Comparison of Blood Pressure Measurement using an Automated Blood Pressure Device in Community Pharmacies and Physicians' Offices: The Collingwood-Creemore randomized controlled trial

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Abstract:	Background: Automated blood pressure devices in community settings such as pharmacies provide opportunities for additional blood pressure measurement; however, it is important to ensure these measurements are comparable to those taken in the physicians' offices using the same devices. To assess whether blood pressure readings assessed with an automated device differed according to the setting in which they were taken, specifically in community pharmacies compared to physicians' offices, we conducted a randomized controlled trial. Methods: Five family physicians mailed invitations to their patients aged 65 years and older to participate in the trial. Eligible and consenting adults were randomly allocated to one of two blood pressure measurement sequences: A.) physician's office/pharmacy/physician's office or B.) pharmacy/physician's office/pharmacy. Differences in mean Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) using automated blood pressure measuring device were calculated comparing the setting and sequence of the assessments. Results: 275 adults completed the trial (mean age 75.9 years, 49.5% male and 46.9% with self-reported diagnosis of hypertension). There were no statistically significant differences in SBP or DBP associated with the sequence or the setting. There was a significant difference in the overall mean SBP between the two arms (122.0 versus 127.8 mmHg, p<.001) which was most likely due to a statistical anomaly. Interpretation: Measurements of blood pressure using an automated device in a community pharmacy provide accurate and valid blood pressure information that can be used in the diagnosis and management of hypertension among community-dwelling older adults.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2,3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	6
Participants	4a	Eligibility criteria for participants	10
	4b	Settings and locations where the data were collected	7,8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11
	6b	Any changes to trial outcomes after the trial commenced, with reasons	6
Sample size	7a	How sample size was determined	12
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	10
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	10
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	6,16

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	7-11
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	12
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	13,24
	13b	For each group, losses and exclusions after randomisation, together with reasons	13,24
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7
	14b	Why the trial ended or was stopped	Not applicable
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	13,21
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	24
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	14,22,23
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	14
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	12
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	14.15
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	15
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	3
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	4

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Comparison of Blood Pressure Measurement using an Automated Blood Pressure Device in Community Pharmacies and Physicians' Offices: The Collingwood-Creemore randomized controlled trial

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Abstract

Background: Accurate measurement of blood pressure is the foundation of appropriate diagnosis, treatment and on-going management of hypertension. Automated blood pressure devices in community settings such as pharmacies provide opportunities for additional blood pressure measurement; however, it is important to ensure these measurements are comparable to those taken in the physicians' offices using the same devices. To assess whether blood pressure readings assessed with an automated device differed according to the setting in which they were taken, specifically in community pharmacies compared to physicians' offices, we conducted a randomized controlled trial.

Methods: Community dwelling adults aged 65 years and older, volunteer peer health educators, family physicians, and pharmacists in two mid-sized communities in Ontario, Canada participated in the trial. Five family physicians mailed invitations to their patients aged 65 years and older to participate in the trial. 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 attending the sessions. Eligible and consenting adults were randomly allocated to one of two blood pressure measurement sequences: A.) physician's office/pharmacy/physician's office or B.) pharmacy/physician's office/pharmacy. Once in the family physician office or pharmacy, the participants were asked to be seated and be quiet before the blood pressure cuff was applied to their arm. Automated blood pressure devices (BpTRU) were used in both settings. Differences in mean Systolic Blood

Pressure (SBP) and Diastolic Blood Pressure (DBP) using automated blood pressure measuring device were calculated comparing the setting and sequence of the assessments.

Results: 275 adults completed the trial (mean age 75.9 years, 49.5% male and 46.9% with self-reported diagnosis of hypertension). There were no statistically significant differences in SBP or DBP associated with the sequence or the setting. There was a significant difference in the overall mean SBP between the two arms (122.0 versus 127.8 mmHg, p<.001) which was most likely due to a statistical anomaly.

