypertension to monitor and track their BP in relation to medication intake, physical activity, well-being, stress and symptoms may be a fruitful way to help them gain first-hand understanding of the importance of adherence and persistence to treatment recommendations.

Trial registration number NCT01510301; Pre-results.

Strengths and limitations of this study

- The study is unique in investigating associations between self-monitored blood pressure (BP) and same-day, self-reported medication intake, well-being, stress, physical activity and symptoms during 56 consecutive days.
- The mobile phone-based self-management support system was designed in collaboration with patients with hypertension as a tool to enable and empower patients to monitor and track their BP in relation to self-reported stress, physical activity, well-being, symptoms and medication intake with a web-based dashboard feedback module.
- The generalisability of the study results may be impeded by the use of convenience sampling for patient selection.
- The patients reported unusually good medication adherence during the study, suggesting the need to perform larger studies with patients with more diverse adherence levels in order to confirm our findings.

INTRODUCTION

Hypertension is the leading modifiable risk factor for premature death and global disease burden.^{1 2} Reducing hypertension has been shown to lower the risk of acute myocardial infarction, stroke, kidney failure, congestive heart failure and cardiovascular death.^{3–5} Despite strong evidence and consensus about the treatment and control of hypertension,^{6–9} nonetheless only an estimated 13.8% of adults with hypertension worldwide have their blood pressure (BP) controlled.¹⁰

As in other chronic conditions, successful treatment outcomes in hypertension depend ultimately on effective patient

self-management.^{11–13} However, patient adherence to hypertension treatment recommendations is notoriously poor, both with respect to medication taking^{14–16} and in particular to lifestyle changes,^{17–19} underlining the need for supporting patients in their self-management efforts. To date, interventions aimed at supporting self-management have focused mainly on self-monitoring of BP (SMBP), educational programmes and counselling.²⁰ SMBP has been found to contribute to improved BP control^{21–23} and medication adherence²⁴; however, evidence for the independent effects of education and counselling remains weak.²⁰

It has been suggested that educational interventions have failed because they have not sufficiently understood, acknowledged and addressed patients' lay perspectives on the causation and risks of hypertension.^{25–27} Lay beliefs are not always consistent with biomedical opinion,²⁶ particularly regarding the impact of stress on BP, the experience of BP symptoms, and drug side effects, tolerance and dependency, which may partly explain why patient adherence and persistence rates are poor. For example, many patients believe that stress is the main cause of hypertension and that headache, palpitations and dizziness are caused by high BP, and hence patients may cease to adhere to treatment during periods of low stress or in the absence of symptoms.²⁵ On the other hand, SMBP may improve medication adherence by providing direct feedback on BP levels, independent of experienced symptoms, and thereby contribute to BP control by reinforcing behaviours that lower BP.²⁸

This study is part of a research programme aimed at developing and evaluating a mobile phone-based self-management system to support hypertension self-management. Recently, we reported significant BP improvements with the use of the system.²⁹ Designed in accordance with patients' expressed wishes and perceived needs for support in self-managing hypertension,^{30–32} the system was hence developed as a tool to enable and empower patients to explore and track variations in their BP in relation to self-reported stress, physical activity, well-being, symptoms and medication intake with a web-based dashboard feedback module. In follow-up interviews, patients indicated that the system helped them to gain insight into the importance of adhering to treatment advice and thereby gain control in managing their condition.³³ However, the usefulness of the feedback module rests on the existence of perceptible links between BP and patient self-reports. A person-centred perspective that emphasises the value of the patient's own experiences of BP by increased participation in care, self-reporting and documentation has earlier been shown to be beneficial.³³ The purpose of the present study was to explore relationships between patients' SMBP and their concurrent self-reports of stress, physical activity, well-being, symptoms and medication intake.

METHODS

This study was a secondary analysis of a prospective cohort study exploring the 8-week effectiveness of a

mobile phone-based self-management support system for patients with hypertension. The study took place between February and June 2012 and was conducted in accordance with the Declaration of Helsinki.

