THE NECESSITY OF THE PATIENT SITTING ALONE IN SILENCE FOR THE MEASUREMENT OF BLOOD PRESSURE USING A BPTRU DEVICE

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Abstract

Context: While previous studies have demonstrated an increase in blood pressure when measured while talking, the effect of conversation on the measurement of blood pressure using a BpTRU device is unknown.

Objective: In adults who have their blood pressure measured using a BpTRU device in the primary care setting, does the presence of a healthcare professional engaging the patient in conversation during the measurement period affect the recorded blood pressure compared to the patient being alone in a private room and silent during the measurement period?

Design: An assessment of two approaches of measuring blood pressure using a BpTRU device in which participants serve as their own control and the order of testing is randomized.

Participants: Adults (n=272) aged ≥ 19 years recruited from an academic family practice unit in St. John's NL.

Intervention: Participant's blood pressure was measured twice using a BpTRU device, once while alone in a quiet room maintaining silence and once while engaging in a health-related conversation. Whether blood pressure was measured first during conversation or during silence was randomized.

Outcome Measures: Systolic and diastolic blood pressure, and the mean difference in systolic and diastolic blood pressures between talking and silent measurement conditions.

Results: Mean systolic blood pressure was 9 mmHg higher (95% CI 8.2 – 10.5) and mean diastolic blood pressure was 8 mmHg higher (95% CI 7.6 – 8.9) when measured during conversation compared to when measured in silence. Systolic and diastolic

blood pressure measured during conversation remained significantly higher after controlling for all other variables in multiple linear regression analysis.
Conclusion: To avoid inaccurate measurement of blood pressure which could result in the overdiagnosis and overtreatment of hypertension, blood pressure measurement with the BpTRU device should be conducted with patients alone and in silence.

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List of Abbreviations and Symbols

mmHg – millimetres of mercury (unit of blood pressure measurement)

BpTRU – the "BpTRU" automated blood pressure device used in this study

ABPM – ambulatory blood pressure monitoring

NL – Newfoundland and Labrador

PI – principle investigator

EMR – electronic medical record

CI – confidence interval

p – p-value

SD – standard deviation

PMH – past medical history

FH – family history

IHD – ischemic heart disease

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Chapter 1: Introduction

Hypertension is common across Canada and globally. The current prevalence of hypertension in Canadian adults is between 20% and 27%[1, 2, 3, 4]. Hypertension is the leading global risk factor for death or disability[5], and is a clinically important risk factor for cardiovascular disease including coronary heart disease, ischaemic and haemorrhagic stroke, heart failure, peripheral vascular disease, renal impairment and visual impairment[6]. Cardiovascular diseases have the highest financial health care cost of all diseases[7] and are responsible for the greatest number of visits to family physicians in Canada, more than 20 million visits annually[8].

Hypertension is frequently diagnosed and managed in the primary care setting. In 2007 the cost of hypertension-related physician visits, laboratory tests and prescribed medications in Canada was estimated to be almost $2.4 billion[9]. One estimate of the implications of inaccurate blood pressure measurement suggested that a 5 mmHg error in measurement of blood pressure would result in 21 million Americans being denied treatment for hypertension or 27 million being exposed to unnecessary treatment for hypertension, depending on the direction of the error[10]. The accurate measurement of blood pressure in the primary care setting therefore has great clinical and economic importance.

In the past, blood pressure was traditionally measured manually in primary care using a mercury sphygmomanometer. However due to inaccuracy of manual blood pressure measurement in routine clinical practice, manual sphygmomanometers are being replaced in clinical practice by automated devices. The most common automated device used in Canada is the BpTRU (BpTRU Medical Devices, Coquitlam, British Columbia, Canada), with over 10,000 BpTRU devices currently in use in Canada[11].

The BpTRU is a fully automated sphygmomanometer which measures blood pressure by the oscillometric method: an electronic sensor in the cuff measures deviations in the cuff pressure due to changes in arterial blood pressure. The BpTRU takes a single 'test' reading to validate that a proper blood pressure measurement is being recorded, and then automatically takes five more blood pressure recordings at a predetermined interval. The mean of these subsequent five recordings is calculated and displayed as the blood pressure measurement. It has been shown that recordings taken at one-minute intervals and two-minute intervals with the BpTRU result in a similar overall average measurement, leading to the recommendation that blood pressure can be measured with the BpTRU using the one-minute interval setting[12]. The operating instructions of the BpTRU device state that patients should be left alone in a quiet room while their blood pressure is measured.

The BpTRU has been shown to be a valid blood pressure measurement instrument[13], to be superior to manual blood pressure measurement in correlation with daytime ambulatory blood pressure monitoring (ABPM)[14, 15, 16], and to eliminate the "white coat" response seen in clinical practice[17, 18]. BpTRU values and AABP values tend to correlate within 1 or 2 mmHg, whereas the difference between routine manual systolic office blood pressure measured in primary care and AABP can be as much as 10 to 20 mmHg[19].

There is evidence from several studies showing that speaking during blood pressure measurement causes an increase in blood pressure readings[20, 21, 22, 23, 24, 25, 26, 27]. However, reports of the magnitude of this increase are varied, and evidence is of varying methodological quality. Most studies have been conducted using a manual

sphygmomanometer, and no studies have been published investigating whether this phenomenon is seen when blood pressure is measured using a BpTRU device.

The purpose of this study is to investigate whether the recorded blood pressure using a BpTRU device is affected by someone being present in the room and engaging the patient in a health-related conversation during the measurement period, compared to measuring their blood pressure with the patient alone in a quiet room maintaining silence.

Literature Review

A 1980 study investigated the effect of quiet conversation on the blood pressure of twenty-four hypertensive patients[20]. The patient's blood pressure was measured every two minutes for three consecutive eight-minute periods using an ultrasonic blood pressure meter. During the first eight-minute period, a doctor sat in front of the patient examining their medical notes but not speaking to them. During the second eight-minute period the doctor engaged the patient in a quiet conversation regarding their blood pressure medication and any experienced side effects. The third eight-minute period was the same as the first period. The investigators found that mean systolic and diastolic blood pressure dropped gradually throughout the first period, rose sharply at the start of the second (conversation) period with a maximum rise of 20.8/11.6 mmHg, then dropped again during the third period to the same levels as the first period. They concluded that engaging a patient in conversation causes a rise in their blood pressure. However, the measurement procedure was not randomized, it is not clear how study participants were selected, the sample size was small, and the setup of the experiment did not simulate a modern-day clinical encounter well.

A 2017 study used a similar study design to investigate the effect of talking with a doctor on systolic and diastolic blood pressure[21]. The investigators measured the blood pressure of 200 outpatients (122 hypertensive and 78 normotensive) at defined intervals of before talking, during talking and after talking with a doctor. They used an oscillometric blood pressure monitor (Omron BP HEM 7201). The investigators found that systolic blood pressure increased significantly when measured after one minute of talking compared to the previous measurements recorded before talking, and then decreased quickly after talking was stopped and returned to baseline roughly five minutes later. The maximum rise in systolic BP was 9.1 mmHg and the maximum rise in diastolic BP was 4.5 mmHg. The authors state that during the talking phase of the study the doctor asked the participant some questions about the disease, but there is no indication in the paper that this conversation was standardized. Whether a sample size calculation was used is not mentioned, and it is unclear how participants for the study were selected.

