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# Education on Caffeine Consumption to Improve Blood Pressure for Adults ages 19-65, who Consume High Amounts of Caffeine Daily.

Merlyn Ann Clarke

# Education on Caffeine Consumption to Improve Blood Pressure for Adults ages 19-65 Who Drink High Amounts of Caffeine Daily

Doctor of Nursing Practice

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## Abstract

**Title**: Education on Caffeine Consumption to Improve Blood Pressure for Adults ages 19-65 who Consume High Amounts of Caffeine Daily.

**Purpose**: This project aimed to examine caffeine consumption in the context of its effects on adults' blood pressure, provide education on high caffeine consumption, and evaluate for a reduction in use over four weeks.

**Methods**: A pretest survey was conducted at a primary care practice to determine caffeine consumption among adults between the ages of 19-65. This session included verbal communication, a 10-minute video, and written educational information. The Caffeine Consumption Questionnaire-Revised was used to obtain information on the participant's caffeine consumption. A post-test survey was conducted at the project site four weeks after the first educational class to assess for a reduction in consumption and improvement in blood pressure.

**Results:** Thirty participants were recruited, including normotensive and hypertensive individuals. However, twenty-eight participants completed the study. Among the respondents, most were African Americans. The sample consisted of twenty women and eight men with a mean age of 49.1, and age ranged between 33-65. Upon completion of the study four weeks after the initial educational session, there was a 65% reduction of caffeine consumption and a 6%-8% reduction of systolic and diastolic blood pressure.

**Conclusion:** Overall, the findings suggest that education on high caffeine consumption can reduce the use and improvement of blood pressure.


**Keywords:** adults, caffeine consumption, hypertension, normotensive, educational classes

## Background and Significance

Caffeine is the world's most widely used psychoactive drug, especially caffeine derived from coffee and tea. According to Temple et al. (2017), the amount of caffeine currently consumed in the United States (U.S.) and Canada has doubled since the 1980's. A survey conducted by the U.S. Department of Health and Human Services found that 95% of adults in the U.S. consume caffeine daily, and adults between the ages of 19-30 consumed an average of 110-250 mg of caffeine daily (U.S. Department of Health and Human Services, 2015). This information from the U.S. Department of Health and Human Services has confirmed that daily caffeine consumption in the U.S. among adults has doubled since the estimated amount consumed back in the '80s. This increase in caffeine consumption could be one of the possible reasons for an increase in health conditions such as hypertension in the U.S. According to Rhee et al. (2016), hypertension is a known risk factor for many health conditions, including coronary artery disease, cardiovascular disease, and chronic kidney disease. Approximately 78 million adults in the U.S. have hypertension, and only about half of this population achieve blood pressure control. Approximately 33.5% of African Americans are diagnosed with hypertension in the U.S., suggesting that this may be due to their diets, which could be the reason hypertension is more prevalent among the African American population (Peters, Aroian, & Flack, 2006). Notably, the total per-person annual expenditures associated with hypertension in the U.S., between 2000-2001 was $1,399, which was similar to the estimated figures in 2012-2013, ($1,494). However, the annual national spending increased significantly from $58.7 billion to $109.1 billion, within that period (Zhang, Wang, Zhang, Fang, & Ayala, 2017).

## Problem Statements

Caffeine is a psychostimulant and one of the most used drugs both in the U.S. and around the world. Caffeine consumption of more than 200 ml per day has shown to cause an increase in cardiac contractility resulting in hypertension. Despite the evidence showing education on high caffeine consumption could cause a reduction in use and improvement in blood pressure, most primary care providers are not currently applying this evidence to practice.

## Clinical Question

*For adults between the ages of 19-65, with or without a diagnosis of hypertension, who consume more than 200 ml of caffeine daily, will education on caffeine consumption cause a reduction in daily use, and improvement in blood pressure over 30 days?*

## Project Objectives

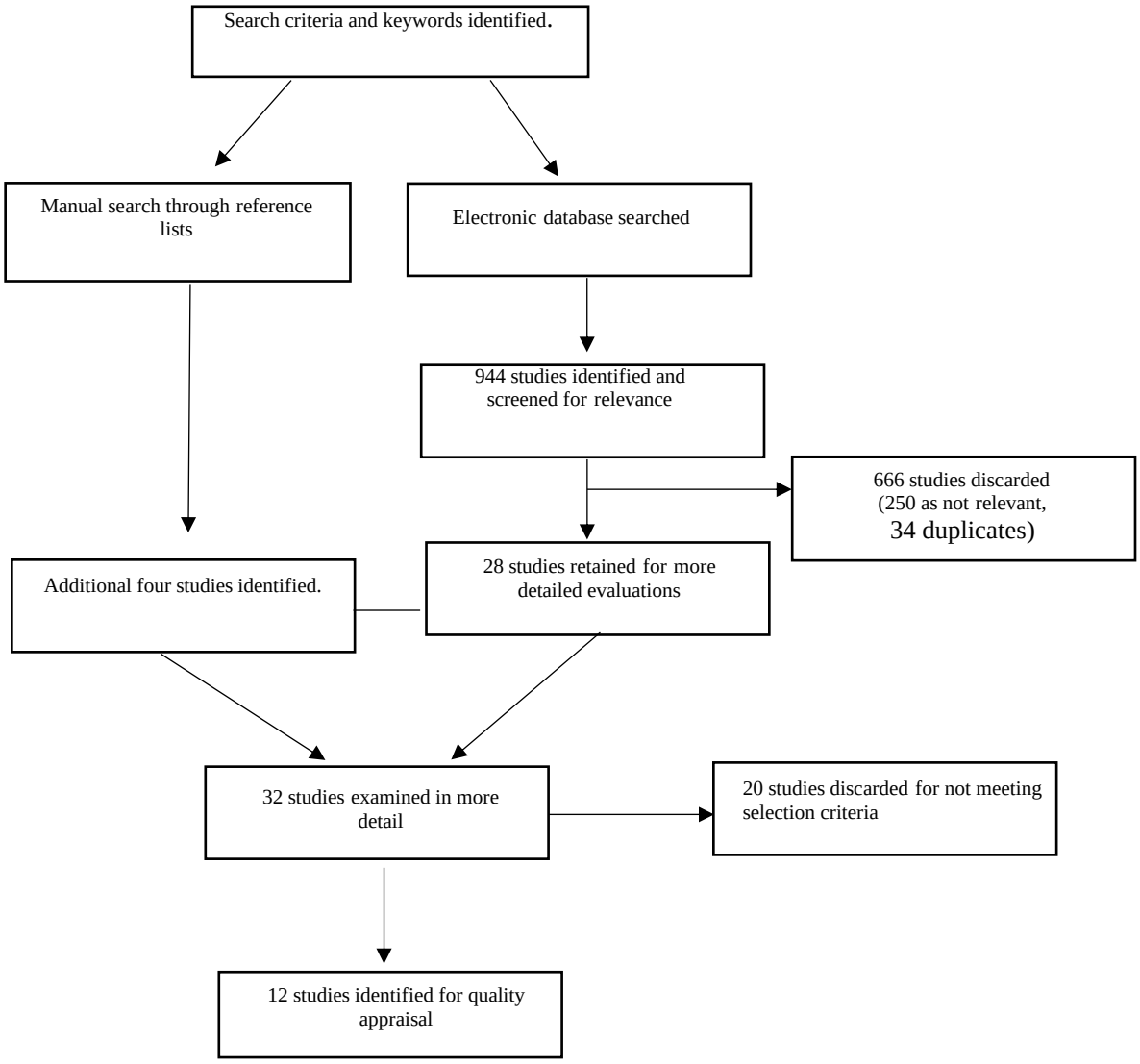
To conduct a quality improvement pretest and post-test study to explore the prevalence of caffeine consumption among adults. To raise awareness of the risks of high caffeine consumption through an educational program and to develop a screening program and practice guidelines for healthcare providers.

## Review of Literature: Organization-Synthesis of Evidence

An extensive search was performed to elicit peer-reviewed journals to support the Doctor of Nursing Practice project. Databases and search engines were utilized to identify literature include CINAHL (Cumulative Index to Nursing and Allied Health Literature), PubMed, Medline, The Joanna Briggs Institute, and Cochrane database. National and international websites were also searched for literature related to caffeine consumption and its effect on blood pressure. Google scholar and Up to date were used to find further evidence, including professional and governmental organizations related to high caffeine consumption and

hypertension. The search terms used included: hypertension*, caffeine*, primary care*, lifestyle changes*, and cost for hypertension treatment*. The Medical Subject Headings (MeSH) terms were obtained from PubMed, resulting in the following keywords: caffeine consumption, adults, hypertension, coffee, tea, soda, energy drinks, chocolate, the economic cost of hypertension, diet, and impact on health. Search parameters span the years between 2005-2020. The searches were limited to adults ages 19-65 in the United States. According to Martyn, Lau, Roberts, & Richardson (2018), there was an increased pattern of caffeine consumption noted among young adults in the United States between 2003-2016. Some of the main caffeinated products consumed were coffee, tea, cocoa, espresso, cappuccinos, lattes, energy drinks, carbonated soft drinks, hot chocolate, chocolate bars, mints, gums, Excedrin, and cold and flu medications. Daily consumption of these products was the leading risk factor for hypertension in individuals between the ages of 19-65 (Lopez-Garcia et al., 2016).