Recruitment and participants

Participants were recruited using convenience sampling. Sample size was estimated for the original study²⁹ based on a SD of 12 for systolic BP (SBP) and 7 for diastolic BP (DBP). For detecting a difference of 8 mm Hg SBP and 5 mm Hg DBP with 90% power and at a 5% significance level, the sample size was estimated to 50 patients. Seventy-three consecutive patients undergoing treatment for hypertension at four primary healthcare centres in southern Sweden were asked to participate. Inclusion criteria were: currently being medically treated for hypertension, age ≥ 30 years, ability to understand and read Swedish, access to a mobile phone with an internet connection. In total, 54 patients agreed to participate, of whom three withdrew before study start.

Patient involvement

Patients with hypertension were involved in all phases of the design, development and evaluation of the mobile phone-based self-management support system. The research question for this study was generated from patient interviews³³ and its merits were confirmed in interviews with professionals. Patients were not involved in drafting the paper. As previously reported,^{30–33} the system was designed based on interviews in which patients were asked to describe what they needed to better self-manage their hypertension; iteratively developed in collaboration with patients, researchers and clinicians^{30–32}; evaluated for content validity, reliability and usability in focus group interviews, cognitive interviews and piloting³²; examined regarding usability and usefulness in individual patient interviews.³³

The intervention

The interactive self-management support system

As previously described in detail, the system includes four components that have not previously been integrated into the same intervention for supporting self-management of hypertension²⁹: (1) a module for self-reporting well-being, symptoms, lifestyle, medication intake and side effects of medication; (2) daily home BP and pulse measurements with a validated BP monitor; (3) tailored weekly motivational messages to encourage lifestyle changes and (4) web-based dashboard to enable patients, as well as physicians and nurses, to examine the patient's BP in relation to the self-reports. The communication platform for the system was developed by Circadian Questions (CQ), 21st Century Mobile (<http://www.cqmobil.se>).

Study procedures

Participants were instructed how to use the self-management system and BP monitors by research nurses. They were requested to perform BP measurements and self-reports every evening for eight consecutive weeks and to answer self-report items first and then to measure their BP.

The reporting system was open in the evenings between 17:00 and 23:00 hours and reminders were sent at 19:00 hours. The actual order in which these two tasks were performed could not be determined from the database, although in the report interface the items were provided first, after which space for BP registration was given. In subsequent interviews participants confirmed that they followed the instructed order.³³ The data reported in through the participants' mobile phones were automatically registered in a secure database.

The system was tailored to the individual patients, such that drug side effects items (delivered maximum twice weekly) were selected based on the patient's antihypertensive medication; use and choice of motivational messages (delivered maximum twice weekly) were based on patients' preferences and use of daily reminders was optional.

Patient self-reports

Development and evaluation of the items comprising the self-report module are described in detail elsewhere.^{31 32} Briefly, items were iteratively developed from analyses of patient and professionals (physicians, nurses and pharmacists) focus group interviews about what they considered helpful for supporting self-management of their BP. Six major areas represented by 16 items were identified: three biomedical markers (SBP, DBP and pulse); three symptoms (dizziness, headache and palpitations); four medication side effects (swollen ankles, dryness of mouth, dry cough and micturition); five quality of life variables (general well-being, stress, restlessness, sleep and fatigue); adherence to medication (medication intake) and one lifestyle variable (physical activity). Items were formulated as questions, with 'today' as the timeframe. Patients rated items against five-step response scales with anchors not at all (0)—extremely (4) or very bad (0)—very well/good (4), except medication intake (Have you taken your medication today?) which was rated on a three-step scale with options yes (0), some of it (1) and no (2) and well-being with an inverse five-step scale from very good (0) to very bad (4) (see online supplementary table 1). BP and pulse were measured and registered as values obtained from BP monitors.