A similar study conducted in 1989 investigated the effects of low affect talking on the blood pressure of 37 patients with coronary heart disease[22]. Whilst in a room with a researcher and monitored by ECG and automated blood pressure recording, patients stood quietly for two minutes, spoke about their normal daily activities whilst standing for two minutes, then stood quietly for a further two minutes. The study found that mean blood pressure was significantly higher during the talking phase than the two silent phases, and that increasing age and higher resting systolic blood pressure were positively correlated with greater increases of systolic blood pressure during talking. This study has similar methodological flaws to those above, and the setup of the talking phase of the study almost simulates an exercise in public speaking.

Furthermore, these results can only be applied to patients with coronary heart disease, and the measurement of blood pressure in the standing position is not routine in clinical practice. A further study conducted by the same researchers found that the rise in diastolic blood pressure during talking was comparable to the rise in diastolic blood pressure during phase three exercise stress testing[23]. Another study published in 1992 also reported a mean increase in systolic and diastolic blood pressure in 109 healthy participants whilst talking about their daily activities, measured using an oscillometric device[24].

A 1984 study investigated the effect of reading aloud from a card on the measurement of blood pressure using a mercury sphygmomanometer[25]. The investigators recruited 48 patients from a hypertensive clinic and measured their diastolic blood pressure during silence, whilst the participant read from a card while the BP cuff was being inflated then stopped reading as the cuff was deflated, and while the participant read from a card during the whole measurement period. They found that diastolic blood pressure increased during reading, and concluded that talking increased the diastolic blood pressure by a clinically significant level. They do not mention any findings related to systolic blood pressure, and the conclusion of the study has been generalised to talking rather than reading aloud.

A 2001 study assessed the blood pressure of 63 patients with essential hypertension using an automated auscultatory device during a sequence of silence, counting aloud, silence, stressful talking, and silence, with the phases of counting and talking being randomized[26]. The investigators found that during stressful talking the mean systolic blood pressure increased by 19 mmHg and the mean diastolic blood pressure increased by 13.3 mmHg compared to measured blood pressure during silence, and

this increase was of greater magnitude than between counting aloud and silence. The investigators also demonstrated similar effects of talking on the measurement of blood pressure in another study investigating the effects of talking and reading on blood pressure[27].

A 2012 study investigated the effect of speech on the measurement of blood pressure in 111 healthy individuals[28]. The researchers in this study reported an increase in systolic blood pressure of 5.3 mmHg and an increase in 6.2 mmHg diastolic blood pressure in talking conditions compared to resting conditions. However, they measured blood pressure using the auscultatory method and the talking phase in the study the participants was counting aloud as opposed to engaging in conversation. The results of this study therefore cannot be generalised to patients whose blood pressure is measured using a BpTRU device, and who are engaged in a health-related conversation.

While there is a general consensus in the literature that speaking during blood pressure measurement results in an increase in recorded blood pressure, none of the above studies compared holding a health-related conversation during the measurement of blood pressure to measuring blood pressure while the patient is alone in a quiet room maintaining silence. There is evidence to suggest that leaving patients alone in a quiet room results in a reduction in their recorded blood pressure. In a study conducted using the BpTRU device, blood pressure readings taken at one-minute intervals after the examining doctor/nurse leaves the examining room show a rapid decrease in blood pressure[29]. About 75% of this decrease in blood pressure occurs within two minutes of the patient being left alone[30].

The evidence in the literature suggests that blood pressure increases while talking, and it decreases when sitting alone in a quiet room. However, these two conditions of blood pressure measurement have never been formally compared, and the effect of conversation on the measurement of blood pressure has never been investigated when measured with a BpTRU device. As it has been shown that the BpTRU device effectively eliminates the "white coat" response, it is possible that the BpTRU could also eliminate the increase in blood pressure seen during conversation.

Two recent studies have investigated whether there is a difference in blood pressure when measured with a BpTRU device in a quiet examining room or in a waiting room. The first was a pilot randomized controlled trial conducted in Toronto, Ontario, in 2011[31]. Fifty patients were recruited and randomly allocated to have their blood pressure measured using a BpTRU device either alone in a quiet examining room or in an open waiting area of the clinic. The authors found no significant difference in systolic or diastolic blood pressure between these measurement conditions, in hypertensive and normotensive participants. They did however find an order effect, with systolic blood pressure decreasing significantly between the first and second set of readings. Because of the small sample size, these findings can be considered preliminary only, and the authors state they will be used to plan a further study which has yet to be published. However, it does suggest that the order of blood pressure readings has a significant effect on the outcome, and measurement order will therefore be randomized and considered as an independent variable in this study.

The second recent study investigating the effect of measurement conditions on blood pressure when measured using a BpTRU device was conducted in 2015 in Kingston, Ontario[32]. The investigators measured the blood pressure of 422 patients seen in a

hypertension specialty clinic, first in an examination room with a nurse present and then the following day in the clinic waiting room after they had returned from 24 hours of ambulatory BP monitoring. The authors found that blood pressure was significantly higher when measured initially in the examining room compared to when measured the next day in the waiting room. However, only one initial blood pressure measurement with the BpTRU was measured in the examination room, and there was no randomization of the order of measurement conditions.

There has been significant recent interest into research comparing attended versus unattended BP measurement. Several recent studies have investigated whether there is a difference in automated office blood pressure with and without an observer in the room[33, 34]. Results of these studies have shown no statistically significant difference in blood pressure between these measurement conditions This could be due to the small sample size (only fifty-one participants in one of the studies), or it could indicate that the presence of another person in the room whilst AOBP is being measured does not have a significant effect on blood pressure. This finding was also supported by a survey conducted after the conclusion of the SPRINT trail. It was found that there were differences in the blood pressure measurement conditions between trial sites, with some measuring BP with the participant unattended and some with the participant attended with study personnel in the room[35]. A post-hoc analysis found that similar blood pressure measurements were obtained whether the measurement technique used was attended or unattended.

Significance

The current recommendation for use of the BpTRU device is to measure a patient's blood pressure while they are alone in a quiet room and maintaining silence. This will be the first study to investigate the effect on recorded blood pressure of holding a health-related conversation with a patient during the measurement of blood pressure using the BpTRU device compared to the recorded blood pressure while the patient is alone and maintaining silence. The results of this study will guide best practice for the accurate measurement of blood pressure using a BpTRU device.

Chapter 2: Research Question

In adults who have their blood pressure measured using a BpTRU device in the primary care setting, does the presence of a healthcare professional in the examination room engaging the patient in a health-related conversation during the measurement period affect the recorded measurement of blood pressure, compared to the patient being alone in the examination room and silent during the measurement period?

The hypothesis is that blood pressure measurements will be higher when measured whilst engaging the patient in a health-related conversation.

