Article details	
Title	Comparison of blood pressure measurement using an automated blood pressure device in community pharmacies and physicians' offices: the Collingwood–Creemore randomized controlled trial
Authors	Larry Chambers, Janusz Kaczorowski, Susan O'Rielly, Sandra Ignagni, Stephen Hearps
Reviewer 1	Richard Birtwhistle
Institution	Queen's Univeristy, Family Medicine, Kingston, Ont.
General comments	This was an elegantly designed randomized study to compare blood pressure measurement in the physician's office as compared to the pharmacy in a small community. The sample size was adequate to detect a difference in measurement arms and the investigators found no differences in patient's blood pressure between office and pharmacy. There was a higher mean systolic BP between groups which the investigators' attributed to the difference in number of patient's diagnosed with blood pressure between groups. While this study is reassuring it does not really answer the pragmatic question of differences in measurement of BP between office and other sites. These BP measurements were done in ideal conditions with trained CHAP volunteers applying the BP tru and supervising the BP measurement by the patient. A similar approach was taken in the physician's office. I suspect that a difference between sites is more related to calibration of the instrument and BP measurement technique than the site of measurement. Both of these were controlled in this study.
Reviewer 2	Martin Wong
Institution	Chinese University of Hong Kong, School of Public Health, Hong Kong
General comments	The authors conducted a randomized controlled trial to compare the difference in BP levels between measurement of blood pressure in community pharmacies and physicians' practice. Patients were allocated to two arms randomly and there were no significant difference between the readings in the two settings. It was concluded by the authors that community pharmacies could accurately measure BP levels as physicians' office. The research question is important and the implications are relevant to a broad international readership, since slight differences in BP levels would lead to significant differences in clinical outcomes. I have the following comments: 1). The introduction is concise and convincing with regards to the justification of the study. However, were there any studies conducted in the past on the same research topic? 2). One of the important issues in this pragmatic trial is the similarity of environment between the pharmacies and the physicians' office. Therefore, the authors might wish to describe the difference between the pharmacies and the physicians' office in terms of their renovation and surroundings (e.g. particularly patient-friendly to reduce white-coat effect?) 3). Were the participants advised to stop smoking or taking meal 30 minutes before the BP measurement, and advised to be seated quietly for at least five mins before? How about caffeine-containing beverages? 4). How high of the BP level would the physicians/researchers recommend the subjects to attend medical consultation? 5). Are there issues surrounding the reliability of the BP machine over time, as well as the "inter-machine" variability? 6). Were there any changes in medications between the 3 measurements for arm A and B, respectively? If so, were they comparable? 7). In the discussion section, I am not certain what this study adds to the existing literature when the authors described the Palmera study – just apart from being pragmatic vs. not. 8). The authors could attempt to adjust for baseline difference between arm A and B when they are drawing conclusions that the 2 arms had different BP outcomes simply because of demographic/clinical difference (or "statistical anomaly"). This will be more convincing to the readers. Otherwise there might raise a suspicion that the randomization was not conducted too well.
Reviewer 3	Pippa Oakeshott
Institution	St George's, University of London, Population Health Sciences and Education, London, UK
General comments	Originality and importance This is a well conducted and reported unblinded trial in 315 older adults (mean age 75) comparing automated BP measurement in community pharmacies and physicians' offices. There was no difference in mean recorded readings between

	settings, though the first set of readings in whichever setting was higher than the subsequent two. These findings are important as older people frequently visit community pharmacies, and these could have an increasing role in the diagnosis and monitoring of hypertension. There are three pre-requisites for this: 1. An automatic validated BP monitor such as the BP Tru which will discard the first and average the remaining five readings. 2. An assistant, who could be a volunteer or pharmacy staff member, with the minimum of training to show people how to apply an appropriately sized cuff, sit correctly positioned and avoid talking or distraction while readings are taken. 3. A system for making people aware that if their blood pressure is above a certain level they should attend their family doctor for a check up. The study is more generaliseable than the other similar study cited which was cross-sectional and where only two experienced health professionals were involved in the measurements. Other strengths include the simple eligibility criteria and community basis. The CHAP website is interesting and easily accessible. Methods Was randomisation done before participants agreed to take part? Was there a difference in response rates between those invited to the pharmacy first rather than the physician? The authors discuss the imbalance in diagnosis and treatment for hypertension between groups. Did participants put on their own cuff and measure their BP independently after the first session? This would make the intervention more practical. Please clarify-does the BPTru monitor automatically measure BP six times (and average the last five) without someone needing to press a button on the machine to tell it to take the next reading? What is the gap between readings? How long does it take in total for the measurements for someone needing to dash into a pharmacy while their car is parked on a meter? Does it produce a printout for the patient to take to their physician? What did the coordinators do with forms which were incomplete or illegible p8? Please clarify BP “very high” when the participant’s physician was notified p9. How many people did this happen to in each group? Results The 27% response rate is apparently similar to the usual response to letters from family physicians. Do you have age and gender of non-participants? Please provide data to confirm “those (how many?) with initially elevated BP (defined as?) experienced a significant decrease between visits 1 and 2….” p14. Trial registration Was this done on 25 7 12? Sample size here was 300. A statistical review would be helpful. I did not see a Consort chart. Minor comments Abstract. I would start the second sentence with: We conducted a RCT to assess…. Interpretation. I don’t think you have shown the measurements are valid, just that they are similar between settings. I would change “prevention” to “diagnosis” of hypertension…. Introduction p6 First word: “by whom” rather than “who”. Delete one of the duplicate sentences but don’t omit the references 6 and 7. I don’t think in practice that many single lifestyle changes such as exercise or weight loss or stopping smoking reduce BP by as much as 10/6 mm Hg (?). Typo Trail p10. I don’t think this needs a capital letter. Also I find talking about arms in a trial of BP measurement confusing-perhaps groups would be better.