BP self-monitoring

Patients were instructed how to measure their BP in accordance with the European Society of Hypertension Practice guidelines for home blood pressure monitoring.³⁴ A home blood pressure monitor (BP A200 AFIB; Microlife USA, Clearwater, Florida, USA) was used and validated according to the international protocol of the European Society of Hypertension.³⁵

Data analysis

Descriptive statistics were used to characterise patient demographic and clinical variables. Repeated measures linear mixed effects modelling was used, with SBP and DBP as dependent variables. The variance/covariance structure was specified as autoregressive to guard against

violations to sphericity assumptions. All models included a random intercept. Models for the two dependent variables included all 10 self-report variables, excluding medication side-effect variables, as fixed effects. Side-effect variables were excluded because they were assessed only biweekly. Individuals with partial missing data but with at least one observation for each of the independent variables were included. As customary in similar BP studies, day 1 of the study was excluded from analyses due to abnormally high BP values, hence 55 days were analysed. Statistical significance was set to p-value <0.05 throughout. Analyses were performed with SPSS V.22 for Windows and Mathematica V.11.0 for Mac (Wolfram Research, Champaign, Illinois, USA).

RESULTS

Patient characteristics, co-morbidity and medication are shown in table 1. Of the 51 recruited patients who started the study, one participated only sporadically during the first weeks and dropped out entirely after 4 weeks and was therefore excluded from the analyses. More men than women took part, as is common in the middle-aged, and other demographics were also comparable with the general hypertensive population in Sweden.³⁶ The self-reported BP data were validated against the BP values saved in the BP monitor. Among 14 consecutive patients selected for comparison,³³ only 21 values of 1448 of both SBP and DBP differed.

Of the potential 2750 observations per variable (50 patients×55 days), the average number of observations was 2475 (range=2473–2478), or about 10% missing. Missing data were clustered to a few participants and primarily over sustained periods of a few days. In follow-up interviews, reported partly in Hallberg *et al*,³³ participants explained that reasons for non-reporting were primarily due to poor internet connections during visits to their countryside vacation homes or to inconvenience, unavailability and/or costs associated with internet use during trips abroad. There were only 22 reported instances of partial or non-adherence and these were spread over 11 individuals, or roughly two times/individual during the 55-day study period.

Links between SBP and self-report variables

Mixed models analysis, including all 10 independent variables, yielded significant associations between SBP and medication intake, physical activity, well-being and stress (table 2). Self-reported medication intake was associated with the largest decrease in SBP, where better adherence was associated with a 3.72 mm Hg decrease in SBP per reported adherence level. SBP increased 1.09 mm Hg with increasing levels of stress, 1.51 mm Hg with decreasing levels of well-being and 0.70 mm Hg with decreasing levels of physical activity. Figure 1A–D show the distribution of SBP in relation to patient ratings along with regression lines for each of the significant self-reported variables.

Table 1 Patient characteristics (n=50)

Women, n (%)	24 (48%)
Mean age (range)	59.5 (33–81)
Mean SBP (range), mm Hg*	142 (115–195)
Mean DBP (range), mm Hg*	84 (61–113)
Mean years with hypertension (range)	8.5 (<1–32)
Co-morbidity, n (%)†	22 (52)
Co-morbidities, n (%)	
Cardiovascular disease	3 (14)
Decreased renal function	2 (9)
Diabetes	7 (32)
Musculoskeletal disorder	3 (14)
Other	7 (32)
Type of antihypertensive medication, n	
Diuretics	12
Potassium-sparing diuretics	4
β-Blockers	18
Calcium channel blockers	22
ACE inhibitors	11
Angiotensin II receptor antagonists	21
ACE inhibitors+diuretic	1
Angiotensin II receptor antagonist+diuretic	5
Number of antihypertensive medications, n	
One	19
Two	19
Three	11
Four	1
Marital status	
Married	39 (78)
Unmarried	10 (20)
Widow/widower	1 (2)
Education, n (%)	
Compulsory school (≤9 years)	5 (10)
High school (9–12 years)	22 (44)
University	22 (44)
Missing	1 (2)
Employment status, n (%)	
Employed	28 (56)
Long-term sick leave	1 (2)
Retired	19 (38)
Missing	2 (4)

*Mean of patients' 3–4 baseline BP measurements.