The initial searches of databases identified a total of 944 studies. The abstracts of the chosen studies were examined for relevance, and 28 articles were retained for detailed examination while 916 articles were eliminated for not being directly relevant or for being duplicated. Then, an additional four studies were identified from the reference lists of the 28 studies. The last search yielded 32 articles that were deemed relevant; however, of these articles, 12 were retained for the appraisal (see Appendix. A). Included in the 12 studies were: One study graded level one (well-designed meta-analysis), two studies graded level II (well-designed studies, systemic reviews), three studies graded level three (moderate level, strong recommendations), and six studies graded level four (cohort studies). Twelve articles were appraised based on the Grade of Recommendation, Assessment, Development, and Evaluation (GRADE) criteria (McCaffrey, 2012).




Appendix A: Literature Review of Flowchart

Review of Literature: Contents

A placebo-controlled, double-blinded, randomized, crossover trial of 165 men and postmenopausal women ages 35-64, was conducted to determine caffeine's effect on blood pressure, without measuring heart rate (Farag, Vincent, McKey, Whitsett, & Lovallo, 2005). The study took place over two weeks. Participants consumed a placebo of three inactive capsules during a home maintenance program for six days, and one inactive capsule on day seven in the

laboratory. During the second week, participants consumed 80 mg of caffeine daily during the home maintenance program for six days, then 250 mg of caffeine on the seventh day. Caffeine saliva specimens were evaluated daily in the lab. The report suggested that there was a significant increase in blood pressure in response to caffeine consumption; this could be due to an increase in peripheral resistance. There was a minimal significant effect of caffeine on cardiac contractility, gender, or hemodynamic responses. There was a significant decrease in stroke volume index in the low tolerance group in response to caffeine consumption, which could be due to the direct effect of a hefty dose of caffeine on the heart or due to a baroreceptor mechanism. The findings suggest a clinically significant effect of caffeine on blood pressure. Bennett, Rodrigues, and Klein (2013) confirmed similar findings in their randomized controlled trial and experimental design study. The limitations of these studies were that researchers could not confirm whether caffeine played a role in blood pressure regulation or uncontrolled hypertension. Also, the study could not confirm if eliminating caffeine from the diet will lower or improve blood pressure.

A randomized controlled trial was carried out by Lovallo et al. (2005), on 97 participants who were recruited from Buffalo, New York, and Oklahoma City, Oklahoma. Their purpose was to evaluate whether daily caffeine consumption would reduce or eliminate acute blood pressure responses after the administration of two doses in a laboratory during a structured program over five days. Caffeine was administered daily to each participant at doses 0 mg, 300 mg, or 600 mg. Participants' saliva was tested every morning to ensure compliance, and non-compliant participants were eliminated from the study. The report suggests that there was minimal difference in caffeine tolerance in both sexes, and caffeine consumption daily had minimal effect on 50% of the participants. However, there were blood pressure changes noted in

participants who used caffeinated capsules consistently over five days, suggesting that consistent use of caffeine in moderate to high doses daily could result in hypertension. However, the caffeine test had minimal effect on 50% of the participants. The researchers assumed that caffeine consumption could cause hypertension in patients who regularly consume caffeine in moderate to high levels daily. The limitation of this study was that all participants selected were healthy adults with no risk factors for hypertension based on their family history. The report of the study was inconclusive, and further studies with the inclusion of participants with a family history of hypertension and participants with a history of mild hypertension should be a consideration.

Similarly, a cross-sectional door-to-door survey conducted by Köksal et al. (2017) sought to establish a relationship between the frequency of consumption of caffeinated foods and beverages and hypertension. A total of 1,329 participants, ages 20 to 60, participated in the study. Approximately 13.5 % of the participants had a diagnosis of hypertension and consumed 122.06 mg to 150.0 mg of caffeine daily. The report suggests that there was no correlation between total caffeine intake and diastolic blood pressure. However, there was a positive correlation observed between caffeine consumption and systolic blood pressure. Voskoboinik, Koh, and Kistler (2019) conducted a systemic review of studies that also shared similar results. Participants with elevated systolic and diastolic blood pressure also had an elevated body mass index, which is a risk factor for hypertension. Smoking and increased waist circumference were associated with elevated systolic blood pressure. The limitations of these studies include participants who were selected randomly, and their dietary factors went unassessed. Also, participants lived sedentary lifestyles, but this study did not factor this in. Participants alcohol intake was also not assessed. This study was epidemiological and does not correlate with the

progression or development of caffeine intake. As a result, it could not be determined if high caffeine consumption was the main factor in the development of hypertension.

A cross-sectional study carried out by Mendes de Oliveira et al. (2017) to determine if coffee consumption in the last 12 months was associated with heart rate variability resulting in cardiovascular disease. The study took place over 12 months, in six states in Brazil, with a total of 15,105 participants, ages 35-74, with a mean age of 52. The recruitment of participants took place regardless of their socio-demographic characteristics, health-related behavior, metabolic alteration marker, and the presence of coronary artery disease. Data was extracted from a semi-food questionnaire, and the heart rate variability was obtained through electrocardiographic tracing after 10-minutes. Participants were evaluated based on the volume and frequency of caffeine intake. The Chi-Square test was used to verify the correlation between coffee and heart rate variability. The result of this study suggests that heart rate variability occurred only in individuals who consumed more than 3 cups of coffee daily over a prolonged period. Most of the effects of heart rate variability were a result of a higher prevalence of unhealthy habits in coffee users, including smoking and alcohol use. The association between coffee consumption and heart rate variability was weakened or non-significant when the health risk factors were adjusted. The researchers suggest that further studies are needed to confirm the effects of a higher daily dose of caffeine on the autonomic nervous system. However, with more extensive studies, there is always the possibility of human error, which was one of the limitations of this study. Participants may have overestimated or underestimated their caffeine consumption.

A prospective cohort study was carried out in Singapore by Chei, Loh, Soh, Yuan, and Koh, (2018) to investigate the association between caffeine consumption and hypertension. A total of 63,257 Chinese participants were recruited from the Singapore Chinese Health Study,

however, only 38,592 participants completed the study. Questionnaires containing 165 items from the semi-quantitative food-frequency food table validated the study data, and the study took place over nine years. The Cox Proportion Hazard Models were used to estimate the hazard ratio and the confidence risk of hypertension that was associated with caffeine intake from coffee, black tea, and green tea. The results suggest that participants who drink less than one cup of coffee or 200 ml weekly experienced a significant reduction in their blood pressure as compared with participants who drank more than 200 ml per day. The study also suggests that a high intake of caffeine was associated with an increased risk of hypertension, suggesting caffeine may have a dose-related effect on hypertension. Also, some participants who consumed high amounts of caffeine were smokers and/or used alcohol, which could be the reason they developed hypertension. The researchers suggest that further studies are needed to confirm these findings and to identify bioactive compounds in coffee that may account for the anti-hypertensive effects when caffeine when consumed in high volume. The limitations of this study were that participants were excluded from the study if they did not attend the follow-up interview; participants were elderly; and many participants died during the study; which could be the reason for the substantial reduction in the number of participants that completed the study. Therefore, younger participants should be a consideration.

Zimmermann-Viehoff et al. (2017) conducted a randomized control trial to investigate short-term effects of espresso coffee on heart rate variability, which is a marker of vagal nerve activity in the healthy habitual and non-habitual coffee consumer. A convenience sample of 77 young, healthy women were recruited for the study, which took place in three laboratories. Heart rates and blood pressure assessment took place at rest before and after the ingestion of the respective beverages. The ANOVA test assessed the pre and post-test samples. The results

suggest that heart rate variability was significantly increased after consumption of caffeinated espresso, decaffeinated espresso, or water, indicating increased vagal activities in the course of the experiments. However, the increase in vagally mediated heart rate variability was significantly lower after the consumption of decaffeinated espresso compared to caffeinated espresso. Increased systolic blood pressure was found only in non-habitual caffeine users. The limitation of the study was that the sample consisted of young and healthy individuals. As a result, this study could not be generalized to the entire population. Caffeinated and decaffeinated drinks were only administered once during the study, and there was no conclusion on the long-term effect of caffeinated beverages.

Conversely, a systemic review was conducted by Rhee et al. (2016) to determine if there was a relationship between caffeinated coffee, decaffeinated coffee, and total caffeine intake, and incidents of hypertension in postmenopausal women. The study was comprised of 29,985 healthy postmenopausal women, ages 59-79, extracted from the women's health initiative observational study in the U.S. None of the participants had a diagnosis of hypertension. The mean intake of caffeinated products was 2-3 cups or 196 mg per day. Women's blood pressure evaluation took place at the third annual visit. Linear regression models were used to assess the associations between caffeinated coffee, decaffeinated coffee, and caffeine intake at the third annual visit. The Cox Proportion Hazard Model was used to estimate the heart rate for incidents of hypertension. There was a total of 112,935 follow-up visits within a year; among these cases, 5,566 participants had a diagnosis of hypertension. The report suggests that caffeinated coffee, decaffeinated coffee, or caffeine, had minimal effect on systolic or diastolic blood pressure. Winkelmayer, Stampfer, Willett, and Curhan (2005) also confirmed similar findings in their cohort study. The limitations of these studies included a lack of information on the different

types of brewing methods used in the concentrations of active chemicals in coffee, and there were also genetic differences in an individual's ability to metabolize caffeine. However, no information on metabolic status was available during the women's health initiative study. Also, coffee and caffeine were assessed only once at baseline consumption, which could be the reason the total intake or change in intake during long-term follow-up was different. Also, the selected group was comprised of only healthy postmenopausal women, which could have created a bias in the study.