Interpretation: Measurements of blood pressure using an automated device in a community pharmacy provide accurate and valid blood pressure information that can be used in the diagnosis and management of hypertension among community-dwelling older adults.

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Competing Interests

None

Introduction

The Canadian Health Measures Survey[1] results estimated that one fifth (19%) or 4.6 million Canadians have hypertension. Over 54% of stroke, 47% of ischemic heart disease, and 13.5% of all deaths worldwide are attributed to high blood pressure[2-4]. While blood pressure (BP) measurement is one of the most commonly performed tests in family practice, because of the inherent variability[5] of BP, the issues about where, by whom, and how it is measured remain paramount. Accuracy issues, which can be due to the equipment, the patient and the operator, include white coat hypertension, masked hypertension, night-time dippers versus non-dippers and extreme variability of blood pressure. The importance of accurate measurement of BP is further underscored by the fact that reductions in SBP >5mmHg or as small as 2–4 mmHg are clinically important. The average effect on blood pressure of a single antihypertensive drug at a standard dose or one lifestyle change can be as high as 10/6 mmHg[6,7]. The end result is that the measurement error frequently exceeds the effect size of therapy or lifestyle modification.

Because community pharmacies are frequent visiting sites for family medicine patients and as pharmacists are encouraged to monitor blood pressure as they counsel patients about their medications[8], it is important that the BP measurement is accurate and reliable.

This trial was designed to determine if blood pressure measurements taken in pharmacies are comparable to measurements in physician offices.

Methods

Study design

This pragmatic randomized trial compared automated blood pressure measurements of participants aged 65 years and over in family physicians' offices and community pharmacies in Collingwood and Creemore, Ontario, Canada. No renovations were made to the pharmacies and the family physician offices to accommodate the trial so that the patients were familiar with these surroundings in these small communities where the pharmacies are geographically close to the family physician offices. Participants in each group attended three blood pressure assessment sessions to complete this parallel group study. Important changes to the methods were not after the trial commenced.

Eligible participants were randomly allocated to one of the following two sequences (groups) for blood pressure assessment (see Figure 1):

- Arm A= Physician's office, then pharmacy, then physician's office or;
- Arm B= Pharmacy, then physician's office, then pharmacy.

Participants were encouraged to complete three visits within four weeks.

Recruitment and training of local Trial coordinators

Two local coordinators were identified by the Cardiovascular Health Awareness Program[9] (CHAP) community lead organization (Collingwood YMCA) to oversee the blood pressure assessment sessions in the two communities. Local coordinators were briefed on the rationale and data collection procedures by the Coordinating Centre team during site visits to the two communities prior to study commencement. The Coordinating Centre team was available by telephone and e-mail for ongoing support to the local coordinators over the course of the trial. The trial's field activities began in April 2010 and ended in September 2010.

As in CHAP, the local coordinators were responsible for scheduling blood pressure assessment sessions and coordinating volunteer peer health educator schedules for each session. After each session, the local coordinators reviewed data collection forms of each participant for completeness and legibility prior to faxing the forms to the central database using fax-to-database technology. In addition, at week's end, data collection forms were mailed to the Centre.

Recruitment of physicians and pharmacies

Two CHAP physicians agreed to participate and they recruited three additional physicians in Creemore. As a pragmatic trial, no other criteria were used to select physician offices. The Coordinating Centre team met with physicians and office staff to outline the rationale for the trial and their role. Two pharmacies, one in each

community, provided space for the blood pressure assessment sessions. The Centre team outlined the rationale for the trial and pharmacies' role. The pharmacies and the physicians' offices were offered leeway so regular staff in all the sites could accommodate the day-to-day operations the trial. As this is a pragmatic trial, no instructions were given to the physicians and pharmacists about any treatments. The assumption is that the randomization process results in balance in the proportion of changes in medications that occurred with participants in the two Arms of the trial.

