A SIMPLE PROTOCOL TO IMPROVE ANTIHYPERTENSIVE MEDICATION ADHERENCE IN MENOPAUSAL/POSTMENOPAUSAL WOMEN: A QUALITY IMPROVEMENT PROJECT

A Doctor of Nursing Practice Project Report

by

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This Doctor of Nursing Practice Project Report meets the standards for scope and quality of Texas A&M University-Corpus Christi College of Nursing and Health Sciences and is hereby approved.

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DEDICATION

I would like to dedicate this work to my parents, husband, and children. Without their patients, never-ending love, and unwavering support over many years, I would not have been successful in this fantastic journey.

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ABSTRACT

Hypertension is a silent killer affecting more than a billion people worldwide and is a crucial risk factor for heart disease and stroke, two of the leading causes of death in adults in the United States. It is well known that enhancing medication adherence is essential for controlling hypertension. The effect of sex on the prevalence and control of hypertension is not clearly understood, but men have a higher propensity for hypertension. During the menopausal transition and after age 60, hypertension becomes more prevalent in women than in men, and women are less likely to control their hypertension than their male counterparts of the same age range. Therefore, the purpose of this quality improvement project was to improve hypertensive medication adherence and blood pressure control among menopausal and postmenopausal women at a rural primary care clinic in central Texas through patient education and implementation of an evidence-based medication adherence protocol. A pre-intervention/post-intervention design was used to evaluate patient beliefs and behaviors related to medication nonadherence and blood pressure control. Ninety-five percent and 37% of women reached the project goal of a 30% increase in medication adherence score and 10 mmHg improvement in BP control, respectively. An important outcome of this project was that the implementation of an evidence-based protocol led to significant improvement in medication adherence and control of blood pressure in menopausal and postmenopausal women seeking care at this clinic.

Keywords: Blood pressure control; DOSE-Nonadherence scale; Hypertension; Medication adherence; Menopausal/postmenopausal women; Motivational interviewing; Pillboxes; Rural primary care clinic; Simple protocol.

A Simple Protocol to Improve Antihypertensive Medication Adherence in Menopausal/Postmenopausal Women: A Quality Improvement Project

Introduction

Hypertension is a worldwide health problem. In the United States, this illness impacts approximately 103 million adults (Muntner et al., 2019). Hypertension is defined as high blood pressure with systolic blood pressure (SBP) level of ≥130 mmHg and or diastolic blood pressure (DBP) level of ≥ 80 mmHg, based on the American College of Cardiology (ACC) and American Heart Association (AHA) guidelines (ACC, 2017). Hypertension is well known as the "silent killer" because it typically has no symptoms in earlier stages until after significant damage to the cardiovascular system has occurred. Symptoms are often not seen until severe medical crises such as heart attack, stroke, or chronic kidney disease occur (Singh, Shankar, & Singh, 2017). Hypertension is a crucial risk factor for heart disease and stroke, two of the leading causes of death in adults in the United States (Hales, Carroll, Simon, Kuo, & Ogden, 2017). Hypertension can be reduced by increasing patients' knowledge about hypertension and maintaining adherence to the treatment plan (Beigi, Zibaeenezhad, Aghasadeghi, Joar, Shekarforoush, & Khazraei, 2014). The effect of sex on the prevalence and control of hypertension is not clearly defined, but men have a higher tendency for hypertension (34.6%) than women (30.8%) (Choi, Kim, & Kang, 2017). However, after the age of 60 years, hypertension becomes more prevalent in women than in men, and women are less likely to control their hypertension than their male counterparts of the same age range (Choi et al., 2017).

Background

In the United States, more than 75% of women older than 60 years are hypertensive, and worldwide about 25% of women are hypertensive (Lima, Wofford, & Reckelhoff, 2013). The

loss of hormones from the ovaries during menopause contributes to coronary heart disease (CHD) risk factors, which are manifested ten years later in women compared to men (Maas & Franke, 2009). During the menopausal transition, vasomotor symptoms such as hot flashes and night sweats in women affect their daily activities due to decreased levels of estrogen, which is a risk factor to CHD, especially hypertension (Maas & Franke, 2009). Increased vascular stiffness of the main arteries with atherosclerotic changes of vessel walls in aging can cause elevated blood pressure (Maas & Franke, 2009). Because women tend to live longer, they need improved therapeutic approaches to improve their hypertension (Lima et al., 2013). One therapeutic approach, medication adherence, is critically important to control hypertension in these women. Medication adherence, or taking medications correctly, is generally defined as the extent to which patients take medication as prescribed by their healthcare providers, this involves factors such as getting prescriptions filled, remembering to take medication on time, and understanding the directions (FDA; 2009).

In the United States, medication adherence is related to 125,000 deaths yearly and accounts for 10% to 25% of hospital and nursing home admissions (Atreja, Bellam & Levy, 2005). Nationally, the annual costs for patients treated for hypertension averaged $733 per adult in 2010 (Park, Wang, Durthaler, & Fang, 2017). Patients with uncontrolled hypertension are at higher risk of coronary disease, cerebrovascular disease, and renal disease; thus, the problem of inadequate adherence to anti-hypertensive medication must be addressed (Conn, Ruppar, Chase, Enriquez, & Cooper, 2015). Barriers to medication adherence include medication cost, practicing, lifestyle modifications, health care system, reduced sexual functioning, and dissatisfaction with communication with their healthcare provider (Holt, 2013).

Therefore, this quality improvement project aims to improve antihypertensive medication adherence and decrease BP in menopausal and postmenopausal women through the application of the SIMPLE (**S**implify the regimen- **I**mpart knowledge- **M**odify patients' beliefs and behavior- **P**rovide communication and trust – **L**eave the bias- Evaluate adherence) protocol (Atreja et al., 2005: Million Hearts, 2017).

Review of the Literature

A comprehensive review of the literature on the effects of interventions on hypertension medication adherence and BP control was conducted, with a focus on menopausal/ postmenopausal women aged 45 years to 75 years. Researchers conducted a randomized control trial study among a sample of sixty adults ages 56-68 years old to determine if the use of pillbox could reduce systolic blood pressure by 10 mmHg in veterans with uncontrolled hypertension, from pre-intervention to post-intervention (Porter et al., 2014). They found that by organizing anti-hypertensive medications in pillboxes for patients, their BP goals were more likely to be attainable. The use of pillboxes resulted in patients maintaining adherence to anti-hypertensive medications and resulted in clinically significant reductions in SBP by 10 mmHg (Porter et al., 2014). Additionally, patients who participated in the pillbox intervention study increased their adherence to anti-hypertensive medications, by more than 80%. And 44-51% of the patients achieved their BP goals per the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-7) guidelines, at their second and third appointments (Porter et al., 2014).

In a retrospective chart review research study conducted among a sample of 29,134 patients with an average age of 49 years old to determine the predictors of medication nonadherence which could lead to improved clinical outcomes, it was found that the predictors

of medication nonadherence were non-Caucasian race, single status, and increasing frequency of medication administrations daily (Davidson, Lam, & Sokn, 2017). Approximately 75% (21,749) of the patients were adherent, and 25% (7,382) nonadherent. According to the authors, the characteristics associated with nonadherence include male versus female gender (AOR = 0.88; $P < .001$); African American (AOR = 0.45; $P < .001$), Hispanic (AOR = 0.62; $P < .001$), or other race (AOR = 0.87; $P = .033$) compared to white race; being single compared to married (AOR = 0.92; $P = .006$); and increasing maximum frequency of administrations per day (AOR = 0.76; $P < .001$). Previous studies have shown that patients who are knowledgeable and educated about their disease process and purpose of treatment are likely to demonstrate medication adherence (Atreja, et al., 2005). In a randomized control trial study of 60 elderly patients aged ≥60 years old to determine the effect of educational program based on the health belief model on medication adherence in older adults with hypertension, it was observed that the post-test mean score of medication adherence obtained by the intervention group was 6.7±0.5 which was significantly higher than that of the control group (3.7±1.0) ($P<0.001$) (Yazdanpanah et al., 2019). Also, they found that the mean score of medication adherence in the intervention group had significantly increased based on the results of the paired t-test.

Motivational Interviewing (MI) is a patient-centered method for helping patients explore and resolve their hesitation to change (Ma, Zhou, Zhou, & Huang, 2014). Ma et al. (2014) tested the effectiveness of MI compared with the usual care for Chinese hypertensive patients in their study. They found that MI used with hypertensive patients is a promising approach for sustaining clinical benefits of medication adherence behavior and for BP control. They reported that the results of their study showed that the total scores and mean scores for each dimension of the adherence questionnaire were increased in the intervention group ($P < 0.05$), and SBP and

DBP of the hypertensive patients substantially decreased in the intervention group during the six months of MI counseling ($P < 0.05$).

Contrary to the findings by Ma et al. (2014), Hedegaard et al. (2015) reported that MI impacts on clinical outcomes were not significant. The primary outcome of the Hedegaard et al. (2015) study focused on adherence and not on BP or clinical events, whereas, the Ma et al. (2014) study focused on adherence and BP outcomes. Hence, one could conclude from these findings that MI could be one of the intervention tools provided to hypertensive patients to help them improve their medication adherence. It should be emphasized that researchers who used the MI intervention, reported it helped providers build rapport with participants and motivated participants towards behavioral change and self-efficacy, which resulted in positive changes with medication adherence and help in controlling BP within the recommended guidelines (Palacio et al., 2016; Vignon Zomahoun et al., 2016).

Hedegaard et al. (2015), conducted a randomized trial to investigate the effectiveness of multifaceted pharmacist intervention in a hospital setting to enhance medication adherence in hypertensive patients. At 12 months, 20.3% of the participants in the study's intervention group ($n = 231$) were non-adherent, compared to 30.2% of the participants in the control group ($n = 285$). They concluded that MI, which was a vital element of the intervention, led to a sustained improvement in medication adherence for hypertensive patients, which had no significant impact on blood pressure.

In 2009, the Candesartan in Heart Failure Assessment of Mortality and Morbidity (CHARM) program studied 7,599 heart failure patients and correlated sex with adherence to prescribed medications. The analysis from the study showed that poor adherers were more likely to be females (12.7% of women were nonadherent when compared with 10.2% of men; P =

0.002), have higher heart rate, and a more significant number of concomitant illnesses (Granger et al., 2009). According to Holt et al. (2013), the dissatisfaction of communication with a healthcare provider is a factor related to low medication adherence scores in women. Health insurance claims data of 2014 from the IBM MarketScan Commercial Database (IBM Corp) were used to assess the association between antihypertensive medications, nonadherence rates, medication regimens, and out-of-pocket costs paid by patients (Baker-Goering, Roy, & Howard, 2019). The results indicated that the likelihood of nonadherence increased as out-of-pocket cost increased (adjusted odds ratios ranged from 1.04 to 1.78; $p < 0.001$). It was reported that among adults aged 35 to 64 who filled prescriptions for antihypertensive medications, 41% (n = 1,428,298) of them did not adhere to the antihypertensive medication regimen. It was also indicated that nonadherence decreased with age and was higher in women than men (Baker-Goering et al., 2019).

In the study by Blair, et al. (2014), 138 primary care clinicians and 4,794 patients selected from a stratified random sample of electronic medical records query, were investigated to determine if implicit ethnic or racial bias was associated with processes and outcomes of treatment for hypertension with black and Latino patients, in relation to white patients. The authors found that black and Latino patients received the same treatment but had lower medication adherence and worse hypertension control than white patients, though Latino patients had lower medication adherence than black patients. The differences in treatment intensification, medication adherence, and hypertension control were unrelated to clinician implicit bias for black patients ($P = 0.85$, $P = 0.06$ and $P = 0.31$, respectively) and for Latino patients ($P = 0.55$, $P = 0.40$ and $P = 0.79$, respectively). The authors concluded that in health care, the

identification bias which does not impact results would help both patients and clinicians to build trust and partnership (Blair, et al., 2014).

Arteja et al. (2005) conducted a systematic review of the literature to evaluate interventions that could improve hypertensive medication adherence. Across studies, authors found common interventions used to improve medication adherence and divided them into six categories represented by the mnemonic SIMPLE (Atreja et al., 2005; Million Hearts, 2017).

S - Simplifying regimen characteristics

I - Imparting knowledge

M - Modifying patient beliefs

P - Patient and family communication

L - Leaving the bias

E - Evaluating adherence.

Description of the problem in the setting

The practice setting for this project was conducted in a rural primary care clinic located in Brookshire, Waller County, Texas. The sole-healthcare provider and owner of the clinic was a Family Nurse Practitioner (FNP), who was also the project director (PD) for this quality improvement initiative. Clinic practices were aligned with the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-7) guidelines, which provide evidence-based approaches to the prevention and management of hypertension. Although the clinic followed the JNC-7 guidelines, it did not have an evidence-based protocol in place to assess patients' medication adherence. In the absence of an evidence-based protocol, patients diagnosed with hypertension would repeatedly contact or returned to the clinic in between scheduled visits with elevated blood pressure readings for

unknown causes which led to the need for this project. The PD desired to improve the quality of patient care for hypertensive women in the clinic. In the time frame of January 2017 to December 2019, one hundred male and female patients were diagnosed with hypertension in the clinic. Fifteen of these patients were menopausal women, and sixty-six were postmenopausal women.

Project Purpose and Aims

The purpose of this quality improvement initiate was to improve hypertensive medication adherence and BP control in women aged 45-75 years of age through the implementation of the SIMPLE protocol with emphasis on the use of pillboxes and MI interventions in a rural primary care clinic in Brookshire, Waller County, Texas. The practice question that guided this quality improvement project was: In hypertensive women aged 45 to 75 years with predictors of medication nonadherence, does the implementation of the SIMPLE protocol of interventions compared to current JNC- 7 guidelines practice improve antihypertensive medication adherence and decrease blood pressure over three months from January to April 2020. The project aims were to improve medication adherence in patients with uncontrolled hypertension seen at the clinic. The specific goal was to decrease average SBP by at least 10 points and DBP by at least 5 points from month one to month three of the intervention.

The American Association of Colleges of Nursing (AACN) Doctor of Nursing Practice (DNP) Essential related to this Quality Improvement (QI) project was Essential VII, Clinical Prevention and Population Health for Improving the Nation's Health (AACN, 2006). Essential VII was associated with this project because hypertension was a chronic illness, and prevention of disease and promotion of health was vital to decreasing health care costs, improving quality of life, and increasing longevity in this primary care clinic. Essential II, Organizational and Systems

Leadership for Quality Improvement and Systems Thinking was related to this project because the goal was to improve hypertension patients' healthcare outcomes, eliminate health disparities, promote patient safety and excellence in practice. These outcomes had better chances of being realized by having a nurse practitioner/provider whose area of specialization was in care and management of hypertensive patients, and whose DNP education project was devoted to improving medication adherence and improving BP control in hypertensive menopausal/postmenopausal women.

Methods

Guiding Frameworks

The theoretical framework guiding this project was Orem's Self-care Deficit Theory developed by Dorothea Elizabeth Orem. It included the theory of self-care, the self-care deficit theory, and the theory of nursing systems (Taylor, 2006). Self-care involves activities to promote ones' health and well-being, and Orem's self-care theory is aimed at patient empowerment to help and maintain personal health based on the patient's ability to participate in the self-care process (Hosseinzadeh et al., 2019). The framework, Orem's self-care model, focuses on providing education, self-care management, and empowering patients to monitor their blood pressure. Orem's self-care theory aims at patient empowerment and maintains personal health care ability. In the case of Self-care deficit theory, the project used MI intervention to help participants be educated on the importance of taking their antihypertensive medication as prescribed to prevent complications. The theory of self-care identifies how people care for themselves (Taylor, 2006), which is related to how the project's participants used pillboxes as a self-care tool to remind them to take their hypertensive medications. Self-care deficit theory was how people could be helped and expressed the relationship between the action capabilities of individuals and their demands for care (Taylor, 2006). The theory of nursing systems proposed that nursing systems were action

systems formed by nurses for persons with health-derived or health-associated limitations in self-care or dependent care (Taylor, 2006). For the project, the theory of nursing systems allowed the provider to diagnose diseases such as hypertension, making sure that treatment guidelines implemented as recommended. Orem's Self-care theory's conceptual framework, as it applies to this project is illustrated in Appendix A.

The conceptual or organizational framework guiding this project was the Chronic Care Model (CCM) by Edward H. Wagner, as illustrated for this project in Appendix B. As described by Pilipovic-Broceta et al. (2018), the CCM was a framework for organizing and improving chronic illness care, based on a proactive, planned approach that incorporated patient self-care, provider, and system-level interventions. The chronic care model was effective with various interventions, and it improved care processes and outcomes with chronic disease individuals such as the management of hypertension (Breaux-Shropshire et al., 2017). The chronic care model guides the PD to be able to the provider to use evidence-based guidelines to manage chronic diseases. The chronic care model was suitable for this project whose aim was to improve medication adherence and improve blood pressure control in hypertensive menopausal/postmenopausal women aged 45 years to 75 years old in the clinic. The concept helped chronic illness patients in primary care settings to self-manage their illnesses. Health care providers could use evidence-based guidelines to manage chronic diseases using decision support (Ogedegbe, 2009).

Ethical issues

This project plan was reviewed by the Texas A & M University-Corpus Christi (TAMUCC) Institutional Review Board (IRB) for project classification and received a determination of "Not Human Subjects Research" and permission to proceed as a Quality Improvement project. Refer

to the Letter of Determination from the TAMUCC IRB in Appendix C. Patients who agreed to participate in the study were requested to sign a consent (see Appendix D). Personal Health Information was collected for project purposes only, following the execution of the Health Insurance Portability and Accountability Act Confidentiality Agreement from the facility. Data collected was stored in a secured locked cabinet in the clinic to which only the PD had access. All data collection forms will be destroyed three years following the completion of the project. The Clinic is owned, directed, and operated by the sole Family Nurse Practitioner (FNP), who is the PD for this project. The physician with whom the PD contracted for practitioner supervising physician provided a letter indicating his support of the project and his willingness to provide consultation and feedback on project implementation and analysis to eliminate conflict of interest (see Appendix E).

Setting

The site of the QI project was in a rural primary care clinic located in Brookshire, Waller County, Texas. The clinic attends to an average of about seven to ten patients daily via scheduled appointments or walk-ins. The clinic accepts private health insurance, Medicaid, Medicare, or cash-pay patients. The clinic is opened Mondays through Fridays for primary care. The clinic was closed on Saturdays and Sundays. Clinic staff included a receptionist, a medical assistant, a family nurse practitioner, who is the project director and a collaborating/supervising physician.

Project Design

The design of this project was a quasi-experimental quality improvement initiative using pre-intervention and post-intervention comparisons of implementation of SIMPLE protocol intervention methods to improve hypertension medication adherence and BP control in middle

age, menopausal/postmenopausal women aged 45 to 75 years old in a rural primary care setting, with emphasis on the use of pillboxes and MI interventions. The staff of the clinic was very motivated and interested in conducting this project because they wanted to help their patients achieve treatment goals. Refer to Appendix G for the Plan-Do-Study-Act (PDSA) cycle (White and Zaccagnini, 2017), used for testing a change process to be implemented in the real practice clinical setting.

Sampling

A search of the clinic's electronic database showed that about forty patients who met most of these inclusion criteria attended the clinic from January 2017 to December 2019. Fifty percent of these patients were interested in participating in the study, resulting in a sample size of twenty participants. The reasons why some of the patients who met the inclusion criteria did not choose to participate in the study were due to illness, lack of availability, or time conflict with other previously scheduled engagements. The PD recruited a convenient sample from interested patients attending the clinic who met the inclusion criteria which are (1) menopausal/postmenopausal women; (2) women aged 45 to 75 years; (3) are cognitive; (4) diagnosed with hypertension; and (5) agree to participate in the project.

Intervention

This project used the SIMPLE protocol of interventions (Atreja et al., 2005; Million Hearts, 2017), by emphasizing simplifying the regimen by using pillboxes to remind, evaluate, and use MI during each patient visit to help them feel understood and to empower them to feel confident and capable of improving their medication adherence and healthy behaviors. The PD designed, implemented, and evaluated an evidence-based protocol for integration into clinical practice to facilitate prevention and management of hypertension through medication adherence.

The protocol consisted of medication adherence screening and the SIMPLE intervention (Atreja et al., 2005; Million Hearts, 2017). This approach was likely to be successful in the clinic because it addressed gaps in existing JNC-7 guidelines that will sustain improvement in medication adherence in hypertensive menopausal/postmenopausal women in the rural primary care clinic.

The project team consisted of the three staff members (1) a receptionist, (2) a medical assistant, and (3) the FNP who is the owner/director of the clinic and was PD for the project. The PD conducted the project by filling the pillboxes with patient specific and prescribed BP medications, MI interventions, measuring the medication adherence and BP outcomes, and analyzed the results. The receptionist called participants to remind them of their clinic appointments and assisted in scheduling their appointments. The PD spent approximately 45 – 60 minutes per visit conducting MI intervention technique with each of the participants. The participants received MI interventions five times over the three months' duration of the study. The MI focused on participants' behavioral change to taking their antihypertensive medication. MI was established to build a rapport with participants, evaluate their motivation for behavioral change, provide strategies of adherence to behavior change, inform them of the pros and cons of the medication adherence, and encourage participants to follow the plan for behavior change by using the pillboxes as reminders in taking their medications. Afterward, the PD asked the patients the following questions: (i) *Do you take your antihypertensive medications every day?* (ii) *Do you think your medications are too many or have too many doses daily?* (iii) *How do you feel about taking antihypertensive medication, and do you have any side effects from the medication?* Before the project was implemented in the clinic, the PD did not typically discuss with patients how they took their medication daily nor asked them if they felt their medications

regimen was overwhelming. The patients were usually only informed about how often they had to take their medications, that is, once or twice daily.

The participants were given an appointment date and time of the week to come to the clinic for the project. On the day of the initial participants' arrival at the clinic, the medical assistant gave them the consent form to sign for their participation in the project. Demographic data and the clinical data of baseline blood pressure were collected. Also, participants were given the DOSE-Nonadherence questionnaire form to complete the extent of their antihypertensive medication adherence and the reasons for their nonadherence. The FNP assessed the participant's pre-intervention history of medication nonadherence and used motivational interviewing during communication with participants by educating them on why it was essential to take antihypertension medications as prescribed. Participants were given pillboxes to manage their medications, and the provider filled the pillboxes for patients who brought their medications to the study appointments. Those who did not bring their medications were given instructions on how to fill the pillboxes by themselves.

The original project plan for participants to come to the clinic every three weeks after the initial project start date was disrupted, and the project plan could not be completed as expected. The disruption in plan was due to the occurrence of the severe acute respiratory syndrome coronavirus disease (COVID-19) pandemic, which resulted in a stay at home order and closure of non-essential businesses starting from mid-March 2020. The third and fourth visits were affected by the stay at home order with safety guidelines which were mandated by the CDC and the Federal government. It resulted in participants completing their remaining follow-up appointments via telehealth, for the nurse practitioner to assess the patients, conduct MI intervention, and collect the necessary data.

The PD implemented the change by calling the participants to give them dates and times for their two remaining follow-up appointments. Before the time of the telehealth appointments, participants were to take their blood pressure readings using a blood pressure monitoring machine of their choice and weigh themselves using a scale at home. The practitioner called each of the participants on their scheduled telehealth appointment, to conduct motivational interviewing, work with the patients to complete the DOSE-Nonadherence extent of adherence questionnaire scale and collect their self-reported BP readings and weight measurements. Table 1 provides a summary of the changes that the clinic's team members implemented throughout the study. The project's original plan was disrupted because of COVID-19 starting from mid-March 2020, and the plan was revised a couple of days later to make it possible for the PD to implement telehealth services for the remaining duration of the study. Except for one participant who was dropped from the project because of the loss of contact, all others completed their follow-up appointments to the end of April 2020.

Table 1:

Example of the changes that occurred in the project over time: Summary of interventions by team members

Phase	Date Complete	Nurse Practitioner	Medical Assistant	Receptionist
1- Original Plan	02/19/2020	Collected pre-intervention history of medication nonadherence. Provided pillboxes to participants. Filled pillboxes with participants	Collected demographic data information. Documented the vital signs (BP, heart rate, height, and weight). Gave DOSE-Nonadherence	Called participants to remind them of their follow-up visits. Assisted in scheduling their appointments.

		prescribed BP medications Gave instructions on how to use pillboxes. Used motivationa l interviewin g intervention .	questionnaire to patients to fill.	
2- Issue Encountered: COVID-19 Pandemic	03/15/2020	Clinic Closed	Clinic Closed	Called participants to remind them of their follow up telehealth visit appointments.
3- Revised Plan	03/17/2020	Used motivational interviewing intervention. Collected the vital signs (including BP, heart rate, height, and weight). DOSE-Nonadherence questionnaire scale completed by phone.	Documented the vital signs (including BP, heart rate, height, and weight	Called participants to remind them of their follow up telehealth visit appointments. Assisted in scheduling their appointments from home.
4- Completion Date	04/27/2020	Used motivational interviewing intervention. Collected the vital signs (including BP, heart rate, height, and weight).	Documented the vital signs (including BP, heart rate, height, and weight	Called participants to remind them of their follow up telehealth visit appointments Assisted in scheduling their appointments from home.