†Information provided by patients.

DBP, diastolic blood pressure; SBP, systolic blood pressure.

Links between DBP and self-report variables

A model including all 10 self-report variables showed significant associations between medication intake, well-being and stress (table 3). Self-reported medication

intake was associated with the largest decrease in DBP, where better adherence was associated with a 2.35 mm Hg decrease in DBP per reported adherence level. Higher levels of stress and poorer well-being were associated with small DBP increases (0.81, 0.70 mm Hg per scale step, respectively). Figure 2A–C show the distribution of DBP in relation to patient ratings along with regression lines for each of the significant self-reported variables.

DISCUSSION

Our results showed that patient self-reports of medication intake, well-being, stress and physical activity were associated variously with same-day SBP and DBP. The single strongest association was found between medication intake and SBP, where failure to take medications was associated with a cumulative increase in SBP of 7.44 mm Hg. To a lesser degree, medication intake was also associated with DBP, where DBP was 4.70 mm Hg higher in cases where medications were not taken. Well-being and stress were consistently associated with SBP and DBP, whereas physical activity was associated only with SBP. None of the assessed symptoms (dizziness, headache, well-being, fatigue and palpitations) were significantly associated with BP, although a near significant association was seen between headache and DBP.

To our knowledge, this is the first study to report independent effects of self-reported non-adherence to medication on same-day BP. Our results, particularly regarding SBP, corroborate and extend longer-term BP effects reported by, for example, Rose *et al*³⁷ that week long periods of poor adherence are associated with about 12–15/7–8 mm Hg higher BP than good adherence, by Hedna *et al*³⁸ that non-adherence during a 1-month period is associated with higher odds of elevated BP, as well as earlier studies showing longer-term effects of non-adherence on BP control.^{39 40} We also have analysed the effects of using the mobile phone system over 8 weeks and found significant decreases in SBP (–7 mm Hg) and DBP (–4.9 mm Hg).²⁹ Our findings of same-day associations may potentially be exploited in SMBP-based self-management programmes to help hypertensives gain an understanding of the immediate impact of hypertensive medication on BP and thereby reinforce medication adherence and persistence. However, caution should be observed in interpreting our results given that few instances of partial or non-adherence were reported over the course of the 8-week study period and the missing data rate was 10%.

Self-reported well-being and stress were significantly associated with same-day BP. Again, stronger effects were seen in relation to SBP, where SBP was an estimated 4.53 mm Hg higher when well-being was rated poor than when rated good and 3.27 mm Hg higher when stress was high versus low. Corresponding DBP values were 2.10 for well-being and 2.43 for stress. Our findings corroborate links between BP and subjective well-being

Table 2 Linear mixed-effect model for associations between systolic blood pressure and self-report variables

Variable	Estimate	SE	df	t	Significance	95% CI
Intercept	134.40	1.93	63.14	69.57	0.000	130.54 to 138.26
Medication intake	3.72	1.19	2311.12	3.13	0.002	1.39 to 6.04
Physical activity	-0.70	0.22	2274.21	-3.14	0.002	-1.13 to -0.26
Well-being	-1.51	0.47	2407.81	-3.23	0.001	-0.59 to -2.42
Stress	1.09	0.36	2400.96	3.04	0.002	0.39 to 1.80
Headache	0.52	0.46	2389.47	1.14	0.253	-0.37 to 1.41
Sleep	0.57	0.29	2208.24	1.95	0.052	-0.00 to 1.15
Dizziness	-0.69	0.65	2381.66	-1.05	0.293	-1.97 to 0.59
Palpitation	-0.14	0.57	2406.14	-0.24	0.808	-1.25 to 0.98
Fatigue	-0.32	0.33	2364.10	-0.98	0.328	-0.96 to 0.32
Restless	0.88	0.55	2403.86	1.59	0.113	-0.21 to 1.96

reported among hypertensive patients with coronary artery disease⁴¹ and lend some support to the lay notion that hypertension is not asymptomatic.²⁵ Moreover, our findings regarding stress are in line with a large body

of research showing strong and consistent associations between stress and increases in BP levels.^{42 43} Although BP spikes associated with acute stress are normal physiological reactions to stressors, chronic stress is acknowledged