Author responses	**Comments and our responses to Reviewer # 1** 1). The introduction is concise and convincing with regards to the justification of the study. However, were there any studies conducted in the past on the same research topic? The only other rigorous study was the ?Palmero? study that is discussed at length in the Discussion section of the manuscript. 2). One of the important issues in this pragmatic trial is the similarity of environment between the pharmacies and the physicians? office. Therefore, the authors might wish to describe the difference between the pharmacies and the physicians? office in terms of their renovation and surroundings (e.g. particularly patient-friendly to reduce white-coat effect?) A sentence has been added to the methods section that explains that no renovations were made to pharmacy 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 were geographically close to

	the family physician offices. 3). Were the participants advised to stop smoking or taking meal 30 minutes before the BP measurement, and advised to be seated quietly for at least five mins before? How about caffeine-containing beverages? The participants received an invitation letter from their family physician to attend the sessions with no other instructions to simplify the task of attending the sessions. Once in the family physician office or pharmacy, the volunteer peer health educators followed the standardized procedures for measuring BP: the participants were asked to be seated and remain quiet before the blood pressure cuff was applied to their arm. This information has been added to the Methods section. 4). How high of the BP level would the physicians/researchers recommend the subjects to attend medical consultation? An Appendix has been added that 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. 5). Are there issues surrounding the reliability of the BP machine over time, as well as the ?inter-machine? variability? 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 that was purchased new by CHAP. We have used BP-Tru devices extensively and found them very reliable and accurate. The intermachine variability was not assessed. Information on accuracy and precision of the BpTRU is available to the readers by contacting the BpTRU website as well as peer-reviewed articles indexed on Medline. The manuscript now includes the reference to the BpTRU website. 6). Were there any changes in medications between the 3 measurements for arm A and B, respectively? If so, were they comparable? As this was a pragmatic trial, no instructions were given to the physicians and pharmacists about any treatments. It is also worth noting that the mean time interval to complete the three BP measurements was less than 12 days in both arms of the trial. 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. These points have been added to the Methods section. 7). In the discussion section, I am not certain what this study adds to the existing literature when the authors described the Palmera study ? just apart from being pragmatic vs. not. As stated in the Discussion section of the manuscript: ?As a cross-sectional study, no attempt was made in the design of the Palmera study to control a sequence effect ? for example, did having blood pressure taken in the pharmacy first affect the readings in the physician office?? The Discussion section goes on to describe a number of other differences between to the two studies that justify the need for the Colllingwood Creemore trial. 8). The authors could attempt to adjust for baseline difference between arm A and B when they are drawing conclusions that the 2 arms had different BP outcomes simply because of demographic/clinical difference (or ?statistical anomaly?). This will be more convincing to the readers. Otherwise there might raise a suspicion that the randomization was not conducted too well. This randomized trial was designed to examine differences in the location and sequencing of blood pressure measurements. The statistical analysis conducted determined that these factors did not affect the accuracy of the blood pressure measurements. It was not a trial to determine the impact of an intervention. If it were such a trial, adjusting for baseline differences between Arm A and Arm B would be appropriate as one would want to rule out the possibility of whether one group was to benefit from the intervention due to important differences in baseline variables. However, as the Results section now reports, a repeated measures analysis of covariance revealed no significant effect either between groups, or between groups over time. **Comments and our responses to Reviewer #2** Methods Was randomisation done before participants agreed to take part? Was there a difference in response rates between those invited to the pharmacy first rather than the physician? The authors discuss the imbalance in diagnosis and treatment for hypertension between groups. As described in the Methods section, randomization occurred before the participants agreed to take part. As shown in Figure 1 and reported in the first