During the first PDSA cycle for this initiative, the nation experienced the COVID-19 pandemic. Governor Abbott issued an executive stay at home orders for the State of Texas. Therefore, participants actively participating in the project were not able to visit the clinic, especially for their third and fourth follow-up appointments. Thus, a new plan to test the evidence-based protocol was rapidly developed and supported by the PDSA framework. Telehealth was implemented where participants were called via telephone to get their vital signs, implement MI intervention, and record their answers to the 3-item DOSE-Nonadherence questionnaire. Participants were relied upon to measure their blood pressure and weight at home and self-report to the PD. Most participants who did not have blood pressure monitors at home were able to buy or borrow a monitor. However, one participant was lost because she did not have a blood pressure monitoring machine and could not afford to get one due to a lack of funds.

The PD discussed the rationale behind using pillboxes and gave instructions on how to use the pillboxes. Participants were then provided with pillboxes and given instructions on how to use them. The provider filled the pillboxes for patients who brought their medications to the study appointments, but the participants who did not bring their medications to the program were asked to fill the pillboxes by themselves. The PD incorporated MI techniques during the patient visit to assist in enhancing medication adherence. The practitioner instructed the participants to take their BP three times a week at home and advised them to write the readings in a log and to bring the record (the log) to the clinic at each appointment.

Data Collection

Patient charts were screened in the clinic for a diagnosis of hypertension, with a prescription of antihypertensive medication filled within two weeks before the project and during the project. The goal was to enroll at least 20 participants. The collection of data was at pre-

intervention and post-intervention periods in 3-week, 6-week, 9-week, and 12-week. Demographic data included patient initials, sex, race, marital status, income, educational levels, employment status, ethnicity, and phone number. Clinical data collected were height, weight, date of last menstrual status. Pulse, SBP, and DBP were measured using an automated BP cuff on the left arm while sitting. Participants sat and rested in a quiet room for five minutes before their BP was taken, and a second BP reading was taken after another five minutes' rest, then the average of these two BP readings was recorded by the medical assistant before the patient's consultation with the provider.

At the time of recruitment, participants completed their demographics data and were interviewed about their medication usage. The medical assistant handed out and collected demographic data forms and the DOSE-Nonadherence questionnaires from the participants. The DOSE-Nonadherence questionnaire was given to participants as a validated tool for the medication adherence questions. Also, the medical assistant performed the vital signs (including BP, heart rate, height, and weight measurements) of the participants and recorded them in the electronic health record during each clinic visit. The project team documented the initial appointment's baseline BP and pre-intervention history of medication nonadherence. Healthcare practitioners used motivational interviewing intervention methods during communication with participants. Please refer to the timeline in Appendix F for a visual diagram of the estimated time duration of each part of this project, from the collection of organization assessment data to the dissemination of results.

Measurement Tools

A self-reported measure of medication nonadherence, referred to as the DOSE-Nonadherence scale, was used to assess medication adherence (Cornelius et al., 2019). Voils et

al. (2012) developed the 2-domain measure to correct for the limited reliability and or validity inherent in many of the previously used self-reporting measures. According to Voils et al. (2019), the internal consistency of their cohort study ranged from acceptable ($\alpha = 0.69$) to very high ($\alpha = 1.00$) and averagely quite high ($\alpha = 0.91$). The scale has a first domain with a 3-item questionnaire, which is used to assess the extent of medication adherence, and the second domain consisting of a 21-item questionnaire used to assess reasons for nonadherence (Voils et al., 2012). The first domain consisting of a 3-item questionnaire scale was the tool used to assess the extent of medication adherence (Cornelius et al., 2019; Voils et al., 2012). The first domain, 3-item, assesses the extent to which patients missed, skipped, or did not take their antihypertensive medication over the past seven days (Cornelius et al., 2019). The three questions are: (1) *I took all doses of my blood pressure medication;* (2) *I missed or skipped at least one dose of blood pressure medication;* and (3) *I was not able to take all my blood pressure medication.* Questions 2 and 3 scored from 1 "Strongly Disagree"; 2 "Disagree"; 3 "Neutral"; 4 "Agree"; and 5 "Strongly Agree." Question1 was reverse coded, from 1 "Strongly agree" to 5, "Strongly Disagree." Averaging responses from these three items gave a total score reflecting patients' levels of nonadherence. Higher scores indicated greater levels of nonadherence (Voils et al., 2012). The highest possible score of nonadherence was 15 points.

For the second domain, the 21-item questionnaire was designed to capture the reasons for nonadherence by assessing how much the situations listed in the items contributed to patients missing a dose of their antihypertensive medications. A couple of example questions asked are: *I was busy; There was no one to remind me; They caused some side effects*. These 21 items are scored from 1 "Not at all" to 5, "Very Much." Higher scores indicate a more significant endorsement of each reason for missing doses (Voils et al., 2012). The participants were

required to complete the 21-item questionnaire only in the pre-intervention period. These 21 items are scored from 1 "Not at all"; 2 "Somewhat not at all"; 3 "Neutral"; 4 "Somewhat very much"; and 5 "Very much."

Data Analysis

The IBM SPSS Statistics version 26.0 software for Windows (IBM Corp., Armonk, NY, USA) was used to analyze the data. Descriptive statistics were used to describe demographic data. The independent samples t-test would be used to examine if there was a statistically significant difference in mean values between the two groups (Moran, 2020), for example, the difference between the pre-intervention and post-intervention outcomes. A two-way ANOVA would be used to analyze nominal and ordinal data to determine if there were any differences, and for example, a two-way ANOVA could be used to identify any relationships between sociodemographic characteristics and adherence or blood pressure control. Run charts, which are line graphs data plotted throughout the time of the project, were used to depict comparisons between categories of data. Control chart graphs were used to study how the quality improvement project process changed over time.

Results

Characteristics of the participants

Twenty eligible menopausal/postmenopausal women enrolled in the quality improvement project. All the participants completed the pre-intervention assessments, but only 19 of them completed all the four sets of post-intervention evaluations. The demographic and social characteristics of the participants, including their pre-intervention blood pressures and pulse rate status, are as shown in Table 2. The sample consisted of 100% women, and their ages ranged from 46 to 68 years, with a mean of 57.5 years (SD = 5.8 years). At the time of the study, 10% of

the women were between ages 45-49 years old, 55% of them were between ages 50-59 years old, 25% of them were between ages 60-64 years old, and 10% of them were aged 65 years and older.

Table 2:

Characteristics of the participants' demographic and clinical information (n = 20)

Participants Characteristics	
Age, yr, mean (SD)	57.5 (5.8)
Age Categories, yr, n (%)	
45 - 49	2 (10)
50 - 59	11 (55)
60 - 64	5 (25)
>= 65	2 (10)
Gender, n (%)	
Female	20 (100)
Male	0 (0)
Race, n (%)	
White	7 (35)
African American	11 (55)
Hispanic	2 (10)
Marital Status, n (%)	
Single	6 (30)
Married	12 (60)
Divorced	1 (5)
Widowed	1 (5)
Height, in, mean (SD)	65.2 (2.1)
Weight, lb, mean (SD)	196.5 (60.4)
Body Mass Index, Kg/m^2, mean (SD)	32.6 (9.8)
Body Mass Index Categories, Kg/m^2, n (%)	
Normal (18.5 - 24.9)	4 (20)
Overweight (25 - 29.9)	7 (35)
Obese Class I (30 - 34.9)	3 (15)
Obese Class II (35 - 39.9)	2 (10)
Obese Class III (> 40)	4 (20)

Participants Characteristics	
Menopause, n (%)	
Menopausal	2 (10)
Post-menopausal	18 (90)
Number of BP Medications, mean (SD)	2.4 (0.7)
Number of BP Medications Categories, n (%)	
1 Medication	1 (5)
2 Medications	11 (55)
3 Medications	7 (35)
4 Medications	1 (5)
Education Level, n (%)	
High School and Below	10 (50)
Some College/Associate Degree	6 (30)
University Graduate	4 (20)
Employment Status, n (%)	
Unemployed	6 (30)
Employed/Self-Employed	13 (65)
Retired	1 (5)
Annual Income, n (%)	
Less than $10,000	6 (30)
$10,000 - $19,999	5 (25)
$20,000 - $49,999	4 (20)
$50,000 - $149,999	4 (20)
$150,000 and above	1 (5)
Pre-intervention SBP, mmHg, mean (SD)	137.1 (16.7)
Pre-intervention DBP, mmHg, mean (SD)	77.7 (12.1)
Pre-interv. Pulse Rate, b.p.m, mean (SD)	75.2 (14.7)

Two women were menopausal, one was postmenopausal due to a hysterectomy, and the remaining seventeen participants were postmenopausal, resulting in 10% of the participants

being menopausal and 90% being postmenopausal. The sample comprised of 35% Whites/Caucasian, 55% African Americans, and 10% Hispanic women. 30% of these women were single, 60% were married, 5% divorced, and 5% widowed. Regarding the number of antihypertensive medications taken by the participants daily at the time of being enrolled in the study, ranged from 1 to 4 medications with a mean of 2.4 medications (SD = 0.7 medication). Five percent of the participants took one medication, 55% were on two medications, 35% were on three medications, and 5% took four medications. The mean systolic and diastolic blood pressure at the beginning of the study (or pre-intervention) was 137.1 (SD = 16.7) mmHg and 77.7 (SD = 12.1) mmHg, respectively. The participants' pre-intervention mean pulse rate was 75.2 (SD = 14.7) beats per minute.

The aims of this study were as follows:

1. To decrease medication nonadherence in participants with uncontrolled hypertension that were being seen at the clinic. The specific goal is to reduce the patients' mean score on the DOSE-Nonadherence questionnaire scale score (Cornelius et al., 2019) by at least 5 points from the pre-intervention to the post-intervention period by the end of the three-month (from January to April 2020) project.
2. To assess/examine the reasons for medication nonadherence in participants with uncontrolled hypertension that were being seen at the clinic.
3. To improve the control of participants' blood pressure. The specific goal is to decrease their mean SBP by at least 10 points and their mean DBP by at least 5 points from the pre-intervention to the post-intervention period by the end of the three-month (from January to April 2020) project.

Extent of Adherence

The first domain consisting of a 3-item questionnaire scale was the tool used to assess the extent of medication adherence (Cornelius et al., 2019; Voils et al., 2012). The participants were required to complete the 3-item DOSE-Nonadherence questionnaire at the pre-intervention and all four post-intervention periods. The 3-items were supposed to assess the extent to which the participants missed, skipped, or did not take their antihypertensive medication over the past seven days (Cornelius et al., 2019. The pre-intervention and post-intervention control chart for the 3-item DOSE-Nonadherence questionnaire scale's extent of medication adherence overall scores is plotted in Figure 1. The central line or the average of the data was 4.8 points, with an upper control limit of 10.9 points and a lower control limit of -1.3 points. The plot showed the progression of participants' extent of medication adherence starting from the pre-intervention period to the duration of the three months' post-intervention periods. It showed the impact of the interventions becoming noticeable in the third week of intervention, and the improvement was significantly noticeable after the sixth week through to the end of the three months' period of interventions. As a reference, a perfect adherer would have an extent of adherence total score of 3 points, and the least compliant adherer would have a total score of 15 points.

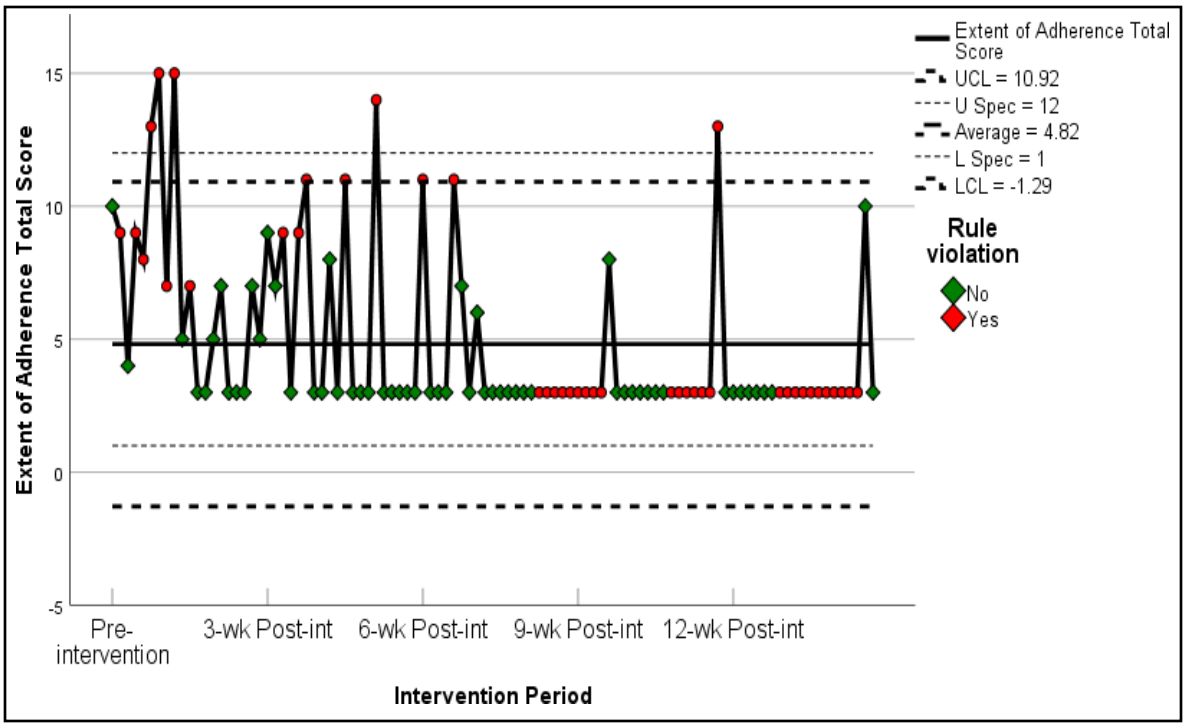

Figure 1:

Control chart for DOSE-Nonadherence 3-item questionnaire scale total scores on participants' extent of adherence

Table 3:

Comparison of extent of adherence for participants at pre- and post-intervention periods

DOSE-Nonadherence 3-items Questionnaire: Extent of Adherence (Cornelius et al., 2019) - Questions	Frequencies of Participants Answers				
	Pre-intervention	3-wk Post-intervention	6-wk Post-intervention	9-wk Post-intervention	12-wk Post-intervention
	n (%)	n (%)	n (%)	n (%)	n (%)
1. I took all the doses of my blood pressure medication					
Strongly agree	9 (45)	12 (60)	17 (85)	18 (90)	18 (95)
Agree	1 (5)	2 (10)	1 (5)	1 (5)	0 (0)
Neutral	4 (20)	3 (15)	1 (5)	0 (0)	1 (5)
Disagree	2 (10)	1 (5)	0 (0)	1 (5)	0 (0)
Strongly disagree	4 (20)	2 (10)	1 (5)	0 (0)	0 (0)
Total	20 (100)	20 (100)	20 (100)	20 (100)	19 (100)
2. I missed or skipped at least one dose of my blood pressure medication					
Strongly disagree	9 (45)	13 (65)	17 (85)	18 (90)	18 (95)
Disagree	2 (10)	0 (0)	1 (5)	0 (0)	0 (0)
Neutral	4 (20)	3 (15)	0 (0)	0 (0)	0 (0)
Agree	1 (5)	0 (0)	1 (5)	1 (5)	1 (5)
Strongly agree	4 (20)	4 (20)	1 (5)	1 (5)	0 (0)
Total	20 (100)	20 (100)	20 (100)	20 (100)	19 (100)
3. I was not able to take all my blood pressure medication					
Strongly disagree	11 (55)	15 (75)	17 (85)	18 (90)	18 (95)
Disagree	3 (15)	0 (0)	1 (5)	1 (5)	0 (0)
Neutral	3 (15)	3 (15)	0 (0)	0 (0)	1 (5)
Agree	0 (0)	1 (5)	1 (5)	1 (5)	0 (0)
Strongly agree	3 (15)	1 (5)	1 (5)	0 (0)	0 (0)
Total	20 (100)	20 (100)	20 (100)	20 (100)	19 (100)

The summary of comparing the results of the three items of the DOSE-Nonadherence questionnaire scale's extent of adherence scores at the pre-intervention versus post-intervention periods showed progressive improvement in the participants' adherence throughout the three months' duration of the project (Table 3). The table shows the characteristics of participants' reported answers for each of the three items in the extent of adherence questionnaire. As shown in Table 4, please note that for each question, the highest "Sum" is 100 points (that is, 5 points multiplied by 20 participants), and the least "Sum" is 20 points. For all the three questions combined, the highest possible total "Sum" for all the participants is 300 points, and the least total "Sum" is 60 points (Table 4). Hence, for improvement in medication adherence, the lesser the "Sum" of the scores, the better. The mean scores for the summation of the 3-items questionnaire for the pre-intervention period was 7.1 (SD = 3.9) (Table 4). The mean scores improved to 5.7 (SD = 3.6), 4.2 (SD = 2.6), 3.8 (SD = 2.4), and 3.2 (SD = 1.7), for the 3-weeks, 6-weeks, 9-weeks and 12-weeks post-intervention periods, respectively. The intervention resulted in improvement in hypertensive medication adherence of a mean score of close to 4 points on the DOSE-Nonadherence questionnaire scale from the pre-intervention to the post-intervention period, at the end of the three months' project.

Table 4:

Mean scores of DOSE-Nonadherence questionnaire scale for participants' extent of adherence at pre-intervention and post-intervention periods

DOSE-Nonadherence 3-items Questionnaire: Extent of Adherence (Cornelius et al., 2019) - Questions	Mean	Std. Deviation	Std. Error Mean	Sum
Pre-intervention				
1. I took all the doses of my blood pressure medication	2.6	1.6	0.4	51
2. I missed or skipped at least one dose of my blood pressure medication	2.5	1.6	0.4	49
3. I was not able to take all my blood pressure medication	2.1	1.5	0.3	41
All Questions 1 - 3	7.1	3.9	0.9	141
3-week Post-intervention				
1. I took all the doses of my blood pressure medication	2.0	1.4	0.3	39
2. I missed or skipped at least one dose of my blood pressure medication	2.1	1.7	0.4	42
3. I was not able to take all my blood pressure medication	1.7	1.2	0.3	33
All Questions 1 - 3	5.7	3.6	0.8	114
6-week Post-intervention				
1. I took all the doses of my blood pressure medication	1.4	1.0	0.2	27
2. I missed or skipped at least one dose of my blood pressure medication	1.4	1.1	0.2	28
3. I was not able to take all my blood pressure medication	1.4	1.1	0.2	28
All Questions 1 - 3	4.2	2.6	0.6	83
9-week Post-intervention				
1. I took all the doses of my blood pressure medication	1.2	0.7	0.2	24
2. I missed or skipped at least one dose of my blood pressure medication	1.4	1.1	0.2	27
3. I was not able to take all my blood pressure medication	1.2	0.7	0.2	24
All Questions 1 - 3	3.8	2.4	0.5	75
12-week Post-intervention				
1. I took all the doses of my blood pressure medication	1.1	0.5	0.1	21
2. I missed or skipped at least one dose of my blood pressure medication	1.1	0.7	0.2	22
3. I was not able to take all my blood pressure medication	1.1	0.5	0.1	21
All Questions 1 - 3	3.2	1.7	0.4	64

Table 5 shows the DOSE-Nonadherence questionnaire scale's extent of adherence improvement rate. Perfect medication adherence (that is, a total extent of adherence score = 3) was displayed by 25% of the participants in the pre-intervention period. The rate of the extent of medication adherence for all the participants significantly improved at post-intervention periods by 60%, 80%, 90%, and close to 95% for post-intervention periods of 3-week, 6-week, 9-week, and 12-week, respectively. The split of the extent of the medication adherence rate between menopausal and postmenopausal women was also shown in the table. At the 12-weeks post-intervention period, the extent of medication adherence rate for menopausal women had increased to 100%, while the rate for postmenopausal women increased to 94%.

Table 5:

DOSE-Nonadherence questionnaire scale for participant's extent of adherence rates at pre-intervention and post-intervention period

Parameter	Period	Extent of Medication Adherence Rate (%)		
		All Participants	Menopausal Women	Post-menopausal Women
Extent of Adherence Rate	Pre-Intervention	25	0	28
(Adherence Goal of: Total	Post-Intervention			
Adherence Score = 3	3-week	60	0	67
Ref: Voils, et al., 2012)	6-week	80	50	83
	9-week	90	100	89
	12-week	95	100	94

Paired samples t-test was used to investigate if the SIMPLE protocol interventions would result in significant differences between the mean extent of medication adherence scores for the pre-intervention versus the post-intervention periods. Table 6 shows the paired samples t-tests for the DOSE-Nonadherence questionnaire scale paired difference mean scores comparisons between pre- and post-interventions. The results of the paired sample t-test showed that the mean score differences for the extent of medication adherence were 1.4 (SD = 4.2), 2.9 (SD = 4.0), 3.3 (4.5), and 3.9 (SD = 4.3) among the participants before the intervention versus post-intervention periods of 3-week, 6-week, 9-week, and 12-week, respectively.

It was observed from Table 6 that the paired mean score differences between the pre-intervention and post-interventions were statistically significant from the 6-week post-intervention to the end of the 12-week post-intervention period. At the end of the 3 months' study period, there was a statistically significant difference between the mean extent of medication adherence scores for the pre- and post-interventions (mean difference = 3.9, SD = 4.3, Standard Error Mean (SEM) = 1.0, 95% Confidence Interval (CI) of the difference = 1.8 - 5.9, $t = 3.997$, $df = 19$, $p < 0.05$).

Table 6:

Paired samples t-test for the 3-item DOSE-Nonadherence questionnaire scale participants' extent of adherence mean score differences at pre-intervention versus post-intervention periods

Variables	Paired Differences							
				95% CI of the Difference				
	Mean	Std. Dev.	Error Mean	Lower	Upper	t	df	p-value
DOSE-Nonadherence Scale: Extent of Adherence Scores								
Pre-intervention vs. 3-week Post-intervention	1.4	4.2	0.9	-0.6	3.3	1.435	19	0.168
Pre-intervention vs. 6-week Post-intervention	2.9	4.0	0.9	1.0	4.8	3.265	19	0.004*
Pre-intervention vs. 9-week Post-intervention	3.3	4.5	1.0	1.2	5.4	3.265	19	0.004*
Pre-intervention vs. 12-week Post-intervention	3.9	4.3	1.0	1.8	5.9	3.997	19	0.001*
* The mean differences that are statistically significant at $p < 0.05$								

Two-way ANOVA was conducted to examine the effect of SIMPLE protocol intervention and the demographic characteristics such as menopausal status, age, race, marital status, body mass index, number of antihypertensive medication(s), educational level, employment status, and annual income on the extent of medication adherence. The resulting plots with emphasis on menopausal status, body mass index, and educational level for both pre- and post-interventions are shown in Figures 2-10, respectively. The corresponding tests of subject effects for the variables in these plots are presented in Tables 7-15, respectively.

As presented in Table 11, the results of the two-way ANOVA showed that there was a statistically significant interaction between the effects of the SIMPLE protocol intervention and

participants' body mass index on their extent of medication adherence ($F(16, 70) = 2.005$, $p < 0.05$). As evidenced in Tables 7-9, 11, 13 and 15, the effects of the SIMPLE protocol intervention alone on the participant's extent of medication adherence were highly statistically significant for the cases focusing on menopausal status ($F(4, 89) = 5.485$, $p < 0.005$), age ($F(4, 79) = 2.642$, $p < 0.05$), race ($F(4, 84) = 3.236$, $p < 0.05$), BMI ($F(4, 70) = 8.093$, $p < 0.001$), educational level ($F(4, 84) = 4.695$, $p < 0.005$), and annual income ($F(4, 74) = 3.194$, $p < 0.05$), respectively. Moreover, as shown in Tables 7 and 13, the interactions between the effects of SIMPLE protocol intervention and participants' menopausal status on their extent of medication adherence ($F(4, 89) = 1.708$, $p = 0.155$) and those between the effects of SIMPLE protocol intervention and participants' education level, on their extent of medication adherence ($F(8, 84) = 0.099$, $p = 0.999$), were not statistically significant. Likewise, the interactions between the effects of SIMPLE protocol intervention and participants' age, race, marital status, number of antihypertensive medication(s), employment status, and annual income on their extent of medication adherence were also not statistically significant ($p > 0.05$), as shown in Tables 8, 9, 10, 12, 14, and 15, respectively.

