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Research

# Comparison of blood pressure measurements using an automated blood pressure device in community pharmacies and family physicians' offices: a randomized controlled trial

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## Abstract

**Background:** Accurate measurement of blood pressure is the foundation of appropriate diagnosis, treatment and ongoing management of hypertension. The use of automated blood pressure devices in community settings such as pharmacies provide opportunities for additional blood pressure measurement; however, it is important to ensure that these measurements are comparable to those taken in physicians' offices using the same devices. We conducted a randomized controlled trial to assess whether blood pressure readings assessed by use of an automated device differed according to the setting, specifically in community pharmacies and family physicians' offices.

**Methods:** We included adults aged 65 years and older who did not live in long-term care facilities or in hospital. The trial was administered by volunteer peer health educators, family physicians and pharmacists in 2 midsized communities in Ontario from April to September 2010. The 5 participating family physicians mailed invitations to their eligible patients. Those who gave informed consent were randomly allocated to 1 of 2 assessment sequences: group A had their blood pressure measured at their physician's office, then at a pharmacy, then again at their physician's office; those in group B had their blood pressure measured at a pharmacy, then at their physician's office, then again at a pharmacy. An automated blood pressure device (BpTRU) was used in both settings. We calculated the differences in mean systolic and diastolic blood pressure, and we compared the readings at both settings and by sequence of assessment.

**Results:** In total, 275 adults completed the trial (mean age 75.9 yr, 49.5% male, 46.9% with a self-reported diagnosis of hypertension). There were no statistically significant differences in systolic or diastolic blood pressure measurements associated with the sequence of assessment or the setting. There was a significant difference in the overall mean systolic blood pressure between the 2 assessment sequences (group A 122.0 v. group B 127.8 mm Hg, $p < 0.001$).

**Interpretation:** Automated devices used in pharmacies to measure blood pressure provide accurate and valid information that can be used in the diagnosis and management of hypertension among older adults in the community. Trial registration: www.controlled-trials.com, no. ISRCTN91799042.

Results from the Canadian Health Measures Survey[1] indicate that 19% of Canadians (4.6 million people) have hypertension. Worldwide, over 54% of stroke, 47% of ischemic heart disease and 13.5% of all deaths are because of high blood pressure.[2–4] Blood pressure measurement is one of the most commonly performed tests in family practice. However, because of the inherent variability[5] of blood pressure, issues about where, by whom and how it is measured are of paramount importance. Accuracy can be affected by factors such as equipment, patient or operator variability, white-coat hypertension, masked hypertension, night-time dippers (hypertensive patients who display nocturnal decreases in blood pressure) versus nondippers and inter-visit variability and episodic peaks. The importance of the accurate measurement of blood pressure is underscored by the fact that reductions in systolic blood pressure of more than 5 mm Hg, or even as small as 2–4 mm Hg, are clinically important.[6] The average effect on blood pressure of a single antihypertensive drug at a standard dose or a single lifestyle change can be as high as 10 mm Hg systolic and 6 mm Hg diastolic.[7,8] The end result is that the measurement error frequently exceeds the effect size of therapy or lifestyle modification.

Because community pharmacies are frequently visited by patients and because pharmacists are encouraged to monitor

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blood pressure when they counsel patients about their medications,[9] it is important that blood pressure measurements in this setting are accurate and reliable.

We designed this trial to test whether blood pressure measurements obtained in pharmacies are comparable to those obtained in physicians' offices.

## Methods

### Study design

We performed a pragmatic randomized controlled trial[10] comparing automated blood pressure measurements obtained from adults aged 65 and older in family physicians' offices and community pharmacies in Collingwood and Creemore, Ontario. No renovations were made to the pharmacies or to the physician offices to accommodate the trial so that the patients were familiar with the surroundings. In these small communities, pharmacies are geographically close to the family physician offices.

Eligible participants were randomly allocated to 1 of 2 groups for blood pressure assessment (Figure 1). Participants in each group attended 3 sessions in the assigned sequence. Participants in group A first had their blood pressure measured in their physician's office, then in a pharmacy, then again in their physician's office. Participants in group B first had their blood pressure measured in a pharmacy, then in their physician's office, then again in a pharmacy. Participants were encouraged to complete all 3 visits within 4 weeks.