A meta-analysis was conducted by Xie et al. (2018) in support of the previous study. PubMed and Embase were searched for recent cohort studies. A total of eight articles and ten studies were chosen for investigation from the databases. A total of 243,869 individuals were included in the studies, and only 58,094 individuals had a diagnosis of hypertension. The result suggests that there is no correlation between daily caffeine consumption and hypertension, however, caffeine consumption >2-8 cups or 400-1600 ml per day was associated with hypertension. Therefore, the association between caffeine consumption and high blood pressure appears to be dose-related. Ngueta (2020), also suggests similar findings in a cohort study. These studies were extracted from databases, which could have affected the creditability of the results. Due to the observational nature of the studies, a correlation between caffeine intake and hypertension could not be established with the use of databases only. Caffeine intake was obtained only by questionnaire, which was self-reported, and this could have resulted in an inaccurate classification of the exposure to caffeine. The volume of caffeine, the duration of intake, and the impact on blood pressure could not be confirmed. Therefore, further research is needed to confirm these findings.

A literature review was performed on the effects of caffeine consumption and its correlation with hypertension. Based on the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) criteria by McCaffrey (2012), and the overall grade of the literature reviewed, there is a strong recommendation with moderate-quality evidence to support a correlation between high caffeine consumption and elevated blood pressure. The literature reviewed contained strong evidence in the meta-analysis, systemic reviews, randomized controlled trials, retrospective, prospective, cohort, and cross-sectional studies to support the evidence that high caffeine consumption could have adverse effects on blood pressure. However, there were various ranges in the volume of caffeine that could harm blood pressure. Therefore, there is insufficient information to inform clinical practice, especially as it relates to the amount of caffeine intake that could result in hypertension. For example, studies conducted by (Köksal et al. 2017; Farag et al. 2005) suggested that 200 ml of caffeine per day was associated with clinically significant effects on blood pressure. While studies conducted by (Xie et al., 2018; Rhee et al. 2016; Lovallo et al., 2005) suggested that 3-8 cups or 600 ml-1600 ml of caffeine can significantly affect the cardiovascular system, resulting in hypertension. Therefore, individuals should consume < 200 ml of caffeine per day, which would be equal to one cup or less of caffeine per day. These findings suggest that the relationship between caffeine and hypertension may be dose-related. The synthesis of these studies has actively supported the fact that education on high caffeine consumption can cause a reduction in use. A study by Laaksonen et al. (2008) suggests that lifestyle factors could significantly improve cardiovascular health and minimize the risks associated with hypertension. Additional articles showed that high caffeine consumption is a contributing factor to increased cardiac contractility and heart rate variability, which could also contribute to hypertension (Mendes de Oliveira et al., 2017;

Zimmermann-Viehoff et al. 2017). Therefore, education on high caffeine consumption can cause a reduction in use and improvement in blood pressure. All of these studies showed clinical significance, and information from these studies suggest that high caffeine consumption could have adverse effects on the body, including blood pressure. Significant differences were found in the methodology of these studies, and comparisons between the findings are challenging to interpret, for example, coffee versus caffeine intake.

Due to the moderate to high levels of evidence currently noted in the literature, and the multiple health risk factors associated with increased caffeine consumption, there was a need for this project to provide an evidenced-based education. This program should target individuals ages 19-65, with or without a diagnosis of hypertension, who consume high amounts of caffeine.

## Conceptual/Theoretical Framework-Overall

The primary purpose of nursing theory is to improve and advance practice for the changing continuum of nursing. The introduction of nursing theories has helped to form the cornerstone for knowledge and advancement in practice (Parker & Smith, 2010). Barbara Dossey's Theory of Integral Nursing was used to implement changes to reduce high caffeine consumption. According to Parker and Smith (2010), Dossey's nursing theory consists of four components: including healing, the meta-paradigm of nursing (nurse, person, and environment), patterns of knowing, and Wilber's four quadrants. Parker and Smith (2010) noted that the primary purpose of these patterns of knowing was to organize nursing knowledge and to provide a foundation for nursing practices. Understanding these patterns of knowing is essential in guiding new research in nursing practice. Dossey's nursing theory is one that incorporates holistic concepts into a comprehensive, integrated worldview that guides nursing practices,

education, research, and health care policies (Dossey, 2008). The patterns of knowing were used to answer the clinical question.

## Conceptual/Theoretical Framework-Key Concepts

The Patterns of Knowing included personal knowing, empirical knowing, aesthetic knowing, and ethical knowing (Parker & Smith, 2010). Personal knowing refers to the knowledge the student investigator acquired about herself and the patients, including what can be seen and experienced. This type of knowledge was used during the research process to establish excellent communication and engage the participants in alternative activities such as watching the educational video presentation on high caffeine consumption. Developing a relationship through alternative activities helped build a more meaningful relationship between the participants and the student investigator. According to Chinn and Kramer (2015), relationships that develop through human connection could help the healing process.

Empirical knowing is the science of nursing, whereby knowledge gained through research focuses on formal expression to replicate and validate scientific competence in nursing education and practices (Dossey, 2008). The student investigator used empirical knowing to research databases for well-documented scientific knowledge that addressed the clinical question relating to high caffeine consumption and hypertension. The evidence obtained in the research formed the evidence-based practice, which provided education for participants who consume high amounts of caffeine daily.

According to Dossey (2008), aesthetic knowing combines all of the other aspects of knowing into the nursing praxis (Dossey, 2008). The student investigator used this pattern of knowing to determine the participants' experience living with high blood pressure. In this process, information on the participants' perception of high caffeine consumption was discussed.

Acquiring this information enabled the student investigator to determine participants' needs, which helped them to move forward with a different perception of consuming caffeine.

The ethical knowing helps a person to develop a moral code and a sense of knowing right from wrong (Dossey, 2008). Ethics in nursing is based on obligations to protect and respect human life. It emphasizes respect for persons, families, and their communities, and encourages relationships that enhance attentiveness, responsiveness, communication, and moral action (Chinn & Kramer, 2015). During the research process, the student investigator adhered to the code of ethics for nursing, as stated by the American Association of Colleges of Nursing (AACN, 2015). The student investigator made all efforts to protect human subjects in the research process. McCaffrey (2012) notes that ethics are an essential aspect when undertaking the doctoral project. Therefore, the student investigator sought permission from the Grady Office of Grant Administration, Grady Nursing Research Council, Grady Research Oversight Committee, and Georgia State University Institutional Review Board (IRB) before initiating this project, (Appendix F). Also, the participants were informed about any possible risks that may result from this study.

## Methodology

A quality improvement study was conducted to obtain information about caffeine consumption from adults ages 19-65, who utilized a health care facility in the Southeastern United States.

### Implementation Evaluation-Setting

The implementation setting was a primary care practice. The demographics of this area included a population of 1,041,423 people with a growth rate of 1.68% in the past year, and 92% of the population is African American and 8% other races (United States Census, 2019). The

patients' population at this facility ranged from the newborn to the elderly, mainly African Americans, but included a few other races. All were English speaking. This primary care practice had a large reception area at the entrance with two receptionists and two self-check-in stations. This facility had two spacious waiting rooms, 16 large examination rooms, and one conference room. Permission was obtained to use one examination room during the study period. The average number of established patients who visited this facility daily was approximately 60, with an average of ten new cases daily. This facility was appropriate because the majority of the patients' population was African American.

## Recruitment

Flyers were placed at the reception desk to advertise the study (Appendix G). Individuals who expressed interest in the study were directed to the student investigator and the research support staff. Patients who indicated their willingness to participate in the study were handed a sealed envelope with the research documents by the receptionist.

## Measure and Intervention Implementation

### Inclusion Criteria

The inclusion criteria included participants ages 19-65, who consumed caffeinated beverages daily: (i.e., coffee, tea, cocoa, espresso, cappuccinos, lattes, energy drinks, carbonated soft drinks, hot chocolates, chocolate, cold or flu medications, or Excedrin tablets), with the inclusion of normotensive and hypertensive patients.

### Exclusion

The exclusion criteria included patients with a history of illicit drug abuse, alcohol abuse, tobacco smokers, and those who refrain from regularly consuming caffeinated products. Patients

who were cognitively and decisionally impaired, or those who lacked proficiency in English, were also excluded from the study.