Recruitment and training of volunteer peer heath educators

With the assistance of the CHAP local lead organization (in this case the local YMCA), the local Coordinators recruited 17 volunteer peer health educators to assist with the blood pressure assessment sessions. Using the CHAP Implementation Guide (www.chapprogram.ca), a community health nurse provided training for all the volunteers on the process of assisting participants in using the automated blood pressure measuring device (www.bptru.com)[6] to appropriately assess their blood pressure. The BpTRU automated blood pressure measuring device meets international standards for accuracy and each machine is the product of a high proficiency production process. The two pharmacies involved in the trail each had a BpTRU device purchased by CHAP. We have used BpTRU devices extensively and found them very reliable and accurate. The inter-machine variability was not assessed.

Blood pressure assessment sessions

The local coordinator led and attended the pharmacy and physician's office blood pressure measurement sessions including scheduling involvement of the volunteers. At the first session, each participant signed a consent form and completed the CHAP cardiovascular risk profile questionnaire on the one page risk assessment form. (www.chapprogram.ca). This form, completed on the first visit only, covered the participant's cardiovascular health history as well as risk factors such as weight, smoking history, physical activity, alcohol intake, stress and diet. In keeping with the BpTRU protocol, during the first visit and subsequent two visits, the BpTRU automated blood pressure measuring device independently assessed the blood pressure with volunteer peer health educators assisting with the cuff if required and assisting with recording the blood pressure taken by the BpTRU on the data collection form. The mean value of the five measurements as produced by the BpTRU was recorded on the participant's form by the volunteer. In CHAP, the BpTRU is set to have a one-minute interval between readings. During the remaining five BpTRU blood pressure measurements, the attending volunteer peer health educator or local Trial coordinator sat quietly nearby. The BpTRU used in this trial had an LED display readout and this information was recorded on the form at each session. Participants were discouraged from talking during the blood pressure assessment. A typical period of time required at a session was 20 minutes. Participants could consult the pharmacist as needed to discuss medications or other concerns. The Appendix provides the "CHAP Session Blood Pressure Recommendation Protocol" that the Volunteer Peer Health Educators referred to when

assisting Trial participants once they had their blood pressure reading. The data collection for this trial did not include keeping track of the number of participants who fit into the categories of risk by BP levels outlined in this Protocol.

Selection, randomization and recruitment of participants

Electronic health records of physician practice rosters 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. All participants who met these criteria were eligible, regardless of their anticipated risk, responsiveness, co-morbidities or past compliance. Age and gender information on non-participants is not available as the physician offices provided a list of names and addresses of patients who were 65 years of age and older with no other accompanying information.

Within each practice, patients were randomized to one of the two blood pressure assessment sequences using random allocation sequence generated by web-based randomization scheme at www.randomizer.org. Patients were randomly allocated to one of two arms in the Trial, in blocks of four to ensure a steady flow of patients arrived in the pharmacies and the physicians' offices. Eligible patients were mailed personalized invitation letters signed by their family physician. They contained locations, dates and times of the blood pressure measurement sessions and assigned location sequences. One quarter of the letters were mailed at two week intervals to manage flow of participants at

sessions. Participants who did not attend after the first invitation were sent another invitation.

Data collection and management

A data collection form was completed for each visit. In order to capture the order of allocated location sequences, the volunteers recorded this on the back of the forms. Participants were encouraged to take their copy of the completed form at each session to their next visit with their family physician. Participants gave permission to send a copy of the completed form to their family physician and their regular pharmacist. Fax-to-database technology was used to forward copies of the completed forms to the physicians, pharmacists and central database. In addition, all the paper versions of the completed, non-completed and illegible forms were forwarded to the Coordinating Centre.

When completed forms arrived each week at the Coordinating Centre, they were verified by SI for completeness as well as adherence to the allocated sequence of local blood pressure assessments.
These data were entered into Microsoft Excel by SI. SO checked a random 10% sample of completed forms against what had been entered into the database and did not find any data entry errors.