The research ethics board of Bruyère Continuing Care approved this study, and all participants gave informed consent. There was minimal risk of harm to the trial participants.

### Recruitment and training of local trial coordinators and volunteer peer health educators

The Cardiovascular Health Awareness Program is a community-based program that brings together local family physicians, pharmacists, other health professionals, public health representatives, volunteers and health and social service organizations to work together to promote and actively participate in the prevention and management of heart disease and stroke. Two local trial coordinators were appointed by the Cardiovascular Health Awareness Program's[11] community lead organization (Collingwood YMCA) to oversee the blood pressure assessment sessions in both communities. The local trial coordinators were briefed on the rationale and data-collection procedures by the coordinating centre's team during site visits before the study began. The coordinating centre's team was available by telephone and email for ongoing support to the local trial coordinators over the course of the trial. The blood pressure assessment sessions began in April 2010 and ended in September 2010.

With the assistance of the local YMCA, the local trial coordinators recruited 17 volunteer peer health educators to assist with the blood pressure assessment sessions. Using the Cardiovascular Health Awareness Program's Implementation

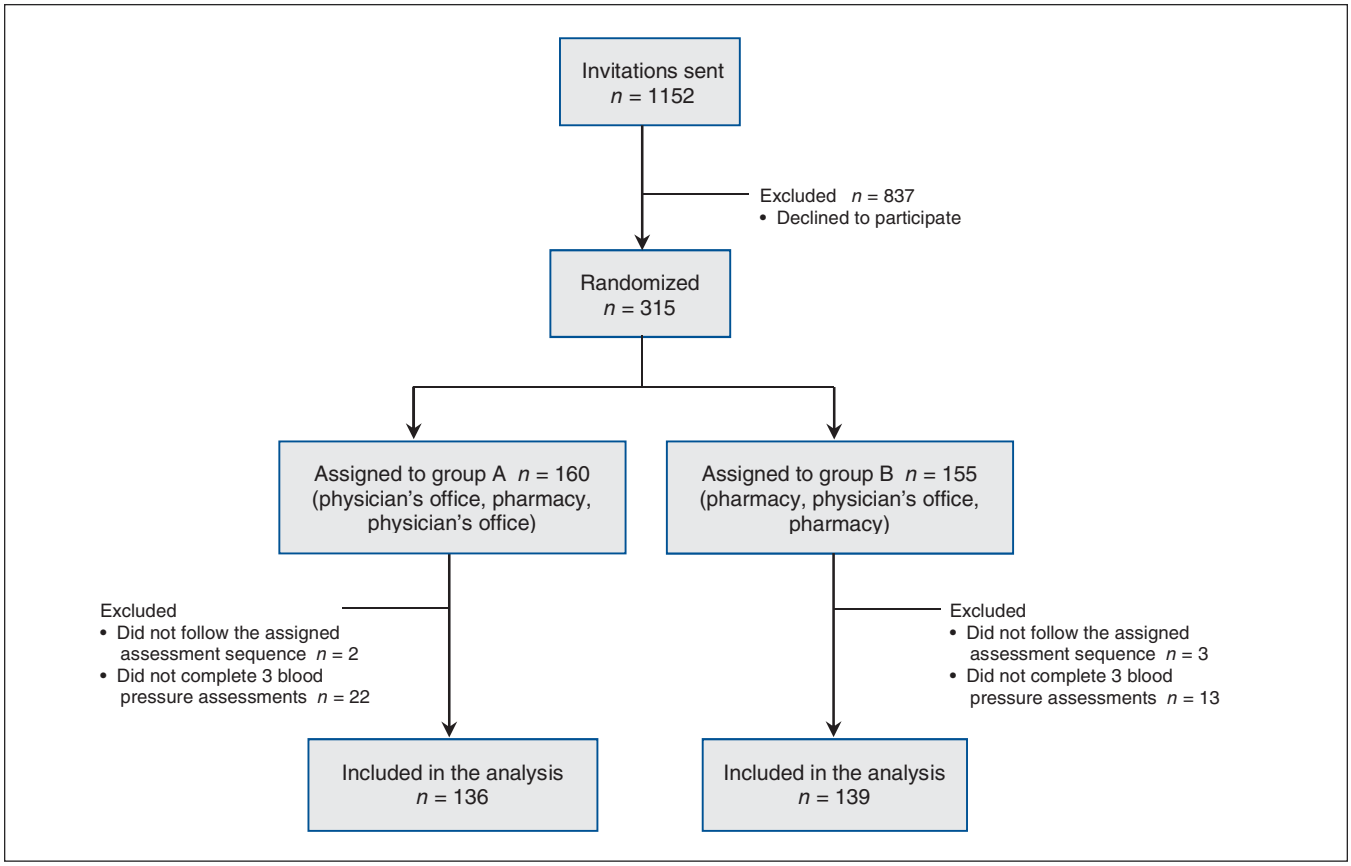


**Figure 1:** Flow of participants in the study.

Guide (www.chapprogram.ca/implementationguide), a community health nurse provided training to all volunteers on how to assist participants in using the automated blood pressure measuring device (BpTRU monitor) to appropriately assess their blood pressure.

The local trial coordinators were responsible for scheduling the blood pressure assessment sessions and coordinating the schedules of the volunteer peer health educators for each session. After each session, the local trial coordinators reviewed the data collection forms for each participant for completeness and legibility before faxing the forms to the central database using fax-to-database technology. At the end of each week, the data collection forms were mailed to the centre.