## Implementation

### Pretest-Intervention/Data Collection

Participants completed the pretest questionnaire about their caffeine consumption over the past six weeks. All responses were placed in sealed envelopes and handed to the student investigator and the research support staff. Participants who met the study criteria were taken individually to a private examination room to receive information about the study, which included the purpose of the study and what to expect as participants. The consent forms were signed after the student investigator provided detailed information about the study. After signing the consent forms, participants watched a 10-minute educational video on the effects of high caffeine consumption. Participants also had the opportunity to provide their perspective on caffeine consumption. Then, their blood pressure was measured and recorded using a manual blood pressure machine. Participants were given instructions on how to complete a seven-day caffeine consumption sheet, which would facilitate the development of a detailed database of caffeine consumed over four weeks. A leaflet was given, which contained information about the risk of high caffeine consumption. The pretest classes ended within 30 minutes, after all the details of the study were clarified. The student investigator followed up with the participants within seven days after the initial education session via telephone to assess for obstacles, to answer any questions, to provide support, and to verify their understanding of the project. Participants were provided with the student investigator's contact information to follow up as needed between visits.

## Post-test Survey

Four weeks after the initial educational class, participants met with the student investigator for the final class. During the post-test survey encounter, the student investigator reviewed the seven-day caffeine consumption sheets with the participants, answered further questions about the study, and measured their blood pressure manually. Participants who did not attend the final encounter attended a make-up session one week later. Twenty-eight participants completed the study, and all participants received a copy of the informed consent at the end of the study. The final education class ended within 30 minutes, and a $5 Kroger Gift card was offered to participants who completed the study. All information collected during the study was stored in combination-locked cases and on an encrypted flash drive. The consent forms were stored separately from other study documents.

All care was taken to protect human subjects and human dignity during the research process. Participants were also made aware that there was no benefit to participating in the study. However, they might have gained information that could cause an improvement in their blood pressure. Participants were made aware that they could withdraw from the study at any time without reprisal, and no foreseeable ethical issues should arise as a result of this study. Participants were made aware that they would not experience any more risks than they would in a typical day of life. Confidentiality and anonymity were maintained during the study, and codes were used on the study documents instead of names. All caution was taken to adhere to the facility practices regarding policies and guidelines to avoid conflicts or any ethical dilemmas.

## Implementation Evaluation-Tools

The original Caffeine Consumption Questionnaire-Revised (CCQ-R) by (Irons, Bassett, Prendergast, Landrum, & Heinz, 2016) was used for this study (Appendix I). After consultation

with the author, permission was granted to use this tool. The CCQ-R questionnaire consisted of twelve “opened-ended” questions for the pretest survey. These questions were designed to obtain information about the number of caffeinated beverages, foods, and medications consumed by the participants. Pictures of caffeinated products and the numerical values for the items were incorporated in this tool to aid in the accurate measurement of caffeine consumption. The visual of various sizes of drinks and details about the other caffeinated products helped in the responses to the questionnaire. This tool also included a seven-day caffeine consumption sheet, which the participants completed weekly over four weeks. The seven-day caffeine consumption sheet was used in the post-test survey to evaluate caffeine consumption during the study period. According to Irons et al. (2016), the CCQ-R was a self-report tool used to measure caffeine consumption, and the data provided evidence to support its validity. The tool was user-friendly for researchers, clinicians, and participants. The CCQ-R tool could be delivered in both paper and web-based formats. The paper format was used for this study because it was more comfortable and suitable for all participants, especially for those technologically challenged. Information about the validity suggested that the CCQ-R offered a logical approach for measuring self-reported caffeine use. The valuable feature of this tool is its ability to identify each caffeinated product and the associated numerical value, which made the tool user-friendly.

## Budget

There was a $600 budget involved in the project, which included items such as flyers, stationary, gift cards, security coded boxes, a flash drive, and student investigator traveling expenses. The student investigator used personal finances to fund this project.

## Data Collection and Intervention

### Components of Analysis

The student investigator analyzed the data on completion of the study after receiving permission from the principal investigator. Also, the student investigator received assistance from a statistician at Georgia State University, who assisted with the analysis of the data using the Statistical Package for Social Science (SPSS). This statistical software is often used in nursing research and was suitable for analyzing statistical responses from questionnaires or coded data (Marston, 2010). The statistician also assisted in identifying the appropriate statistical test that applied to the analysis of the data.

## Result

Thirty participants were enrolled in the study: twenty-one women and nine men. The age range of the studied participants was 33-65, and the mean age was 49.1. The majority of the participants were African Americans. However, 28 participants or 93% of the participants completed the study. The total duration of the study was four months.

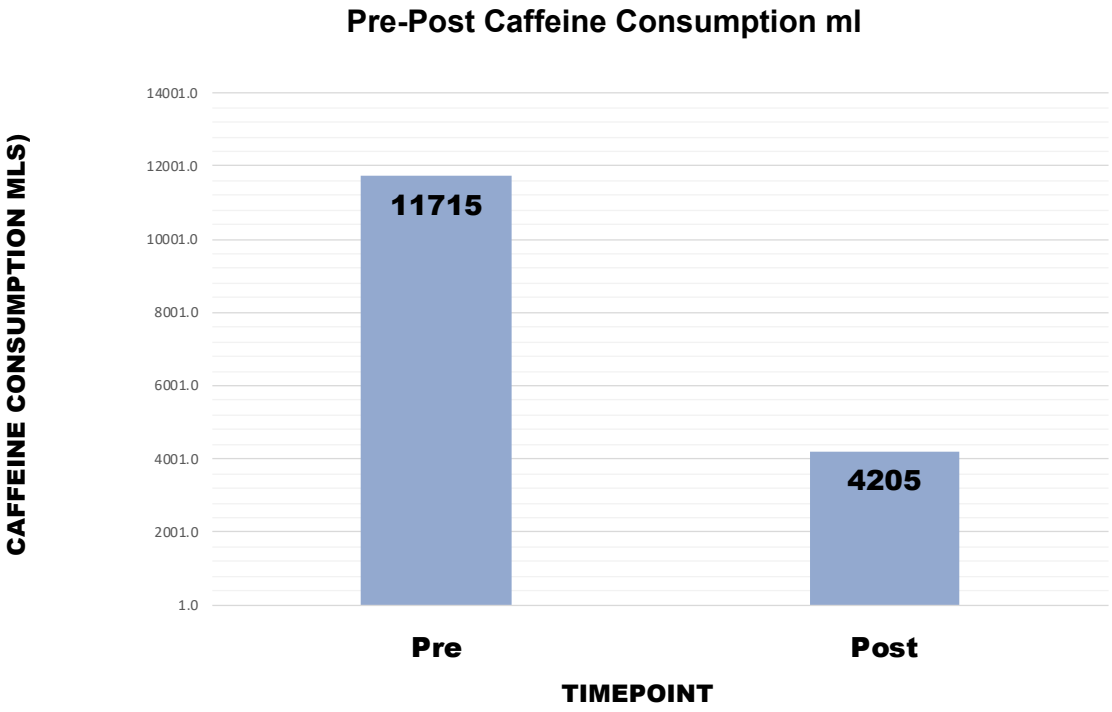
## Statistical Tests

The Non- Parametric Wilcoxon Signed Rank Test was used to analyze the data from the pretest and post-test questionnaires. This test compared the distribution of the values in two groups. This statistical test required a minimum of five-paired measures to compare. The Wilcox Signed Rank Test was similar to the Paired t-test; however, it compared the medians of two correlated groups rather than the means (Plichta & Kelvin 2013).

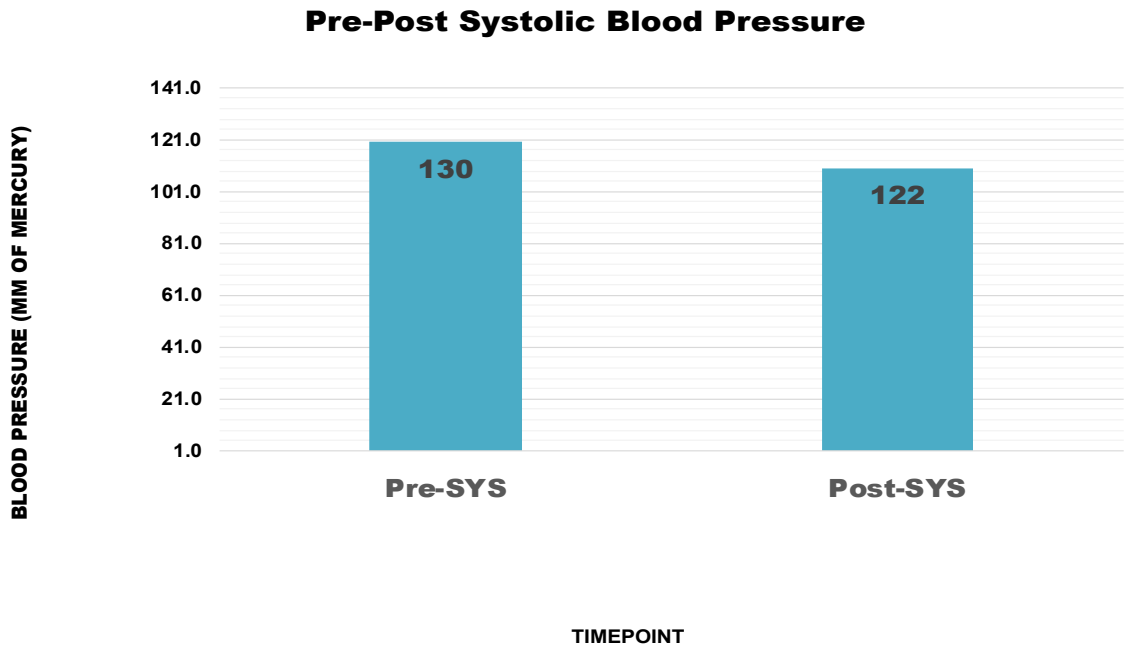
The Paired Sample Statistics t-test was run, but was not applicable to the study because it returned errors in the report. The Paired Sample t-test analysis technique was the most common parametric analysis technique used in nursing studies to detect a significant difference between two independent samples (Groves, Burns & Gray, 2013). This statistical test was developed to examine the differences between two matched groups or paired groups or comparison of pretest

and post-test measurements. However, the Paired Sample t-test required a total sample of at least 30 pairs (Plichta & Kelvin 2013). Therefore, this test was inappropriate for the current sample because the sample consisted of 30 participants.