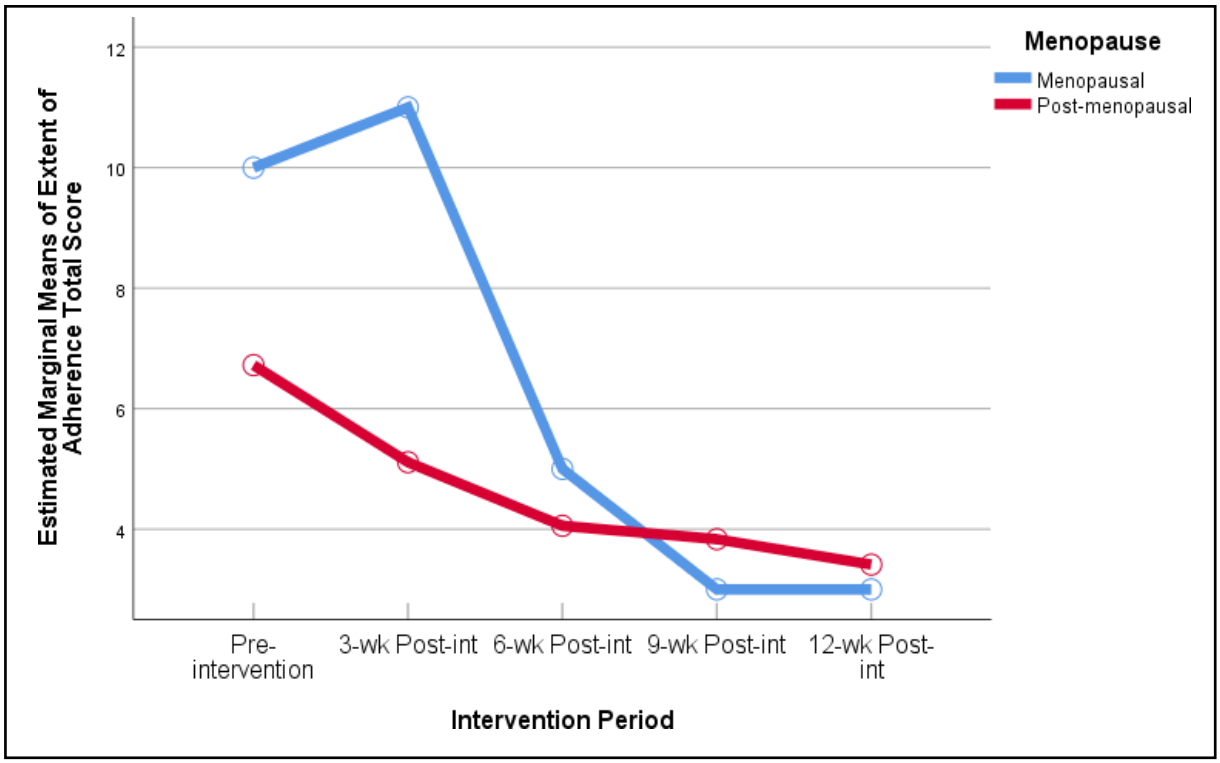

Figure 2:

Participants' mean extent of adherence score versus their menopausal status

Table 7:

Tests of between-subject effects on participants' extent of adherence total scores versus SIMPLE protocol intervention effect on their menopausal status

Tests of Between-Subjects Effects								
Dependent Variable: Extent of Adherence Total Score								
Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	271.776[a]	9	30.197	3.647	0.001	0.269	32.822	0.986
Intercept	1093.026	1	1093.026	132.002	0.000	0.597	132.002	1.000
Intervention	181.679	4	45.420	5.485	0.001	0.198	21.941	0.970
Menopause	28.265	1	28.265	3.414	0.068	0.037	3.414	0.447
Intervention * Menopause	56.573	4	14.143	1.708	0.155	0.071	6.832	0.504
Error	736.951	89	8.280					
Total	3307.000	99						
Corrected Total	1008.727	98						
a R Squared = .269 (Adjusted R Squared = .196)								
b Computed using alpha = .05								

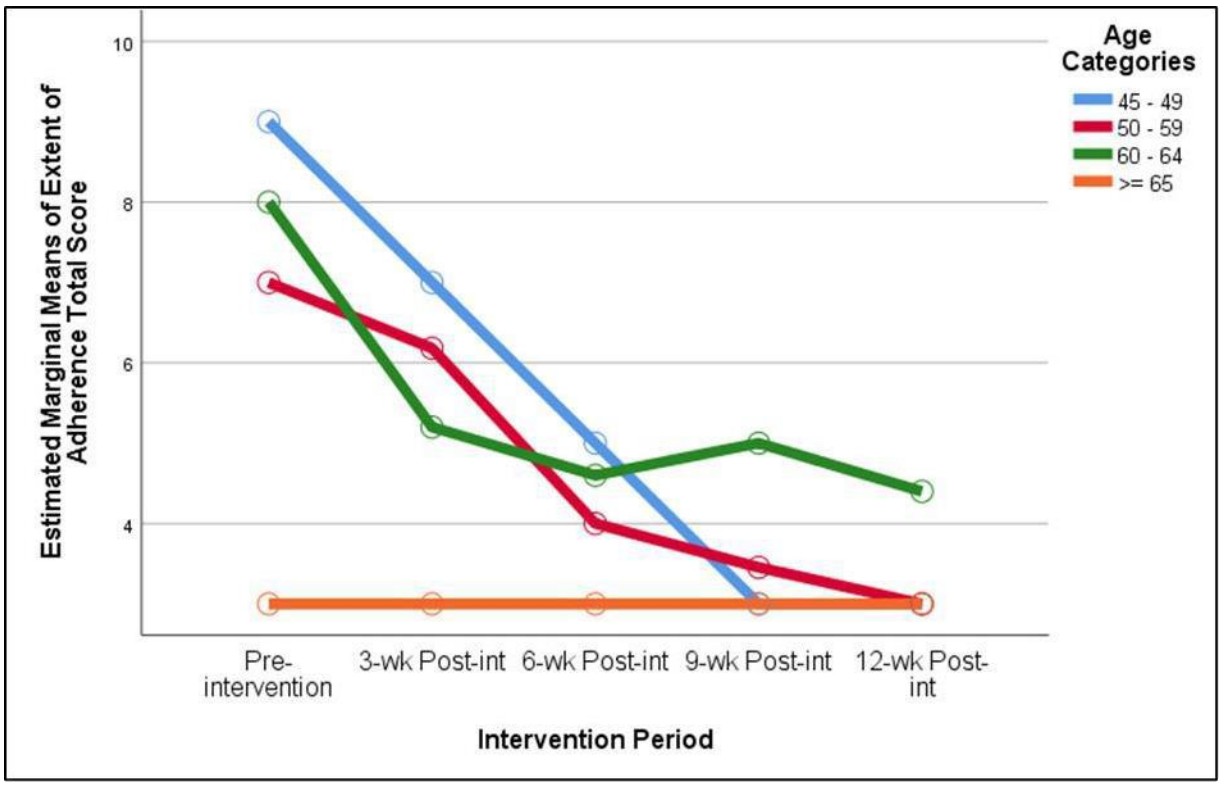

Figure 3:

Participants' mean extent of adherence score versus their age

Table 8:

Tests of between-subject effects on participants' extent of adherence total scores versus SIMPLE protocol intervention effect on their age

Tests of Between-Subjects Effects

Dependent Variable: Extent of Adherence Total Score

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	277.164[a]	19	14.588	1.575	0.084	0.275	29.930	0.891
Intercept	1333.397	1	1333.397	143.991	0.000	0.646	143.991	1.000
Intervention	97.862	4	24.466	2.642	0.040	0.118	10.568	0.714
Age	46.525	3	15.508	1.675	0.179	0.060	5.024	0.423
Intervention * Age	43.824	12	3.652	0.394	0.962	0.057	4.732	0.206
Error	731.564	79	9.260					
Total	3307.000	99						
Corrected Total	1008.727	98						

a R Squared = .275 (Adjusted R Squared = .100)

b Computed using alpha = .05

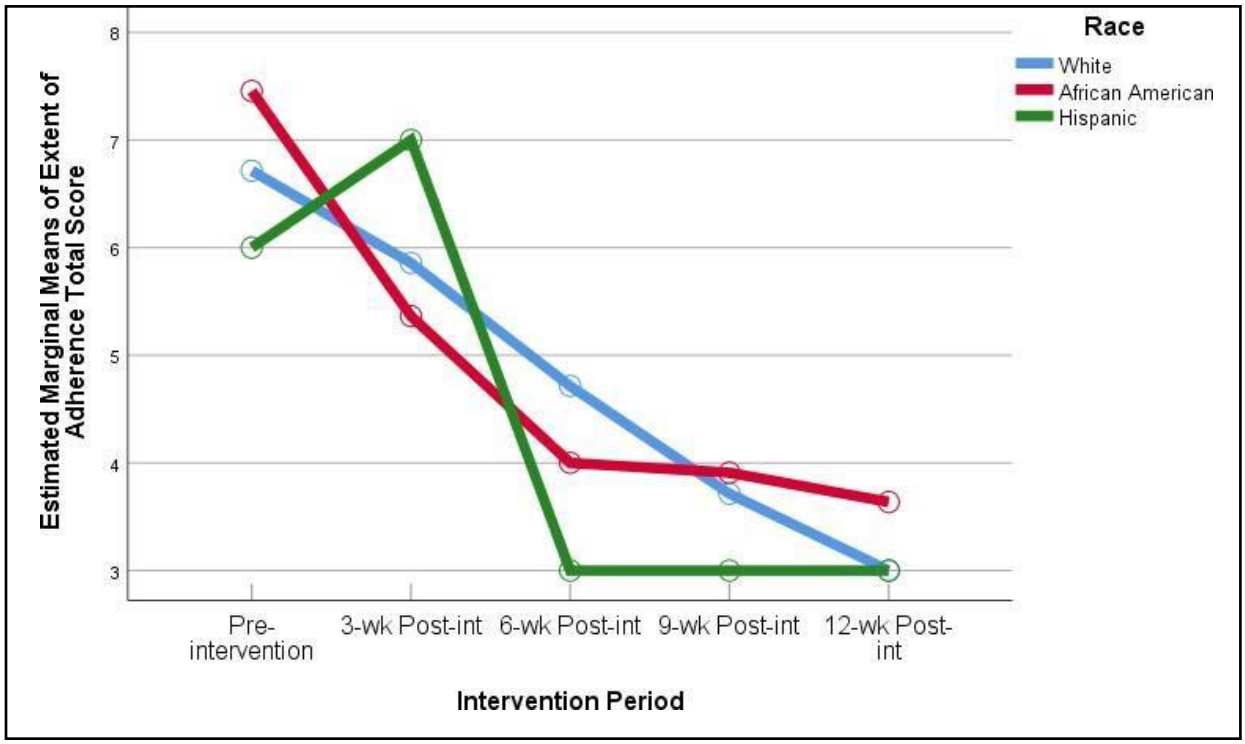

Figure 4:

Participants' mean extent of adherence score versus their race

Table 9:

Tests of between-subject effects on participants' extent of adherence total scores versus SIMPLE protocol intervention effect on their race

Tests of Between-Subjects Effects								
Dependent Variable: Extent of Adherence Total Score								
Source	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**	**Effect Size**	**Noncent. Para-meter**	**Observed Power[b]**
Corrected Model	204.857[a]	14	14.633	1.529	0.118	0.203	21.406	0.810
Intercept	1340.786	1	1340.786	140.105	0.000	0.625	140.105	1.000
Intervention	123.865	4	30.966	3.236	0.016	0.134	12.943	0.811
Race	1.891	2	0.945	0.099	0.906	0.002	0.198	0.065
Intervention * Race	16.107	8	2.013	0.210	0.988	0.020	1.683	0.110
Error	803.870	84	9.570					
Total	3307.000	99						
Corrected Total	1008.727	98						
a R Squared = .203 (Adjusted R Squared = .070)								
b Computed using alpha = .05								

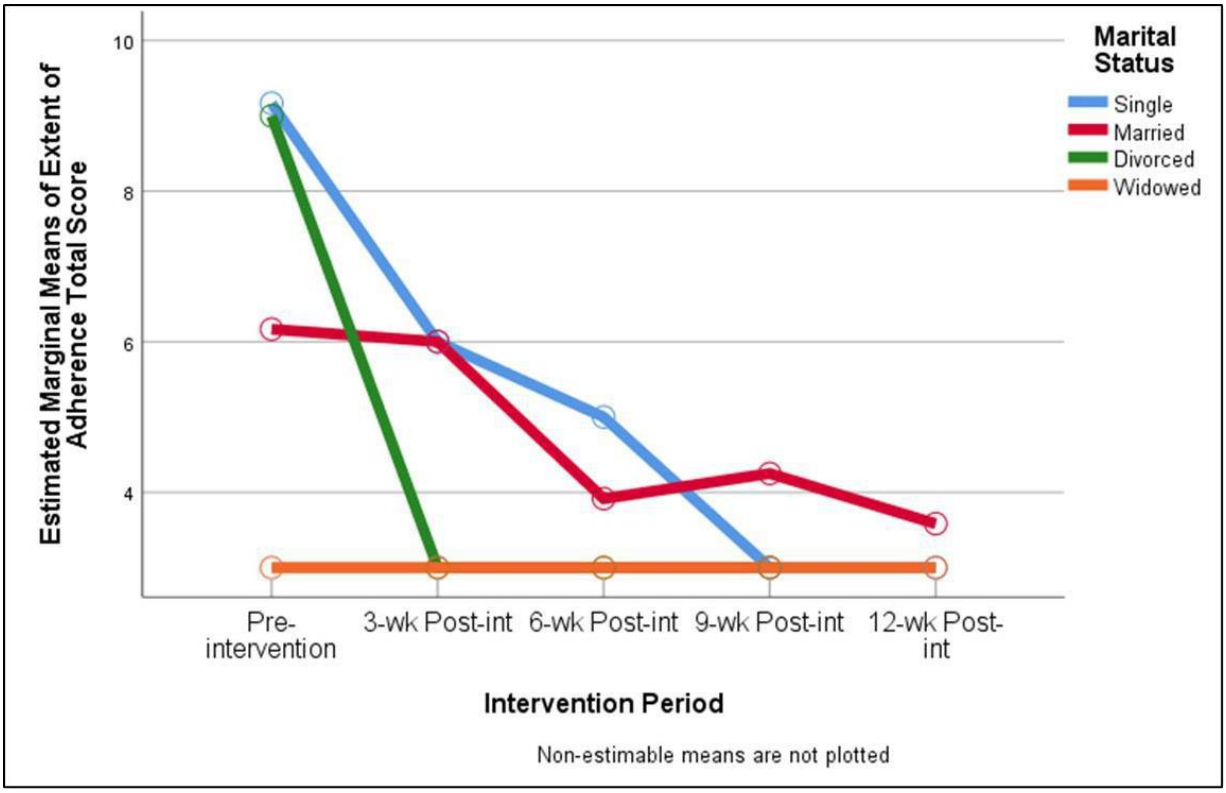

Figure 5:

Participants' mean extent of adherence score versus their marital status

Table 10:

Tests of between-subject effects on participants' extent of adherence total scores versus SIMPLE protocol intervention effect on their marital status

Tests of Between-Subjects Effects								
Dependent Variable: Extent of Adherence Total Score								
Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	276.144[a]	18	15.341	1.675	0.062	0.274	30.156	0.905
Intercept	609.246	1	609.246	66.531	0.000	0.454	66.531	1.000
Intervention	64.507	4	16.127	1.761	0.145	0.081	7.044	0.516
Marital_Status	23.182	3	7.727	0.844	0.474	0.031	2.532	0.226
Intervention * Marital_Status	65.684	11	5.971	0.652	0.779	0.082	7.173	0.330
Error	732.583	80	9.157					
Total	3307.000	99						
Corrected Total	1008.727	98						

a R Squared = .274 (Adjusted R Squared = .110)

b Computed using alpha = .05

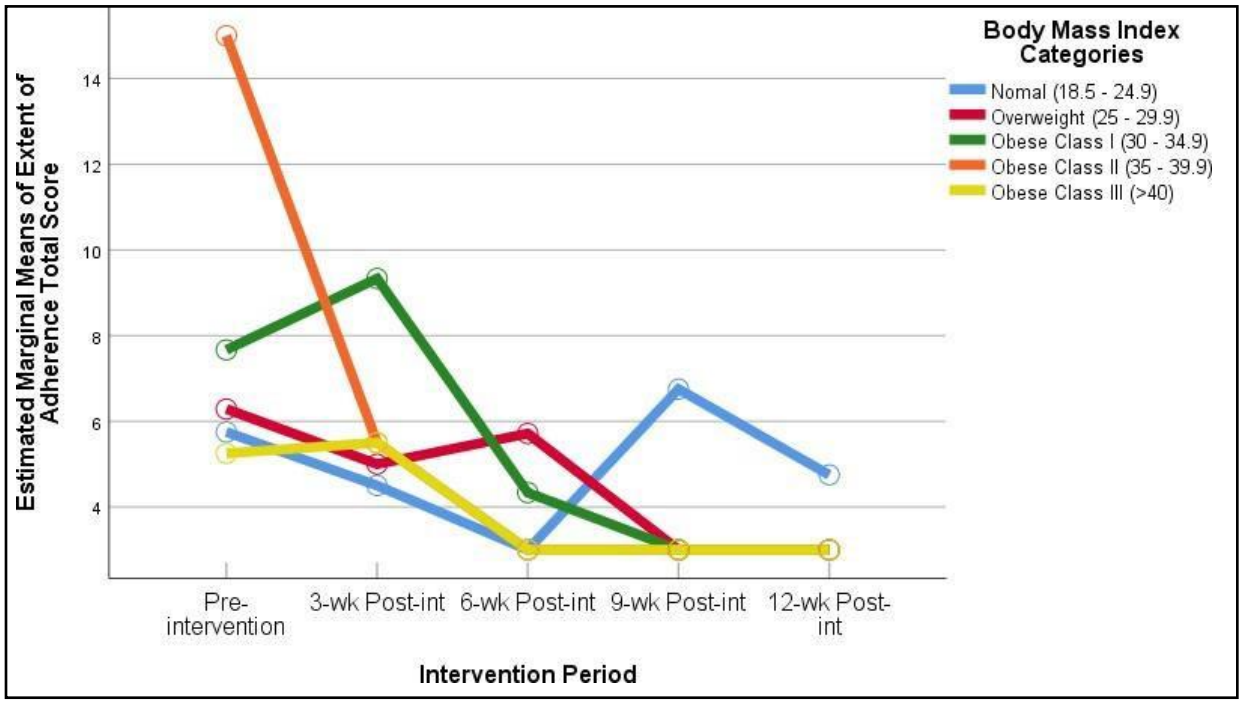

Figure 6:

Participants' mean extent of adherence score versus their body mass index

Table 11:

Tests of between-subject effects on participants' extent of adherence total scores versus SIMPLE protocol intervention effect on their body mass index

Tests of Between-Subjects Effects

Dependent Variable: Extent of Adherence Total Score

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Parameter	Observed Power[b]
Corrected Model	458.590[a]	24	19.108	2.494	0.002	0.461	59.851	0.996
Intercept	1909.614	1	1909.614	249.224	0.000	0.781	249.224	1.000
Intervention	248.031	4	62.008	8.093	0.000	0.316	32.371	0.997
BMI	32.028	4	8.007	1.045	0.390	0.056	4.180	0.313
Intervention * BMI	245.767	16	15.360	2.005	0.025	0.314	32.075	0.935
Error	536.357	70	7.662					
Total	3271	95						
Corrected Total	994.947	94						

a R Squared = .461 (Adjusted R Squared = .276)

b Computed using alpha = .05

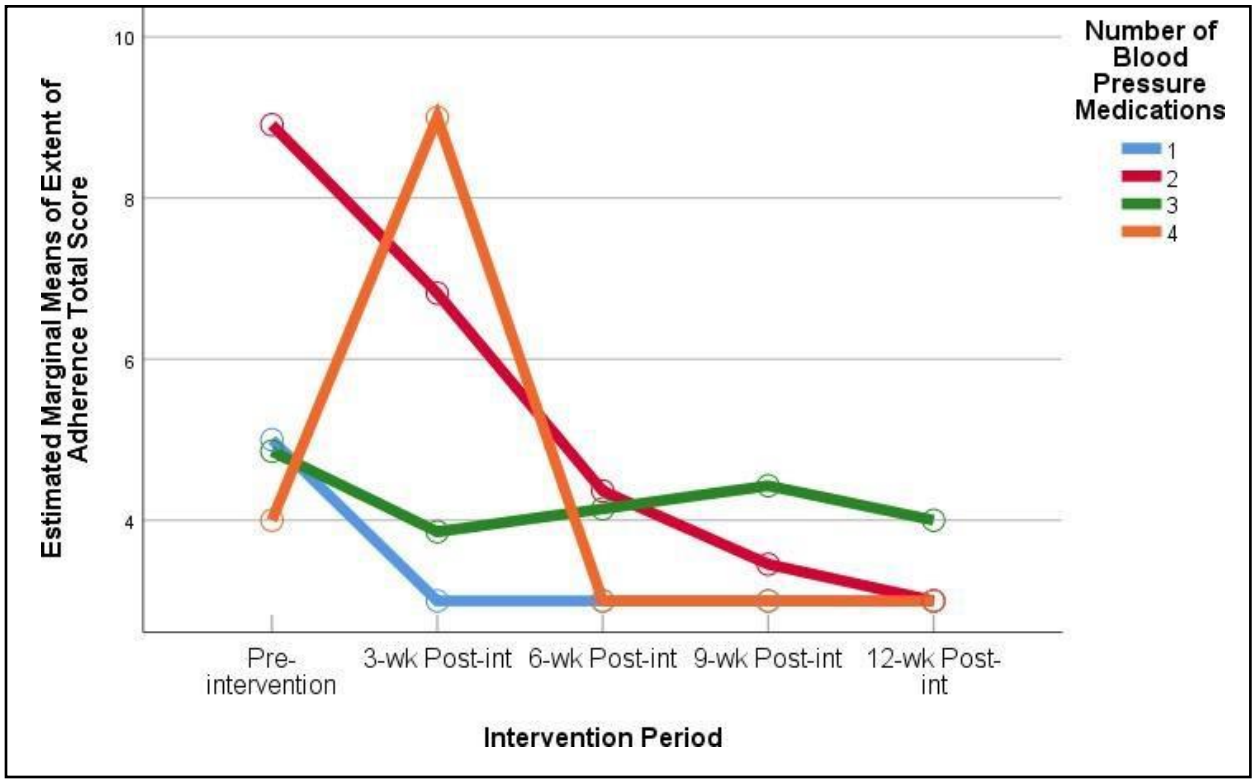

Figure 7:

Participants' mean extent of adherence score vs. their number of blood pressure medication(s)

Table 12:

Tests of between-subject effects on participants' extent of adherence total scores versus SIMPLE protocol intervention effect on their number of blood pressure medication(s)