### Recruitment of physicians and pharmacies

Two physicians in the Cardiovascular Health Awareness Program agreed to participate, and they recruited 3 additional physicians in Creemore. Because this was a pragmatic trial, we used no other criteria to select the physicians' offices. The coordinating centre team met with the physicians and their office staff to outline the rationale and their role in the trial. Two pharmacies, one in each community, provided space for the blood pressure assessment sessions. The coordinating centre team outlined the rationale for the trial and the pharmacies' role to both pharmacists and pharmacy staff. The pharmacies and physicians' offices were given latitude to operate the sessions in a way that was compatible with the other operations ongoing in these sites at the time of the trial. Neither the physicians nor pharmacists were given any special instructions about recommended treatments or therapies. The assumption was that the randomization process would balance the proportion of changes in medications that occurred for participants in both study groups.

### Recruitment, selection and randomization of participants

The electronic health records of the participating physicians were used to generate lists of patients aged 65 years and older who were not in hospital or residing in a long-term care facility. We considered all patients who met these criteria to be eligible to participate in this study. The age and sex of the patients who were not eligible for inclusion are not available because the physicians' offices provided a list of only the names and addresses of the patients who met our inclusion criteria.

Within each practice, we randomly assigned patients to 1 of 2 assessment sequences using a random allocation sequence generated using a web-based randomization scheme (www.randomizer.org). Patients were randomly allocated in blocks of 4 to ensure that a steady flow of patients would arrive in the pharmacies and physicians' offices. Eligible patients were mailed personalized invitation letters signed by their family physician. The letters contained the locations, dates and times of the blood pressure measurement sessions and the assigned sequence of sessions. No other instructions that might affect their blood pressure readings during the sessions were included in the letters to simplify the task and increase the number of participants attending the sessions. The letters were mailed at 2-week intervals (one-quarter at each interval) to manage the flow of participants at the sessions. Eligible patients who did not attend after the first invitation were sent a second invitation.

### Blood pressure assessment sessions

Blood pressure was assessed using the BpTRU device. This device meets international standards for accuracy (www.bptru.com). The pharmacies involved in the trial each had a BpTRU device purchased by the Cardiovascular Health Awareness Program. The BpTRU devices have been validated and are used extensively in clinical practice and research in Canada.[7] We did not assess intermachine variability.