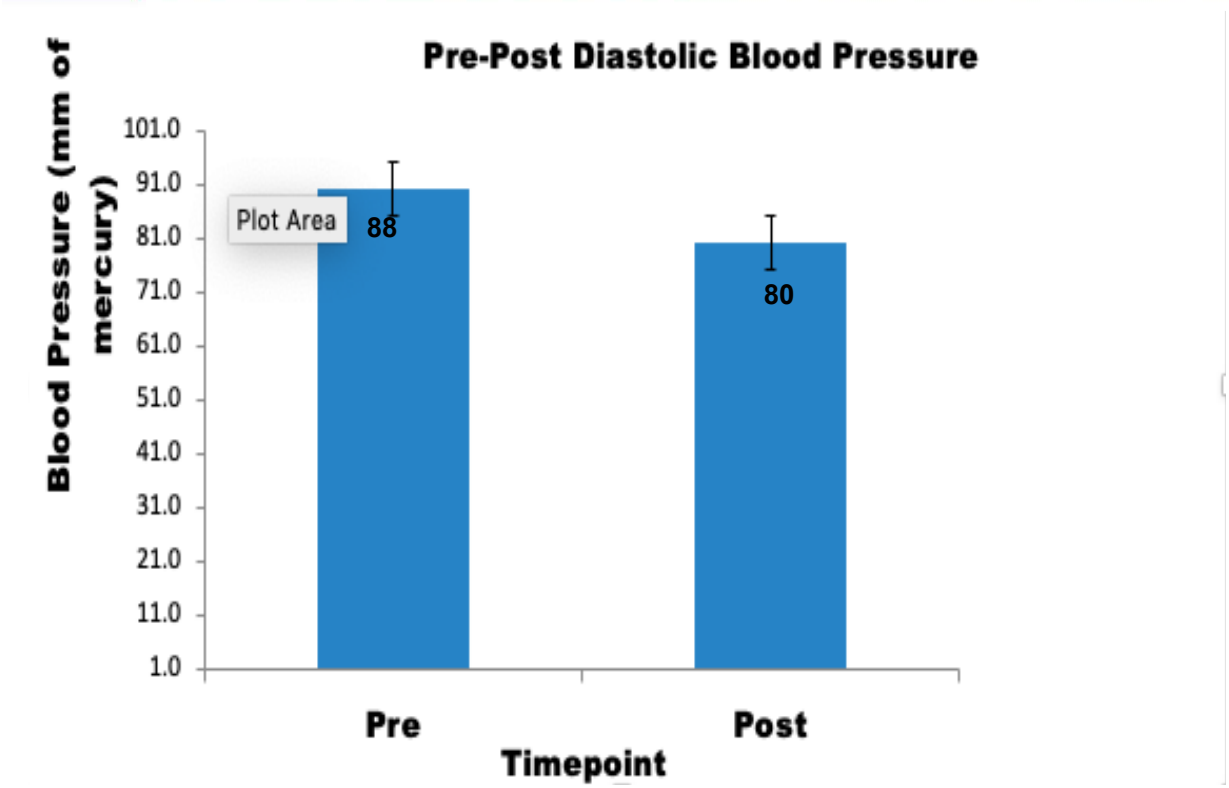
The Non-Parametric Wilcoxon Rank Test was conducted to evaluate the impact of the educational intervention on participants' caffeine consumption and blood pressure. The Wilcoxon Rank Test revealed a statistically significant reduction in consumption of caffeine after the educational classes, $z = -4.623$, $p < .000$, with a large effect size ($r = -0.62$). The median score on caffeine consumption decreased from pretest (Md = 11,715ml) to post-test (Md = 4,205 ml); see Appendix B. There was statistical significance in the differences in the average scores, indicating a significant reduction in caffeine consumption after the educational classes. There was also a 6%-8% reduction noted in systolic and diastolic blood pressure (Appendices C and D). This study demonstrated that education on caffeine consumption could cause a reduction in use.




Appendix B




Appendix C




Appendix D

Discussion

High caffeine consumption has emerged as a significant problem resulting in hypertension in adults, particularly African Americans. The findings in this study aligned with previous studies which suggested caffeine consumption > 200 ml per day can have a negative effect on adults' blood pressure resulting in hypertension. This study also suggests that education played a significant role in the reduction of daily caffeine consumption among adults ages 19-65, which is consistent with the findings in the previous studies. Utilizing the CCQ-R questionnaire tool allowed the student investigator to engage the participants in meaningful discussions regarding their caffeine consumption on a one-on-one basis and provided the opportunity to answer questions that the participants had regarding the study. Many of the participants

requested further education on high caffeine consumption after the study ended. One participant expressed gratitude for the one-on-one sessions. Three participants experienced clinically significant improvement in their blood pressure.

Furthermore, developing a screening tool to identify high caffeine users and providing education to assist high caffeine users should be a consideration in primary care. The screening tool and educational guidelines will help guide decision-making regarding the management of patients with a diagnosis of hypertension and those that are pre-hypertensive who consume >200 ml of caffeine daily. Early education and intervention will help to raise awareness of the risks associated with high caffeine consumption, which could help with reduction in use. This study has shown that education on high caffeine consumption may cause a reduction in use and improvement in blood pressure.

## Practice Implications

This project has demonstrated that using the original Caffeine Consumption Questionnaire-Revised (CCQ-R) aided in the identification of high caffeine users. Utilizing the educational leaflets and the educational video to guide teaching helped to inform individuals of the risks associated with high caffeine consumption. Also, this project highlighted that the rate of caffeine consumption in the African American community might be a cause for concern. Implementing a screening protocol in primary care, which could be added to the annual physical examination, could aid in early detection of individuals who consume high amounts of caffeine daily.

Further investigation with other ethnic groups and demographic regions could be the next step for a future project. Also, introducing another educational measure such as online classes, posters in primary care practices, and flyers could potentially reach a larger population. It may

not only help with the identification and reduction of caffeine use but may also help with maintaining the new lifestyle.

High caffeine consumption is emerging as an opportunity for APRNs to provide evidence-based care. Hypertension is one of the leading causes of coronary artery disease. Coronary artery disease is the leading cause of death in the United States (Heron & Anderson, 2016). Therefore, APRNs providing evidence-based education on high caffeine consumption could assist individuals with making better choices. Utilizing screening tools will assist providers in their efforts to identify and educate individuals who consume high amounts of caffeine daily. It is important to note that not all consumers of caffeine will change their habits or thoughts concerning high caffeine consumption. However, they may have the opportunity to discuss their concerns openly, and hopefully, one day may change their lifestyles. Therefore, this study was needed, and APRNs can play a significant role in introducing this evidence-based knowledge into practice.

## Limitation

The sampled population consisted mainly of African Americans within one specific demographic location. Therefore, the results can only be compared with individuals within that particular ethnic group and location. Participants were dropped from the study if they did not attend the post-test class. Maybe utilizing both web-based and paper formats of the CCQ-R tool could have aided this problem and improved responses. In the future, investigators can provide follow-up via an online tool. The data obtained from the study was self-reported, which meant that participants could have misreported their caffeine consumption. The CCQ-R tool did not provide the specific caffeine contents in each item on the survey, and this was the main

limitation of this tool. The sample size was too small to apply to the general population of that area.

## Summary

In conclusion, health care providers can play a significant role in raising awareness of the risks associated with high caffeine consumption. Identifying individuals who consume high amounts of caffeine daily and offering education on high caffeine consumption caused a reduction in use and improvement in blood pressure. The potential to improve blood pressure through education on high caffeine consumption should be a priority in particular for African Americans, as this population was identified as having the highest risk for hypertension and other medical conditions that may develop as a result of hypertension. In addition, there is a need for education on high caffeine consumption for all ethnic groups, including African Americans from various parts of the United States, as well as pediatric and adolescent populations. There is also a need to measure and record blood pressure at various times, including one to two hours after consumption of caffeine to determine if the effects of caffeine consumption are reversible with time. It is also essential to evaluate the impact decaffeinated products will have on blood pressure. Sleep assessment would also be a consideration in addition to the caffeine screening tool since researchers also highlighted that caffeine could impact sleep. This study could be used as a pilot study to help create a more extensive study that would be beneficial to the community and the entire nation.