Chapter 3: Methods

Design

This study assessed two approaches to measuring blood pressure in the primary care setting using a BpTRU device in which participants serve as their own control and the order of testing is randomized. The study was conducted in the setting of an academic family practice unit in St. John's NL, Canada, which serves an urban population. The target population of the study was the patient population of this family practice. Inclusion criteria for the study were adults aged 19 years and over with the ability to give informed consent to study participation. Patients with and without a diagnosis of hypertension were eligible for inclusion in the study. There were no exclusion criteria. Pregnant women were eligible to participate.

Study participants were recruited by mail. The family practice manager provided the principle investigator (PI) with two lists of eligible patients of the practice, with and without a prior diagnosis of hypertension. The PI worked down this list, using no selection strategy other than the order that patients appeared on the list, and drafted information letters to be sent to each patient (*see Appendix 1*). The letter gave a brief outline of the study, and informed patients they could contact the PI of the study for more information if they wished to volunteer as a participant in the study. Each letter was reviewed and signed by the patient's family doctor prior to sending. Family doctors were able to decline sending a letter to any of their eligible patients if they felt it was inappropriate for them to be contacted regarding the study at that time, for example if they were recently bereaved or had recently received a serious diagnosis. Recruitment of participants was targeted to recruit equal numbers of participants with and without a prior diagnosis of hypertension, and to recruit roughly equal numbers of

men and women to the study. When enough patients with hypertension were recruited only patients without hypertension were recruited from then on. The recruitment letters were sent in several batches throughout the recruitment and data collection process. As recruitment progressed the PI monitored responses to ensure balance between male and female participants was achieved, and sent further recruitment letters accordingly to the targeted sex.

Each participants blood pressure was measured twice using a BpTRU device, once while alone in a room and maintaining silence and once while engaging in a health-related conversation with the PI. Whether the participant's blood pressure was measured first during conversation or during silence was randomized. Randomization was stratified by whether a participant had a prior diagnosis of hypertension: this was ascertained during the consent process before the participant was randomized to the order of measurement conditions.

Randomization was blocked in groups of eight to ensure equal numbers of participants in each measurement order group. Randomization was achieved by generation of random number sequences by the Research Coordinator of the Memorial University of Newfoundland Primary Healthcare Research Unit. When participants gave consent to participation in the study, the PI consulted the sequence to determine the randomization category for the participant.

The BpTRU device was set to measure blood pressure at one-minute intervals, and recorded six blood pressure readings for each recording cycle. There was only a short period of time between the first and second blood pressure measurement cycle, in which time the PI explained that the participants blood pressure would be measured a second time in either silence or during conversation.

Sample Size Calculation

As the participants serve as their own controls in this study, they are not independent. In order to account for the paired nature of the data, the sample size calculation for this study was based on a sample size equation for a test-retest study based on means.

$$n = \frac{(SD)^2(Z_{\alpha/2} + Z_{\beta})^2}{\bar{X}}$$

$\bar{X}$ = mean of the difference between initial test and repeat test values (or the clinically significant difference between groups hoped to detect)

SD = standard deviation of the mean of the difference between initial test and repeat test values

Data used to calculate the standard deviation of the difference between paired systolic and diastolic blood pressure readings were taken from the CAMBO trial by Myers, Godwin *et al*[36]. These data were appropriate for use in this study sample size calculation as they comprised paired blood pressure measurements from a Canadian primary care patient population measured using a BpTRU device. A subset of this trial data was analysed, comprising the systolic and diastolic blood pressure readings of 80 participants measured using a BpTRU device at an interval of two weeks. Blood pressure measurements were performed with each participant alone in a quiet room maintaining silence. From this analysis, the standard deviation (SD) of the difference between paired systolic blood pressure readings was 14.8 mmHg, and the SD of the difference between paired diastolic blood pressure readings was 9.58 mmHg.

The clinically significant difference between groups for this study was set at 5 mmHg for systolic blood pressure, and 3 mmHg for diastolic blood pressure.

$\alpha = 0.05$

$1-\beta = 0.95$

Systolic Blood Pressure

$$n = \frac{(SD)^2\left(Z_{\frac{\alpha}{2}} + Z_{\beta}\right)^2}{(\overline{X})^2} \quad n = \frac{(14.8)^2(1.96 + 1.64)^2}{5^2} \quad n = \frac{(219.04)(12.96)}{25}$$

$$n = 114$$

Diastolic Blood Pressure

$$n = \frac{(SD)^2\left(Z_{\frac{\alpha}{2}} + Z_{\beta}\right)^2}{(\overline{X})^2} \quad n = \frac{(9.58)^2(1.96 + 1.64)^2}{(3)^2} \quad n = \frac{(91.78)(12.96)}{9}$$

$$n = 132$$

At significance level of 0.05 and power of 95%, a sample size of 132 participants is sufficient to test the hypothesis that the mean difference between paired systolic blood pressure measurements is 5 mmHg or greater, and the mean difference between paired diastolic blood pressure measurements is 3 mmHg or greater.

In order to allow for complete randomization of participants in blocks of eight, the study sample size was increased to 136 participants. Doubling this sample size allowed for subgroup analysis based on diagnosis of hypertension, provided there were roughly equal numbers of hypertensive and non-hypertensive participants. Therefore, the total sample size required for this study was two hundred and seventy-two participants.

Data Collection

All study data were collected by the PI of the study. The PI is a physician with clinical experience in the primary care and hospital setting. In order to simulate a primary care encounter as closely as possible, data were collected in a consultation room of a family medicine office. The PI introduced himself to participants as a doctor and dressed professionally in a shirt and dress pants. The PI did not wear a white coat. This simulated a clinical encounter between a patient and a health professional during the collection of study data.

The PI was fully trained in the operation of the BpTRU device prior to initiation of the study. Under both study measurement conditions, the PI applied the blood pressure cuff, ensured the participant was sitting in the correct position, and activated the BpTRU device. The BpTRU device was set to take blood pressure recordings at one-minute intervals. All six individual BpTRU recordings and the average of the last five recordings were noted.

Except for diagnosis of hypertension, which was extracted from the electronic medical record (EMR) and displayed in the patient recruitment lists, all independent variables considered in the study were collected by patient self-report. The PI did not have access to the patient's EMR during the study. Participant age was the only continuous variable collected, and categorical variables collected were sex, race, previous diagnosis of hypertension, taking antihypertensive medication, past medical history of diabetes, past medical history of ischaemic heart disease, family history of hypertension, family history of diabetes, family history of ischaemic heart disease, smoking status (never smoked or ever smoked) and excessive alcohol consumption. Excessive alcohol consumption was defined as greater than 14 units of alcohol per

week, which is the current weekly limit for men recommended by the Centre for Addiction and Mental Health in Canada[37]. A unit of alcohol is commonly defined as 5 ounces (oz) of wine, 12 oz of beer, or 1.5 oz of distilled alcohol. The PI asked participants how much alcohol they drank in an average week, and then calculated weekly intake in units based on the response. The category "ever smoked" included current smokers and ex-smokers with any duration of smoking history.