The local trial coordinator attended and led each blood pressure measurement session at the pharmacies and physicians' offices. During the first session, each participant signed a consent form and completed a 1-page cardiovascular risk assessment questionnaire, which collected data about participants' cardiovascular health history and risk factors, including weight, smoking history, physical activity, alcohol intake, stress and diet. The BpTRU is a fully automated sphygmomanometer that records blood pressure using the oscillometric method. The device takes 6 readings, discards the first reading and averages the mean of the 5 readings. In our study, the BpTRU was set to take readings at 1-minute intervals (from the start of one reading to the start of the next one). The volunteer peer health educators assisted participants with the cuff if required during the first measurement. During the remaining measurements, the volunteer peer health educator or local trial coordinator sat quietly nearby. Participants were discouraged from talking during the assessment. Volunteers recorded the mean value of the 5 readings on each participant's data collection form. Each session took about 20 minutes. Participants were able to consult the pharmacists as needed to discuss medications or other concerns. Appendix 1 (available at www.cmajopen.ca/content/1/1/E37/suppl/DC1) provides the Cardiovascular Health Awareness Program protocol that the volunteer peer health educators referred to when assisting trial participants after their blood pressure assessment. The protocol divides blood pressure levels into categories of risk, with actions or recommendations for peer health educators to undertake depending on the patient's category. We did not record the number of participants who fit into the categories outlined in this protocol.

### Data collection and management

A data collection form was completed for each patient at each visit. The order of allocated location sequences was recorded by volunteers on the back of the forms. Participants were encouraged to take a copy of the completed form from each session to their next visit with their family physician. Participants gave permission to send a copy of their completed form to their family physician and regular pharmacist. Fax-to-database technology was used to forward copies of the completed forms to the physicians, pharmacists and central database. All paper versions of the completed, not completed and illegible forms were forwarded to the coordinating centre.

When the completed forms arrived at the coordinating centre, they were reviewed by one of us (S.I.) for completeness and adherence to the assigned sequence of assessment. The data from the completed risk assessment forms, including allocation group, were entered into Microsoft Excel (by S.I.) One of use (S.O.) checked a random 10% sample of completed forms against the database entries; she did not find any data-entry errors.

### Outcomes

Our primary outcome was the mean relative difference for systolic and diastolic blood pressure measurements within participants at pharmacies and physicians' offices and the sequence of the assessments.

### Statistical analysis

We used $\chi^2$ tests to compare characteristics of the participants in the 2 groups. The mean systolic and diastolic blood pressure values were compared by setting and sequence of assessment using a 2 × 3 repeated-measure analysis of variance. We considered mean differences of more than 5 mm Hg to be clinically significant.[7] We calculated correlations (Pearson $r$) of blood pressure readings within the study groups to determine between-setting blood pressure consistency. Strong correlations were defined as those over 0.5. We used a 2-tailed $\alpha$ level of 0.05 to determine statistical significance, and all analyses were carried out using SPSS for Windows v.17.0.0. To test the hypothesis of equivalence (i.e., that blood pressure measurements taken at a pharmacy are equivalent to those taken at a physician's office [within 7.5 mm Hg]), we required 102 patients for each study group.

See Appendix 2 (available at www.cmajopen.ca/content/1/1/E37/suppl/DC1) for the CONSORT Statement Checklist for this trial.

## Results

Invitation letters were mailed to 1152 patients from 5 family medicine practices. In total, 27.3% (315/1152) agreed to participate and were randomly assigned to one of the study groups (Figure 1). Five participants were excluded from the analysis (2 in group A and 3 in group B because they did not adhere to the assigned sequence of blood pressure measurements). Twenty-two participants in group A and 13 participants in group B did not complete all 3 blood pressure assessments. The characteristics of the excluded participants did not differ between groups and did not differ from the included participants. In total, 275 patients completed the trial (136 in group A, 139 in group B).

The characteristics of participants in group A and B were comparable across most measures (Table 1). However, the 2 groups differed for self-reported diagnosis of high blood pressure (44.4% in group A v. 57.3% in group B) and taking medication for high blood pressure (43.0% in group A v. 56.8% in group B). Interviews with the pharmacy staff, physicians' office staff and local trial coordinators gave no reasons to explain this difference. The mean time to complete the 3 blood pressure assessments for group A (11.1 d) and group B (11.8 d) was similar ($p = 0.4$).

