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**Expanded methods**

*Population*

This was an observational cohort study. Participants comprised individuals screened for inclusion in the TASMINH2 trial who were subsequently randomised to undertake self-monitoring of blood pressure at home.(1) The protocol and main findings of this trial have been described elsewhere.(1;2) Participants were recruited from 24 general practices in the West Midlands, UK, between March 2007 and May 2008 following written informed consent. A favourable ethical opinion was gained from Sandwell and West Birmingham Local Research Ethics Committee (reference; 05/Q2709/103) as well as the relevant local research management and governance approvals.

Inclusion criteria for the trial were age 35-84 years, receiving treatment for hypertension and blood pressure not controlled below 140/90mmHg at baseline. Patients randomised to the intervention arm of the trial, with at least four days of home blood pressure readings in the first month after randomisation, were included in the analysis.

*Data collection*

At baseline, 6 month and 12 month follow-up, clinic blood pressure was measured in a standardised fashion using a validated(3) BpTRU BPM-100 blood pressure monitor (BpTRU Medical Devices Inc., Coquitlam, British Columbia, Canada). After participants had been seated for five minutes of rest, six blood pressure measurements were taken automatically at one minute intervals (choice of 1-5 minute intervals), all of which were recorded (i.e. including the first reading which is usually discarded)(4;5) by a researcher who was present throughout the measurement period. Patient demographics (age, gender and ethnicity) and details of previous history of cardiovascular disease were obtained from the patient or extracted from their medical records.

Home blood pressure was measured by patients themselves, using the Omron 705IT (Omron Healthcare Europe, Hoofddorp, Netherlands). Each patient was trained to use the home monitoring device by a research nurse during two sessions following the baseline visit. Patients were asked to measure their blood pressure whilst seated, twice a day at 5 minute intervals, during the first week of each month, over a 12 month period. All blood pressure data were transmitted to the research team via an automated modem device (i-modem; Netmedical, De Meern, Netherlands), which was connected to the sphygmomanometer and plugged into a normal telephone socket. This analysis focused on clinic and home blood pressure measured in the first month of the trial before treatment changes had been instigated.

No attempt was made to impute missing data. Those patients with missing self-monitoring data were excluded from the analysis.

*Analysis*

The focus of the analysis was on the characteristics of systolic, rather than diastolic blood pressure as this is considered to be more closely associated with underlying cardiovascular disease risk.(6;7) Descriptive statistics were used to describe the mean (±95% confidence intervals) clinic systolic blood pressure for each of the six measurements taken using the BpTRU device. All statistical analyses were performed in SPSS version 21.0 (SPSS Inc, Chicago, USA). Summary data are presented as means ± standard deviation (or 95% confidence intervals) and percentages of trial population (unless otherwise stated).

Home blood pressure was measured over a period of up to seven days and mean home blood pressure was calculated having discarded the first day’s readings in accordance with recommendations (up to 12 readings).(8) To calculate the home-clinic difference, the first clinic blood pressure reading (measured at baseline using BpTRU) was subtracted from the mean home blood pressure (measured in the first month after baseline measurement, prior to any changes in antihypertensive medication). The first clinic reading was used in order to maximise the white coat or masked effects under investigation.

Previous studies have used simple descriptive statistics to describe clinic blood pressure measured using the BpTRU device.(9-13) In order to maximise the discriminatory ability of the data, we chose to study the characteristics of the change in blood pressure across all six clinic readings using both simple and more complex calculations. We estimated the drop in systolic blood pressure (sixth minus the first reading) in each individual patient at baseline and generated coefficients to represent the slope (linear) and quadratic (curve) components of this drop using polynomial regression modelling (the algorithm used to estimate these components is given in the online data supplement). These ‘characteristics’ were chosen because they represent a simple straightforward approach (BP drop) which would be easy to implement in clinical practice and also a more complex model which more accurately represents the trends observed previously when blood pressure is measured repeatedly in a clinic setting.[13]

Using baseline measurements, the blood pressure drop, slope and quadratic coefficients were calculated and plotted against the corresponding home-clinic difference for each individual. This study focused on baseline measurements as this time point provided the largest number of comparisons between clinic blood pressure readings and the home-clinic difference. The relationship between clinic blood pressure characteristics and the home-clinic difference was investigated using Pearson’s correlation coefficient. The relationship between clinic systolic blood pressure and white coat and masked *effects* was also examined*.* It was not possible to study white coat and masked *hypertension* because this terminology conventionally refers to treatment naïve patients and all patients enrolled into the TASMINH2 trial had uncontrolled treated hypertension, and therefore their blood pressures did not straddle the diagnostic threshold. Because there are no standard definitions of what constitutes a white coat or masked effect, the sample population was divided into three groups on the basis of the degree of difference between home and clinic blood pressure. An arbitrary range of group boundaries were examined and one way analysis of variance was used to identify a boundary combination for the final analysis which provided the largest between group variation (different home-clinic differences between white coat, normal and masked effect groups) relative to the smallest within group variation (patients within each group with similar home-clinic differences):

* White coat effect; any patient with a home-clinic blood pressure difference of greater than or equal to 0.2 standard deviations below the mean home-clinic difference for the total population.
* Masked effect; any patient with a home-clinic blood pressure difference of greater than or equal to 1.1 standard deviations above the mean home-clinic difference for the total population.
* No white coat or masked effect (normal); any patient with a home-clinic blood pressure difference between 0.2 standard deviations below the mean and 1.1 standard deviations above the mean home-clinic difference for the total population.