Once study participants gave their consent to participate in the study, the PI consulted the randomization list for the order in which to measure the participant's blood pressure. The order of blood pressure measurement was randomized for each participant (during conversation first then alone in silence second, or alone in silence first and during conversation second). During the "silent" blood pressure measurement the participant sat in a quiet room and the PI started the BpTRU device, waited until the first 'test' blood pressure was recorded to ensure the device was working properly, then left the participant alone in the room while the BpTRU device completed a blood pressure measurement sequence. Participants were instructed to maintain silence while the device was measuring their blood pressure. During the "conversation" blood pressure measurement, the PI accompanied the participant in the room. After starting the BpTRU device and waiting for a successful first 'test' reading, the PI engaged the participant in conversation for the remaining measurement period by asking the participant a series of health-related questions. This simulated the clinical situation of a healthcare worker taking a history from the patient. The PI followed a standardised questionnaire for each conversation, which was designed to be long enough to last for the five minutes required by the BpTRU device to complete the measurement sequence (*see Appendix 3*). Approximately one minute elapsed between the first and

second blood pressure measurement cycles. All blood pressure measurements were conducted with the participants seated facing away from the BpTRU monitor, with their legs uncrossed and feet flat on the floor, and with the measurement arm resting on a table.

Data were initially recorded on paper and then entered into an SPSS file stored on a laptop computer. The file was password protected and encrypted, and the laptop was password protected. Study participants were assigned a de-identified ID number, which was recorded on the paper data sheet and in the computer database. No identifying information was recorded.

Data Analysis

Data were analysed on an intention-to-treat basis. The primary outcome variables were systolic and diastolic blood pressure. Independent variables were measurement conditions of talking or silence, order of blood pressure measurement conditions, age, sex, race, previous diagnosis of hypertension, taking antihypertensive medication, past medical history of diabetes, past medical history of ischaemic heart disease, family history of hypertension, family history of diabetes, family history of ischaemic heart disease, smoking status (never smoked or ever smoked) and excessive alcohol consumption.

Descriptive statistics of the study population were calculated for each independent variable. Categorical variables were reported as frequencies and percentages, and continuous variables were reported as mean and standard deviation. Descriptive statistics for the randomized groups of "silent first" and "talking first" were calculated for each independent variable, and significant differences between groups was

assessed for using a paired samples *t*-test. If significant differences between groups were found for an independent variable, this variable went on to be included in multivariate analysis.

For systolic and diastolic blood pressure, the mean of blood pressure measurements taken during conversation and in silence and the difference between these measurements was calculated. A statistically significant difference between mean blood pressure measurements during silence and during conversation was assessed using a paired sample *t*-test. This process was repeated for each independent variable. Assessment of the association of individual independent variables on systolic and diastolic blood pressure without adjustment for other variables was performed using independent student *t*-test analysis. Independent variables that were found to be associated with systolic or diastolic blood pressure with statistical significance of $p \leq 0.2$ in univariate analysis were entered into multivariate linear regression analysis. Independent variables were initially entered into the model to assess the significance of each variable in predicting the outcome with adjustment for all other variables. Independent variables that no longer significantly predicted the outcome after adjustment were then removed from the model in a stepwise manner in the order of least statistical significance. At each step the impact on the overall model resulting from removal of each variable was assessed. If removal of a variable resulted in a large degree of change on the overall model ($R^2 > 0.1$), it was deemed to be significantly associated with the outcome and was returned to the model. After their removal, each variable was then added to the model again individually to see if they altered the model. If it altered R^2 by > 0.1 the variable was returned to the model.

Data analysis was carried out for all participants, and then in subgroups of participants with hypertension and without hypertension. Data were analysed using SPSS.

Ethical Issues

Informed consent was obtained from all participants prior to participation in the study. Participants were initially told that the purpose of the study was to improve the accuracy of blood pressure measurement using the BpTRU device. They were told that their blood pressure would be measured twice using the device: once while sitting alone in a quiet room in silence, and once while the researcher asked them some questions related to their health. Participants were not initially told that the purpose of the study was to investigate whether there was a difference in measured blood pressure between the two measurement conditions. The rationale for this was the possibility that the participant's own expectations of what their blood pressure may be in each setting, or the knowledge that a change in their blood pressure was being assessed may have led to fluctuations in their blood pressure at the time of measurement which may have affected the accuracy of the study results.

After participants completed participation in the study, there was a debrief period in which the participant was told the true purpose of the study. This information was provided in both verbal and written form (*see Appendix 4*). Participants were able to withdraw their consent for participation in the study at that time if they wished. Information given to potential participants before enrolment in the study otherwise outlined fully what they may expect from participation in the study. Individuals were informed that by consenting to participation in the study their blood pressure would be measured twice using the BpTRU device, and that each measurement consisted of six

contractions and relaxations of the blood pressure cuff on their arm: their blood pressure would be recorded twelve times in total, which comprises two BpTRU blood pressure measurements. Participants were also told they would be asked a series of questions related to their health. It was emphasised that participation in the study was entirely voluntary, that participants could terminate their involvement in the study at any time they chose, and that participation should take between 20 and 30 minutes of their time. It was emphasised that their decision to participate or not participate in the trial would have no effect on their current or future medical care. The risks of participation in the study outlined to patients were discomfort from the tightness of the blood pressure cuff on their arm, and the potential psychological distress of finding that they have a high blood pressure reading that they were not previously aware of. The outlined benefits of participation in the study were that they would be helping to improve the accuracy of the measurement of blood pressure using the BpTRU device which could result in a better standard of care for patients, and that they would be told what their current blood pressure measurement was.

All participants in the study were informed of their blood pressure measurements orally and in writing. They were told whether their blood pressure reading was within normal range, higher than the normal range or lower than the normal range. It was emphasised to patients that if their reading was high, this did not mean they had been diagnosed with high blood pressure: it was explained that hypertension is diagnosed following more sophisticated tests and over a longer period of time. Patients with blood pressure readings found to be outside normal reference ranges were encouraged to discuss this with their family doctor. In the unlikely situation that a participant was found to have a dangerously high or low blood pressure reading during the study, a