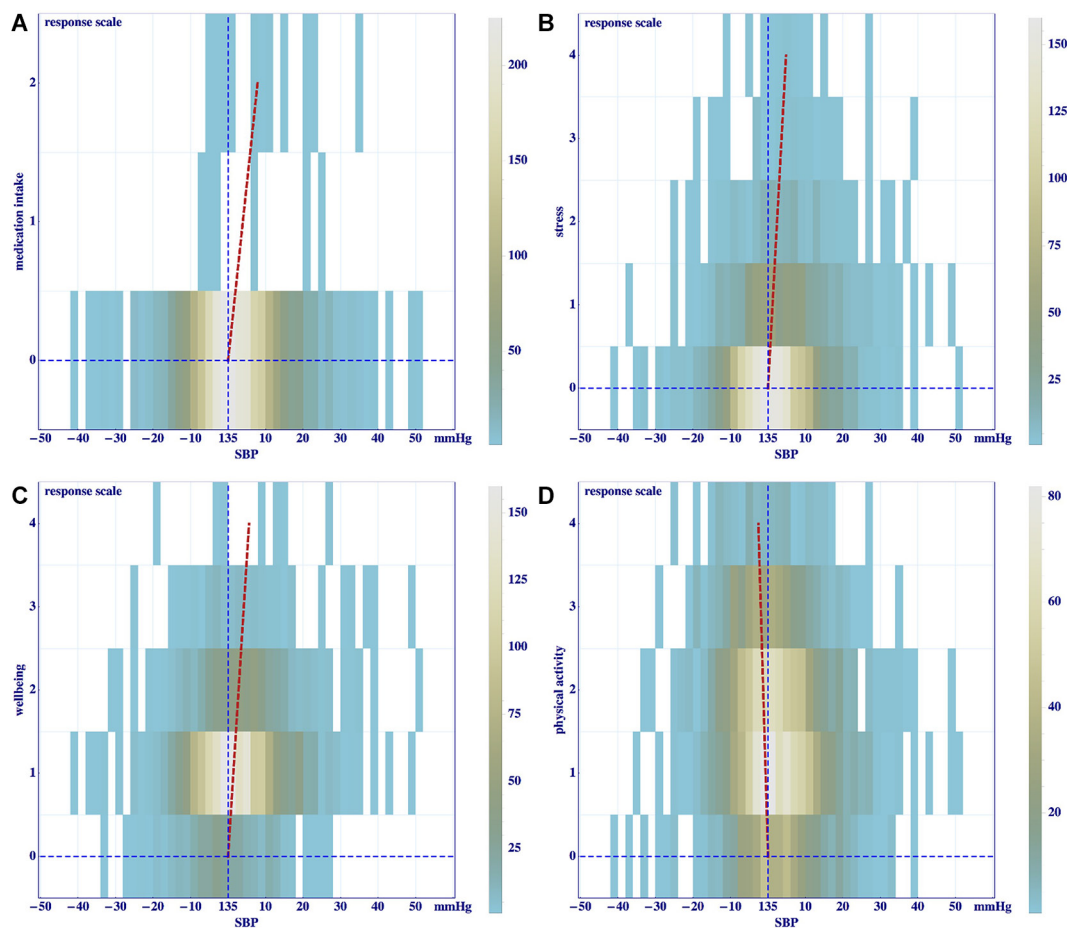


Figure 1 (A–D) Distributions of systolic blood pressure (SBP) values by reported level of medication intake (yes–some–no), stress (no–high), well-being (good–poor) and physical activity (no–high). Regression lines for the relationships between SBP and the independent variables are shown in red. Colours denote concentrations of SBP values, where light yellow indicates higher concentrations of observations and light blue lower concentrations. The x-axis has been transformed to indicate deviations from the intercept SBP value (135 mm Hg). NB: medication intake includes seven observations where partial medication adherence (1) was reported and 11 observations where medication adherence was reported as none (2).