Mean systolic and diastolic blood pressure values were similar in both trial groups across measurements taken in different settings (Table 2). There was no significant interaction between allocation group or time for either systolic or diastolic blood pressure. For systolic blood pressure, there was a significant group main effect, reflecting difference in the overall mean systolic blood pressure between the 2 groups (group A 122.0 mm Hg v. group B 127.8 mm Hg, $p < 0.001$), most likely because of the higher proportion of adults with self-reported high blood pressure in group B. After adjustment for baseline differences in self-reported high blood pressure, the results remained unchanged.

There was strong correlation between readings taken at physicians' offices and pharmacies for both groups for both systolic and diastolic blood pressure for the different assessment sequences (all $r > 0.5$, Table 3).

**Table 1: Self-reported baseline participant characteristics**

| Characteristic | % (no. of participants)* | |
|---|---|---|
| | Group A† $n = 136$ | Group B† $n = 139$ |
| Age, mean ± SD | 75.9 ± 6.5 | 75.9 ± 6.8 |
| Men | 51.5 (70) | 47.5 (66) |
| History of transient ischemic attack | 9.6 (13) | 9.4 (13) |
| History of stroke | 3.7 (5) | 3.6 (5) |
| History of heart attack | 7.4 (10) | 11.5 (16) |
| Diagnosed diabetes | 10.3 (14) | 10.9 (15) |
| Diagnosed high blood pressure | 44.4 (60) | 57.3 (79) |
| Taking medication for high blood pressure | 43.0 (59) | 56.8 (80) |

Note: SD = standard deviation.
*Unless otherwise indicated.
†Sequence of blood pressure measurement: group A: physician's office, pharmacy, physician's office; group B: pharmacy, physician's office, pharmacy.

**Table 2: Mean blood pressure readings obtained at family physicians' offices and pharmacies**

| Assessment | Mean* blood pressure ± SD, mm Hg | |
|---|---|---|
| | Systolic | Diastolic |
| Group A, $n = 136$ | | |
| Measurement 1 (physician's office) | 122.5 ± 14.6 | 70.2 ± 9.4 |
| Measurement 2 (pharmacy) | 121.8 ± 14.1 | 70.1 ± 8.3 |
| Measurement 3 (physician's office) | 121.8 ± 14.3 | 69.6 ± 9.3 |
| Group B, $n = 139$ | | |
| Measurement 1 (pharmacy) | 128.7 ± 17.0 | 70.5 ± 10.2 |
| Measurement 2 (physician's office) | 127.6 ± 17.0 | 70.1 ± 9.9 |
| Measurement 3 (pharmacy) | 127.6 ± 16.5 | 69.8 ± 10.8 |

Note: SD = standard deviation.
*Mean value of 5 readings at each session.

## Interpretation

Because this was a pragmatic trial, we used simple eligibility criteria: we included only patients from family physicians' practices who were aged 65 and over. The intervention was flexible because the study was implemented in such a way that was compatible with the other operations ongoing in these sites at the time of the trial. Also, the volunteer peer health educators were trained in the usual way that Cardiovascular Health Awareness Program volunteers are trained, and the participating physicians and pharmacists were not provided with special training in hypertension measurement, monitoring or management. We used the standard data collection forms used by the Cardiovascular Health Awareness Program to record blood pressure measurements and data about risk of cardiovascular disease. There was no follow-up data collection performed. Similar to procedures used by the Cardiovascular Health Awareness Program, we used no special strategies to increase adherence, because a letter from a family physician usually results in over 25% of patients who receive a letter attending a session.[12]

To the best of our knowledge, only one other study[13] has compared blood pressure readings obtained in pharmacies with those obtained in family physicians' offices; this study found no clinically important differences in readings between the 2 sites. However, the study by Sendra-Lillo and colleagues[13] was more of an explanatory study than a pragmatic one, as ours was. In that study, because they sought to enhance clinician adherence to the protocol, 1 experienced physician and 1 experienced pharmacist who already worked in each site were responsible for all measurements, and each was given 20 minutes of training to standardize the blood pressure measuring process. Because theirs was a cross-sectional study, the authors made no attempt to control for sequence effect (e.g., did having blood pressure taken in the pharmacy first affect the readings obtained in the physician's office?). Despite the different methodologies, the results reported by Sendra-Lillo and colleagues[13] are consistent with our results reported here. In both studies, blood pressure measurements were similar at each site, supporting an increased role for pharmacies as appropriate additional sites to accurately and reliably measure blood pressure, thus enhancing the prevention and control of cardiovascular disease beyond physicians' offices.