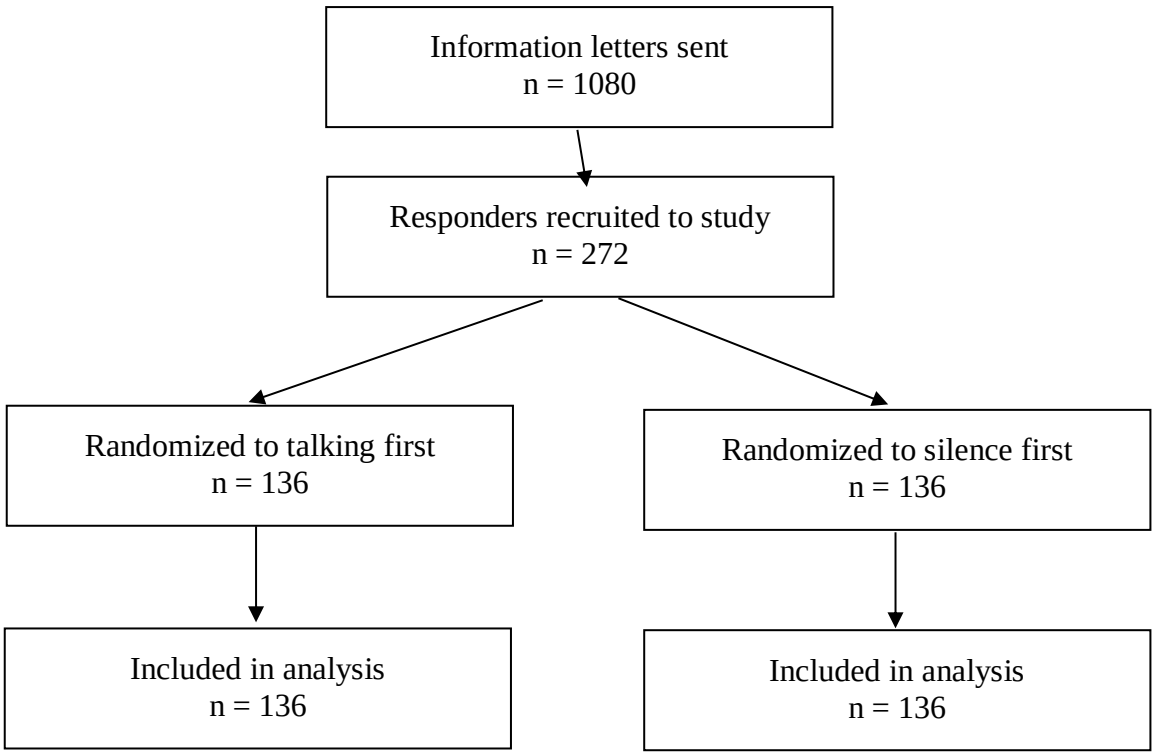
family doctor in the clinic would be promptly notified, or the patient would be directed to the emergency department situated adjacent to the family medicine clinic in the same building.

Participants were told how they could access the results of the study upon completion. This was achieved by asking interested participants to leave an email address or mail address with the PI, and a summary of the study results would be sent to them. This identifying information was kept in a separate file to the study data and not linked in any way to study data.

A copy of data collected during the study is stored on a secure computer in the Memorial University of Newfoundland Primary Healthcare Research Unit, and will be kept for five years following the study. After this time, the data will be destroyed.

Chapter 4: Results

Descriptive statistics for the study population are shown in *Table 1*, along with a comparison of the participants randomized to the "silent first" and "talking first" groups. There was a statistically significant difference in mean age and race between groups, so these two variables were automatically included in multivariate analysis. Participants were recruited between September 2015 and May 2016. One thousand and eighty information letters were sent out in order to achieve the required sample size, with a response rate of 25%. Two-hundred and seventy-two participants were included in the study (n=272). The study ended after the required sample size of participants was recruited. There was a roughly equal representation of men and women in the study population. 50% of the study population had a previous diagnosis of hypertension (n=136).



The difference in mean blood pressure during conversation and silence is shown in Table 2. A statistically significant difference in both mean systolic and diastolic blood pressure measurements was found between talking and silent measurement conditions. In analysis of all participants, mean systolic blood pressure was 9 mmHg (95% CI 8.2 – 10.5) higher when measured during conversation, and mean diastolic blood pressure was 8 mmHg (95% CI 7.6 – 8.9) higher when measured during conversation.

Table 3 shows the effect of independent variables on systolic and diastolic blood pressure. Silent or talking measurement conditions and past medical history of hypertension had a significant effect ($p<0.05$) on systolic blood pressure. Measurement order, sex and excessive alcohol consumption were associated with systolic blood pressure with a p-value of <0.2 and were therefore included in multivariate analysis.

Silent or talking measurement conditions, excessive alcohol consumption, past medical history of diabetes, past medical history of ischemic heart disease and family history of hypertension had a significant ($p<0.05$) effect on diastolic blood pressure in univariate analysis. Sex was associated with diastolic blood pressure with a p-value of <0.2 and was therefore included in multivariate analysis.

The results of multivariate analysis are shown in Table 4. Measurement condition of talking or silence had a significant effect on both systolic and diastolic blood pressure after adjustment for all other variables included in multivariate analysis ($p<0.000$). With adjustment for all variables, mean systolic blood pressure increased by 9 mmHg when measured during conversation and diastolic blood pressure increased by 8 mmHg when measured during conversation.

The increase in systolic and diastolic blood pressure seen during conversation was also statistically significant in subgroup analysis of participants with and without a previous diagnosis of hypertension. In participants with a prior diagnosis of hypertension, the mean blood pressure increase seen during conversation was 8 mmHg for both systolic and diastolic blood pressure. In participants without a prior diagnosis of hypertension, the mean blood pressure increase seen during conversation was 10 mmHg for systolic blood pressure and 9 mmHg for diastolic blood pressure.

Table 1. Characteristics of Study Population

		All Participants n = 272	Silent First n = 135	Talking First n = 137
Variable		**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
Age (years)*		64.6 (12.2)	62.8 (12.2)	66.4 (12.1)
Variable		**n (%)**	**n (%)**	**n (%)**
Sex	Female	142 (52.2)	75 (55.6)	67 (48.9)
	Male	130 (47.8)	60 (44.4)	70 (51.1)
Race*	Caucasian	264 (97.0)	135 (100.0)	129 (94.2)
	Other	8 (3.0)	0 (0.0)	8 (5.8)
Hypertension	Yes	136 (50.0)	67 (49.6)	69 (50.4)
	No	136 (50.0)	68 (50.4)	68 (49.6)
Antihypertensive Medication	Yes	131 (48.2)	66 (48.9)	65 (47.4)
	No	141 (51.8)	69 (51.1)	72 (52.6)
Diabetes	Yes	27 (9.9)	12 (8.9)	15 (10.9)
	No	245 (90.1)	123 (91.1)	122 (89.1)
IHD	Yes	29 (10.7)	12 (8.9)	17 (12.2)
	No	243 (89.3)	123 (91.1)	120 (87.8)
FH Hypertension	Yes	164 (60.3)	82 (60.7)	82 (59.9)
	No	108 (39.7)	53 (39.3)	55 (40.1)
FH Diabetes	Yes	120 (44.1)	60 (44.4)	60 (43.8)
	No	152 (55.9)	75 (55.6)	77 (56.2)
FH IHD	Yes	149 (54.8)	70 (51.9)	79 (57.7)
	No	123 (45.2)	65 (48.1)	58 (42.3)
Ever smoked	Yes	128 (47.1)	61 (45.2)	67 (48.9)
	No	144 (52.9)	74 (54.8)	70 (51.1)
Excessive Alcohol Consumption	Yes	73 (26.8)	34 (25.2)	39 (28.5)
	No	199 (73.2)	101 (74.8)	98 (71.5)