Tests of Between-Subjects Effects

Dependent Variable: Extent of Adherence Total Score

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	340.623[a]	19	17.928	2.120	0.011	0.338	40.277	0.972
Intercept	674.513	1	674.513	79.758	0.000	0.502	79.758	1.000
Intervention	43.265	4	10.816	1.279	0.285	0.061	5.116	0.383
Num_BPMed	34.886	3	11.629	1.375	0.257	0.050	4.125	0.352
Intervention * Num_BPMed	117.944	12	9.829	1.162	0.325	0.150	13.946	0.614
Error	668.104	79	8.457					
Total	3307.000	99						
Corrected Total	1008.727	98						

a R Squared = .338 (Adjusted R Squared = .178)

b Computed using alpha = .05

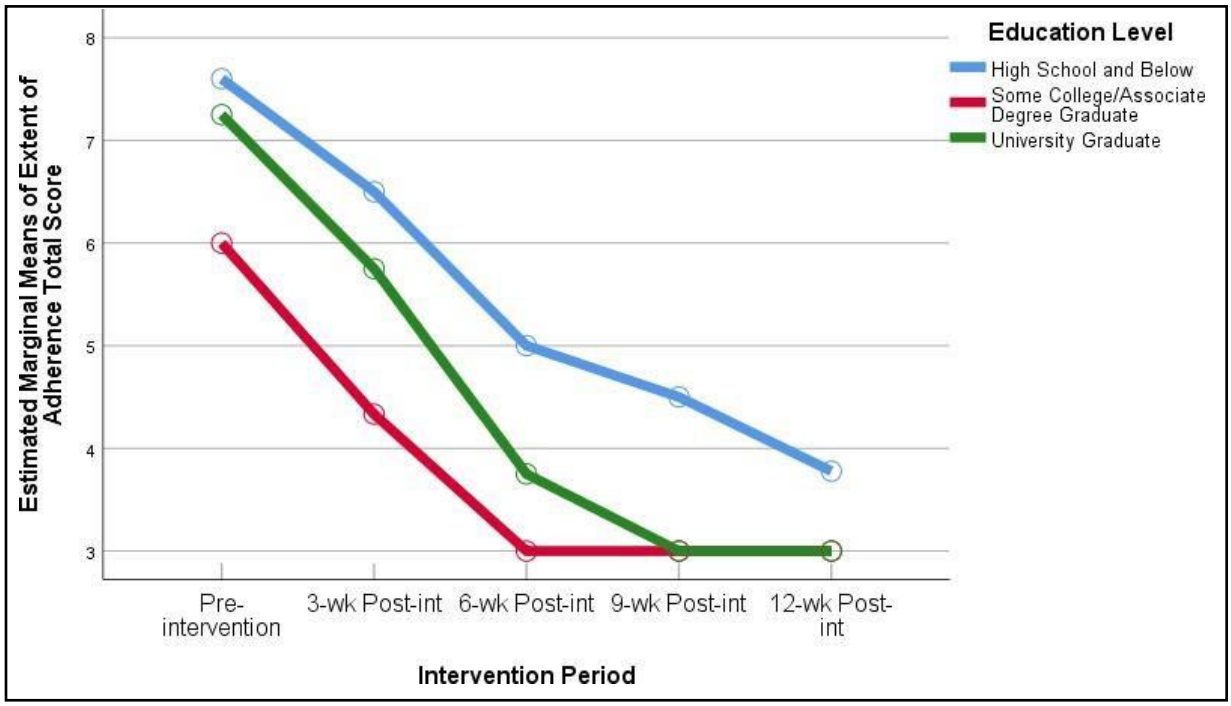

Figure 8:

Participants' mean extent of adherence score versus their educational level

Table 13:

Tests of between-subject effects on participants' extent of adherence total scores versus SIMPLE protocol intervention effect on their educational level

Tests of Between-Subjects Effects								
Dependent Variable: Extent of Adherence Total Score								
Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	244.188[a]	14	17.442	1.916	0.036	0.242	26.829	0.907
Intercept	1859.684	1	1859.684	204.324	0.000	0.709	204.324	1.000
Intervention	170.942	4	42.735	4.695	0.002	0.183	18.781	0.940
Education	49.706	2	24.853	2.731	0.071	0.061	5.461	0.526
Intervention * Education	7.213	8	0.902	0.099	0.999	0.009	0.792	0.076
Error	764.539	84	9.102					
Total	3307.000	99						
Corrected Total	1008.727	98						
a R Squared = .242 (Adjusted R Squared = .116)								
b Computed using alpha = .05								

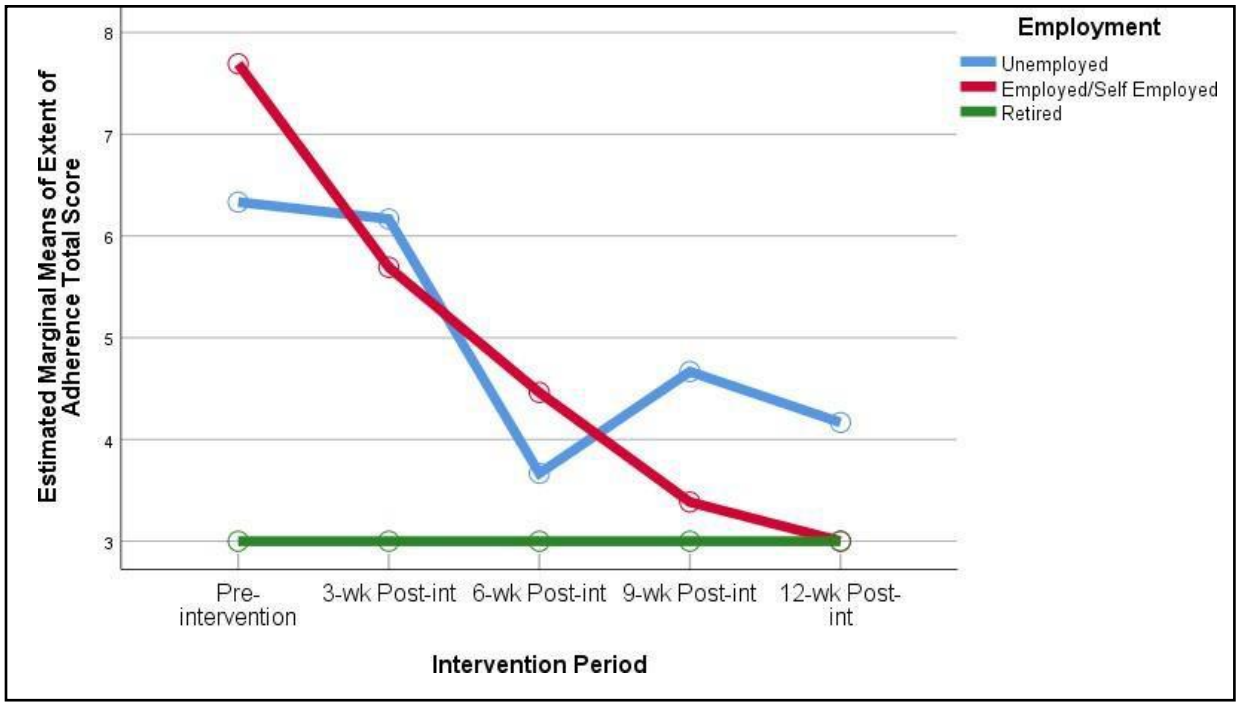

Figure 9:

Participants' mean extent of adherence score versus their employment status

Table 14:

Tests of between-subject effects on participants' extent of adherence total scores versus SIMPLE protocol intervention effect on their employment status

Tests of Between-Subjects Effects

Dependent Variable: Extent of Adherence Total Score

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	237.214[a]	14	16.944	1.845	0.045	0.235	25.827	0.893
Intercept	662.814	1	662.814	72.165	0.000	0.462	72.165	1.000
Intervention	28.012	4	7.003	0.762	0.553	0.035	3.050	0.236
Employment	17.536	2	8.768	0.955	0.389	0.022	1.909	0.211
Intervention * Employment	32.783	8	4.098	0.446	0.890	0.041	3.569	0.196
Error	771.513	84	9.185					
Total	3307.000	99						
Corrected Total	1008.727	98						

a R Squared = .235 (Adjusted R Squared = .108)

b Computed using alpha = .05

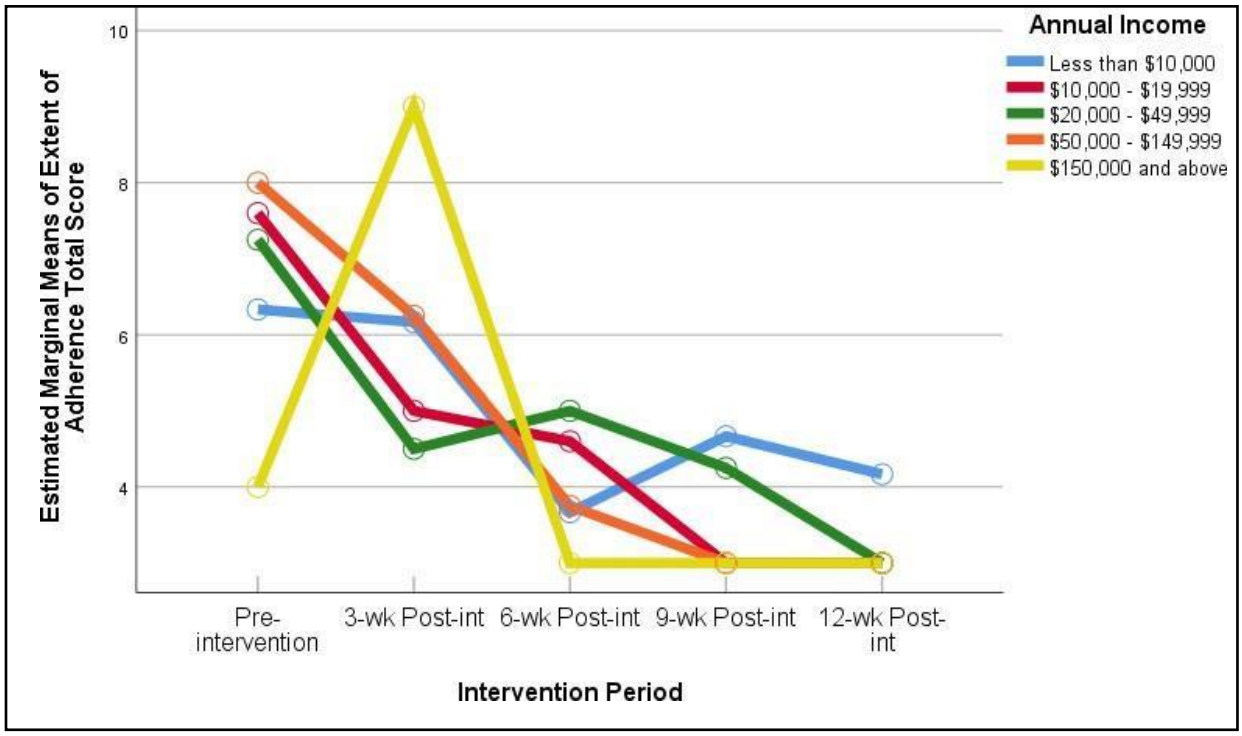

Figure 10:

Participants' mean extent of adherence score versus their annual income

Table 15:

Tests of between-subject effects on participants' extent of adherence total scores versus SIMPLE protocol intervention effect on their annual income

Tests of Between-Subjects Effects

Dependent Variable: Extent of Adherence Total Score

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Parameter	Observed Power[b]
Corrected Model	250.661[a]	24	10.444	1.020	0.454	0.248	24.469	0.725
Intercept	1488.942	1	1488.942	145.346	0.000	0.663	145.346	1.000
Intervention	130.873	4	32.718	3.194	0.018	0.147	12.775	0.802
Annual_Income	2.609	4	0.652	0.064	0.992	0.003	0.255	0.062
Intervention * Annual_Income	61.254	16	3.828	0.374	0.985	0.075	5.979	0.218
Error	758.067	74	10.244					
Total	3307.000	99						
Corrected Total	1008.727	98						

a R Squared = .248 (Adjusted R Squared = .005)

b Computed using alpha = .05

Reasons for Nonadherence

The second domain of the DOSE-Nonadherence questionnaire scale consisting of a 21-item questionnaire was the tool used to assess reasons for nonadherence (Cornelius et al., 2019; Voils et al., 2012). Figure 11 is a graphical presentation of the control chart for the pre-intervention DOSE-Nonadherence questionnaire scale scores for reasons for nonadherence, with each participant's total score, plotted on the graph. The chart shows the overall scores of the participants' self-reported answers for the 21-item DOSE-Nonadherence questionnaire for each

participant, which helped the team in understanding the variation in the participants' reasons for nonadherence. The central line or the average of the data was 32 points, with an upper control limit of 51 points and a lower control limit of 14 points. The control chart also helped the team in identifying opportunities for improvement. A perfect adherer with no adverse reason for nonadherence would have a total score of 21 points, and a poor adherer with adverse reasons for nonadherence would have an overall score of 105 points.

Hence, despite the plot showing the participants were not poor adherers, it also showed that up to 90% of the participants could still benefit from a planned intervention initiative. As evidenced in the participants' reported answers to the 21-item questionnaire, most of the participants (50-95%) selected "Not at all" for their answers to each of the questions. In comparison, the remaining 5-50% of them split their selected answers between the four remaining selection options (Table 16).

The mean scores, standard deviation, standard error mean, and summation of the scores of the 21-item questionnaire of the DOSE-Nonadherence scales' reasons for nonadherence was evaluated (Table 17).

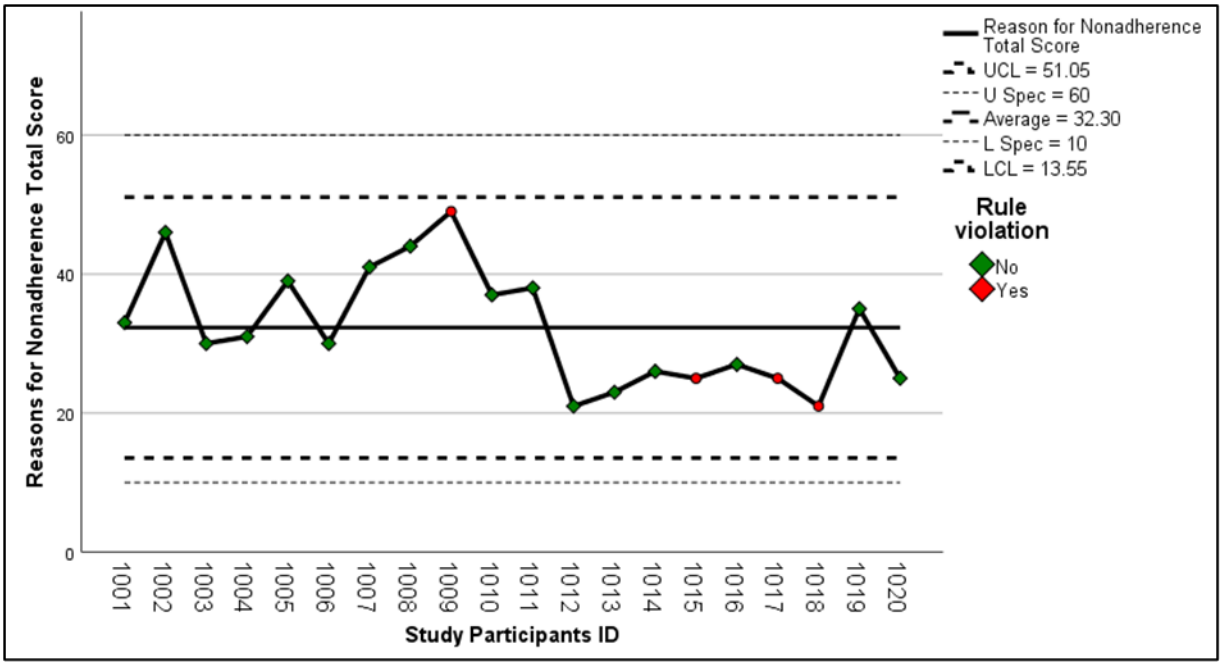

Figure 11:

Control chart for DOSE-Nonadherence 21-item questionnaire scale total scores on participants' reasons for nonadherence

Table 16:

Characteristics of participants' reasons for nonadherence at the pre-intervention period

DOSE-Nonadherence 21-items Questionnaire: Reasons for Nonadherence (Cornelius et al., 2019) - Questions	Frequencies of Participants Answers					
	Not at all	Somewhat not at all	Neutral	Somewhat very much	Very much	Total
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
1. I was busy	11 (55)	1 (5)	1 (5)	1 (5)	6 (30)	20 (100)
2. There was no one to remind me	10 (50)	4 (20)	1 (5)	3 (15)	2 (10)	20 (100)
3. They caused some side effect	18 (90)	0 (0)	1 (5)	0 (0)	1 (5)	20 (100)
4. I worried about taking them for the rest of my life	15 (75)	1 (5)	0 (0)	0 (0)	4 (20)	20 (100)
5. They cost a lot of money	15 (75)	1 (5)	1 (5)	1 (5)	2 (10)	20 (100)
6. I came home late	16 (80)	0 (0)	2 (10)	0 (0)	2 (10)	20 (100)
7. I did not have any symptoms of high BP	12 (60)	1 (5)	6 (30)	0 (0)	1 (5)	20 (100)
8. I was with friends of family members	17 (85)	0 (0)	0 (0)	0 (0)	3 (15)	20 (100)
9. I was in a public place	18 (90)	0 (0)	1 (5)	0 (0)	1 (5)	20 (100)
10. I was afraid of becoming dependent on them	17 (85)	1 (5)	0 (0)	0 (0)	2 (10)	20 (100)
11. I was afraid that they may affect my sexual performance	18 (90)	1 (5)	0 (0)	0 (0)	1 (5)	20 (100)
12. The time to take them was between my meals	17 (85)	0 (0)	1 (5)	0 (0)	2 (10)	20 (100)
13. I felt I did not need them	19 (95)	1 (5)	0 (0)	0 (0)	0 (0)	20 (100)
14. I was traveling	18 (90)	1 (5)	0 (0)	0 (0)	1 (5)	20 (100)
15. I was supposed to take them more than once a day	15 (75)	1 (5)	0 (0)	2 (10)	2 (10)	20 (100)
16. I had other medications to take	16 (80)	0 (0)	2 (10)	0 (0)	2 (10)	20 (100)
17. They make me want to urinate whil away from home	18 (90)	1 (5)	0 (0)	0 (0)	1 (5)	20 (100)
18. I ran out of medication	16 (80)	0 (0)	0 (0)	0 (0)	4 (20)	20 (100)
19. I was afraid the medication would interact with other medication I take	19 (95)	1 (5)	0 (0)	0 (0)	0 (0)	20 (100)
20. My blood pressure was too low	18 (90)	0 (0)	1 (5)	0 (0)	1 (5)	20 (100)
21. I was feeling too ill to take them	19 (95)	0 (0)	1 (5)	0 (0)	0 (0)	20 (100)

Table 17:

Mean scores of participants' reasons for nonadherence at the pre-intervention period

DOSE-Nonadherence Scale Questionnaire: Reasons for Nonadherence (Cornelius et al., 2019) - Questions	Mean	Std. Dev.	Std. Error Mean	Sum
1. I was busy	2.5	1.9	0.4	50
2. There was no one to remind me	2.2	1.5	0.3	43
3. They caused some side effect	1.3	1.0	0.2	26
4. I worried about taking them for the rest of my life	1.7	1.6	0.4	37
5. They cost a lot of money	1.7	1.4	0.3	34
6. I came home late	1.6	1.3	0.3	32
7. I did not have any symptoms of high BP	1.9	1.2	0.3	37
8. I was with friends of family members	1.6	1.5	0.3	32
9. I was in a public place	1.3	1.0	0.2	26
10. I was afraid of becoming dependent on them	1.5	1.2	0.3	29
11. I was afraid that they may affect my sexual performance	1.3	0.9	0.2	25
12. The time to take them was between my meals	1.5	1.3	0.3	30
13. I felt I did not need them	1.1	0.2	0.1	21
14. I was traveling	1.3	0.9	0.2	25
15. I was supposed to take them more than once a day	1.8	1.4	0.3	35
16. I had other medications to take	1.6	1.3	0.3	32
17. They make me want to urinate whil away from home	1.3	0.9	0.2	25
18. I ran out of medication	1.8	1.6	0.4	36
19. I was afraid the medication would interact with other medication I take	1.4	0.7	0.2	23
20. My blood pressure was too low	1.3	1.0	0.2	26
21. I was feeling too ill to take them	1.1	0.4	0.1	22
Total of Questions 1 - 21	32.3	8.5	1.9	646

The reported reasons for nonadherence with the top three highest total scores were: "*I was busy*" with a mean score of 2.5 (SD = 1.9) and total score = 50 points; "*There was no one to remind me*" with a mean score of 2.2 (SD = 1.5) and total score = 43 points; and "*I did not have any symptoms of high BP*" with a mean score of 1.9 (SD = 1.2) and total score of 37 points. The reported reasons for nonadherence with the three least total scores were "*I felt I did not need them*" with a mean score of 1.1 (SD = 0.2) and total score = 21 points, "*I was feeling too ill to take them*" with a mean score of 1.1 (SD = 0.4) and total score = 22 points, and "*I was afraid the medication would interact with other medications I take*" with a mean score of 1.2 (SD = 0.7) and total score of 23 points. However, summing up all the 21 questions, the mean score for the reasons for nonadherence was 32.3 (SD = 8.5). Please note that for each item, the highest "Sum" is 100 points (that is, 5 points multiplied by 20 participants), and the least "Sum" is 20 points. For all the 21 questions combined, the highest total "Sum" for all the participants is 2,100 points, and the least total "Sum" is 420 points (Table 17).

Systolic and Diastolic Blood Pressure

The control charts for the pre- and post-intervention systolic blood pressures and diastolic blood pressures were plotted in Figures 12 and 13, respectively. The figures showed that the participants were able to control their blood pressures from the pre-intervention period to the end of the three months' post-intervention period. The SIMPLE protocol interventions implemented helped the participants to reduce their systolic blood pressures from the third week of intervention, and their SBP reduction continued gradually to the sixth, ninth, and twelfth week of the project (Figure 12). The central line or the average of the data SBP control chart was 134.9 mmHg, with an upper control limit of 169.9 mmHg and a lower control limit of 100.0 mmHg. In the case of the participants' diastolic blood pressures, a slight reduction was noticed in the third week of intervention, but their DBP was slightly more improved at the ninth and twelfth weeks

(Figure 13). The central line or the average of the data DBP control chart was 77.5 mmHg, with an upper control limit of 100.6 mmHg and a lower control limit of 54.5 mmHg. The absence of any points above the upper control limit in the SBP and DBP control charts (Figures 12 and 13) suggests that the participants' blood pressures are well managed. Hence, the SIMPLE protocol intervention techniques implemented in this project were considered successful.