Outcome Measure

The primary outcome measure for the trial was the mean relative change within participants in systolic blood pressure (SBP) and diastolic

blood pressure (DBP) measurements using the BpTRU (comparing the setting for the assessment (pharmacy or physician office) and sequencing of the assessments (pharmacy first or physician office first, second or third).

Statistical Analysis

Using chi-square tests, participant characteristics in the two arms were compared based on responses to risk profile forms. Mean SBP and DBP obtained by the BpTRUs were compared by setting and sequence of the assessments using 2x3 repeated measures analysis of variance (ANOVA). Blood pressure mean differences in excess of 5 mmHg were considered clinically significant as this is the amount of decrease in blood pressure that is possible with anti-hypertension therapy. Correlations (Pearson *r*) of blood pressure readings within Trial arms were calculated to determine between-setting BP consistency. Strong correlations were defined as those over 0.5. Two-tailed alpha level of 0.05 was used to determine statistical significance, and all analyses were carried out using SPSS for Windows v.17.0.0. In order to test the hypothesis of equivalence, in other words blood pressure measurements taken at the pharmacy are equivalent to those taken in the physicians' offices (that is, a margin of +/- 7.5 mmHg), required 102 patients per Trial arm.

The Research Ethics Board of Bruyère Continuing Care approved the study and all participants gave informed consent. There was minimal risk of harm to trial participants.

Results

Invitation letters were mailed to 1,152 patients. Over 27% (315/1,152) agreed to participate and they were randomized to one of the two trial arms (Figure 1). Five participants were excluded from the analysis, two in Arm A and three in Arm B as they did not adhere to their assigned sequence of sites for blood pressure measurements. Twenty-two participants in Arm A and 13 participants in Arm B did not complete all three blood pressure assessments. The characteristics of these participants did not differ across arms and did not differ from participants. A total of 275 patients were enrolled and completed the trial (136 in Arm A; 139 in Arm B).

The characteristics of the participants in Arms A and B were comparable across most measures (Table 1). However, the two Arms differed for self-reported diagnosed with high blood pressure (A= 44.4% and B=57.3%) and taking medication for high blood pressure (A=44.0% versus B=56.8%). Interviews with the pharmacy staff, physician office staff and the local trial coordinators by Coordinator Centre (SI) yielded no reasons to explain further this difference. The mean time interval to complete the three BP measurements for Arm A versus Arm B was comparable (Arm A = 11.1 days versus Arm B = 11.8 days, p=0.36).

Mean SBP and DBP were comparable in both trial arms across measurements taken at different settings (Table 2). Results of the repeated measures ANOVA models showed no significant interaction effect in differences between Arms or over time for either SBP or DBP. The SBP ANOVA model also revealed a significant Arm main effect, reflecting difference in the overall mean SBP between the two arms (122.0 versus 127.8 mmHg, p<.001), most likely due to higher proportion of adults with self-reported high blood pressure in one arm of the trial. The previous models were then rerun as repeated measures analysis of co-variance. A adjusting for baseline differences in self-report previous diagnosis of high blood pressure between the two Arms revealed no model improvement, with a remaining significant main effect between groups, a nonsignificant main effect over time, and a nonsignificant interaction between groups over time.

Correlation coefficients comparing blood pressure readings for each sequence and setting (labeled as One, Two or Three in Table 3) in Arms A and B for both SBP and DBP were strong and consistent across settings and the measurement sequence (i.e., all $r > 0.5$, Table 3).