IHD - ischemic heart disease; FH – family history

* = $p < 0.05$

Table 2.1. Mean Difference in Systolic Blood Pressure between Conversation and Silence Periods

		Systolic BP Conversation Mean (SD)	Systolic BP Silence Mean (SD)	BP Increase During Conversation (95% CI)	p value
Full Study Population N=272		130.1 (17.6)	120.8 (15.0)	9.3 (8.2 - 10.5)	<0.001
Order	Silence First	127.8 (18.4)	121.0 (14.7)	6.8 (5.1 - 8.5)	<0.001
	Talking First	132.4(16.6)	120.6(14.4)	11.8 (10.3 - 13.2)	<0.001
Sex	Male	128.4 (16.9)	120.4(14.4)	7.9 (6.5 - 9.5)	<0.001
	Female	131.7 (18.2)	121.2 (15.6)	10.5 (8.7 - 12.3)	<0.001
PMH Hypertension	Yes	133.5 (17.0)	125.1 (14.2)	8.4 (6.7 - 10.1)	<0.001
	No	126.7 (17.7)	116.5 (14.5)	10.3 (8.7 - 11.8)	<0.001
Antihypertensive medication	Yes	132.8 (17.3)	124.7 (14.8)	8.1 (6.4 - 9.8)	<0.001
	No	127.6 (17.9)	117.2 (14.3)	10.5 (8.9 - 12.2)	<0.001
PMH Diabetes	Yes	131.6 (17.3)	123.7 (14.2)	7.9 (4.2 – 11.6)	<0.001
	No	130.0 (17.7)	120.5 (15.1)	9.5 (8.2 – 10.7)	<0.001
PMH IHD	Yes	130.3 (16.0)	122.6 (17.7)	7.7 (4.3 – 11.1)	<0.001
	No	130.1 (17.9)	120.6 (14.7)	9.5 (8.3 – 10.7)	<0.001
FH Hypertension	Yes	130.8 (18.1)	121.0 (15.0)	9.7 (8.2 – 11.2)	<0.001
	No	129.2 (16.9)	120.4 (15.0)	8.7 (6.9 – 10.6)	<0.001
FH Diabetes	Yes	130.5 (16.1)	121.1 (13.8)	9.4 (7.7 – 11.1)	<0.001
	No	129.8 (18.8)	120.6 (15.9)	9.3 (7.7 – 10.8)	<0.001
FH IHD	Yes	130.7 (17.6)	120.7 (14.0)	10.0 (8.4 – 11.5)	<0.001
	No	129.5 (17.8)	120.9 (16.2)	8.5 (6.8 – 10.3)	<0.001
Ever Smoked	Yes	130.6 (17.3)	121.1 (15.0)	9.5 (7.8 - 11.2)	<0.001
	No	129.7 (17.9)	120.5 (15.0)	9.1 (7.5 - 10.7)	<0.001
Excessive alcohol consumption	Yes	132.3 (17.7)	122.3 (15.1)	10.0 (7.8 – 12.3)	<0.001
	No	129.3 (17.6)	120.3 (15.0)	9.1 (7.7 – 10.4)	<0.001

PMH – past medical history; IHD – ischemic heart disease; FH – family history

Table 2.2. Mean Difference in Diastolic Blood Pressure between Conversation and Silence Periods

		Diastolic BP Conversation Mean (SD)	Diastolic BP Silence Mean (SD)	BP Increase During Conversation 95% CI	p value
Full Study Population N=272		81.2 (10.8)	72.9 (9.7)	8.3 (7.6 – 8.9)	<0.001
Order	Silence First	80.9 (11.1)	73.5 (9.9)	7.4 (6.4 – 8.3)	<0.001
	Talking First	81.5 (10.4)	72.3 (9.5)	9.1 (8.3 – 10.0)	<0.001
Sex	Male	81.6 (10.9)	74.1 (9.8)	7.5 (6.5 – 8.5)	<0.001
	Female	80.8 (10.7)	71.8 (9.5)	9.0 (8.1 – 9.9)	<0.001
PMH Hypertension	Yes	81.4 (10.5)	73.8 (9.7)	7.6 (6.6 – 8.5)	<0.001
	No	81.0 (11.0)	72.0 (9.6)	9.0 (8.1 – 9.9)	<0.001
Antihypertensive Medication	Yes	80.4 (11.0)	72.9 (10.2)	7.5 (6.5 – 8.5)	<0.001
	No	81.9 (10.5)	72.9 (9.2)	9.0 (8.1 – 9.9)	<0.001
PMH diabetes	Yes	76.0 (10.0)	69.0 (7.8)	7.0 (5.0 – 9.0)	<0.001
	No	81.7 (10.7)	73.3 (9.8)	8.4 (7.7 – 9.1)	<0.001
PMH IHD	Yes	74.8 (9.4)	67.8 (7.8)	7.1 (5.1 – 9.0)	<0.001
	No	81.9 (10.7)	73.5 (9.7)	8.4 (7.7 – 9.1)	<0.001
FH Hypertension	Yes	81.9 (10.8)	73.7 (9.6)	8.2 (7.4 – 9.1)	<0.001
	No	80.0 (10.7)	71.6 (9.7)	8.4 (7.4 – 9.4)	<0.001
FH Diabetes	Yes	81.2 (10.5)	73.2 (9.3)	8.0 (7.0 – 8.9)	<0.001
	No	81.2 (11.0)	72.7 (10.0)	8.5 (7.6 – 9.4)	<0.001
FH IHD	Yes	81.7 (10.4)	73.1 (9.4)	8.6 (7.8 – 9.5)	<0.001
	No	80.5 (11.2)	72.7 (10.0)	7.8 (6.8 – 8.9)	<0.001
Ever Smoked	Yes	81.2 (10.8)	72.6 (9.8)	8.6 (7.6 – 9.5)	<0.001
	No	81.2 (10.8)	73.2 (9.6)	8.0 (7.1 – 8.9)	<0.001
Excessive Alcohol Consumption	Yes	84.0 (11.1)	74.8 (10.2)	9.2 (7.9 – 10.6)	<0.001
	No	80.1 (10.5)	72.2 (9.4)	7.9 (7.2 – 8.7)	<0.001