The predictive abilities of the blood pressure drop, the slope and the quadratic coefficients for patients displaying white coat and masked blood pressure characteristics were investigated using two binary logistic regressions. This generated probabilities that a given drop, slope or quadratic coefficient would predict a white coat or masked effect which were used in a Receiver Operating Characteristic analysis to estimate the coefficient thresholds with the highest sensitivity and specificity combination (where sensitivity was >90%) and positive/negative predictive values for a given effect.

*Sensitivity analyses*

To test the impact of the assumptions made in the main analysis on the relationship between clinic blood pressure characteristics and the home-clinic difference, a series of sensitivity analyses were undertaken using Pearson’s correlation coefficient.

The first set of sensitivity analyses used alternative definitions of home blood pressure measurement or home-clinic difference:

1. Seven days of home blood pressure measurements within the first month (not necessarily on consecutive days) (n=174).
2. Seven consecutive days of home blood pressure measurements within the first month (n=142).
3. The home-clinic difference estimated using the mean of clinic readings 1-3 instead of just the first reading (n=220).
4. The home-clinic difference estimated and compared to clinic blood pressure characteristics at 6 months follow up and 6 month home readings (n =186).

The second set of sensitivity analyses examined the reliability of the definition of the white coat and masked effect by studying whether the use of alternative thresholds for both conditions altered the results. Ten alternative thresholds for the white coat effect were tested (0.1 to 1.0 standard deviations below the mean and one arbitrary threshold [less than -20mmHg home-clinic blood pressure difference]). Similarly, ten different thresholds for the masked effect (1.0 to 1.9 standard deviations above the mean and one arbitrary threshold [greater than 0mmHg home-clinic difference]) were also evaluated. The predictive abilities of the drop, slope and quadratic coefficients for these alternative definitions of the white coat and masked effect were estimated as previously described.

**Table s1.** Sensitivity analyses showing the correlation between clinic blood pressure characteristics and the home-clinic difference by population studied, the estimate of home-clinic difference used and the time point in the trial at which variables were compared.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sensitivity analysis | Number of comparisons | BP drop | Slope coefficient | Quadratic coefficient |
| **Pearson correlation** | **P value** | **Pearson correlation** | **P value** | **Pearson correlation** | **P** **value** |
| Main analysis: baseline clinic data and at least four days of home blood pressure measurements within the first month (not necessarily on consecutive days). | 220 | 0.540 | <0.001 | 0.512 | <0.001 | -0.443 | <0.001 |
| Baseline clinic data and seven days of home blood pressure measurements within the first month (not necessarily on consecutive days). | 174 | 0.516 | <0.001 | 0.505 | <0.001 | -0.439 | <0.001 |
| Baseline clinic data and seven consecutive days of home blood pressure measurements within the first month. | 142 | 0.514 | <0.001 | 0.540 | <0.001 | -0.474 | <0.001 |
| Baseline clinic data with the home-clinic difference estimated using the mean of clinic readings 1-3 instead of just the first reading. | 220 | 0.345 | <0.001 | 0.259 | <0.001 | -0.202 | 0.003 |
| 6 month follow-up clinic data and at least four days of home blood pressure measurements within the sixth month (not necessarily on consecutive days). | 186 | 0.456 | <0.001 | 0.376 | <0.001 | -0.285 | <0.001 |

**Table s2.** Mean home-clinic difference and slope/quadratic coefficients for patients displaying white coat, normal and masked effects.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Group\* | Total | Clinic SBP(mmHg)† | Home SBP (mmHg)‡  | Home-clinic SBP difference (mmHg) | Clinic SBP drop (mmHg) | Clinic SBP slope coefficient | Clinic SBP quadratic coefficient |
| White coat effect | 92 (42%) | 169 ± 15 | 138 ± 11 | -30 ± 11 | -21 ± 10 | -11.58 ± 8.73 | 1.07 ± 1.17 |
| Normal  | 95 (43%) | 154 ± 10 | 146 ± 10 | -8 ± 6 | -13 ± 10 | -5.67 ± 6.64 | 0.43 ± 0.84 |
| Masked effect | 33 (15%) | 147 ± 10 | 160 ± 11 | 13 ± 8 | -7 ± 13 | -0.30 ± 8.69 | -0.24 ± 1.33 |

SBP = systolic blood pressure.

All blood pressure, slope and quadratic estimates are given as means ± standard deviation.

†Clinic SBP = 1st clinic reading measured using the BpTRU device.

‡Home SBP = Mean of 1 weeks’ home blood pressure readings after the first days reading is discarded (12 readings in total).

\*The white coat group was defined as any patient with a home-clinic difference of less than -17.7mmHg, 0.2 standard deviations below the mean (-14.2mmHg). The masked effect group was defined as any patient with a home-clinic difference of greater than 5mmHg, +1.1 standard deviations above the mean. The normal group was defined as any patient with a home-clinic difference falling in between these boundary thresholds.

**References**

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