Discussion

As a pragmatic Trial[11], this trial had simple participant eligibility criteria with only patients in family physicians offices who were aged 65 and over being included. The intervention was flexible as the local coordinators in Collingwood and Creemore had the latitude to operate the sessions in the pharmacies and physician offices in 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 CHAP volunteers are trained and, like CHAP, practicing practitioners in the study's family physician offices and pharmacies were not provided with special training in hypertension measurement, monitoring and management. The trial used the standard CHAP data collection forms that capture blood pressure and other cardiovascular disease risk information. No other special follow-up data collection was conducted on study participants. Also, no special strategies were used to increase participants' adherence to the protocol. In the operation of CHAP, similarly there are no special strategies to increase adherence as a letter from the family physician usually results in over 25 percent of those receiving the letter attending the CHAP sessions.

As far as we know, only one other study[12] has been published comparing blood pressure readings in pharmacies with readings in family physician offices. In that study[12], also, no clinically important differences were reported in readings between the two sites. However, the study, called the Palmera study, was designed more as an explanatory study than a pragmatic study like the Collingwood Creemore Trial. In order to enhance participating clinician adherence to the protocol, only one experienced physician and one experienced pharmacist who already worked in each site were responsible for all the measurements and they were given 20 minutes of training to standardize the blood pressure measuring process. As a cross-sectional study, no attempt was made in the design of the trial to control a

sequence effect – for example, did having blood pressure taken in the pharmacy first affect the readings in the physician office? Despite these differences between the Palmero[12] and Collingwood-Creemore studies, the results are consistent. In both cases, blood pressure measurements were comparable in each site thus supporting an increased role for pharmacies as appropriate additional sites to measure accurately and reliably BP and thus enhancing the prevention and control of cardiovascular disease beyond the physicians' office.

Higher baseline mean blood pressure readings were found in Arm A when compared to Arm 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 on the other patient measures (see Table 1), suggesting that this was a chance event that can occur even when randomization is used to allocate participants. This is reflected in subsequent ANOVA models, adjusting for self-reported hypertension diagnosis, where the significant difference between groups in SBP was not removed. This further suggests that the mean blood pressure difference between the two arms was a statistical anomaly.

The inability to blind participants is a common feature of pragmatic trials. Given the nature of our intervention (measuring BP in different settings), the likelihood of performance bias is quite low. As indicated above, the attrition rates were also low and not likely to influence the results of the trial.

The trial was successfully completed in five busy family physician offices and fully operational pharmacies. The day to day operation of the trial was the responsibility of local coordinators who were not researchers and employed by the local organization responsible for running the trial. They were not employed by the physicians or pharmacists. They had no interest in the results of the trial. It is likely that the order of the assessments as to whether they would be in the pharmacy or physician office was not an issue for the volunteer peer health educators or the participants as all participants would be assessed at least once in the family physician office as well as in the pharmacy. The local coordinators and the volunteer peer health educators were on a tight schedule as over 300 people had to be entered into the study and assessed three times, ideally, within four weeks. Very few did not complete the trial reflecting the excellent performance of the people in Collingwood and Creemore who were responsible for the day to day operation of the trial. The Trial Centre provided clear instructions about the allocation of participants to the two study groups. Visits to the trial location by Coordinating Centre personnel as well as frequent telephone conversations about the reason for the trial and the importance of adherence to the protocol also reduced the possibility of issues arising that might be due to the absence of blinding, but also guaranteed a high level of performance locally in conducting the trial and minimized attrition of participants in the trial, which, after all, had little benefit to the participants other than monitoring their blood pressure over a couple of weeks. As the Methods section

outlines, the assignments were checked by the Trial Centre as the trial progressed. In addition, an independent assessment of 10% of the participants assignment to the two Arms of the trial were reviewed to confirm that they correctly has been assigned to one of the two Arms of the trial. When interviewed about these issues at the end of the trial, the local coordinators and the volunteers could not explain why 22 versus 13 participants in the two sequences did not complete the trial. They also could not explain why the one Arm had slightly on average higher blood pressure that the other Arm.

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

The evidence arising from this trial demonstrates that measurements of blood pressure using an automated device in a community pharmacy can provide accurate and valid blood pressure information to be used in the diagnosis and management of hypertension among community-dwelling older adults.