	paragraph of the Results section, two participants in Arm A and three participants in Arm B that arrived at the wrong site for the first session. These five individuals were excluded from the analyses. As a pragmatic trial, no consideration was given to diagnosis or treatment for hypertension in selection of patients to participate in the trial at the time of identifying patients in family physician offices nor at the time they arrived in a family physician office or a pharmacy. Did participants put on their own cuff and measure their BP independently after the first session? This would make the intervention more practical. Many older adults have difficulty putting on cuff without assistance. Thus, the volunteer peer health educators were available to assist any who had difficulty every time they attended any of the three sessions. 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. This sentence has been added to the Methods section. The BpTRU is fully automatic in that the machine completes all six reading independently. In CHAP, the BpTRU is set to have a one-minute interval between readings. The BpTRU used in this trial had LED display readout and this information was recorded on the one page risk profile form that each participant completed at each session. A typical period of time required at a session was 20 minutes. This information has been added to the Methods section. What did the coordinators do with forms which were incomplete or illegible p8? All the forms were returned to the Trial Coordinating Centre for review. This information has been added to the Methods section. Please clarify BP ?very high? when the participant?s physician was notified p9. How many people did this happen to in each group? The trial did not include keeping track of the number of participants that required the volunteer peer health educators to use the CHAP Session Blood Pressure Recommendation Protocol which is now included in the Appendix. It is important to note that family physicians? received summary data on ALL patients from their practices who participated in the study. Results The 27% response rate is apparently similar to the usual response to letters from family physicians. Do you have age and gender of non-participants? 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. This information has been added to the Methods section. Please provide data to confirm ?those (how many?) with initially elevated BP (defined as?) experienced a significant decrease between visits 1 and 2?.? p14. The paragraph on elevated blood pressure conceptualized as a dichotomy of high and low blood pressure has been removed as this was not the way that the analyses were performed and presented in the results section. That is, the blood pressure results were presented as a continuous variable, not dichotomous. Trial registration Was this done on 25 7 12? Sample size here was 300. A statistical review would be helpful. I did not see a Consort chart. Figure 1 and the Methods section is modelled according to a Consort Statement. Earlier in this letter, we responded to the issues raised by the statistician who reviewed the manuscript. Minor comments Abstract. I would start the second sentence with: We conducted a RCT to assess?. Interpretation. I don?t think you have shown the measurements are valid, just that they are similar between settings. I would change ?prevention? to ?diagnosis? of hypertension?. The abstract has been revised accordingly. The words valid and accurate were removed. Also, ?prevention? was replaced with the word ?diagnosis?. Introduction p6 First word: ?by whom? rather than ?who?. Delete one of the duplicate sentences but don?t omit the references 6 and 7. I don?t think in practice that many single lifestyle changes such as exercise or weight loss or stopping smoking reduce BP by as much as 10/6 mm Hg (?). The manuscript has been revised as suggested. Typo Trail p10. I don?t think this needs a capital letter. Also I find talking about arms in a trial of BP measurement confusing-perhaps groups would be better.

	The typo was corrected. We have left the terms ?arms? as this is consistently used throughout the manuscript. **Response to Reviewer 3 (CMAJOpen-2013-0005)** While this study is reassuring it does not really answer the pragmatic question of differences in measurement of BP between office and other sites. These BP measurements were done in ideal conditions with trained CHAP volunteers applying the BP tru and supervising the BP measurement by the patient. A similar approach was taken in the physician?s office. I suspect that a difference between sites is more related to calibration of the instrument and BP measurement technique than the site of measurement. Both of these were controlled in this study. These comments are confusing. The purpose of the trial was to rule out the possibility that measurements take in the physicians? offices differed from those taken in pharmacies. In order to answer this question, the same type of automated blood pressure measuring device and the same blood pressure measurement techniques were used in both sites. In addition, the trial was designed to determine if having blood pressure taken first in one site instead of the other made a difference. At the beginning of this letter and in the Discussion section, a number of issues are identified to demonstrate that methodologically this was a pragmatic trial not an explanatory trial. In addition, CHAP is well documented as a pragmatic approach. Finally, CHAP, while pragmatic, has been shown to be a good alternative to other possible more costly approaches even though it may not be ideal to have volunteer peer health educators involved compared to regulated health professionals with these types of activities.