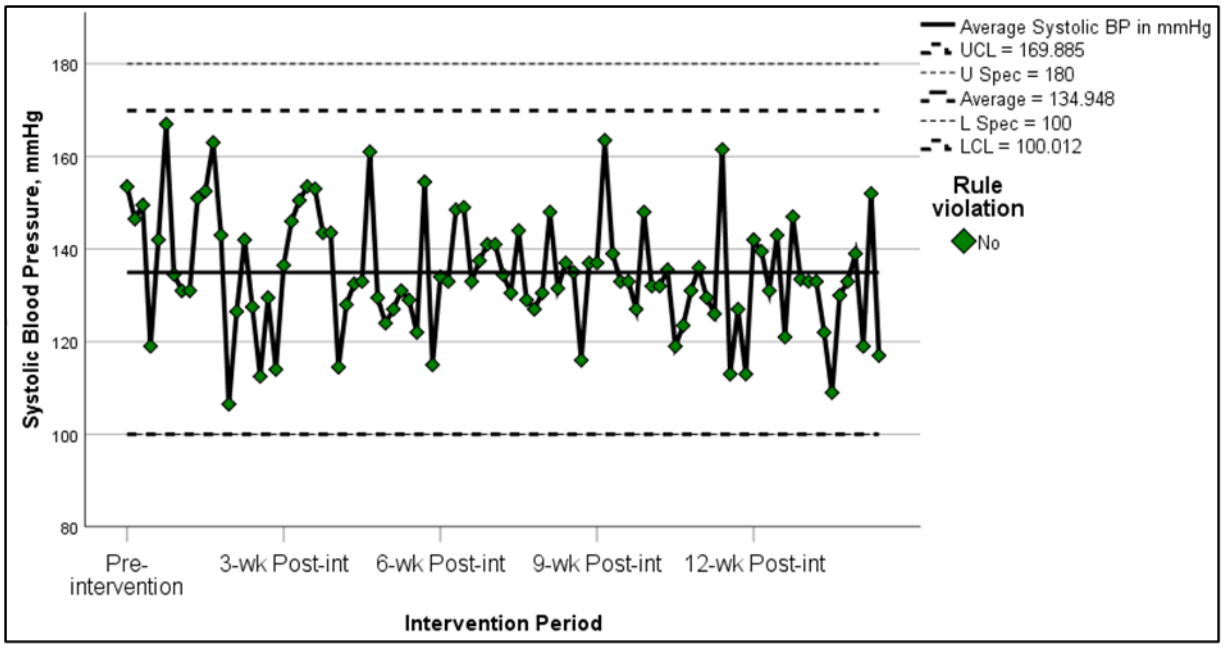

Figure 12:

Control chart for participants' systolic blood pressure outcomes

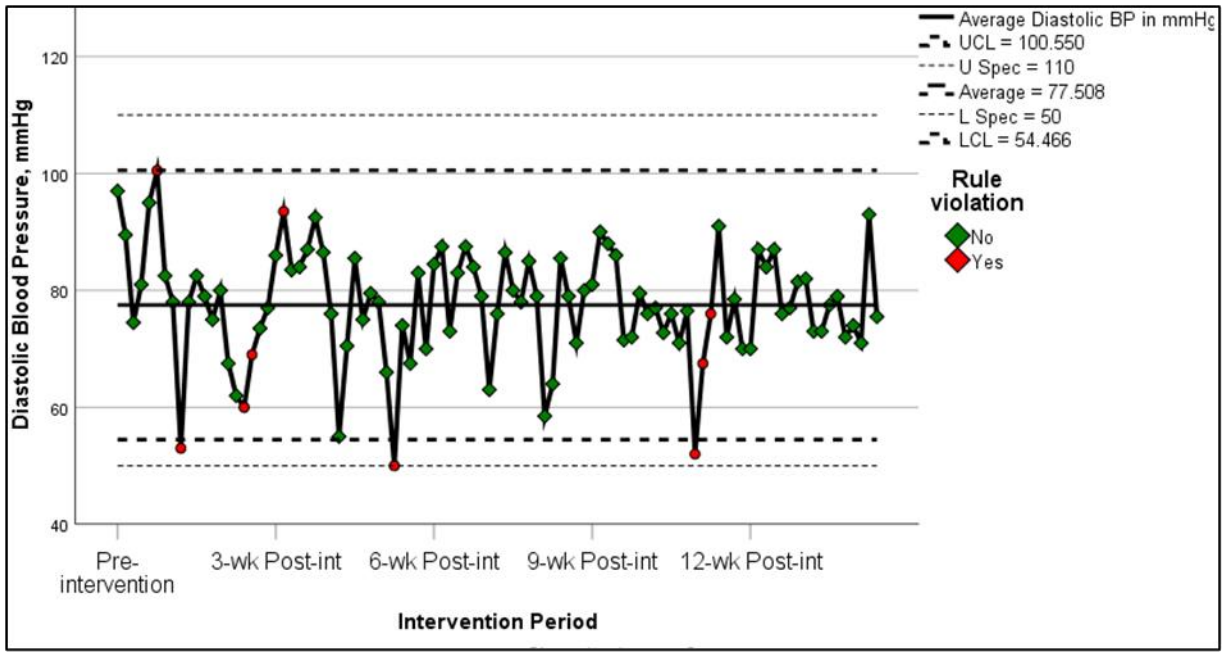

Figure 13:

Control chart for participants' diastolic blood pressure outcomes

The mean systolic blood pressure and diastolic blood pressure for all the pre- and post-intervention periods are presented in Table 18. Comparing the pre- and post-intervention blood pressures, it was evident that the participants' mean SBP was reduced from 137.1 (SD = 16.8) mmHg at pre-intervention to 130.7 (SD = 11.7) mmHg at the end of the three months' post-intervention period. For the DBP, there was no visible difference between the pre-intervention mean of 77.7 (SD = 12.1) mmHg compared to 77.9 (SD = 6.4) mmHg at the end of the three months' post-intervention period. Table 19 shows the BP control rates for pre- and post-interventions, concerning the current ACC/AHA guideline of a BP goal of SBP < 130 mmHg and DBP < 80 mmHg. In the pre-intervention period, only 25% of the participants were able to have controlled blood pressures. The participants' BP control rate increased to 37% at the end of the three months' post-intervention period. None of the menopausal women were able to get

their BP controlled at <130/80 mmHg throughout the study. However, 28% of the postmenopausal women had their BP controlled at the pre-intervention period, and this rate increased to 41% at the end of the three months of post-intervention.

Table 18:

Participants' mean systolic blood pressure and diastolic blood pressure outcomes at pre-intervention and post-intervention periods

Blood Pressures	Mean	Std. Deviation	Std. Error Mean
Systolic Blood Pressure, mmHg			
Pre-Intervention	137.1	16.8	3.7
Post-Intervention			
3-week	136.4	13.6	3.0
6-week	135.8	8.2	1.9
9-week	134.6	12.5	2.9
12-week	130.7	11.7	2.7
Diastolic Blood Pressure, mmHg			
Pre-Intervention	77.7	12.1	2.7
Post-Intervention			
3-week	77.2	11.5	2.6
6-week	78.1	8.7	2.0
9-week	76.6	9.0	2.1
12-week	77.9	6.4	1.5

Table 19:

Participants' blood pressure control rates at pre-intervention and post-intervention periods

Parameter	Period	Blood Pressure Control Rate (%)		
		All Participants	Menopausal Women	Post-menopausal Women
Blood Pressure Control Rate	Pre-Intervention	25	0	28
(BP Goal of:	Post-Intervention			
SBP < 130 mmHg and	3-week	40	0	44
DBP < 80 mmHg	6-week	16	0	18
Ref. ACC/AHA (ACC, 2017)	9-week	32	0	35
Guidelines)	12-week	37	0	41

The paired samples t-tests for the SBP and the DBP paired differences comparisons between the pre- and post-intervention periods are shown in Table 20. The results of the paired sample t-test show that the mean SBP differences were 0.7 (SD = 15.5) mmHg, 2.3 (SD = 15.5) mmHg, 3.5 (17.4) mmHg, and 7.3 (SD = 17.3) mmHg among the participants before the intervention and post-intervention 3-week, 6-week, 9-week and 12-week periods, respectively. For the DBP, the results of the paired sample t-test show that the mean differences were 0.6 (SD = 7.1) mmHg, -0.6 (SD = 7.9) mmHg, 0.9 (11.7) mmHg, and -0.4 (SD = 11.9) mmHg at pre-intervention and post-intervention 3-week, 6-week, 9-week and 12-week periods, respectively. At the end of the three months' study period, the SIMPLE protocol interventions did not result in a statistically significant difference between mean of the participants' SBP at pre-intervention versus the post-intervention periods (mean difference = 7.3 mmHg, SD = 17.3 mmHg, SEM = 4.0 mmHg, 95% CI of the difference = -1.0 – 15.7, t = 1.839, df =18, p = 0.082). Likewise, there were no statistically significant differences between the mean of the participants' DBP at pre-

intervention versus post-intervention periods (mean difference = -0.4 mmHg, SD = 11.9 mmHg, SEM = 2.7 mmHg, 95% CI of the difference = -6.1 – 5.3, t = -0.147, df =18, p = 0.887).

Table 20:

Paired samples t-test for participants' mean systolic blood pressure and diastolic blood pressure outcome differences at pre-intervention versus post-intervention periods

	Paired Differences							
				95% CI of the Difference				
Variables	Mean	Std. Dev.	Std. Error Mean	Lower	Upper	t	df	p-value
Systolic Blood Pressure, mmHg								
Pre-intervention vs. 3-week Post-intervention	0.7	15.5	3.5	-6.5	8.0	0.209	19	0.836
Pre-intervention vs. 6-week Post-intervention	2.3	15.5	3.6	-5.2	9.7	0.637	18	0.532
Pre-intervention vs. 9-week Post-intervention	3.5	17.4	4.0	-4.9	11.9	0.875	18	0.393
Pre-intervention vs. 12-week Post-intervention	7.3	17.3	4.0	-1.0	15.7	1.839	18	0.082
Diastolic Blood Pressure, mmHg								
Pre-intervention vs. 3-week Post-intervention	0.6	7.1	1.6	-2.8	3.9	0.361	19	0.722
Pre-intervention vs. 6-week Post-intervention	-0.6	7.9	1.8	-4.4	3.3	-0.304	18	0.764
Pre-intervention vs. 9-week Post-intervention	0.9	11.7	2.7	-4.7	6.6	0.347	18	0.732
Pre-intervention vs. 12-week Post-intervention	-0.4	11.9	2.7	-6.1	5.3	-0.145	18	0.887

Two-way ANOVA was conducted to examine the effect of SIMPLE protocol intervention and the demographic characteristics such as menopausal status, age, race, marital status, body mass index, number of antihypertensive medication(s), educational level, employment status, and annual income on systolic blood pressure outcomes, respectively. The resulting plots are shown in Figures 14-22, respectively. The corresponding tests of subjects' effects for the nine sets of SBP analyses are presented in Tables 21-29, respectively. As shown in Tables 22, 25, and 26, the results of the two-way ANOVA showed that the effect of participants' age on their SBP outcomes ($F(3, 77) = 3.678$, $p < 0.05$), the effect of participants' BMI on their SBP outcomes ($F(4, 70) = 3.303$, $p < 0.05$), and the effect of participants' number of antihypertensive medication(s) on their SBP outcomes ($F(3, 77) = 8.618$, $p < 0.001$) were respectively statistically significant. Similarly, as shown in Tables 27 and 29, the results showed that the effect of participants' educational level on their SBP outcomes ($F(2, 82) = 5.374$, $p < 0.05$), and the effect of participants' annual income on their SBP outcomes ($F(4, 72) = 2.902$, $p < 0.05$), were also statistically significant. The plots showing how these five demographic characteristics related to SBP outcomes are shown in Figures 15, 18-20, and 22, respectively. As shown in Tables 21, the effect of participants' menopausal status on their SBP outcomes ($F(1, 87) = 1.055$, $p = 0.307$) was not statistically significant. Likewise, the effect of participants' race on their SBP outcomes ($F(2, 82) = 0.306$, $p = 0.737$), the effect of participants' marital status on their SBP outcomes ($F(3, 80) = 1.529$, $p = 0.213$), and the effect of participants' employment status on their SBP outcomes ($F(2, 82) = 0.621$, $p = 0.540$) were also not statistically significant. For the SIMPLE protocol interventions alone or with their interactions with any of the nine demographic characteristics on SBP, the results showed that none of them were statistically significant, as shown in Tables 21-29, respectively.

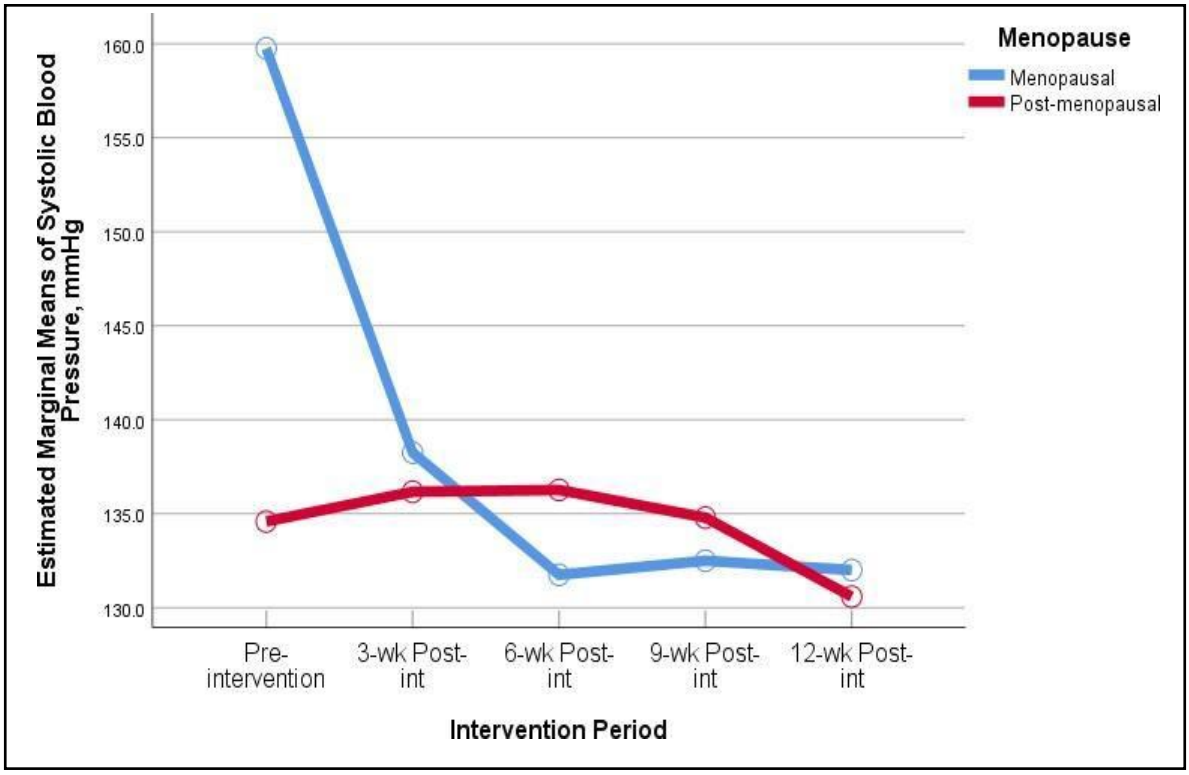

Figure 14:

Participants' mean systolic blood pressure outcomes versus their menopausal status

Table 21:

Tests of between-subject effects on participants' systolic blood pressure outcomes versus SIMPLE protocol intervention effect on their menopausal status

Tests of Between-Subjects Effects

Dependent Variable: Systolic Blood Pressure in mmHg

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	1684.036[a]	9	187.115	1.153	0.336	0.107	10.373	0.534
Intercept	670016	1	670016	4127	0.000	0.979	4127	1.000
Intervention	1118.402	4	279.600	1.722	0.152	0.073	6.889	0.507
Menopause	171.314	1	171.314	1.055	0.307	0.012	1.055	0.174
Intervention * Menopause	1024.299	4	256.075	1.577	0.187	0.068	6.310	0.468
Error	14123.706	87	162.341					
Total	1782283	97						
Corrected Total	15807.742	96						

a R Squared = .107 (Adjusted R Squared = .014)

b Computed using alpha = .05

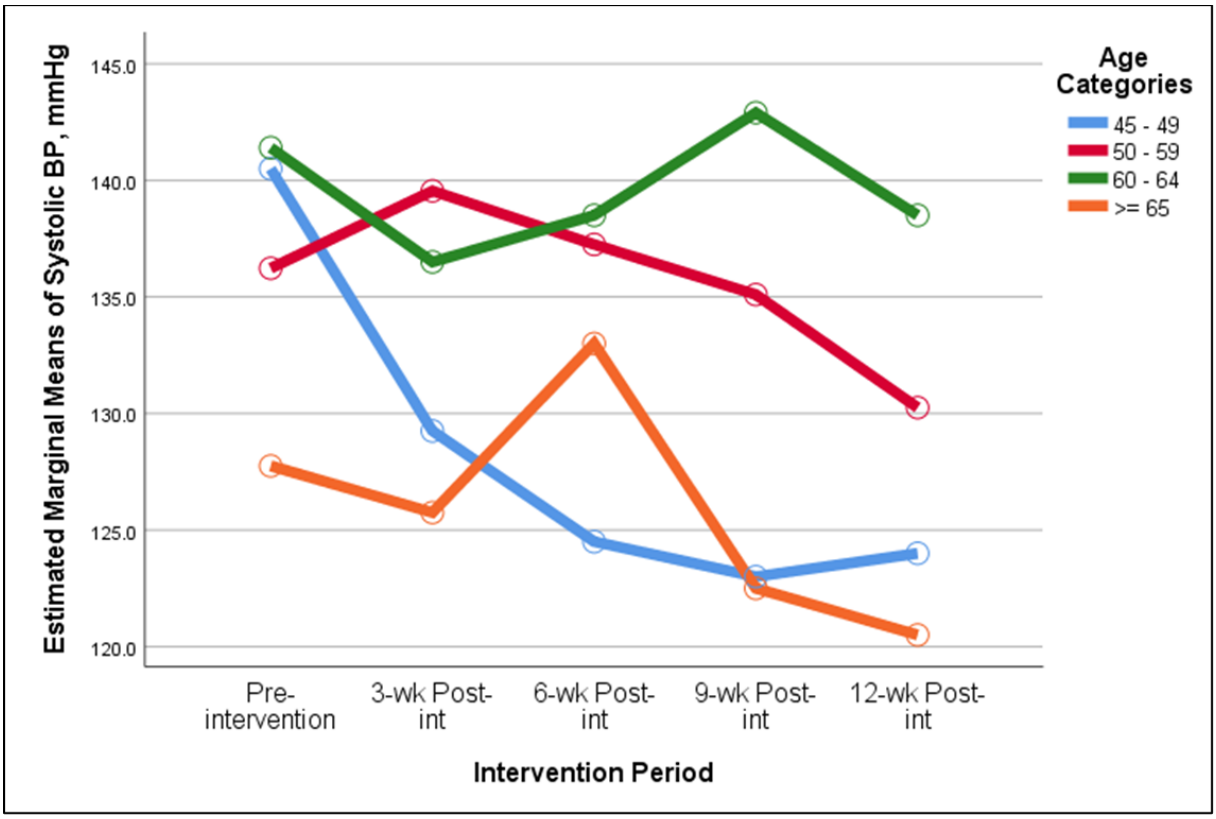

Figure 15:

Participants' mean systolic blood pressure outcomes versus their age

Table 22:

Tests of between-subject effects on participants' systolic blood pressure outcomes versus SIMPLE protocol intervention effect on their age

Tests of Between-Subjects Effects

Dependent Variable: Systolic Blood Pressure in mmHg

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	3064.908[a]	19	161.311	0.975	0.499	0.194	18.520	0.641
Intercept	1080900	1	1080900	6531	0.000	0.988	6531	1.000
Intervention	451.226	4	112.806	0.682	0.607	0.034	2.727	0.212
Age	1826	3	608.748	3.678	0.016	0.125	11.035	0.783
Intervention * Age	750.652	12	62.554	0.378	0.968	0.056	4.536	0.197
Error	12743	77	165.491					
Total	1782283	97						
Corrected Total	15808	96						

a R Squared = .194 (Adjusted R Squared = -.005)
b Computed using alpha = .05

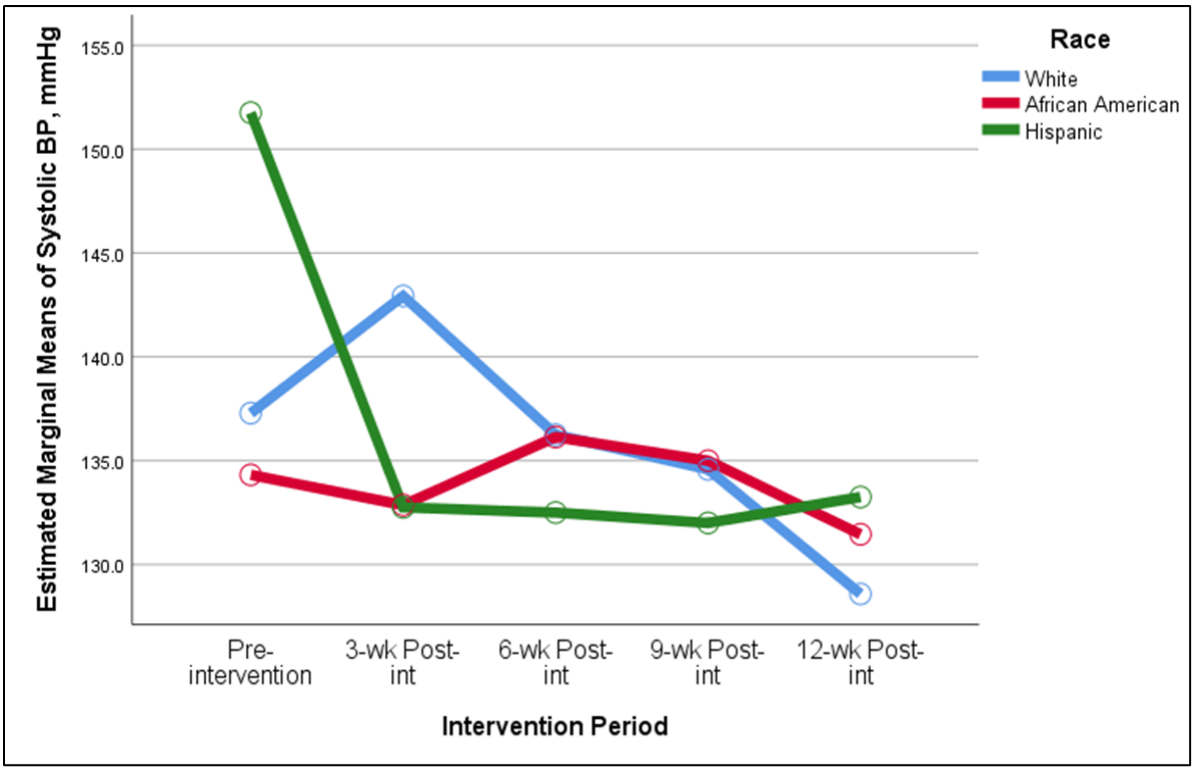

Figure 16:

Participants' mean systolic blood pressure outcomes versus their race

Table 23:

Tests of between-subject effects on participants' systolic blood pressure outcomes versus SIMPLE protocol intervention effect on their race

Tests of Between-Subjects Effects

Dependent Variable: Systolic Blood Pressure in mmHg

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	1549.478[a]	14	110.677	0.637	0.827	0.098	8.911	0.363
Intercept	1103564.18	1	1103564.2	6346.654	0.000	0.987	6346.654	1.000
Intervention	658.553	4	164.638	0.947	0.441	0.044	3.787	0.288
Race	106.542	2	53.271	0.306	0.737	0.007	0.613	0.097
Intervention * Race	945.448	8	118.181	0.680	0.708	0.062	5.437	0.294
Error	14258.264	82	173.881					
Total	1782283	97						
Corrected Total	15807.742	96						

a R Squared = .098 (Adjusted R Squared = -.056)
b Computed using alpha = .05

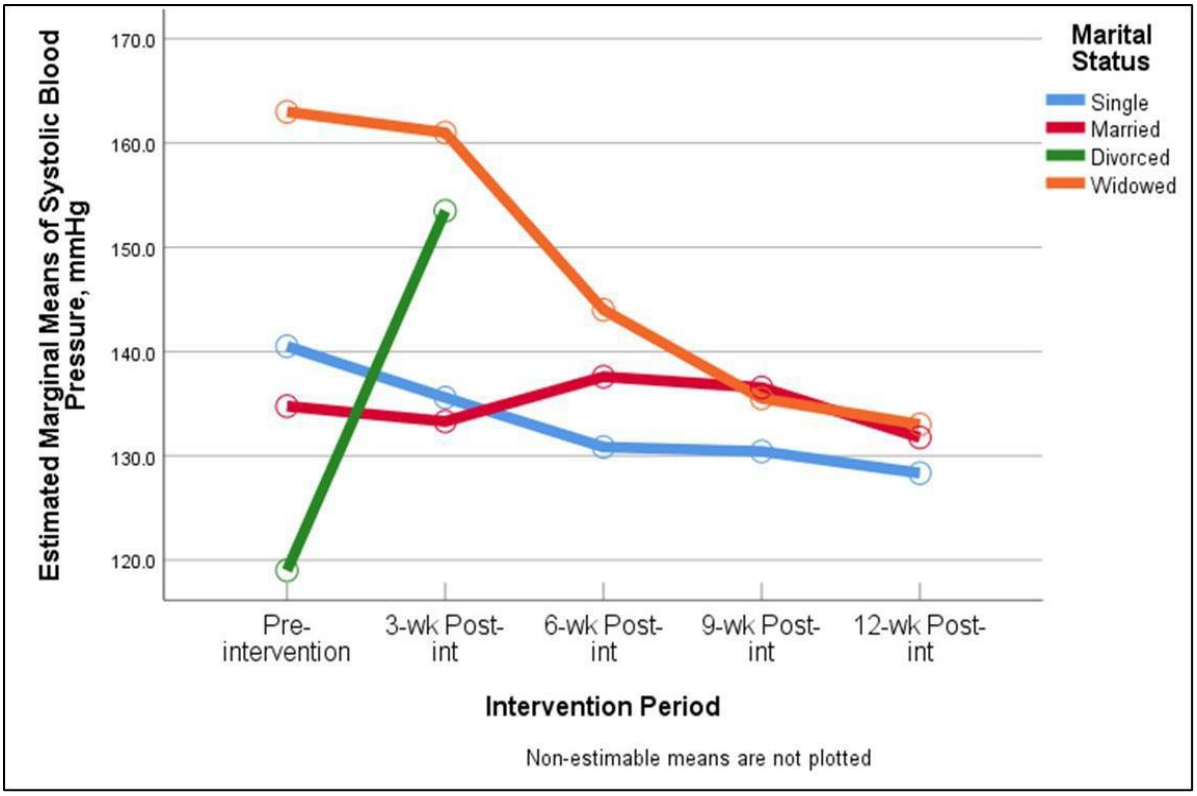

Figure 17:

Participants' mean systolic blood pressure outcomes versus their marital status

Table 24:

Tests of between-subject effects on participants' systolic blood pressure outcomes versus SIMPLE protocol intervention effect on their marital status