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Table 1 Baseline characteristics of Collingwood-Creemore Trial participants

	Arm A (O, Ph, O)* n=136	Arm B (Ph, O, Ph)* n=139
Characteristic (self-reports)	M (SD)	M (SD)
Age	75.9 (6.5)	75.9 (6.8)
	% (n)	% (n)
Sex (male)	51.5 (70)	47.5 (66)
History of transient ischeamic attacks	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 with diabetes	10.3 (14)	10.9 (15)
Diagnosed with high blood pressure	44.4 (60)	57.3 (79)
Taking medication for high blood pressure	43.0 (59)	56.8 (80)

*O=Physician Office, Ph=Pharmacy

Table 2 Mean blood pressure readings in the Collingwood-Creemore Trial

Assessment	Systolic Blood Pressure (mmHg) M (SD)	Diastolic Blood Pressure (mmHg) M (SD)
Arm A (O, Ph, O)*, n=136		
Assessment 1 (O)	122.5 (14.6)	70.2 (9.4)
Assessment 2 (Ph)	121.8 (14.1)	70.1 (8.3)
Assessment 3 (O)	121.8 (14.3)	69.6 (9.3)
Arm B (Ph, O Ph)*, n=139		
Assessment 1 (Ph)	128.7 (17.0)	70.5 (10.2)
Assessment 2 (O)	127.6 (17.0)	70.1 (9.9)
Assessment 3 (Ph)	127.6 (16.5)	69.8 (10.8)