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https://www-cochranelibrary-com.ezproxy.gsu.edu.

Appendix E Evidence *Matrix Table* 3

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| Bennett, J. M., Rodrigues, I. M., & Klein, L. C. (2013). Effects of caffeine and stress on biomarkers of cardiovascular disease in healthy men and women with a family history of hypertension. *Stress & Health: Journal of the International Society for the Investigation of Stress, 29(5), 401–409.* | | | | **Grade Level of Evidence:** Moderate level, strong recommendation (III) |
| **Hypothesis/ Questions** | **Design** | **Sample** | **Measurement** | **Results/Implications** |
| To examine the effects of caffeine and stress on B.P., cortisol, CRP, and fibrinogen, in healthy male and female participants with a family history of hypertension. | Randomized Controlled Trial. Experimental design. | Healthy men (N = 26) and women (N = 26), between the ages of 18 and 29 were recruited. The sample contained a control group and an intervention group. | A 7-point Likert scale was used to collect data during the study. Labs were drawn 20 mins after consumption, and blood pressure and H.R. measured. | Findings suggested that caffeine administration resulted in a more significant SBP response from the baseline and remained elevated during the post-stress recovery period for both men and women. DBP has shown to adapt to repeated caffeine exposure, where SBP appears to increase in response to caffeine consistently. **Limitations:** Small sample size study. Caffeine dose was tailored. The methodology was different from other studies. |
| Chei, C.L., Loh, J. K., Soh, A., Yuan, J.M., & Koh, W.P. (2018). Coffee, tea, caffeine, and risk of hypertension: The Singapore Chinese Health Study. *European Journal of Nutrition, 57(4), 1333–1342.* | | | | **Grade Level of Evidence:** Strong recommendation; low - quality evidence (IV). |
| **Hypothesis/ Questions** | **Design** | **Sample** | **Measurement** | **Results/Implications** |

| | | | | |
|---|---|---|---|---|
| To investigate the association between caffeine consumption and hypertension. | A prospective Cohort Study | The original sample included 63,257 participants. However, 38,592 participants completed the study. Researchers extracted the sample from the Singapore Chinese Health Study. | A questionnaire with 165-item semi-quantitative food-frequency was used to validate the studied population. | Less than one cup of coffee daily or 200 ml per week caused a significant reduction in blood pressure as compared with more than 2 cup of coffee per day. Three cups of coffee per day were associated with an increased risk of hypertension, suggesting that caffeine may have a dose-related effect on hypertension. **Limitations:** Many of the participants were elderly; and died during the study. Younger participants could have been recruited, given the length of the study. |
| Farag, N.H., Vincent, A.S., McKey, B.S., Whitsett, T.L., & Lovallo, W.R. (2005). Hemodynamic mechanisms underlying the incomplete tolerance to caffeine's pressor effects. *American Journal of Cardiology, 95(11), 1389–1392.* | | | | **Grade Level of Evidence:** Moderate level, strong recommendation (III) |
| **Hypothesis/ Questions** | **Design** | **Sample** | **Measurement** | **Results/Implications** |
| The researchers hypothesized that men and postmenopausal women would show the most substantial blood pressure response to caffeine, without measuring heart rate. | A placebo-controlled-double blind randomized, crossover trial over two weeks. | A total of 165 healthy men and postmenopausal women, ages 35-64, non-smokers, with BMI<30, participated in the study. | Participants consumed a placebo of three inactive capsules during home maintenance for six days and one inactive capsule on day 7 in the lab. The second week involved ingestion of 80 mg caffeine during home maintenance for six days and 250 mg on day seven. Saliva specimens were analyzed daily in the lab. | High blood pressure was associated with caffeine consumption which could be due to an increase in peripheral resistance. There was minimal effect of caffeine on cardiac contractility. There were no significant effects on gender, blood pressure, or hemodynamic responses to the caffeine challenges in the samples. The findings suggest a clinically significant effect of caffeine on blood pressure. **Limitations:** The study could not confirm whether caffeine played a role in blood pressure regulation or uncontrolled hypertension. Neither could this study |

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| | | | | confirm if eliminating caffeine will result in lower or improved B.P. |
| Köksal, E., Yardımcı, H., Kocaadam, B., Deniz -Güneş, B., Yilmaz, B., & Karabudak, E. (2017). Relationship between dietary caffeine intake and blood pressure in adults. *International Journal of Food Sciences and Nutrition, 68(2), 227–233*. | | | | **Grade Level of Evidence:** Strong recommendation; low - quality evidence (IV). |
| **Hypothesis/ Questions** | **Design** | **Sample** | **Measurement** | **Results/Implications** |
| To determine the frequency of caffeine consumption including foods and beverages among adults. To examine the relationship between caffeine consumption and hypertension. | A cross-section door-to-door interview survey. | A total of 1,329 participants ages 20-60, were recruited from Ankara, Turkey, 650= males, and 679= females. About 13% of participants had a diagnosis of hypertension and consumed 122.06 mg – 150 mg of caffeine daily. | The data was analyzed using the SPSS statistical package program. The Mann-Whitney U test was used to compare means. Systolic and diastolic blood pressure, age, gender, BMI, waist circumference, caffeine intake, and smoking were evaluated with a linear regression analysis. | There was no significant association found between total caffeine intake and diastolic blood pressure. However, a positive association was found between daily caffeine intake and systolic blood pressure. **Limitations:** Participants were selected randomly, and dietary factors were not assessed. Participants lived sedentary lifestyles, and their alcohol intake could not be assessed. Also, this study was epidemiological and does not correlate with the progression or development of caffeine intake. As a result, this study could not determine if caffeine played a role in the development of hypertension. Therefore, more studies are required to confirm these results. |

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| Lovallo, W.R., Wilson, M.F., Vincent, A.S., Sung, B.H., McKey, B.S., & Whitsett, T.L. (2005). Blood pressure response to caffeine shows incomplete tolerance after short-term regular consumption. *Hypertension, 43(4), 760-765.* | **Grade Level of Evidence:** Moderate level, strong recommendation (III) |

| Hypothesis/ Questions | Design | Sample | Measurement | Results/Implications |
|---|---|---|---|---|
| To evaluate whether daily caffeine consumption would reduce or eliminate acute blood pressure responses. | Randomized control trial. A double-blind, crossover trial. | Men (n=49) and women (n=48) recruited from Buffalo, NY, and Oklahoma City, OK, completed the study. | The results were analyzed by the Student t-test, $\chi 2$ test, and ANOVA using SAS (SAS System for Windows, ver. 8.2; SAS Institute, Cary, NC) and SPSS. | There was no difference in caffeine tolerance in both sexes. The caffeine challenge had minimal effect on 50% of the participants. However, there was a change in blood pressure after five days of consistent use of caffeine. The researchers concluded that caffeine consumption might cause hypertension in patients who regularly consume caffeine in moderate to high levels daily. **Limitations:** All participants were healthy adults; none of the participants had any risk factors for hypertension. The report was inconclusive. |

| Mendes de Oliveira, R.A., Araújo, L.F., Carvalho de Figueiredo, R., Goulart, A.C., Schmidt, M.I., Barreto, S.M. & Pinho Ribeiro, A.L. (2017). Coffee consumption and heart rate variability: The Brazilian Longitudinal Study of Adult Health. *Nutrients, (7), 741.* | | | | **Grade Level of Evidence:** Strong recommendation; low - quality evidence (IV). |
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| **Hypothesis/ Questions** | **Design** | **Sample** | **Measurement** | **Results/Implications** |

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| To determine if coffee consumption in the previous 12 months was associated with heart rate variability, which has an effect on the cardiovascular system resulting in high blood pressure. | A retrospective study with cross-sectional study designs. | A total of 15,105 participants, male and female, ages 35-74, completed the study. | A semi-quantitative food frequency questionnaire was used, and the heart rate variability was obtained through electrocardiographic tracing during a 10-minute rest period. | A total of 34.8% of the participants consumed 2 to 3 cups of caffeine daily and 23.6% consumed >3 cups daily. Heart rate variability occurred only in individuals who consumed more than 3 cups of caffeine daily over a prolonged period. **Limitations:** The study was large; therefore, human errors could have occurred in the data collection. Participants could have overestimated or underestimated their caffeine consumption. |