We found higher mean blood pressure readings at the first of 3 assessments in group A than in group B. The pharmacists, physicians and their staff, as well as the local trial coordinators, could not provide any explanation for this difference. The groups were comparable for other patient characteristics, suggesting that this was a chance event despite the use of randomization to allocate participants to the study groups. This was reflected in our analysis of variance models that adjusted for self-reported diagnosis of hypertension, in which the significant difference in systolic blood pressure between groups was not removed. This suggests that the mean blood pressure difference between the groups was a statistical anomaly.

### Limitations

The inability to blind participants as to their group allocation is a common feature of pragmatic trials. Given the nature of our intervention (measuring blood pressure in different settings), the likelihood of performance bias is quite low. The attrition rates were also low and were unlikely to influence the results of the trial.

This trial was successfully completed in 5 busy family physicians' offices and 2 fully operational pharmacies. The day-to-day operation of the trial was the responsibility of the local coordinators who were not researchers and who were employed by the local organization responsible for running the trial. They were not employed by the physicians or pharmacists. The local coordinators had no interest in the results of the trial. It is likely that the order of assessment was not an issue for the volunteer peer health educators or participants because all participants were assessed at least once in their family physician's office as well as in the pharmacy. The local coordinators and volunteer peer health educators were on a tight schedule because over 300 people had to be entered into the study and assessed 3 times, ideally within 4 weeks. Very few participants did not complete the trial, reflecting the excellent performance of the people responsible for the day-to-day operation of the trial.

**Table 3: Correlation coefficients comparing the sequence and setting of blood pressure measurements**

| | Group A | | | Group B | |
|---|---|---|---|---|---|
| Measure | Measurement 2 (pharmacy) | Measurement 3 (physician's office) | Measure | Measurement 2 (physician's office) | Measurement 3 (pharmacy) |
| **Systolic** | | | **Systolic** | | |
| Measurement 1 (physician's office) | 0.55 | 0.61 | Measurement 1 (pharmacy) | 0.64 | 0.61 |
| Measurement 2 (pharmacy) | — | 0.55 | Measurement 2 (physician's office) | — | 0.56 |
| **Diastolic** | | | **Diastolic** | | |
| Measurement 1 (physician's office) | 0.63 | 0.72 | Measurement 1 (pharmacy) | 0.66 | 0.71 |
| Measurement 2 (pharmacy) | — | 0.57 | Measurement 2 (physician's office) | — | 0.62 |

The trial centre provided clear instructions to the local coordinators about the allocation of participants to the 2 study groups. Visits to the trial location by coordinating centre staff, as well as frequent telephone conversations with the local trial coordinators about the reason for the trial and the importance of adherence to the protocol, also reduced the possibility of issues arising that might be a result of the absence of blinding; this contact also guaranteed a high level of performance locally in conducting the trial and minimized the attrition of participants. The group assignments were verified by the trial centre as the trial progressed. In addition, we performed an independent assessment of 10% of the participants assigned to the study groups to confirm that they had been correctly randomized. When interviewed at the end of the trial, the local coordinators and volunteers could not explain why more participants in group A than in group B did not complete the trial. They also could not explain why one group had a slightly higher mean systolic blood pressure.

## Conclusion

Our findings show that measurements of blood pressure using an automated device in a pharmacy can provide accurate and valid blood pressure information that can be used in the diagnosis and management of hypertension among older adults in the community.

Future studies may be conducted using more complex study designs, including a fourth assessment, comparisons of blood pressure measurements with a "gold-standard" such as ambulatory blood pressure measurement, and comparisons of the extent of white-coat and masked hypertension that occurs in pharmacies and family physicians' offices.

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