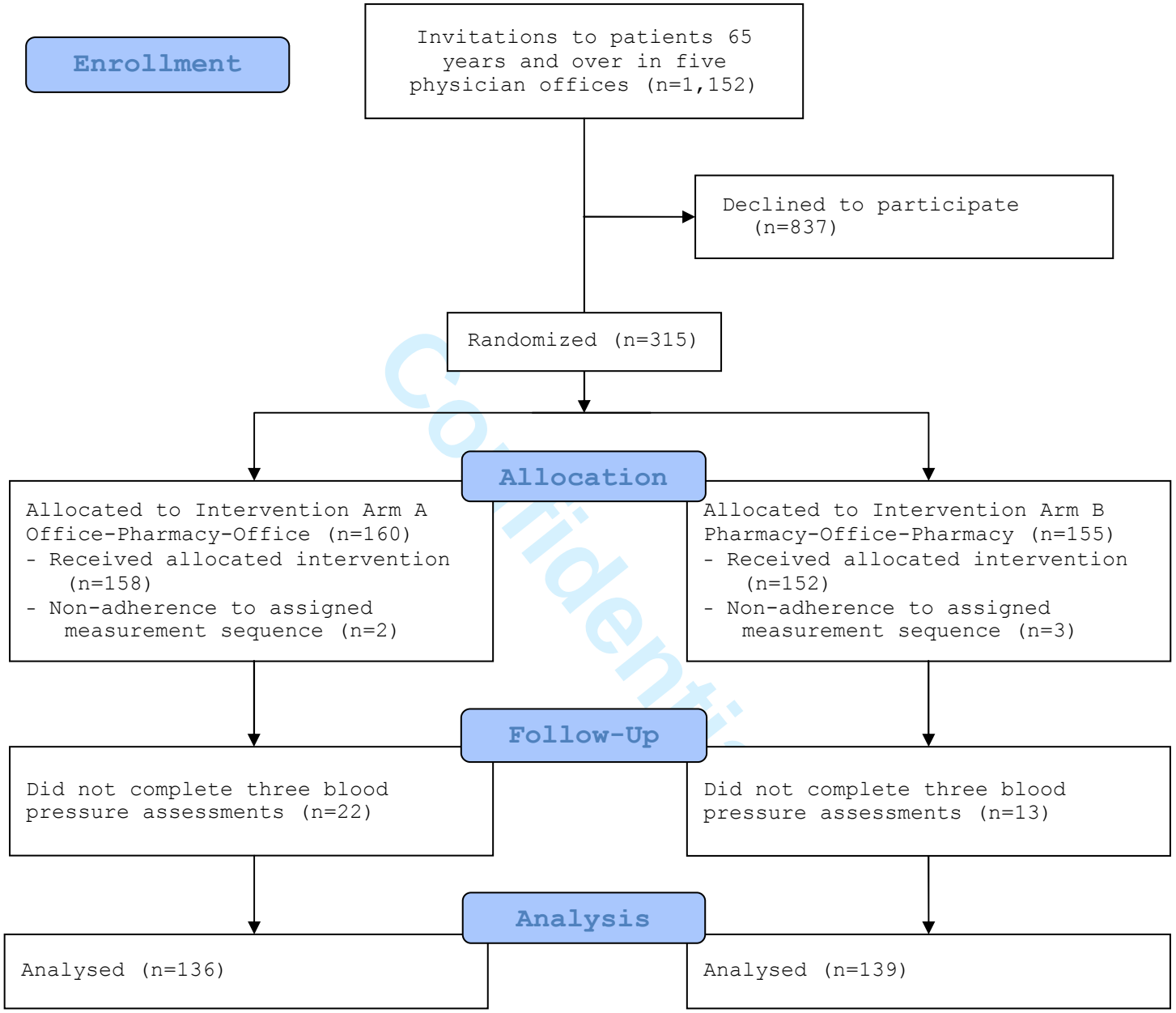
*O=Physician Office, Ph=Pharmacy

Table 3 Correlation coefficients comparing sequences/settings (1, 2 and 3) of blood pressure measurements in the Collingwood-Creemore Trial

Arm A (O, Ph, O)* n=136			Arm B (Ph, O, Ph)* n=139		
Systolic	2	3	Systolic	2	3
1	0.55	0.61	1	0.64	0.61
2	--	0.55	2	--	0.56
Diastolic	2	3	Diastolic	2	3
1	0.63	0.72	1	0.66	0.71
2	--	0.57	2	--	0.62

*O=Physician Office, Ph=Pharmacy

Figure 1: Collingwood-Creemore Pharmacy versus Physician Office Randomized Controlled Trial Flow Diagram



CHAP Session Blood Pressure Recommendation Protocol **Community Name:** _____

Systolic (mm Hg)	Diastolic (mm Hg)	Definition (NOT DIAGNOSIS)	Required Recommendation(s) / Action(s)	Additional Recommendations
<90	**<60**	***Low***	If symptoms present (e.g. dizziness): - **Nurse alerted → assessment + follow-up** - **Session Pharmacist may be alerted and a MedsCheck appointment** - **Consider booking a consultation or MedsCheck appointment with Regular or Session Pharmacist**	- Review educational materials and consider following-up with CHAP session referrals and suggested community resources - Discuss with Family Physician at next visit - Consider booking a consultation or MedsCheck appointment with Regular or Session Pharmacist
90-129	**60-79**	***Normal***	- **Option to return for another CHAP session to discuss modifiable risk factors with Peer Health Educator**	
130-139	**80-89**	***High Normal***	If diabetes or other cardiovascular risk factors present: - **Attend another CHAP session for reassessment and discussion with Peer Health Educator** If BP >130/80 on re-assessment: - **Make appointment with Family Physician**	
140+	**90+**	***Hypertensive range – Lifestyle modification and/or antihypertensive medication may be needed***		
140-159	**90-99**	***Stage 1 – mild***	- **Attend another CHAP session for reassessment and discussion with Peer Health Educator** *If BP >140/90 on re-assessment:* - **Make appointment with Family Physician**	
160-179	**100-109**	***Stage 2 – moderate***	- **Data form faxed to Family Physician TODAY** - **Attend another CHAP session for reassessment and discussion with Peer Health Educator** - **See Regular Pharmacist (may be Session Pharmacist); a consultation or MedsCheck appointment may be booked** *If BP > 160/100 on re-assessment:* - **Make appointment with Family Physician**	
180-209	**110-119**	***Stage 3 – severe***	- **Nurse alerted → assessment + follow-up** - **Nurse to CALL Family Physician today to ensure patient is followed-up** - **Data form faxed to Family Physician TODAY** - **Session Pharmacist may be alerted; a consultation or MedsCheck appointment may be booked with Regular Pharmacist** - **See Family Physician as soon as possible** - **Attend another CHAP session for reassessment and discussion with Peer Health Educator**	
210+	**120+**	***Stage 4 – very severe***	- **Nurse alerted → assessment + follow-up** - **Nurse to CALL Family Physician immediately for urgent appointment;** ***if FP not available, send to Emergency*** - **Data form faxed to Family Physician TODAY;** - **Session Pharmacist may be alerted; a consultation or MedsCheck appointment may be booked with Regular Pharmacist**	