Table 3 Linear mixed-effect model for associations between diastolic blood pressure and self-report variables

Variable	Estimate	SE	df	t	Significance	95% CI
Intercept	78.44	1.00	69.14	78.43	0.000	76.44 to 80.43
Medication intake	2.35	0.71	2326.88	3.31	0.001	0.96 to 3.77
Physical activity	-0.11	0.13	2300.01	-0.79	0.428	-0.37 to 0.15
Well-being	-0.70	0.28	2411.21	-2.51	0.012	-0.15 to -1.24
Stress	0.81	0.22	2404.96	3.79	0.000	0.39 to 1.23
Headache	0.52	0.27	2383.25	1.92	0.055	-0.01 to 1.05
Sleep	0.30	0.18	2239.18	1.69	0.090	-0.05 to 0.64
Dizziness	-0.60	0.39	2390.90	-1.52	0.128	-1.36 to 0.17
Palpitations	0.11	0.34	2415.45	0.32	0.746	-0.55 to 0.77
Fatigue	-0.178	0.20	2383.60	-0.88	0.381	-0.55 to 0.21
Restless	0.28	0.33	2408.78	0.85	0.395	-0.37 to 0.93

as an important risk factor for cardiovascular disorders and events.⁴³ It may therefore be beneficial to monitor stress levels in connection with SMBP, both to help patients understand the importance of stress avoidance

and to help clinicians assess the need for instituting stress reduction therapy.

High levels of self-reported physical activity were associated with moderately lower levels of same-day SBP