Tests of Between-Subjects Effects								
Dependent Variable: Systolic Blood Pressure in mmHg								
Source	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**	**Effect Size**	**Noncent. Para-meter**	**Observed Power[b]**
Corrected Model	1028.223[a]	16	64.264	0.656	0.828	0.116	10.493	0.399
Intercept	156931.606	1	156931.61	1601.530	0.000	0.952	1601.53	1.000
Intervention	64.619	4	16.155	0.165	0.956	0.008	0.659	0.083
Marital_Status	449.602	3	149.867	1.529	0.213	0.054	4.588	0.389
Intervention * Marital_Status	529.145	9	58.794	0.600	0.793	0.063	5.400	0.274
Error	7839.083	80	97.989					
Total	591589.813	97						
Corrected Total	8867.307	96						

a R Squared = .116 (Adjusted R Squared = -.061)

b Computed using alpha = .05

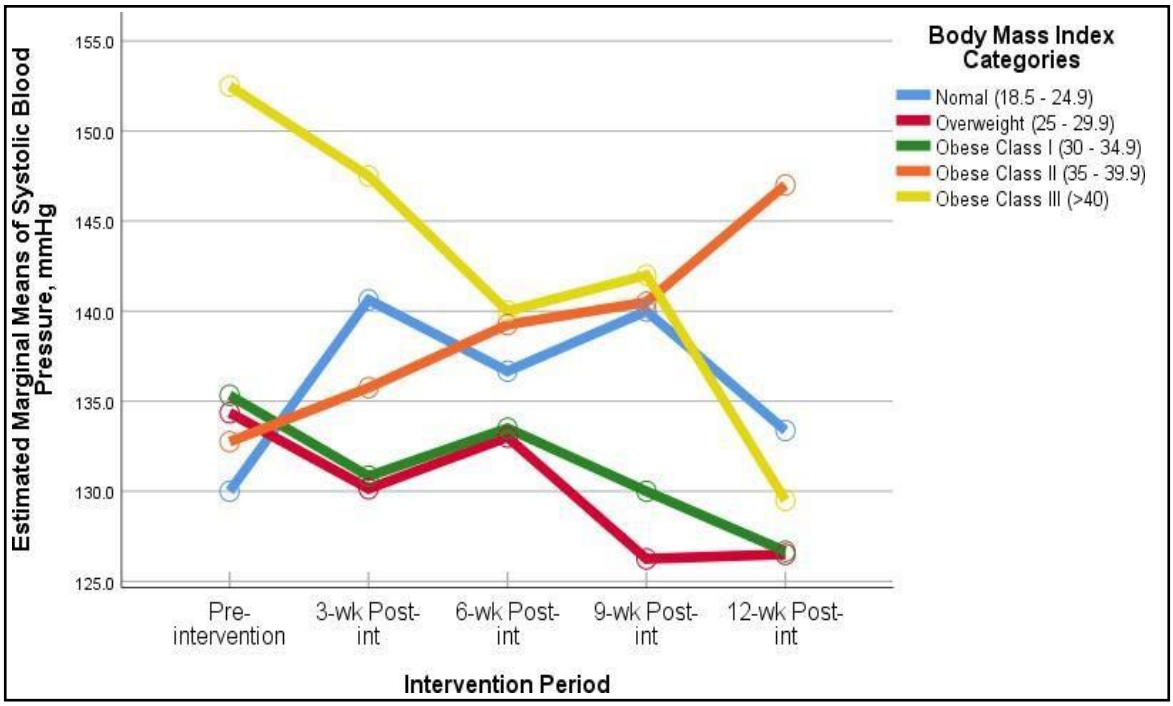

Figure 18:

Participants' mean systolic blood pressure outcomes versus their body mass index

Table 25:

Tests of between-subject effects on participants' systolic blood pressure outcomes versus SIMPLE protocol intervention effect on their body mass index

Tests of Between-Subjects Effects

Dependent Variable: Systolic Blood Pressure in mmHg

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	4264.220[a]	24	177.676	1.084	0.384	0.271	26.014	0.753
Intercept	1422964	1	1422964	8681	0.000	0.992	8681	1.000
Intervention	175.106	4	43.776	0.267	0.898	0.015	1.068	0.105
BMI	2165.488	4	541.372	3.303	0.015	0.159	13.211	0.815
Intervention * BMI	1467.163	16	91.698	0.559	0.903	0.113	8.950	0.329
Error	11474.506	70	163.922					
Total	1744145	95						
Corrected Total	15738.726	94						

a R Squared = .271 (Adjusted R Squared = .021)

b Computed using alpha = .05

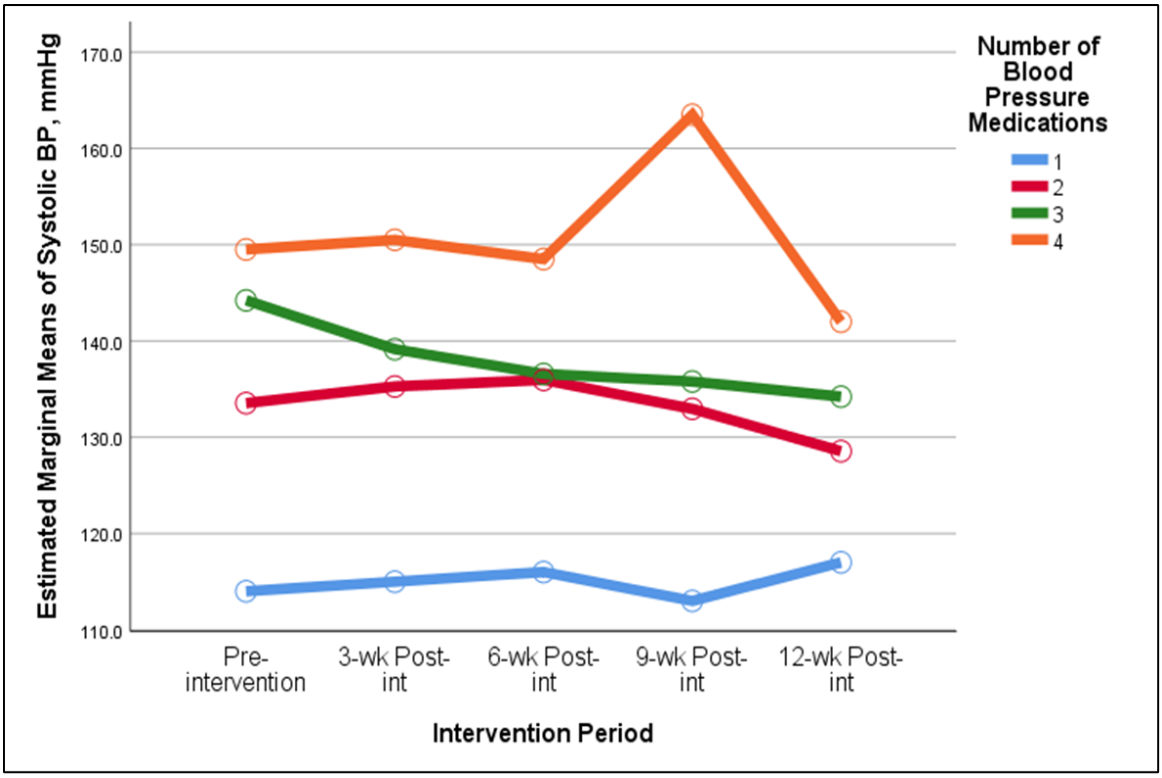

Figure 19

Participants' mean systolic blood pressure outcomes versus their number of blood pressure medication(s)

Table 26:

Tests of between-subject effects on participants' systolic blood pressure outcomes versus SIMPLE protocol intervention effect on their number of blood pressure medication(s)

Tests of Between-Subjects Effects

Dependent Variable: Systolic Blood Pressure in mmHg

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	4735.301[a]	19	249.226	1.733	0.048	0.300	32.930	0.923
Intercept	643999.169	1	643999.17	4478.501	0.000	0.983	4478.501	1.000
Intervention	145.662	4	36.415	0.253	0.907	0.013	1.013	0.103
Num_BPMed	3717.929	3	1239.310	8.618	0.000	0.251	25.855	0.992
Intervention * Num_BPMed	525.664	12	43.805	0.305	0.987	0.045	3.656	0.163
Error	11072.441	77	143.798					
Total	1782283	97						
Corrected Total	15807.742	96						

a R Squared = .300 (Adjusted R Squared = .127)

b Computed using alpha = .05

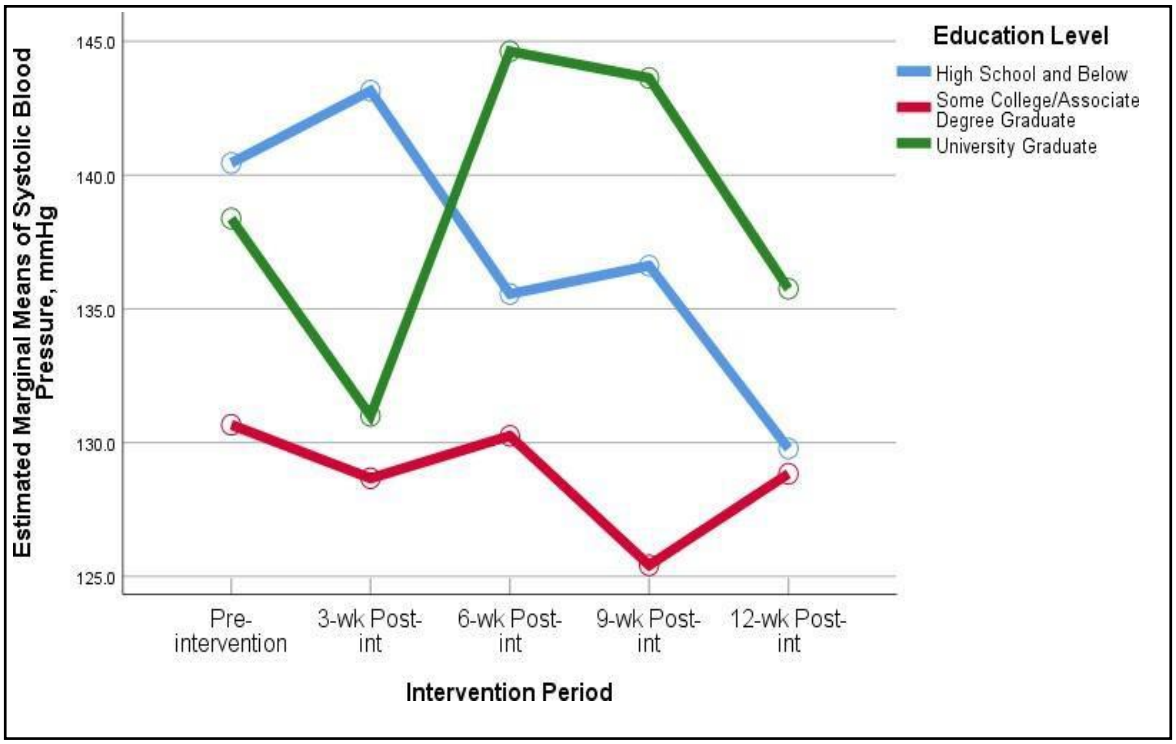

Figure 20:

Participants' mean systolic blood pressure outcomes versus their educational level

Table 27:

Tests of between-subject effects on participants' systolic blood pressure outcomes versus SIMPLE protocol intervention effect on their educational level

Tests of Between-Subjects Effects

Dependent Variable: Systolic Blood Pressure in mmHg

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Parameter	Observed Power[b]
Corrected Model	3280.430[a]	14	234.316	1.534	0.117	0.208	21.473	0.810
Intercept	1563642	1	1563642	10235	0.000	0.992	10235	1.000
Intervention	317.603	4	79.401	0.520	0.721	0.025	2.079	0.169
Education	1642.004	2	821.002	5.374	0.006	0.116	10.748	0.830
Intervention * Education	1124.521	8	140.565	0.920	0.504	0.082	7.361	0.400
Error	12527	82	152.772					
Total	1782283	97						
Corrected Total	15807.742	96						

a R Squared = .208 (Adjusted R Squared = .072)

b Computed using alpha = .05

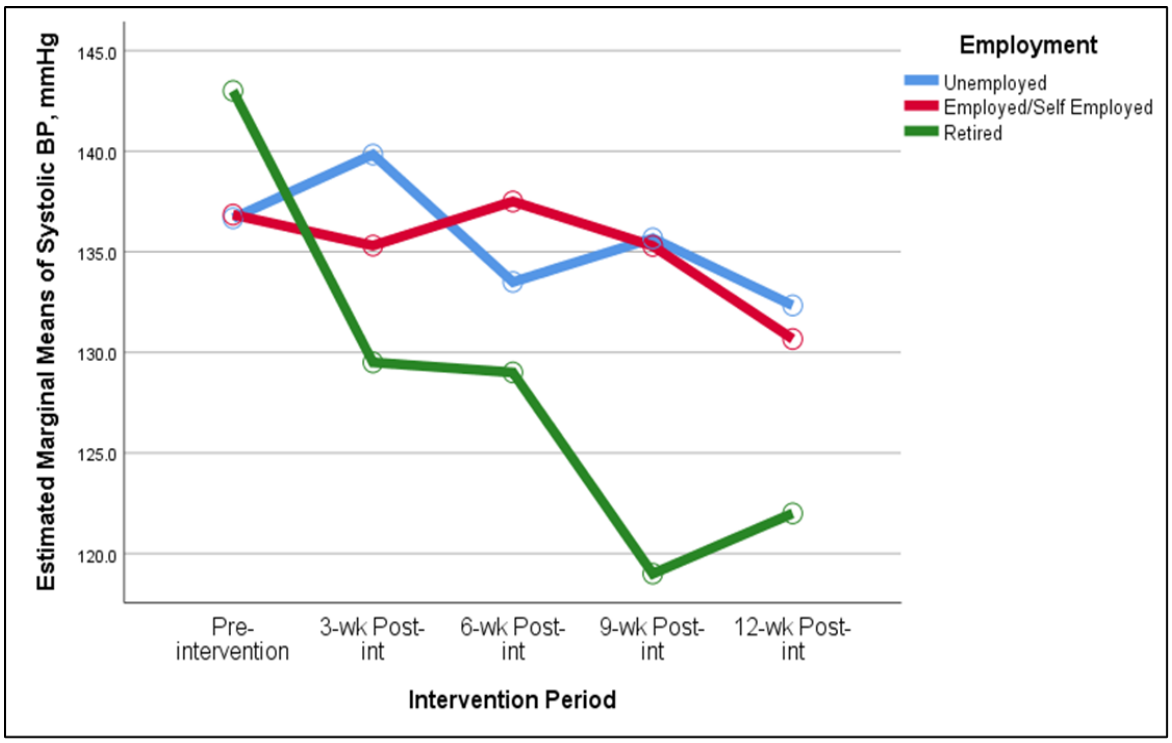

Figure 21:

Participants' mean systolic blood pressure outcomes versus their employment status

Table 28:

Tests of between-subject effects on participants' systolic blood pressure outcomes versus SIMPLE protocol intervention effect on their employment status

Tests of Between-Subjects Effects

Dependent Variable: Systolic Blood Pressure in mmHg

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	1117.552[a]	14	79.825	0.446	0.954	0.071	6.238	0.250
Intercept	638824.623	1	638825	3566	0.000	0.978	3566	1.000
Intervention	494.971	4	123.743	0.691	0.600	0.033	2.763	0.215
Employment	222.484	2	111.242	0.621	0.540	0.015	1.242	0.150
Intervention * Employment	409.005	8	51.126	0.285	0.969	0.027	2.283	0.135
Error	14690.191	82	179.149					
Total	1782283	97						
Corrected Total	15807.742	96						

a R Squared = .071 (Adjusted R Squared = -.088)

b Computed using alpha = .05

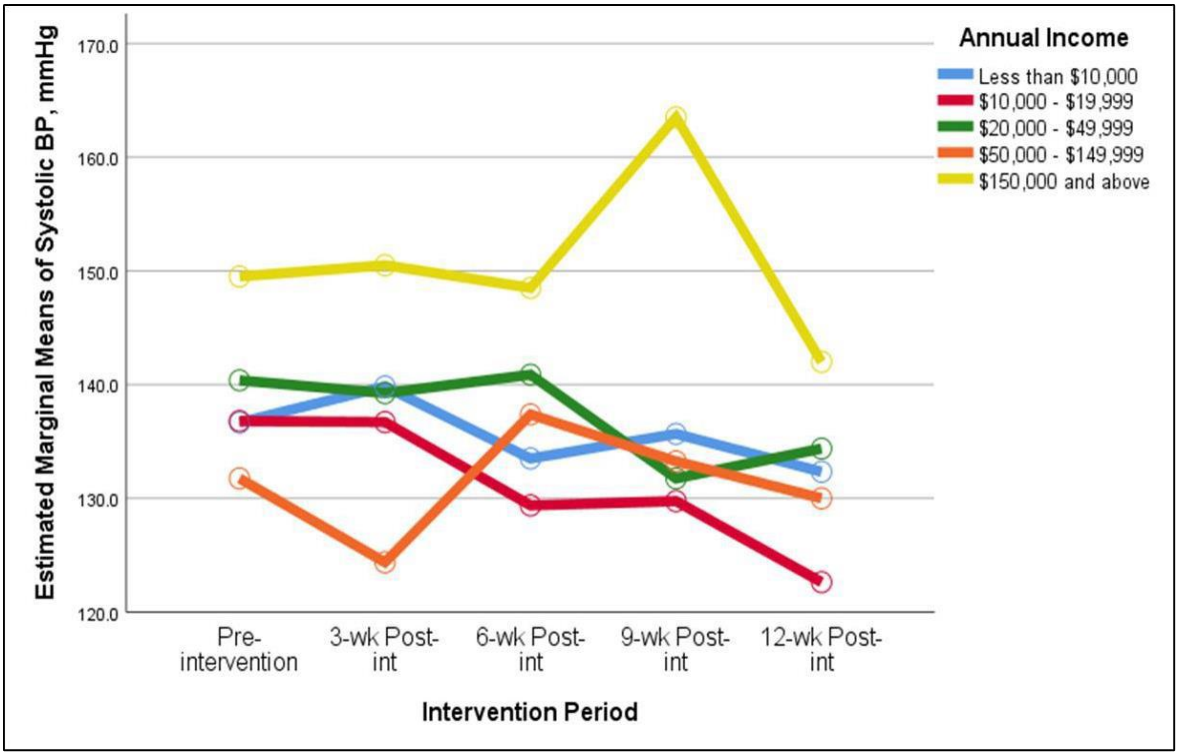

Figure 22:

Participants' mean systolic blood pressure outcomes versus their annual income

Table 29:

Tests of between-subject effects on participants' systolic blood pressure outcomes versus SIMPLE protocol intervention effect on their annual income

Tests of Between-Subjects Effects

Dependent Variable: Systolic Blood Pressure in mmHg

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	3587.746[a]	24	149.489	0.881	0.625	0.227	21.139	0.636
Intercept	1241039.15	1	1241039	7312.181	0.000	0.990	7312	1.000
Intervention	412.809	4	103.202	0.608	0.658	0.033	2.432	0.191
Annual_Income	1970	4	492.576	2.902	0.028	0.139	11.609	0.757
Intervention * Annual_Income	1182.7	16	73.919	0.436	0.967	0.088	6.968	0.254
Error	12219.996	72	169.722					
Total	1782283	97						
Corrected Total	15807.742	96						

a R Squared = .227 (Adjusted R Squared = -.031)

b Computed using alpha = .05

Furthermore, two-way ANOVA was conducted to examine the effect of SIMPLE protocol intervention and the demographic characteristics such as menopausal status, age, race, marital status, body mass index, number of antihypertensive medication(s), educational level, employment status, and annual income on diastolic blood pressure outcomes, respectively. The resulting plots for participants' DBP outcomes are shown in Figure 23-31, respectively. The corresponding tests of subjects' effects for the nine sets of DBP analysis are presented in Tables 30-38, respectively. As shown in Tables 30, 32, and 36, the results of the two-way ANOVA show that the effect of participants' menopause status on their DBP outcomes ($F(1, 87) = 9.789$, $p < 0.005$), the effect of participants' race on their DBP outcomes ($F(2, 82) = 3.218$, $p < 0.05$) and the effect of participants' educational level on their DBP outcomes ($F(2, 82) = 13.790$, $p < 0.001$) were respectively statistically significant. The plots showing how these three demographic characteristics relate to DBP outcomes are shown in Figures 23, 25, and 29, respectively. As shown in Tables 31, 33 and 34, the effect of participants' age on their DBP outcomes ($F(3, 77) = 2.173$, $p = 0.098$), the effect of participants' marital status on their DBP outcomes ($F(3, 80) = 1.529$, $p = 0.213$), and the effect of participants' BMI on their DBP outcomes ($F(4, 70) = 0.572$, $p = 0.684$) were not statistically significant. Regarding the SIMPLE protocol interventions alone or with their interactions with any of the nine demographic characteristics on DBP, the results show that none of them were statistically significant, as shown in Tables 30-38, respectively.

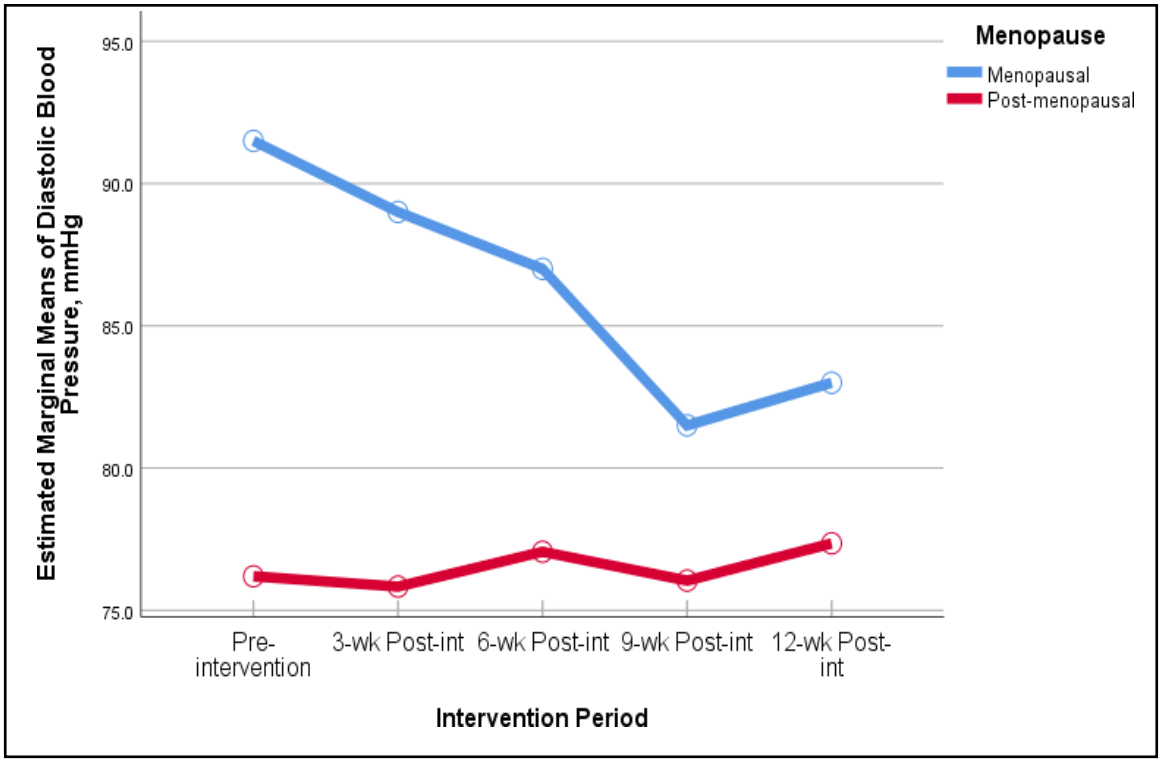

Figure 23:

Participants' mean diastolic blood pressure outcomes versus their menopausal status

Table 30:

Tests of between-subject effects on participants' diastolic blood pressure outcomes versus SIMPLE protocol intervention effect on their menopausal status