| Ngueta, G. (2020). Caffeine and caffeine metabolites hypertension in U.S. adults. *European Journal of Clinical Nutrition, 74(1), 77–86.* | | | | **Level of Evidence:** Strong recommendation; low - quality evidence (IV). |
|---|---|---|---|---|
| **Hypothesis/ Questions** | **Design** | **Sample** | **Measurement** | **Results/Implications** |
| To examine the association of caffeine and 13 direct and indirect caffeine metabolites with hypertension in U.S. adults. | Cohort Studies National Health and Nutrition Examination Survey. | A total of 2,278 individuals aged 18 to 80 participated. | Urinary methyl uric acids and methylxanthines products of caffeine metabolism were measured using high-performance liquid chromatography-electrospray ionization-tandem quadrupole mass spectrometry. | Metabolites of caffeine significantly reduce the odds of hypertension in the population studied. **Limitation:** This study was observationally extracted from databases, which could have affected the credibility of the results. |
| Rhee, J. J., Qin, F., Hedlin, H. K., Chang, T. I., Bird, C. E., Zaslavsky, O., … & Winkelmayer, W. C. (2016). Coffee and caffeine consumption and the risk of hypertension in postmenopausal women. *The American Journal of Clinical Nutrition, 103(1), 210–217.* | | | | **Grade Level of Evidence:** Strong recommendations; high - quality evidence (II) |

| Hypothesis/ Questions | Design | Sample | Measurement | Results/Implications |
|---|---|---|---|---|
| Is there a relationship between caffeinated coffee, decaffeinated coffee, and total caffeine intakes with mean blood pressure and incidence of hypertension in healthy postmenopausal women? | Systemic Reviews. Prospective study. | The study comprised 29, 985 healthy postmenopausal women aged 59-79, extracted from the Women's Health Initiative Observational Study in the U.S. | The mean intake of caffeinated products was 2-3 cups per day. Blood pressure was analyzed once at the third annual visit. Linear regression models were used to assess associations of caffeinated coffee, decaffeinated coffee, and caffeine intake. The Cox proportional hazard model was used to estimate the heart rate for the incidence of hypertension. | A total of 112,935 person-year follow-up visits and 5,566 cases of incidence of hypertension was reported. Neither caffeinated coffee, caffeine, or decaffeinated coffee intake was associated with mean systolic or diastolic blood pressure. **Limitations:** There was a lack of information on the different brewing methods. Coffee and caffeine were assessed only once at baseline. The selected group comprised only of healthy postmenopausal women which could create a bias in the study. |
| Voskoboinik, A., Koh, Y., & Kistler, P. M. (2019). Cardiovascular effects of caffeinated beverages. *Trends in Cardiovascular Medicine, 29(6), 345–350.* | | | | **Level of Evidence:** Strong recommendation; low-quality evidence (II). |
| **Hypothesis/ Questions** | **Design** | **Sample** | **Measurement** | **Results/Implications** |
| To provide a patient-centered comprehensive review of the cardiovascular effects of caffeinated beverages as it relates to various common cardiovascular conditions. | A systematic review of studies extracted from EMBASE, Web of Science, Medline, and PubMed. | Twenty-eight prospective studies with 1,109,272 participants were analyzed. | A comprehensive review of literature for databases, focusing on human and animal studies examined the effects of caffeine on the cardiovascular system. | Regular consumption of tea and coffee had no association with long-termed effects on blood pressure. The acute rise noted in blood pressure occurred immediately after consumption. No difference noted after several hours of intake. Mild- moderate caffeine consumption appears to be safe. However, a high amount (>3 cups) per day appears to increase the risk for high blood pressure. **Limitations:** The studied participants were selected randomly, and their dietary factors were not assessed. Also, participants lived |

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| | | | | sedentary lifestyles, and alcohol intake was not determined. This study was epidemiological and does not correlate with the progression or development of caffeine intake. |
| Winkelmayer, W. C., Stampfer, M. J., Willett, W. C., & Curhan, G. C. (2005). Habitual caffeine intake and the risk of hypertension in women. *JAMA, 294(18), 2330–2335*. | | | | **Level of Evidence:** Strong recommendation; low - quality evidence (IV). |
| **Hypothesis/ Questions** | **Design** | **Sample** | **Measurement** | **Results/Implications** |
| To examine the association between caffeine intake and incidence of hypertension in women. | Prospective Cohort Study Conducted from the U.S. Nurses Health Studies. | A total of 155, 594 female registered nurses ages 30 to 55, completed and returned a mailed questionnaire. Followed up over 12 years. | Food frequency questionnaires were used to measure dietary intake. Age-adjusted Cox proportional hazards regression models were used to estimate relative risks. Also, multivariate models constructed that adjusted for other known risk factors of the study outcome. | A total of 19, 541 cases of physician-diagnosed hypertension was reported and no linear association between caffeine consumption and the risk of hypertension was observed. Habitual coffee consumption was not associated with an increased risk of hypertension. Consumption of cola beverages was associated with an increased risk of hypertension, independent of whether it was sugared or diet cola. The results for the consumption of caffeinated tea was inconclusive. **Limitation:** This study was subject to human errors because the participants completed the questionnaire, which was subjective. |

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| Xie, C., Cui, L., Zhu, J., Wang, K., Sun, N., & Sun, C. (2018). Coffee consumption and risk of hypertension: A systematic review and dose-response meta-analysis of | **Grade Level of Evidence:** High quality of evidence |

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|---|---|---|---|---|
| cohort studies. *Journal of Human Hypertension*. doi-org.ezproxy.gsu.edu/10.1038/s41371-017-0007-0. | | | | report, moderate-quality evidence (I). |
| **Hypothesis/ Questions** | **Design** | **Sample** | **Measurement** | **Results/Implications** |
| This study aimed to find a precise estimation of the association between caffeine consumption and hypertension. | Meta-analysis with the use of recent cohort studies. | Data was extracted by using a pre-designed extraction form. Eight articles and ten studies were selected for investigation. A total of 243,869 individuals and 58,094 incident cases of hypertension was observed. | **Semi**-parametric and parametric methods were used to assess the data. For the semi-parametric method, four coffee consumption groups were generated: lowest, third highest, second highest, and highest. The pooled result of the different levels of coffee consumption categories were compared with the lowest category. | The risk of hypertension was reduced with each cup of coffee or caffeine per day. However, caffeine consumption of 2-8 cups per day was associated with hypertension. Caffeine relation to high blood appears to be dose related. The volume of caffeine required and the duration of intake in order to impact blood pressure negatively could not be confirmed. Further research is needed to confirm these findings. **Limitations:** Studies were observationally extracted from databases, which could affect the credibility of the result. Due to the observational nature of the studies, a causal relationship could not be established with the database only. Inaccurate self-reporting of caffeine consumption was also a possibility. |
| Zimmermann-Viehoff, F., Thayer, J., Koenig, J., Herrmann, C., Weber, C.S., & Deter, H.C. (2017). Short-term effects of espresso coffee on heart rate variability and blood pressure in habitual and non-habitual coffee consumers – A randomized crossover study. *Nutritional Neuroscience, 19:4, 169-175*. | | | | **Grade Level of Evidence:** Strong recommendation; low -quality evidence (IV). |
| **Hypothesis/ Questions** | **Design** | **Sample** | **Measurement** | **Results/Implications** |

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| To investigate the short-term effects of espresso coffee on heart rate variability in young, healthy habitual, and non-habitual coffee consumers. | Randomized control trial with a convenient sample. | 77 healthy women were recruited into the study. A total of 38 habitual, and 39 non-habitual coffee users. Average age 27 years old. | Heart rate and blood pressure were assessed at rest before and after the ingestion of the respective beverages. ANOVA test assessed the pre and post-test samples. | Heart rate variability was significantly increased after consumption of caffeinated espresso, decaffeinated espresso, or water, indicating increased vagal activity in the course of the experiments.<br>The increase in vagally mediated heart rate variability was significantly lower after the consumption of decaffeinated espresso compared to caffeinated espresso. Increased systolic blood pressure was found only in non-habitual caffeine users.<br>**Limitations:** Only young, healthy individuals participated in the study. As a result, the study could not be generalized to the general population.<br>The caffeinated and decaffeinated drinks were only administered once during the study. There was no conclusion on the long-term effects of caffeinated beverages. |

INSTITUTIONAL REVIEW BOARD

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In Person: 3rd Floor
58 Edgewood
FWA: 00000129

Georgia State University

June 07, 2019

Principal Investigator: Michelle Nelson

| | |
|---|---|
| Key Personnel: | Clarke, Merlyn; Nelson, Michelle; Nelson, Michelle |
| Study Department: | B.F. Lewis School of Nursing |
| Study Title: | Education on Caffeine Consumption to Improve Blood Pressure for Patients ages 19-65 who Drink High Amounts of Caffeine Daily. |
| Review Type: | Expedited Amendment |
| IRB Number: | H19595 |
| Reference Number: | 355404 |

Approval Date: 05/28/2019

Status Check Due By: 05/27/2022

Amendment Effective Date: 06/07/2019

The Georgia State University Institutional Review Board reviewed and **approved** the amendment to your above referenced Study.

This amendment is approved for the following modifications:

- Addition of statements to the consent form required by Grady Health Services Compliance Department

The amendment does not alter the approval period which is listed above and the study must be renewed at least 30 days before the expiration date if research is to continue beyond that time frame. Any unanticipated events or problems resulting from this investigation must be reported immediately to the University Institutional Review Board.

For more information visit our website at www.gsu.edu/irb.

Sincerely,

Lisa Cranwell-Bruce, IRB Member

Appendix F: Permission from IRB to conduct the study

**Merlyn Clarke- NP-C, APRN, MS, Doctor of Nurse Practice Student. Georgia State University**

# Research on High Caffeine Consumption

Do you drink more than 2 cups of caffeinated beverages a day? If your answer is yes, please join us to discover the effects of caffeine on your blood pressure.