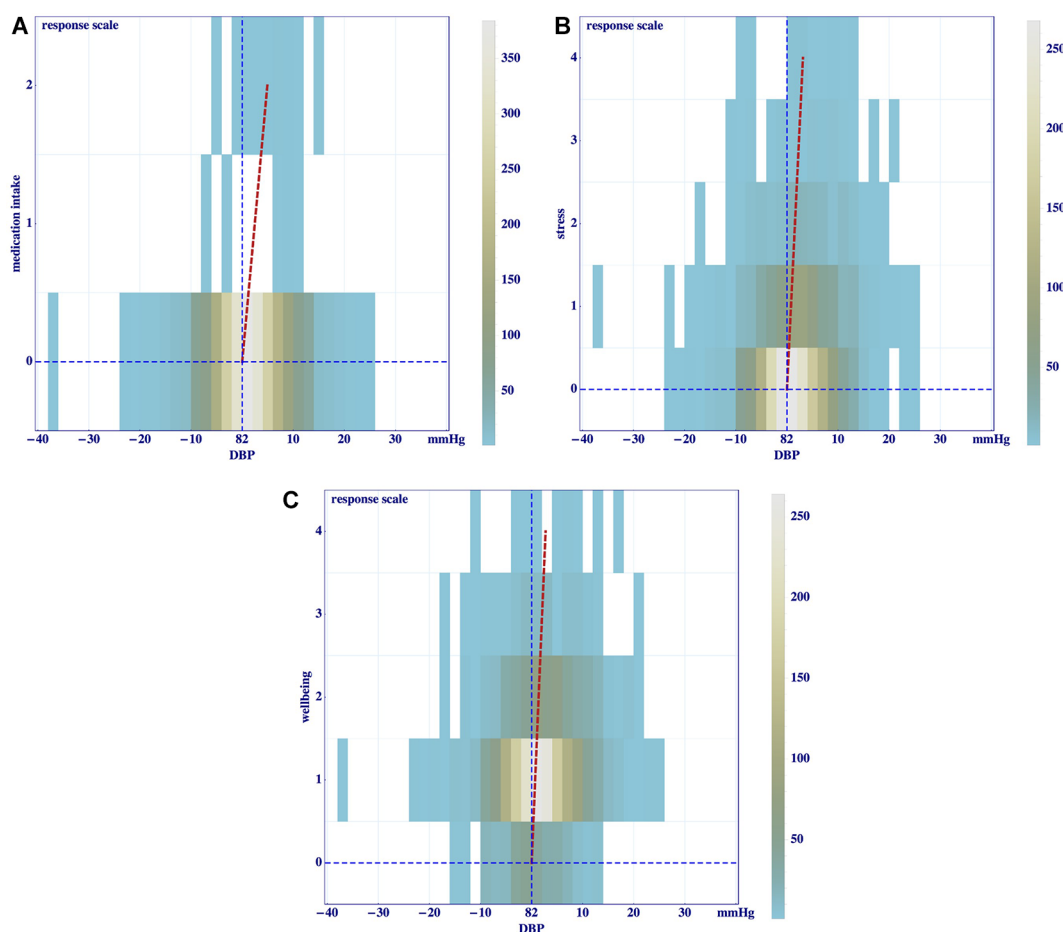


Figure 2 (A–C) Distributions of diastolic blood pressure (DBP) values by reported level of medication intake (yes–some–no), stress (no–high) and well-being (good–poor). Regression lines for the relationships between DBP and the independent variables are shown in red. Colours denote concentrations of DBP values, where light yellow indicates higher concentrations of observations and light blue lower concentrations. The x-axis has been transformed to indicate deviations from the intercept DBP value (82 mmHg). NB: medication intake includes seven observations where partial medication adherence (1) was reported and 11 observations where medication adherence was reported as none (2).

(−2.10 mm Hg). This finding was not unexpected given that BP-mitigating effects of physical activity are yielded after sustained periods of training.⁴⁴ Physical activity is a recommended lifestyle modification for the prevention and management of hypertension⁴⁵ and tracking physical activity in relation to BP may help to motivate patients to adhere to this recommendation.

No significant associations were found between symptoms (dizziness, headache and palpitations) and BP, although a near significant association ($p=0.055$) was found between headache and DBP. The lack of associations between symptoms and BP may possibly be due to the fact that patients reported few symptoms during the study period. Nevertheless, our finding is in line with earlier studies indicating a lack of association between elevated BP and symptoms (dizziness, headache and palpitations).^{46 47} Monitoring symptoms in connection with SMBP may, however, serve to inform patients who base their medication intake on the presence or absence of symptoms²⁵ that symptom experience is an imperfect indicator of BP levels.

There are a number of limitations to this study. Although the sociodemographic distribution of the sample corresponded to that of the hypertensive population in Sweden,³⁶ the sample was selected using convenience sampling, which has clear-cut implications for the generalisability of our results. The patient sample also reported unusually good medication adherence during the study, where only 11 patients reported any non-adherence (in total, 7 reports of partial medication intake and 15 of no medication intake were reported over the course of the 8-week study period). We cannot preclude that our high adherence rates may owe to sampling, reactivity or social desirability bias. Larger and randomised studies including patients with more diverse adherence levels are needed to confirm our findings.

CONCLUSIONS

Significant same-day associations were evidenced between BP and medication intake, stress, physical activity and well-being; however, symptoms that patients often associate with high BP were not associated with BP.

The mobile phone system enables patients to monitor and track BP in relation to patient behaviours and experiences and may have important implications for adherence to treatment recommendations by helping patients gain first-hand insight into the BP-lowering effects of medication intake and physical activity, stress avoidance, etc and inform patients who base adherence decisions on symptom experience that symptoms are poor indicators of BP levels.

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Contributors CT: designed the study, performed data analyses and drafted and revised the paper. He is guarantor. IH: designed the study, monitored data collection and revised the paper. UB: designed the study, monitored data collection and revised the paper. KM: drafted and revised the paper. KK: initiated the project, designed the study and drafted and revised the paper. She is guarantor. All authors have approved the submitted manuscript and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval Regional Ethics Board in Gothenburg, Sweden (study code 551-09 and T-100-12).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Patient-level data may be obtained by contacting the corresponding author. There are no additional data available for data sharing. Consent for data sharing was not obtained from participants but the presented data are anonymised and risk of identification is low.

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