PMH – past medical history; IHD – ischemic heart disease; FH – family history

Table 3. Effect of Independent Variables on Mean Blood Pressure

		Systolic BPTRU Mean (SD)	P Value	Diastolic BPTRU Mean (SD)	*t*-test p value
Measuring Condition	Talking	130.1 (17.6)	**<0.001**	81.2 (10.8)	**<0.001**
	Silence	120.8 (15.0)		72.9 (9.7)	
Order	Talking First	126.5 (17.0)	**0.160**	76.9 (11.0)	0.774
	Silent First	124.4 (17.0)		77.2 (11.1)	
Sex	Female	126.4 (17.7)	**0.169**	76.3 (11.0)	**0.098**
	Male	124.4 (16.2)		77.9 (11.0)	
PMH Hypertension	Yes	129.3 (16.2)	**<0.001**	77.6 (10.8)	0.270
	No	121.6 (17.0)		76.5 (11.3)	
Antihypertensive Medication	Yes	129.6 (16.3)	0.462	76.6 (11.2)	0.421
	No	127.2 (15.0)		77.4 (10.9)	
Ever Smoked	Yes	125.9 (16.9)	0.588	76.9 (11.1)	0.736
	No	125.1 (17.2)		77.2 (11.0)	
Excess Alcohol Consumption	Yes	127.3 (17.2)	**0.132**	79.4 (11.6)	**0.003**
	No	124.8 (16.9)		76.2 (10.7)	
PMH diabetes	Yes	127.6 (16.1)	0.306	72.5 (9.6)	**0.001**
	No	125.2 (17.1)		77.5 (11.1)	
PMH IHD	Yes	126.5 (17.1)	0.639	71.3 (9.3)	**<0.001**
	No	125.3 (17.0)		77.7 (11.0)	
FH Hypertension	Yes	125.9 (17.3)	0.461	77.8 (11.0)	**0.038**
	No	124.8 (16.6)		75.8 (11.0)	
FH Diabetes	Yes	125.8 (15.7)	0.700	77.2 (10.7)	0.776
	No	125.2 (18.0)		76.9 (11.3)	
FH IHD	Yes	125.7 (16.7)	0.748	77.4 (10.8)	0.393
	No	125.2 (17.5)		76.6 (11.3)	

PMH – past medical history; IHD – ischemic heart disease; FH – family history

p value <0.2 (bold font): included in multivariate analysis

Table 4.1 Effect of Measurement Condition on Mean Systolic Blood Pressure After Controlling for Some Associated Factors, Multiple Linear Regression

Model Variable	Coefficient	Standard Error	p value
(Constant)	105.548	3.718	0.000
Measurement Condition	9.316	1.354	0.000
PMH Hypertension	6.524	1.406	0.000
Age	0.186	0.058	0.001

PMH – past medical history

Table 4.2 Effect of Measurement Condition on Mean Diastolic Blood Pressure After Controlling for Some Associated Factors, Multiple Linear Regression

Model Variable	Coefficient	Standard Error	p value
(Constant)	81.988	2.459	0.000
Age	-0.174	0.035	0.000
Measurement Conditions	8.272	0.818	0.000
Sex	1.743	0.844	0.039
Excessive Alcohol	3.466	0.938	0.000
PMH Diabetes	-3.444	1.399	0.014
PMH IHD	-5.499	1.381	0.000
FH Hypertension	2.216	0.849	0.009

PMH – past medical history; IHD – ischemic heart disease; FH – family history

Chapter 5: Discussion

Holding a health-related conversation with participants during the measurement of their blood pressure with a BpTRU device resulted in a clinically significant increase in mean systolic and diastolic blood pressures. The mean increase in blood pressure whilst measured during conversation was 9/8 mmHg. This increase remained after adjustment for the independent variables measured, and was seen in participants with and without a previous diagnosis of hypertension. The results of this study can be applied to adult men and women, with and without hypertension, and should be generalizable to the patient populations of most primary care clinics. The increases in blood pressure seen during conversation in this study are similar to those reported in previous studies, which adds strength to the findings of this study.

This finding has significant implications for clinical practice. It is currently recommended that patients' blood pressure be measured with a BpTRU device whilst they are alone in a room and maintaining silence. This study supports this recommendation, finding that mean systolic and diastolic blood pressures measured during conversation are increased by a clinically significant margin. If this recommendation is not followed and blood pressure is measured whilst engaging patients in conversation, many patients may be incorrectly diagnosed with hypertension or overtreated for hypertension. This has the potential to create several adverse outcomes. It may contribute to increased spending costs with patients being started on antihypertensive medications unnecessarily and being brought back for unnecessary visits. It may lead to overtreatment of hypertension, which could expose patients to unnecessary treatment or side effects from antihypertensive medication. Overtreatment of hypertension is a significant concern in the elderly population, and

can lead to dizziness, orthostatic hypotension and falls, which in turn are a significant cause of morbidity and mortality in this patient population.

In multivariate analysis, age also had a significant effect on mean systolic and diastolic blood pressure. As age increased, mean systolic blood pressure increased and mean diastolic blood pressure decreased. This is consistent with data from the Framingham Heart Study, which found that systolic blood pressure rises from age 30 to 84 and after, and that diastolic blood pressure increases until the fifth decade then slowly decreases thereafter[38].

Past medical history of hypertension had a significant effect on systolic blood pressure. Participants with a past medical history of hypertension had significantly higher systolic blood pressure than participants without a past medical history of hypertension. Sex had a significant effect on diastolic blood pressure, with male participants having significantly higher diastolic blood pressure than female participants.

Past medical history of diabetes, past medical history of ischemic heart disease, family history of hypertension and excessive alcohol intake were also found to have a significant effect on diastolic blood pressure. Because they were not also found to have a significant effect on systolic blood pressure, and because the self-reported data collection of these variables is less reliable, these findings should be interpreted with caution.

Notably, the order of measurement of blood pressure did not significantly affect mean blood pressure. This suggests that blood pressure measurements do not significantly differ if recorded at the beginning of the visit or at a later stage during the visit.

There were a number of limitations to this study which should be highlighted. Firstly, the design of the study compared measuring blood pressure whilst holding a health-related conversation with the patient against measuring blood pressure while the patient sat alone in a quiet room in silence. This experimental design does not allow distinction between just "sitting in silence" or "sitting *alone* in silence" as the factor which results in any change in blood pressure. To address this, the experimental design could have included a three-way comparison between the patient conditions of "sitting alone in silence", "sitting in silence, but with the PI in the room" and "holding a health-related conversation". Whilst this experimental design may allow for a clearer distinction of whether it is the presence of another person in the room or the act of talking that results in changes in blood pressure, that was not the objective of this study. Our aim was to design a clinically relevant study which tested whether time and space could be saved in clinical practice by taking a history from patients whilst measuring their blood pressure, or whether the recommendation to measure blood pressure using the BpTRU with the patient alone and in silence in a quiet room should be followed. It may be an area of interest for further studies to investigate whether sitting alone in silence or sitting alone in silence in the presence of other people results in a clinically significant difference in blood pressure.

During the "silence" blood pressure measurement condition, it cannot be guaranteed that patients followed the instruction to sit in silence after the PI left the room. No steps were taken to enforce this or to observe participants during this period. Participants may have sat alone in silence, or they may have engaged with their smartphone or even talked to themselves under their breath. In clinical practice, when we ask patients to sit in silence in a room while their blood pressure is being

measured, we have no way of knowing that they are actually sitting in silence; we can only trust that they are doing as they have been asked. Therefore, this study mirrors real-life clinical practice, which can be seen as a strength for clinically-relevant research. It is more important that the study conditions mirror the conditions of real-life practice than taking excessive steps to ensure that patients are truly sitting in silence for the purposes of the study.

Ninety-seven percent of the study population were of Caucasian race. This rather homogenous population reflects the population of the island of Newfoundland where the study was conducted, which was mostly settled by Irish and British immigrants. The results of this study may not be applicable to people of other ethnic backgrounds. In order to further investigate this, the study could be repeated with a more diverse patient population.