**Ph. No. 347-397-1987**

**Georgia State University**

·Do you drink coffee, tea, cocoa, espresso, lattes, cappuccinos, soda, energy drinks, energy shots, iced tea, root beer, hot chocolate, chocolate bars, mini chocolate bars, candy bars, mini candy bars or use Excedrin migraine tablets every day?

Please contact the reception desk if you would like to be a part of this study.

Ph. No. 347-397-1987 or
email: mclarke25@student.gsu.edu.



Appendix G: Recruitment Flyer

Education on Caffeine Consumption to Improve Blood Pressure for Patients ages 19-65, who Drink High Amounts of Caffeine Daily: DNP Project Planning

**Student principal Investigator**: Hello, my name is Merlyn Clarke.

- I am a Doctor of Nursing Practice degree Student at Georgia State University.
- I am enrolling people for a research that I am doing for the completion of my Doctor of Nursing Practice Degree.
- I want to see how we can better help patients from the Sbutheast of the United States.
- The purpose of the study is to find out how caffeinated drinks could affect blood pressure for people between the ages of 19-65 who drink more than two cups daily.

Would you like to hear more? Please circle one

**Potential Participant**: No

SI: Okay, thank you so much. Enjoy the rest of your day.

**Potential Participant**: Yes

PI: Okay, thank you so much. From start to finish the study should take no more than four hours of your time.

- 30 people will be enrolled in the study
- You will be invited to attend two study classes.
- Each class will last for about one hour.
- You will be asked to complete a caffeine consumption form over four weeks.
- This form will take 30 minutes per week to complete.
- A total of two hours over a four-week period to complete the caffeine consumption sheet.
- Total time commitment for the entire study will be four-hours over a four-week period.
- The entire study will run from June to December 2019.
- You will receive a $5 Visa card at the end of the study

As I said earlier, I'm interested in learning about your caffeine habits.

Before we begin, I need to ask you a few questions:

- Are you between the ages of 19- 65 years old?

**Answer**:

- Do you drink coffee, tea, cocoa, espresso, lattes, cappuccinos, soda? energy drinks, energy shots, iced tea, root beer, hot chocolate, chocolate bars, mini chocolate bars, candy bars, mini candy bars or use Excedrin migraine tablets every day?

**Answer:**

- How many cups of tea or bottles, chocolate or any of the beverages listed above did you? drink daily in the last six months?

**Answer:**

- Have you ever had any problems with your blood pressure?

**Answer:**

- Are you taking any medications currently?

**Answer:**

Please list all medications:

- Do you consume alcoholic beverages? How much? How often?

**Answer:**

- Do you use recreational drugs?

**Answer**

- Do you smoke cigarette?

**Answer**

- Highest educational level?

Appendix H: Pre-Survey form

## Caffeine Consumption Questionnaire-R

Please answer the following questions as accurately as you can. **Indicate how many servings per week you normally consume of each item. Use the pictures to help guide your responses.**

Do you drink coffee at least once a week?

- ○ Yes
- ○ No

Please indicate how many servings of coffee you consume, on average, each week.

8 oz. coffee (short)

12 oz. coffee (tall)

16 oz. coffee (grande)

20 oz. coffee (venti)

Please indicate how many servings of **decaffeinated** coffee you consume, on average, each week.

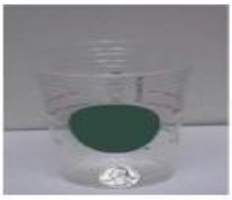
8 oz. decaffeinated coffee (short)

12 oz. decaffeinated coffee (tall)

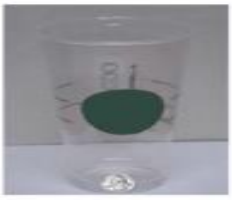
16 oz. decaffeinated coffee (grande)

20 oz. decaffeinated coffee (venti)

Please indicate how many servings of **iced** coffee you consume, on average, each week.



12 oz. iced coffee (tall)



16 oz. iced coffee (grande)

24 oz. iced coffee (venti)

31 oz. iced coffee (trenta)

**Soda**

Do you drink soda at least once a week?

- ○ Yes
- ○ No

Please indicate how many servings of **soda** and **diet soda** you consume, on average, each week. Some sodas do not contain caffeine. Examples include: Sprite, 7-Up, Orange soda, and Root Beer.

12 oz. soda

16.9 oz. soda

20 oz. soda

32 oz. soda

**Energy Drinks**

Do you drink energy drinks at least once a week?

- Yes
- No

Please indicate how many servings of energy drinks you consume, on average, each week.

2 oz. Energy Shot

8.4 oz. energy drink

12 oz. energy drink

16 oz. energy drink

**Teas**

Do you drink tea at least once a week?

- Yes
- No

Please indicate how many servings of tea you consume, on average, each week.

8 oz. tea

12 oz. tea (tall)

16 oz. tea (grande)

24 oz. tea (venti)

**Chocolate Beverages**

Do you drink chocolate beverages at least once a week?

- Yes
- No

Please indicate how many servings of hot chocolate you consume, on average, each week.

8 oz. hot chocolate (short)

12 oz. hot chocolate (tall)

16 oz. hot chocolate (grande)

20 oz. hot chocolate (venti)

Please indicate how many servings of chocolate milk you consume, on average, each week.

8 oz. chocolate milk (short)

12 oz. chocolate milk (tall)

16 oz. chocolate milk (grande)

20 oz. chocolate milk (venti)

**Food**

Do you consume any food that contains caffeine (food including chocolate or coffee are prime examples)?

- ○ Yes
- ○ No

Please indicate how many chocolate bars (**purely chocolate**) you consume, on average, each week.

Chocolate Bars (1.55 oz.)

Mini Chocolate Bars

Please indicate how many candy bars (snickers, twix, butterfinger, etc.) you consume, on average, each week.

Candy Bars (full size)

Mini Candy Bar

Food containing **chocolate** (4 oz. servings)

| | Please indicate how many servings of the following foodstuffs (4 oz.) you consume, on average, each week. servings |
|---|---|
| Yogurt | |
| Ice cream | |
| Baked goods | |

Food containing coffee (4 oz. servings)

| | Please indicate how many servings of the following foodstuffs (4 oz.) you consume, on average, each week. servings |
|---|---|
| Yogurt | |
| Ice cream | |
| Candy | |
| Baked goods | |

Mint or Gum containing caffeine (Jolt gum, Alert Energy gum, Foosh mints, Hero

| | Please indicate how many pieces of the following foodstuffs you consume, on average, each week. pieces |
|---|---|
| Mint | |
| Gum | |

**Drugs**

Do you consume any of the following over-the-counter caffeinated drugs?

| | Please enter how many days each week you consume the drug(s), the serving size of each dose, and the number of times you consume the drug(s) each day. days | serving size | amount |
|---|---|---|---|
| Vivarian | | | |
| NoDoz | | | |
| Excedrin | | | |
| Vanquish | | | |
| Anacin | | | |
| Dristan | | | |
| Xendrine | | | |
| Trimspa | | | |
| Other | | | |

Caffeine Consumption Questionnaire Revised
Appendix: I

POSTTEST SURVEY FORM

Subject ID _____

**CAFFEINE CONSUMPTION QUESTIONNAIRE (CCQ)**

Please answer the following questions as completely and honestly as you can. This information is STRICTLY CONFIDENTIAL – do not write your name anywhere on this page. Thank you for your cooperation.

Please answering the following questions about your caffeine usage. Respond to items that you consume at least once a week.

| COFFEE (5 oz servings/week) | MORNING 6am-12nn | AFTERNOON 12nn-6pm | EVENING 6pm-2am | NIGHT 2am-6am |
|---|---|---|---|---|
| Regular brewed | | | | |
| Percolated | | | | |
| Drip-brewed | | | | |
| Regular instant | | | | |
| Decaffeinated | | | | |
| Brewed | | | | |
| Instant | | | | |
| Iced tea/TEA (5 oz serv/week) | | | | |
| COCOA (5 oz serv/week) | | | | |
| CHOCOLATE (8 oz serv/week) | | | | |
| SOFT DRINKS (12 Oz. Serv/Week) | MORNING 6am-12nn | AFTERNOON 12nn-6pm | EVENING 6pm-2am | NIGHT 2am-6am |
| Coca-Cola | | | | |
| Diet Coca-Cola | | | | |
| Dr. Pepper | | | | |
| Diet Dr. Pepper | | | | |
| Mountain Dew | | | | |
| Diet Mountain Dew | | | | |
| Pepsi Cola Diet | | | | |
| Pepsi Cola | | | | |
| Root Beer | | | | |
| Red Bull | | | | |
| OVER-THE-COUNTER DRUGS (Tablets/week) | | | | |
| Vivarin | | | | |
| NoDoz | | | | |
| Excedrin | | | | |
| Vanquish | | | | |
| Anacin | | | | |
| Dristan | | | | |
| Dexatrim | | | | |

Appendix J
Post-test Survey Form