BP READING AT SESSION

NOTE: If systolic and diastolic pressures fall in different ranges, the higher range is used; e.g. 165 / 90 mm Hg = Stage 2.

FOLLOW-UP RECOMMENDATION

NOTE: A Peer Health Educator typically discusses follow-up recommendation with participant, unless involvement of Nurse and/or Pharmacist is indicated, or participant has additional questions/concerns.

The on-call Community Nurse or Session Pharmacist may be contacted at any time by the Peer Health Educator with questions/concerns relating to any participant.

Participants will receive targeted health education materials / information about local resources / appropriate referrals.

Rationale for CHAP Session Blood Pressure Recommendations

Recommendation / Action	Rationale
CHAP Session	
- Attend another CHAP session for reassessment and discussion with Peer Health Educator	- Blood pressure fluctuates naturally - Multiple blood pressure readings using an accurate device provide more complete and accurate information for your doctor - Volunteer Peer Health Educators can provide support with modifiable risk factors by reviewing your CHAP risk profile recording form and Heart and Stroke Blood Pressure Action Plan™, discussing priorities and strategies for addressing risk factors and providing helpful resources/referrals
Appointment with Family Physician	
- Make appointment with Family Physician	- Your doctor knows your health history and can diagnose high blood pressure or make changes to keep your blood pressure under control - High blood pressure is often diagnosed over several visits, and is monitored regularly by your family doctor
- See Family Physician as soon as possible	- When blood pressure is very elevated, you may be at risk of serious health problems; your doctor will need to diagnose high blood pressure and/or make changes to keep your blood pressure under control
Pharmacist and MedsCheck Appointment	
- See Regular Pharmacist (may be Session Pharmacist) and a MedsCheck appointment may be booked	- Your regular pharmacist is aware of your prescriptions and can identify drug-related problems that can contribute to hypertension - Your pharmacist can also help with questions about side effects and taking your antihypertensive medication(s) regularly - The MedsCheck appointment is an annual 30 minute discussion with your pharmacist about how your medications may be affecting each other ▪ Participants who are currently taking three or more prescriptions are eligible ▪ For more information call the INFOline 1-866-255-6701 or TTY 1-800-387-5559
- Session Pharmacist may be alerted and a MedsCheck appointment may be booked	- The session pharmacist can provide on-site assessment of potential drug-related problems that can contribute to hypertension
Nurse	
- Nurse alerted → assessment + follow-up	- The program nurse will do a brief on-site health assessment and blood pressure measurement, to confirm elevated blood pressure and determine necessary care - Depending on results, the nurse may call your doctor right away or later today to ensure follow-up - If you require urgent care and your doctor is not available, you will be sent to Emergency
Risk Profile Data Form	
- Data form faxed to Family Physician TODAY	- The CHAP data form provides your doctor with new information that can be used in managing your blood pressure at your next visit or right away