The study design relied fully on patient self-report for data on all explanatory variables. Several studies have found patient self-report of diagnoses or lifestyle factors to be less accurate than other more rigorous forms of data collection[39, 40, 41]. Participation in the study was voluntary, which may create an unavoidable element of selection bias. The recruitment of patients to the study was not random, but was targeted to achieve roughly equal representation of men and women in the study and equal numbers of participants with and without hypertension. While this recruitment method was intentional in the design of the study in order to achieve the desired patient population, it may also have introduced an element of recruitment bias.

There was a roughly four-minute period before blood pressure measurement commenced, during which time the PI obtained written consent from participants. There was no standardised amount of time before this during which participants sat

and rested, which is often seen in previous studies investigating the effect of talking on blood pressure. While this may lead to variation in the state of stress or rest in which participants entered the study (e.g. arrived half an hour early and sat quietly in the waiting room vs. stuck in traffic, running late and rushing in without a minute to spare) which could affect the results of the study, it does simulate the real world variation in which patients present to the primary care setting for blood pressure measurement.

Similarly, there was only a short period of time of roughly one minute between the two sets of full blood pressure measurements under each measurement condition. A longer wash out period may have been incorporated into the study design, as there is a chance that the first measurement may then impact on the results of the second measurement. However, the possibility of this was controlled for in the study by randomizing the order of measurement condition and then considering measurement order as an independent variable in the study. In the analysis measurement order did not result in a significant difference in blood pressure, so we can conclude that the short wash out period did not have a significant effect on the study results.

Before data analysis, it was decided to create dichotomous variables for alcohol intake and smoking status. For smoking status, the dichotomous variable of "ever smoked" compared participants who had never smoked with those who were current or past smokers. For alcohol intake, the dichotomous variable of "excessive alcohol" compared participants who reported to drink fourteen or less alcohol units per week with those who reported to drink fifteen or greater alcohol units per week. Greater than fourteen units of alcohol per week was chosen as the definition of excessive alcohol intake, as this is the current recommended weekly alcohol limit for men in

Canada. Although the current recommended weekly alcohol limit for Canadian women is nine drinks per week, it was decided to apply the men's limit to both men and women to simplify the analysis in this study. It should be noted that it would have also been possible to have analysed these variables as continuous variables (average units of alcohol per week; total smoking pack years) or to have created different dichotomous variables, which may have led to different findings of the effect of smoking and alcohol on mean blood pressure.

This study used only one automated office blood pressure (AOBP) monitor for the measurement of blood pressure, the BpTRU. The BpTRU was chosen for use in the study as it is a Canadian device commonly used throughout Canada, and has been used in prior hypertension research conducted in Canada. Unfortunately, since the study commenced the company producing the BpTRU have gone out of business and production of this device has ceased. While this study relied exclusively on the BpTRU, the findings of the study may be generalized to other forms of automated office blood pressure measurement.

In conclusion, holding a health-related conversation with patients while measuring their blood pressure using a BpTRU device results in a clinically significant increase in systolic and diastolic blood pressure. To avoid inaccurate measurement of blood pressure which could result in overdiagnosis and overtreatment of hypertension, the findings of this study suggest that blood pressure measurement with the BpTRU device should be conducted with the patient alone and in silence.

Appendices

Appendix 1 – Information Letter

Dear (patient name),

A masters student from the Faculty of Medicine of Memorial University of Newfoundland is currently conducting a medical research study in the Family Medicine Unit. The purpose of this study is to improve the accuracy of blood pressure measurement using a BpTRU device. The BpTRU device is the blood pressure machine used in our clinic.

The student is looking for adults aged 19 years and above to volunteer as a participant in this study. If you are interested, you can contact him to volunteer.

Taking part in the study will take between 20 and 30 minutes. You will be required to come to the Family Practice Unit to participate. You will have your blood pressure measured twice using a BpTRU device, and you will be asked some general questions about your health. You only have to participate in the study once. All information you give during the study will be kept confidential.

By participating in this research study, you will be helping to improve the accuracy of blood pressure measurement with the BpTRU device. Your decision to participate or not will have no effect on your current or future medical care.

If you are interested in participating, please contact the masters student by phone or email to arrange an appointment time.

Masters Student Name: Douglas Dorward

Telephone: 709-771-1803

Email: douglas.dorward@med.mun.ca

Yours sincerely, Doctor name

Appendix 2 – Health Conversation Questionnaire

I'm going to ask you a series of questions related to your health. If you do not feel comfortable answering any of these questions, then you are free to answer the question by saying "I would rather not answer this question".

1) Age? Sex?
2) Race?
3) Do you have a diagnosis of hypertension?
   How long have you had that for?
4) Do you take any medication for high blood pressure?
5) Do you have any other medical problems?
   Diabetes / Ischaemic heart disease
6) Do you smoke?
   Current / past / never
   Pack years
   Years since quitting
7) Do you drink alcohol?
   Units/week
8) Are there any medical problems which run in your family?
   Hypertension / Diabetes / Ischaemic heart disease
9) What does your diet mainly consist of?
10) How much fruit and vegetables do you eat per day?
11) How much exercise do you normally take per week?
12) Do you currently do anything to try to maintain your health?
13) Do you have any worries about your health?

Appendix 3 – Debrief Form

Thank you for taking part in this medical research study.

The true purpose of this study is to see whether there is a difference in the measurement of your blood pressure with a BpTRU device when you are talking to someone about your health, compared to when you are sitting alone in a quiet room.

I did not inform you of the true purpose of the study before your participation. This is because knowing I am looking for a difference in your blood pressure between each measurement situation could lead to a change in your normal blood pressure. This could affect the accuracy of the results.

If you are happy for me to use your measurements and information in the study you do not need to do anything more. If you would like to be informed of the results of this study when they are known, please leave your contact details below. It is estimated that the results of this study will be known in spring 2016. Your contact details will be kept private and will not be linked to the study data in any way. Your contact details will be securely destroyed after we have contacted you.

Name: _____

Address: _____ Email: _____

Would you like to be contacted by mail { } or email { }

If you would not like your measurements to be used in this study, please check the box below and sign your name.

Now that I know the true purpose of this study, I no longer wish my information to be included in this study { }

Signature of participant	Name printed	Year Month Day
Signature of researcher	Name printed	Year Month Day

Appendix 4 – CONSORT Statement Checklist

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	N/A
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	10
	2b	Specific objectives or hypotheses	18
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	19
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	19
	4b	Settings and locations where the data were collected	19
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	20
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	24-25
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	21
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	20
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	20
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	20

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	20
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	25
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	25
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	30
	13b	For each group, losses and exclusions after randomisation, together with reasons	30
Recruitment	14a	Dates defining the periods of recruitment and follow-up	30
	14b	Why the trial ended or was stopped	30
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	33
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	33
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)	34
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	36-37
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	40
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	38
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	43

Other information			
Registration	23	Registration number and name of trial registry	N/A
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	4

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