Tests of Between-Subjects Effects

Dependent Variable: Diastolic Blood Pressure in mmHg

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	1049.884[a]	9	116.654	1.298	0.250	0.118	11.684	0.596
Intercept	237978	1	237978	2648	0.000	0.968	2648	1.000
Intervention	113.448	4	28.362	0.316	0.867	0.014	1.263	0.118
Menopause	879.568	1	879.568	9.789	0.002	0.101	9.789	0.872
Intervention * Menopause	139.515	4	34.879	0.388	0.817	0.018	1.553	0.136
Error	7817.422	87	89.855					
Total	591590	97						
Corrected Total	8867.307	96						

a R Squared = .118 (Adjusted R Squared = .027)

b Computed using alpha = .05

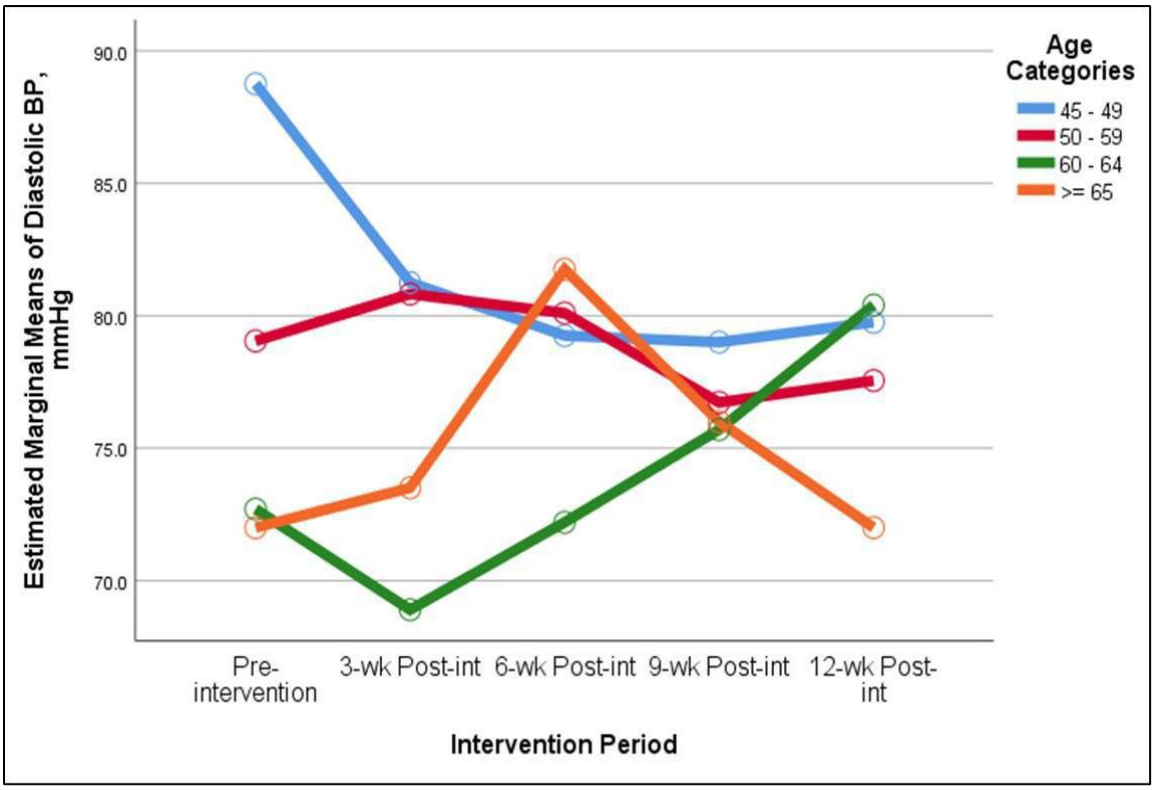

Figure 24:

Participants' mean diastolic blood pressure outcomes versus their age

Table 31:

Tests of between-subject effects on participants' diastolic blood pressure outcomes versus SIMPLE protocol intervention effect on their age

Tests of Between-Subjects Effects

Dependent Variable: Diastolic Blood Pressure in mmHg

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	1400.337[a]	19	73.702	0.760	0.745	0.158	14.440	0.503
Intercept	369404.313	1	369404	3809	0.000	0.980	3809	1.000
Intervention	41.012	4	10.253	0.106	0.980	0.005	0.423	0.071
Age	632.105	3	210.702	2.173	0.098	0.078	6.518	0.533
Intervention * Age	732.572	12	61.048	0.630	0.811	0.089	7.554	0.330
Error	7466.97	77	96.974					
Total	591589.813	97						
Corrected Total	8867.307	96						

a R Squared = .158 (Adjusted R Squared = -.050)

b Computed using alpha = .05

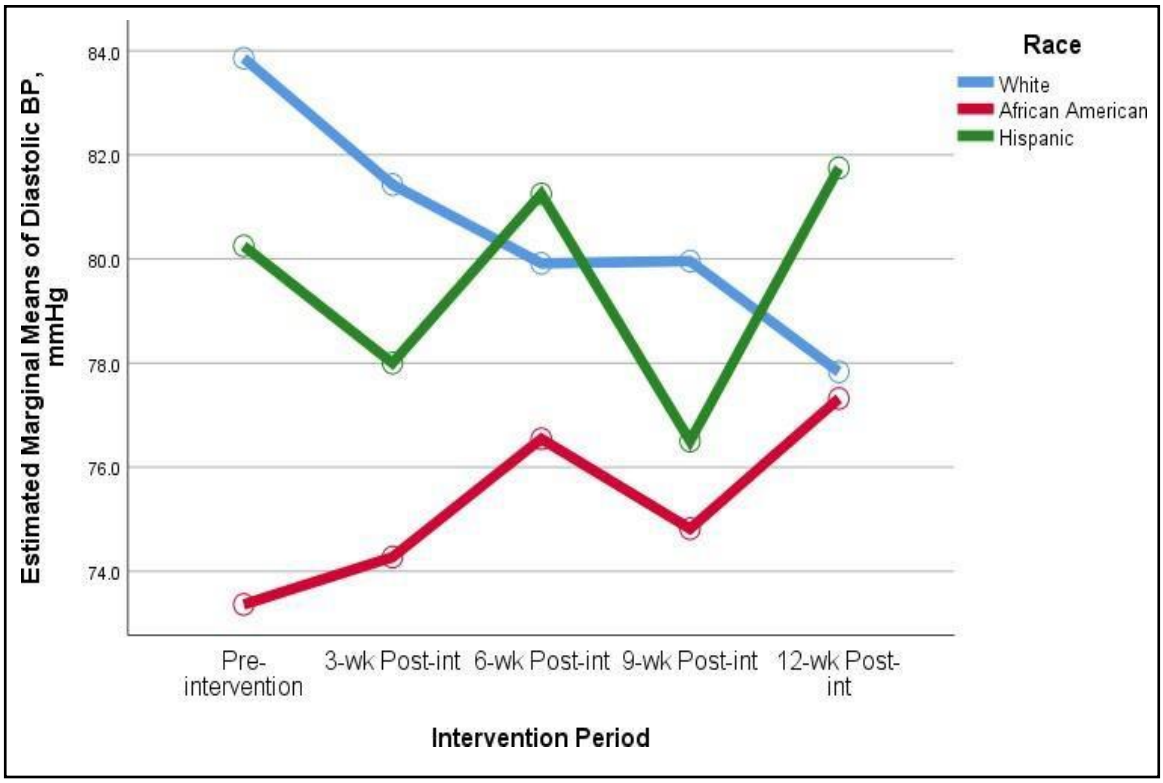

Figure 25:

Participants' mean diastolic blood pressure outcomes versus their race

Table 32:

Tests of between-subject effects on participants' diastolic blood pressure outcomes versus SIMPLE protocol intervention effect on their race

Tests of Between-Subjects Effects

Dependent Variable: Diastolic Blood Pressure in mmHg

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Parameter	Observed Power[b]
Corrected Model	937.039[a]	14	66.931	0.692	0.776	0.106	9.689	0.397
Intercept	370422	1	370422	3830	0.000	0.979	3830.215	1.000
Intervention	42.252	4	10.563	0.109	0.979	0.005	0.437	0.071
Race	622.478	2	311.239	3.218	0.045	0.073	6.437	0.599
Intervention * Race	256.258	8	32.032	0.331	0.952	0.031	2.650	0.152
Error	7930.267	82	96.711					
Total	591590	97						
Corrected Total	8867.307	96						

a R Squared = .106 (Adjusted R Squared = -.047)

b Computed using alpha = .05

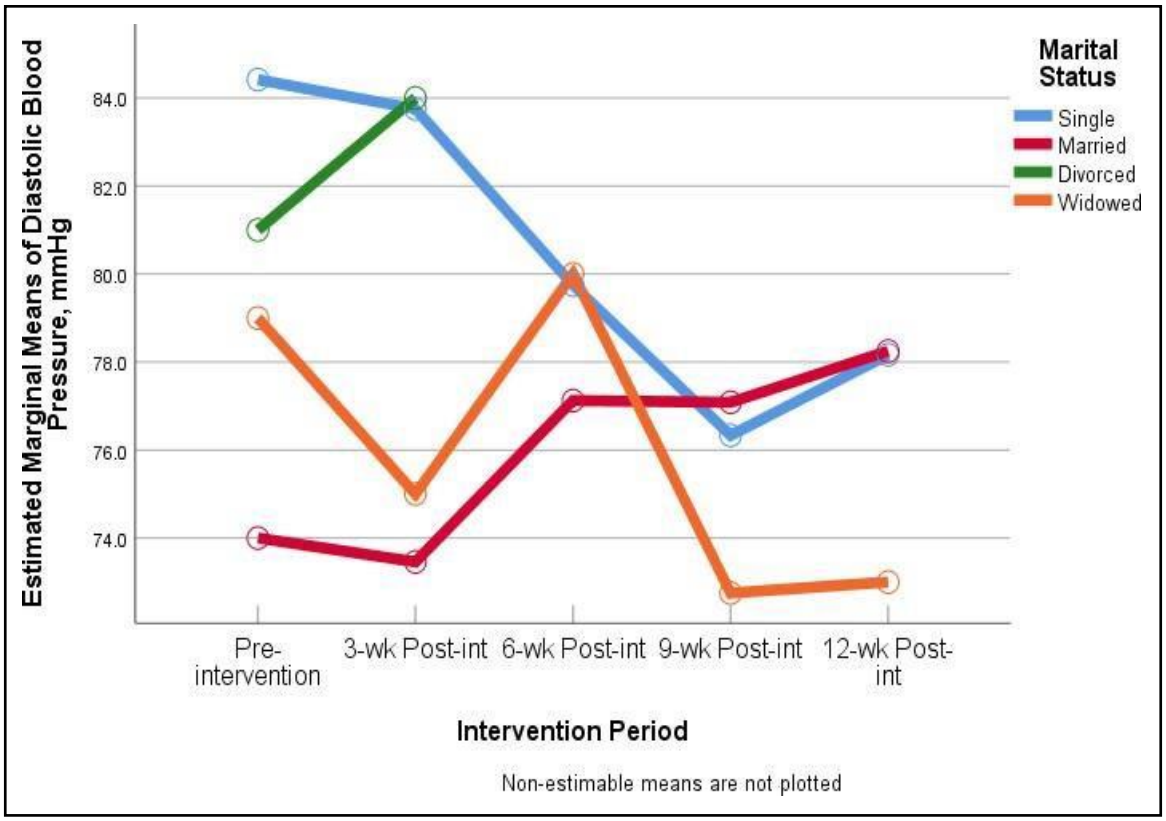

Figure 26:

Participants' mean diastolic blood pressure outcomes versus their marital status

Table 33:

Tests of between-subject effects on participants' diastolic blood pressure outcomes versus SIMPLE protocol intervention effect on their marital status

Tests of Between-Subjects Effects

Dependent Variable: Diastolic Blood Pressure in mmHg

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	1028.223[a]	16	64.264	0.656	0.828	0.116	10.493	0.399
Intercept	156932	1	156932	1602	0.000	0.952	1602	1.000
Intervention	64.619	4	16.155	0.165	0.956	0.008	0.659	0.083
Marital_Status	449.602	3	149.867	1.529	0.213	0.054	4.588	0.389
Intervention * Marital_Status	529.145	9	58.794	0.600	0.793	0.063	5.400	0.274
Error	7839	80	97.989					
Total	591590	97						
Corrected Total	8867	96						

a R Squared = .116 (Adjusted R Squared = -.061)

b Computed using alpha = .05

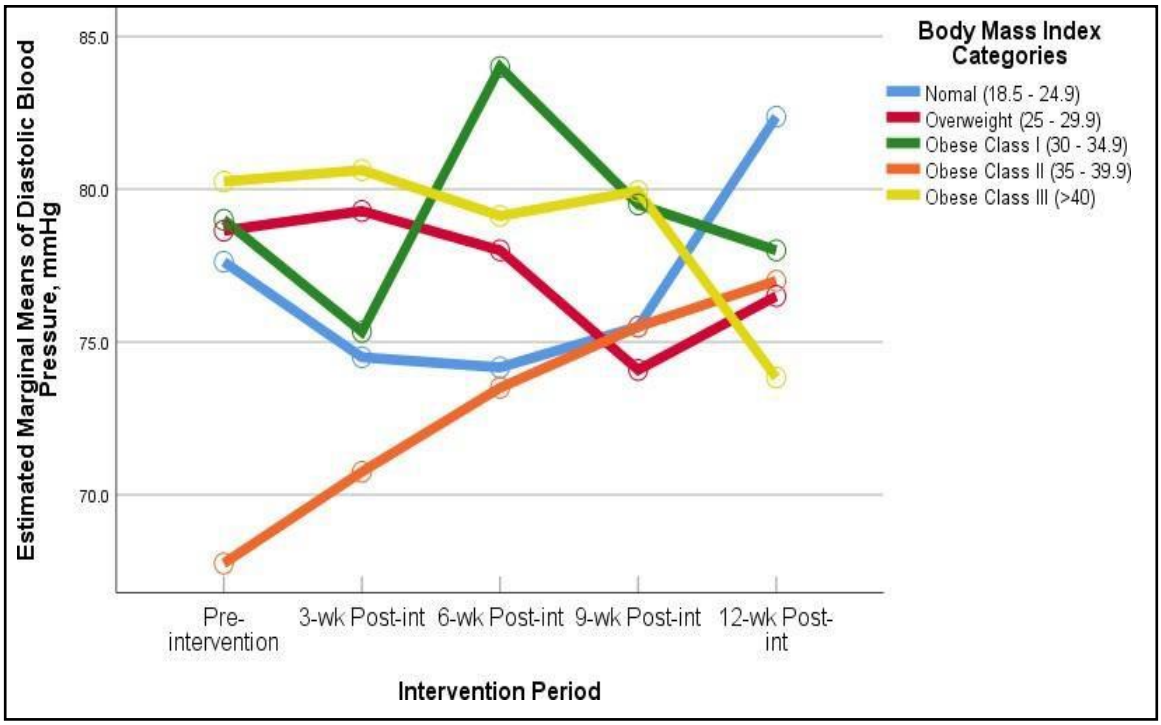

Figure 27:

Participants' mean diastolic blood pressure outcomes versus their body mass index

Table 34:

Tests of between-subject effects on participants' diastolic blood pressure outcomes versus SIMPLE protocol intervention effect on their body mass index

Tests of Between-Subjects Effects

Dependent Variable: Diastolic Blood Pressure in mmHg

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	915.331[a]	24	38.139	0.340	0.998	0.105	8.171	0.231
Intercept	457650	1	457650	4085	0.000	0.983	4085	1.000
Intervention	28.468	4	7.117	0.064	0.992	0.004	0.254	0.062
BMI	256.280	4	64.070	0.572	0.684	0.032	2.288	0.181
Intervention * BMI	570.863	16	35.679	0.319	0.993	0.068	5.096	0.186
Error	7841.291	70	112.018					
Total	578692	95						
Corrected Total	8756.622	94						

a R Squared = .105 (Adjusted R Squared = .202)

b Computed using alpha = .05

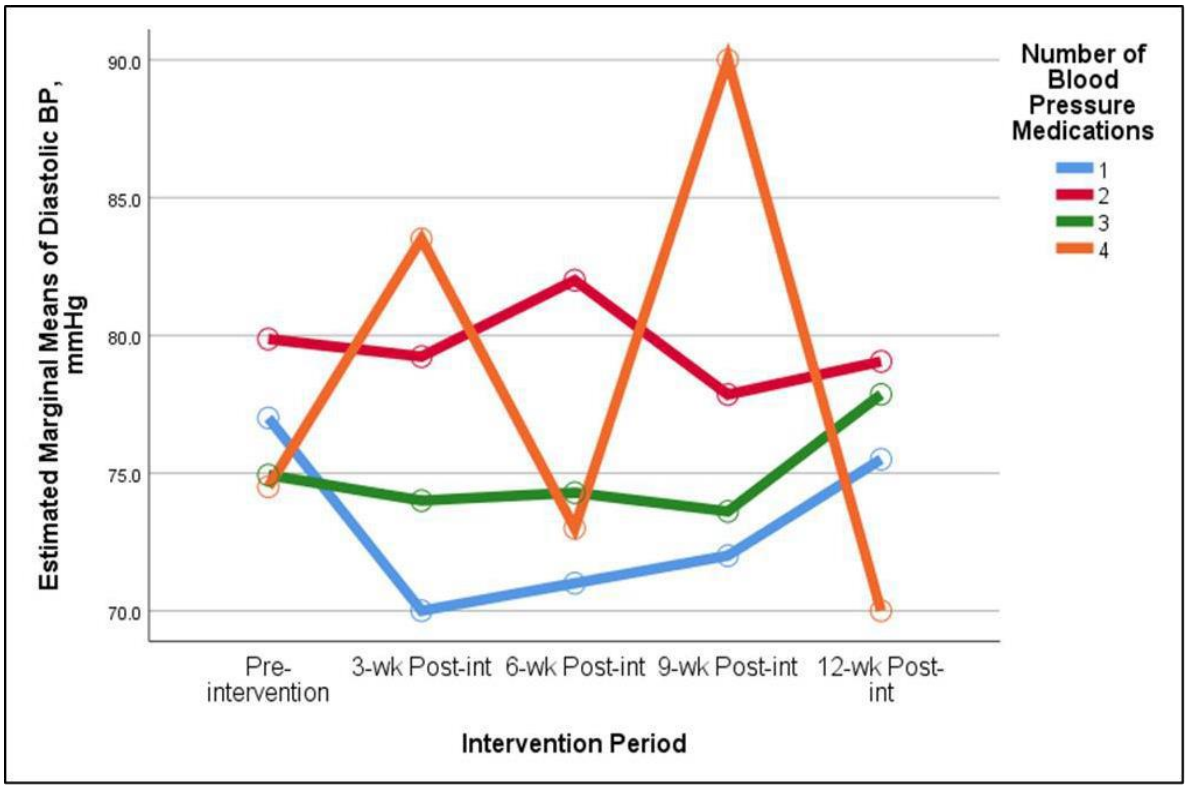

Figure 28:

Participants' mean diastolic blood pressure outcomes versus their number of blood pressure medication(s)

Table 35:

Tests of between-subject effects on participants' diastolic blood pressure outcomes versus SIMPLE protocol intervention effect on their number of blood pressure medication(s)

Tests of Between-Subjects Effects

Dependent Variable: Diastolic Blood Pressure in mmHg

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	1044.097[a]	19	54.952	0.541	0.934	0.118	10.277	0.350
Intercept	208855	1	208855	2056	0.000	0.964	2056	1.000
Intervention	45.322	4	11.331	0.112	0.978	0.006	0.446	0.072
Num_BPMed	557.815	3	185.938	1.830	0.149	0.067	5.490	0.458
Intervention * Num_BPMed	456.374	12	38.031	0.374	0.969	0.055	4.492	0.196
Error	7823.209	77	101.600					
Total	591590	97						
Corrected Total	8867.307	96						

a R Squared = .118 (Adjusted R Squared = -.100)

b Computed using alpha = .05

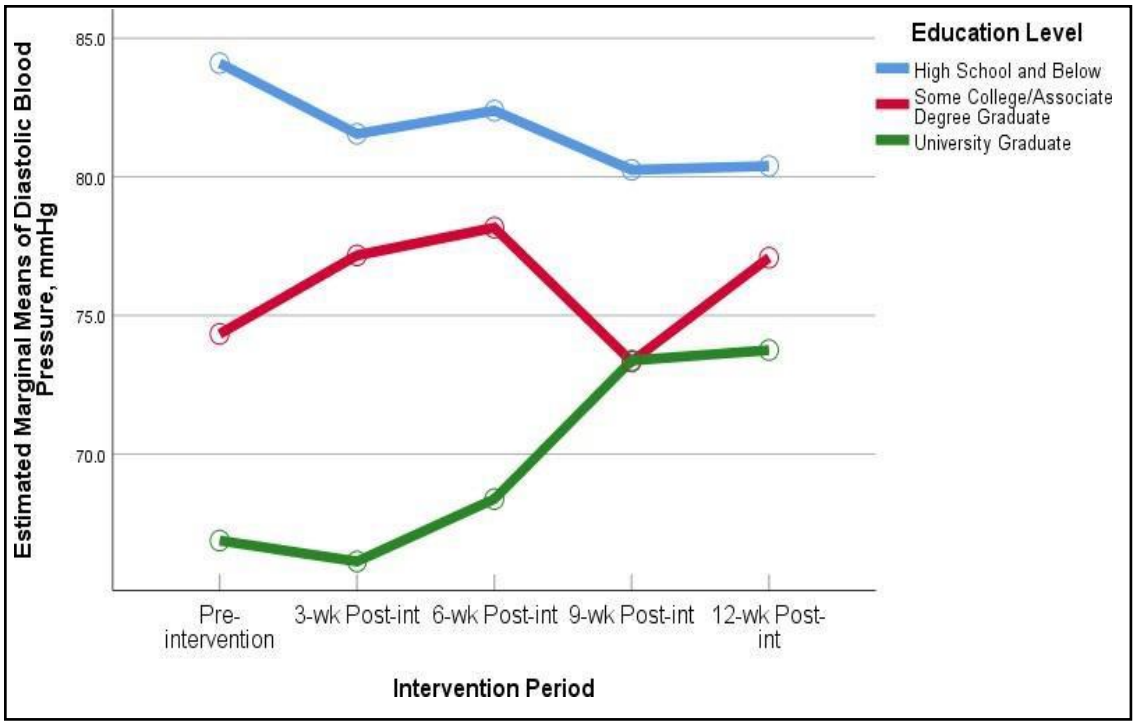

Figure 29:

Participants' mean diastolic blood pressure outcomes versus their educational level

Table 36:

Tests of between-subject effects on participants' diastolic blood pressure outcomes versus SIMPLE protocol intervention effect on their education level

Tests of Between-Subjects Effects

Dependent Variable: Diastolic Blood Pressure in mmHg

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	2553.112[a]	14	182.365	2.368	0.008	0.288	33.156	0.963
Intercept	494279	1	494279	6419	0.000	0.987	6419	1.000
Intervention	53.615	4	13.404	0.174	0.951	0.008	0.696	0.085
Education	2123.703	2	1061.852	13.790	0.000	0.252	27.580	0.998
Intervention * Education	377.241	8	47.155	0.612	0.765	0.056	4.899	0.265
Error	6314.194	82	77.002					
Total	591590	97						
Corrected Total	8867.307	96						

a R Squared = .288 (Adjusted R Squared = .166)

b Computed using alpha = .05

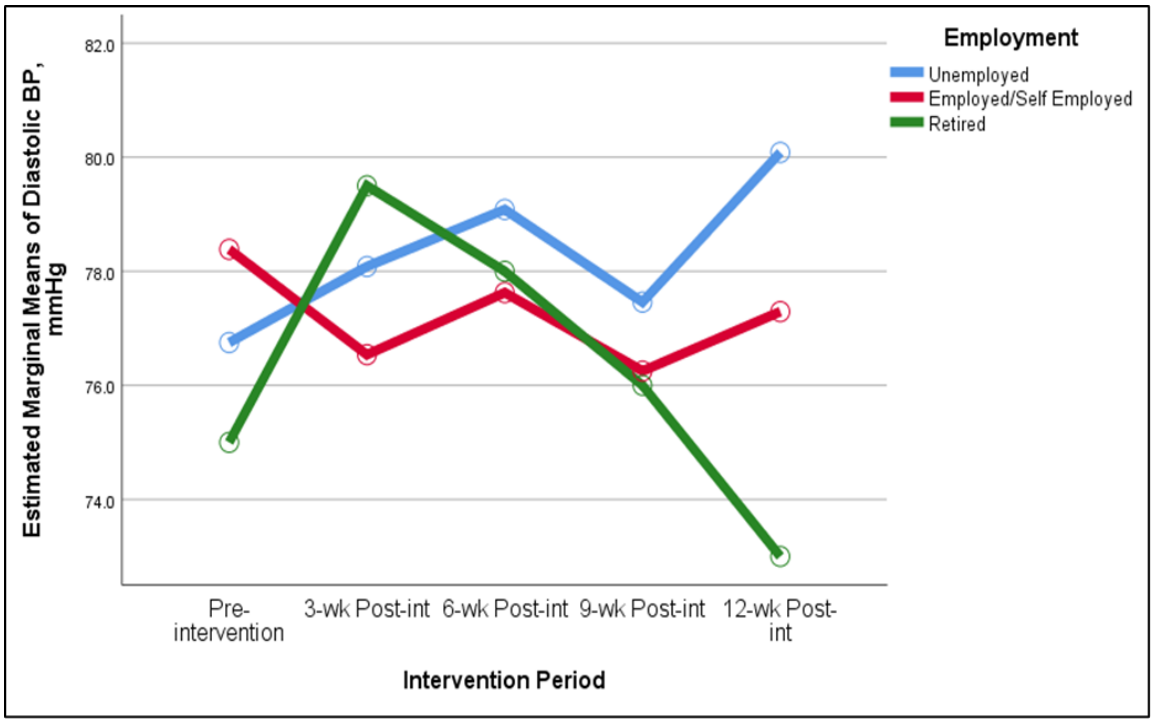

Figure 30:

Participants' mean diastolic blood pressure outcomes versus their employment status

Table 37:

Tests of between-subject effects on participants' diastolic blood pressure outcomes versus SIMPLE protocol intervention effect on their employment status

Tests of Between-Subjects Effects

Dependent Variable: Diastolic Blood Pressure in mmHg

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	135.155[a]	14	9.654	0.091	1.000	0.015	1.269	0.079
Intercept	215385	1	215385	2023	0.000	0.961	2023	1.000
Intervention	18.456	4	4.614	0.043	0.996	0.002	0.173	0.058
Employment	30.926	2	15.463	0.145	0.865	0.004	0.290	0.072
Intervention * Employment	75.587	8	9.448	0.089	0.999	0.009	0.710	0.073
Error	8732	82	106.490					
Total	591590	97						
Corrected Total	8867	96						

a R Squared = .015 (Adjusted R Squared = -.153)

b Computed using alpha = .05

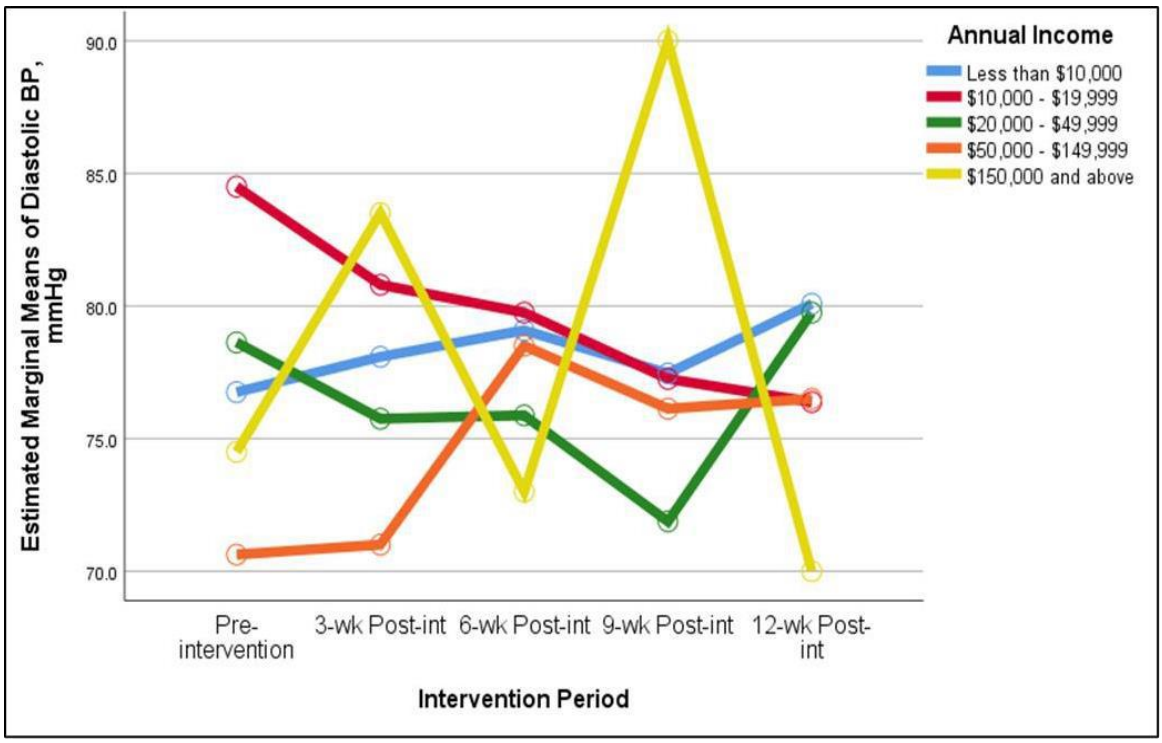

Figure 31:

Participants' mean diastolic blood pressure outcomes versus their annual income

Table 38:

Tests of between-subject effects on participants' diastolic blood pressure outcomes versus SIMPLE protocol intervention effect on their annual income

Tests of Between-Subjects Effects

Dependent Variable: Diastolic Blood Pressure in mmHg

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Effect Size	Noncent. Para-meter	Observed Power[b]
Corrected Model	1211.580[a]	24	50.482	0.475	0.978	0.137	11.395	0.332
Intercept	395131	1	395131	3716	0.000	0.981	3716	1.000
Intervention	31.459	4	7.865	0.074	0.990	0.004	0.296	0.064
Annual_Income	328.875	4	82.219	0.773	0.546	0.041	3.093	0.237
Intervention * Annual_Income	823.386	16	51.462	0.484	0.947	0.097	7.744	0.283
Error	7656	72	106.330					
Total	591590	97						
Corrected Total	8867	96						

a R Squared = .137 (Adjusted R Squared = -.151)

b Computed using alpha = .05

Discussion

The key success of the intervention is the gradual change noted with adherence of medication compliance. The motivational interviewing and the use of pillboxes as a reminder to take their medication helped in improving the participants' medication adherence. The interventions implemented results in participants' education, improve self-care management, and empower participants to take charge of their health conditions. The participants were more empowered, which improved their understanding of hypertension, the importance of taking

antihypertensive medications and preventing complications of hypertension such as heart disease, preventing strokes, severe cardiovascular conditions, and even death.

Results of this project indicated that the implementation of the SIMPLE protocol with emphasis on the use of pillboxes and MI interventions in hypertensive menopausal/postmenopausal women led to significant improvement in their medication adherence and enabled them to control their SBP. There was no statistically significant difference found between the participants' mean DBP at pre-intervention compared with the post-intervention mean DBP at the end of the three months QI project.

The findings of this QI project on MI were comparable to published studies. Ruppar (2010) conducted a randomized control trial (RCT) with the purpose of testing an eight-week behavioral feedback intervention for BP control and to improve antihypertensive medication adherence. The sample size for the study was 15 participant adults aged ≥ 60 years old, the median age of the participants was 71 years old, and 73% of them were women. In the study, which was conducted in participants' homes, medication adherence was monitored with the use of electronic monitoring for 20 weeks, and BP was measured by nurses at 12 and 20 weeks after randomization. The results of Ruppar (2010) RCT study found that at the end of the intervention, the participants in the intervention group (n = 10) had better anti-hypertensive medication adherence than the participants in the control group (n = 5). The participants' median medication adherence was 100% for the intervention group compared to 27.3% for the control group, $U = 5.0$ and $p = 0.013$. Hence, like the findings concerning the SIMPLE protocol intervention, the RCT study indicated the potential effectiveness of the feedback intervention protocol in increasing medication adherence for hypertensive older adults.

Uchmanowicz et al. (2019) implemented a systematic review/meta-analysis, with the purpose to estimate medication adherence in hypertensive patients aged ≥60 years, and to explore the determinants of adherence with antihypertensive medications among the age group. The authors used thirteen eligible studies published between 1 January 2000 and 30 June 2018, for their meta-analysis comprising of a total of 5,247 hypertensive patients. Self-reported Morisky 8-item self-report measure of medication-taking behavior (MMAS-8) and Morisky Green Levine Medication Adherence Scale (MGL) tools were used for assessing medication adherence in the meta-analysis study. If the patients scored ≥6 points on the MMAS-8 or ≥3 points on the MGL, they were medication adherent. The results of the study found that the pooled percentage of adherence was 68.9% (95% CI = 57.8-79.9%). The authors concluded that medication adherence in older hypertensive patients were found to be higher than in younger hypertensive patients.

Wang et al. (2014) investigated the factors that influence medication adherence among hypertensive adults in Chinese community-dwelling. The study was a cross-sectional study with 382 hypertensive older adults' participants, 51.6% of whom were women. Among these participants, 46.3% were 55-65 years old, and 53.7% of them were >65 years old. The setting of the study was 6 health centers in Macao, China, and the study was conducted from January to June 2012. The results of the study indicated that participants > 65 years ($\beta = .118$, $p < .05$), with a low level of education ($\beta = .128$, $p < 0.05$), who had more than one other common disease ($\beta = .120$, $p < 0.001$), were on long-term hypertensive medication ($\beta = .221$, $p < 0.05$), and who reported higher self-care ($\beta = .188$, $p < 0.001$), had better medication adherence. The authors concluded that to improve medication adherence among Chinese older adult hypertensive

patients, healthcare professionals should use the learning from the study when developing a treatment plan for such patients.

The facility learned that the implementation of SIMPLE protocol intervention methods, including the provision of pillboxes and motivational interviewing to hypertensive patients, enabled them to significantly improve their extent of medication adherence and allowed them to control their blood pressures better. The implementation and usefulness of the results of the project would encourage other providers to emphasize medication adherence behavior by better educating their patients on the importance of taking their medications as prescribed. Hence, the outcome of the project will improve rapport, behavioral change, and self-efficiency with patients, which will result in positive changes with medication adherence and help in controlling BP within the recommended JNC-7 guidelines.

Recommendations for future health care providers that join the primary care clinic would be to implement motivational interviewing and consistently provide pillboxes, in managing the disease process of the clinic's hypertensive patients. All providers that would be employed in the clinic would be educated on how to use motivational interviewing to help patients to be medication adherent and better control their blood pressures. Otherwise, patients not adequately trained about their health conditions could fall back to being medication nonadherent, which could result in health complications and increase their morbidity and mortality. To minimize the project's barriers going forward, the PD plans to make it mandatory for all providers in the clinic to implement motivational interviewing with all hypertensive patients during their follow-up visits and encourage the use of pillboxes.

Limitations

The accuracy of some of the results of this project could have been affected because of the following reason: The small sample size of 20 participants that was later reduced to 19 participants, because of the loss of one participant due to the effect of COVID-19 pandemic, was the most significant limitation. One of the patients moved out of state after the first follow-up clinic visit, and it was difficult for the PD to engage with her remotely because she did not have a blood pressure monitor machine and was not in the proximity of where she could get one. She was later considered to have withdrawn from the project, resulting in a noticeable effect on the project's results, especially since she was the only divorced participant in the project. Menopausal women made up 10% of the participants in the project, which was very small and made it difficult for more reliable comparisons between the Menopausal versus the postmenopausal groups. The baseline/pre-intervention blood pressures of many of the participants were low and not too far off from the set BP goal, making it difficult to achieve a considerable reduction with the intervention was a limitation. The COVID-19 pandemic, which resulted in a stay home order and made it impossible for the participants to visit the clinic for their third and fourth follow-up appointments, was another limitation of this QI initiative. As a result, there could be some bias because the PD had to use telehealth services to complete the rest of the project and relied on the participants' self-reported blood pressure and weight measurement readings.

Interpretation

The occurrence of the SARS coronavirus COVID-19 pandemic is the biggest limitation affecting the project. Participants were not able to come to the clinic for post-intervention follow-up visits three and four due to the stay at home order. The pandemic was a stressful

period for everyone, including the participants in the project, and their heightened stress levels could have affected the blood pressures of some of them. The plan is to routinely continue the use of MI intervention with chronic care patients by making sure that they continue to be educated on their disease process, maintain their follow-up visit appointments and be able to achieve self-management at home.

The outcomes plan for the QI project were met, and participants are now able to monitor their blood pressure at home. In the next PDSA cycle, the use of a larger sample size, extension of intervention, and data collection period would be encouraged to improve medication adherence and blood pressure control better.

Conclusion

The key take-away message from this QI project is to educate patients regarding their disease process and empower them to implement self-care management of their health condition. Also, day-by-day monthly pillbox organizers will be given to patients in the clinic to fill their prescribed hypertensive medications to make it easier for them to remember to take their medications daily. The pillboxes will help the patients with the continuous process of independent self-care practice. Patient engagement will lead to improved outcomes and lead to the safe and efficient management of hypertension.

One key learning from this project was that providing the necessary education to patients through motivational interviewing enabled them to achieve recommended guidelines for hypertension treatment. It also helped them to change undesirable behaviors that usually resulted in complications such as heart disease, stroke, severe cardiovascular conditions, and even death.

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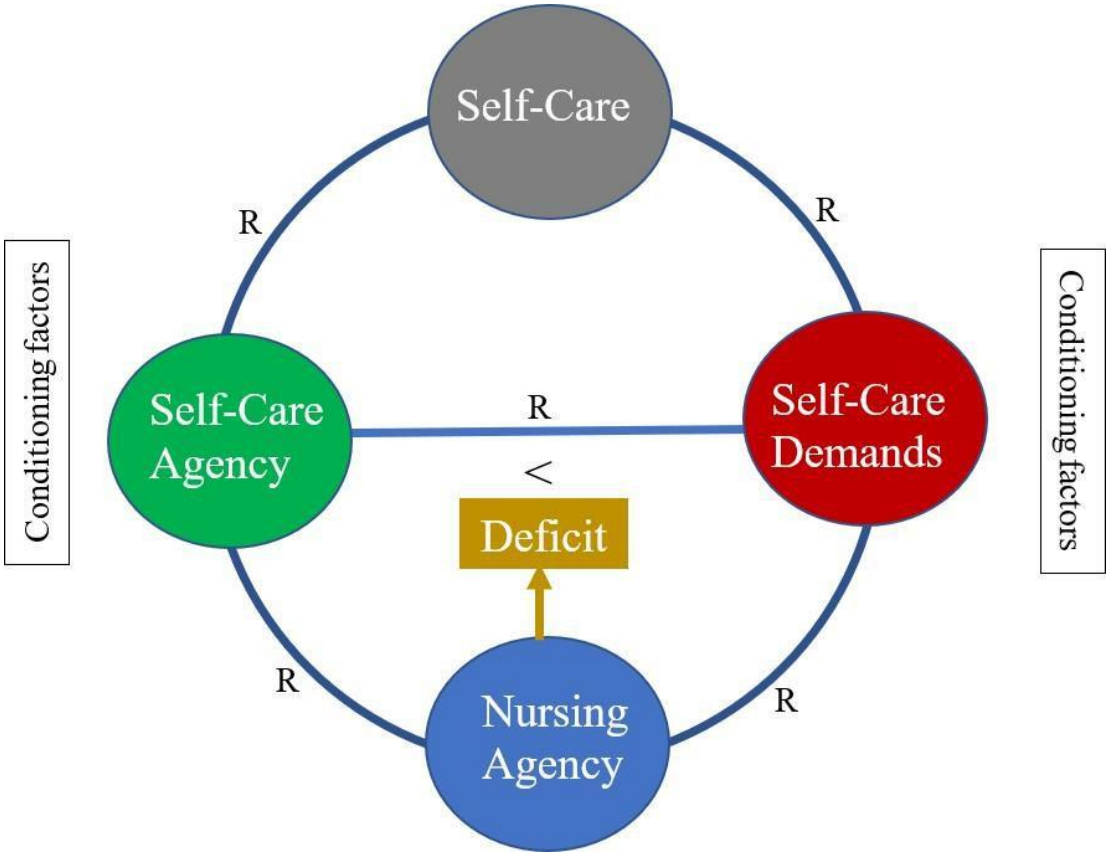
LIST OF APPENDICES

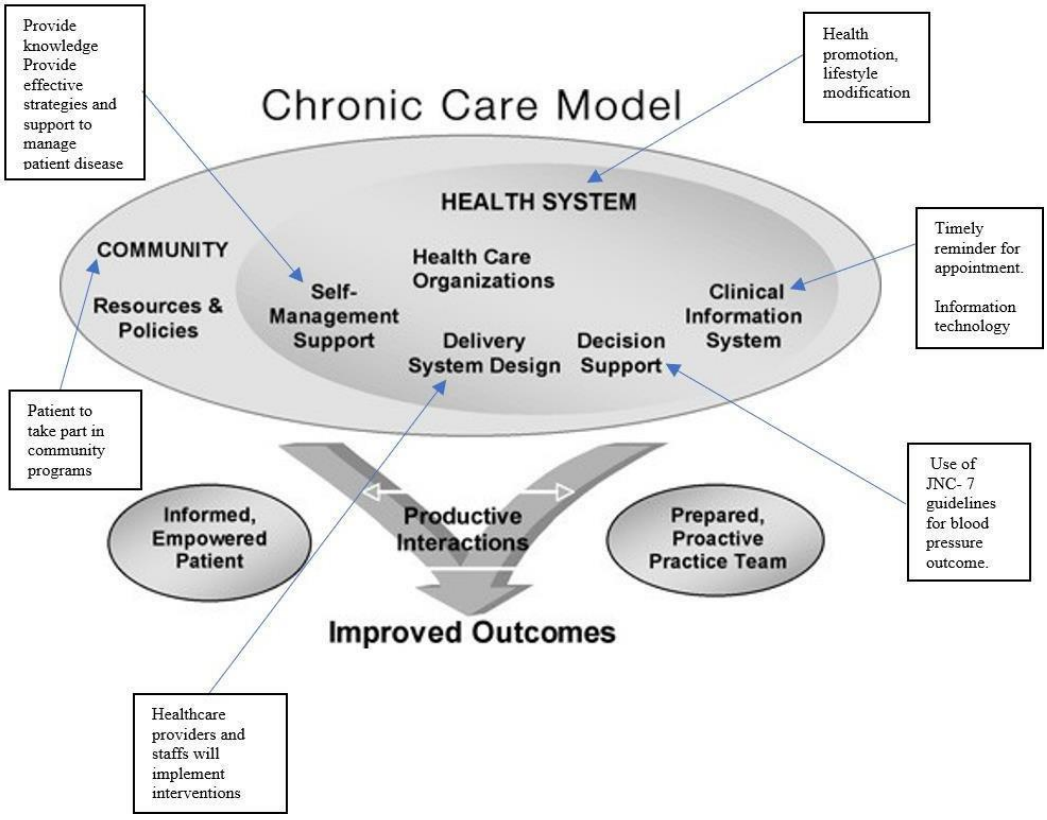
APPENDIX PAGE

APPENDIX A: Orem's Self-Care Theory: Conceptual Framework (Taylor, 2006)

R, Relationship; <, deficit relationship, current, or projected



APPENDIX B: The Chronic Care Model developed by E. H. Wagner (Ogedegbe, 2009)



APPENDIX C: Institutional Review Board (IRB) letter

TEXAS A&M UNIVERSITY
CORPUS CHRISTI

OFFICE OF RESEARCH COMPLIANCE
Division of Research and Innovation
6300 Ocean Drive, Unit 5844
Corpus Christi, Texas 78412
O 361.825.2497

Human Subjects Protection Program | Institutional Review Board

DATE: February 5, 2020

TO: Christina Murphey, College of Nursing and Health Sciences

CC: Sandra Owolabi, Student

FROM: Office of Research Compliance

SUBJECT: Not Human Subjects Determination

Activities meeting the DHHS definition of research or the FDA definition of clinical investigation and involves human subjects are subject to IRB review and approval.

On February 5, 2020, the Texas A&M University-Corpus Christi Institutional Review Board reviewed the following submission:

Type of Review:	Not Human Subjects Determination
Title:	A SIMPLE Method to Improve Antihypertensive Medication Adherence in Menopausal/postmenopausal Women: A Quality Improvement Project.
Project Lead:	Christina Murphey
IRB ID:	NHS 67-19
Funding Source:	None
Documents Reviewed:	OwolabiS_600.02 QI Project (2020)-Travel incentive NHS determination letter

Texas A&M University-Corpus Christi Office of Research Compliance determined that the proposed activity does not meet the DHHS definition of research or the FDA definition of a clinical investigation.

Therefore, **this project does not require IRB approval. You may proceed with this project.**

This determination applies only to the activities described in the documents reviewed. **Any planned changes require submission to the IRB to ensure that the research continues to meet criteria for a non-human subject research determination.**

Please do not hesitate to contact me with any questions at irb@tamucc.edu or 361-825-2497.

Respectfully,

Matthew R. Gaynor, J.D. Digitally signed by Matthew R. Gaynor, J.D. Date: 2020.02.05 14:58:59 -06'00'

Office of Research Compliance

Page **1** of **1**

APPENDIX D: Consent to participate in the project form

A SIMPLE Method to Improve Antihypertensive Medication Adherence in Menopausal/Postmenopausal Women: A Quality Improvement Project.

Consent to participate in the project

- I .....(initials of participants) voluntarily agree to participate in this quality improvement study.
- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind.
- I understand that I can withdraw permission to use data from my participation within two weeks after the start of the study, in which case the material will be deleted.
- The purpose and nature of the study will be explained to me, and I have had the opportunity to ask questions about the survey.
- I understand that participation involves pillbox use, motivational interviewing, blood pressure readings, questionnaire completions, and attending four follow-up appointments.
- I agree that my motivational interviewing sessions will not be recorded.
- I understand that all the information I provide for this study will be treated confidentially.
- I understand that I am free to contact the study's project director to seek further clarification and information if needed.

Signature of participant:..... Date: .....

I believe the participant is giving informed consent to participate in this study.

Signature of project director ----------

APPENDIX E: Facility support letter

PATTISON FIRST
FAMILY CLINIC

3603 Front street, Suite 103. Brookshire, Texas 77423. Phone # (281) 934-4444. Fax: (281) 934-4443

Dr. Sara Baldwin
Associate Dean for Academic Programs
College of Nursing and Health Sciences
Texas A & M University – Corpus Christi
6300 Ocean Drive
Corpus Christi, TX 78412

Dear Dr. Baldwin,

The purpose of this letter is to provide Sandra Owolabi, a Doctor of Nursing Practice student at Texas A&M University College of Nursing and Health Sciences, support in conducting a quality improvement project at Pattison First Family Clinic. The project, *A SIMPLE Method to Improve Antihypertensive Medication Adherence in Menopausal/Postmenopausal Women: A Quality Improvement Project*. The project goal entails the implementation of the SIMPLE method with emphasis on the use of pillboxes and motivational interviewing interventions.

The purpose of this project is to improve hypertensive medication adherence and blood pressure control in women aged 45-75 years of age and improve provider management practices through implementation of the SIMPLE method interventions. Pattison First Family Clinic is a rural primary care facility. Ms. Sandra Owolabi is a Family Nurse Practitioner (FNP) who owns/operates this clinic and has a sincere interest in improving the quality of care for clients at this facility. This site was chosen for this project because there is a need to provide evidenced based intervention aimed at helping hypertensive menopausal/postmenopausal women improve their medication adherence and meet their prescribed blood pressure goals.

I, Dr. Clyde McMorris, the supervising physician for family nurse practitioner services offered by Ms. Owolabi at Pattison First Family Clinic, do hereby fully support her in the conduct of this quality improvement project. I am willing to provide guidance and feedback on her project implementation and analysis to eliminate any perceived conflict of interest. I also approve Sandra Owolabi to access protected health information (PHI) for purposes of conducting this quality improvement project. She has signed a HIPAA release form.

Sincerely,

Dr. Clyde McMorris, Supervising Physician

APPENDIX F: Timeline for the project

Project Timeline

Initial Visit 01/15/2020 to 01/31/2020	• Research eligible patients from clinic database. • Discuss with patients about the project. • Initiation of project. • Collection of patient's demographic information. • Provide pillboxes to patients. • Pre- questionnaires are given patients. • Motivational interview with patients.
First follow-up: 3weeks 02/17/2020 - 01/22/2020	• Continue to monitor patient compliance, and reminder calls for three weeks follow up in the clinic. • Motivational interview with patients.
Second follow-up: 6weeks 03/09/2020 - 03/14/2020	• Continue to monitor patient compliance, and reminder calls for six weeks follow up in the clinic. • Motivational interview with patients.
Third follow-up: 9weeks 03/30/2020 - 04/03/2020	• Continue to monitor patient compliance, and reminder calls for ninth weeks follow up in the clinic. • Motivational interview with patients.
Fourth follow-up: 12 weeks 04/20/2020 - 04/25/2020	• Continue to monitor patient compliance, and reminder calls for ninth weeks follow up in the clinic. • Motivational interview with patients. • Post - questionnaires were given to patients.
04/27/2020- 04/30/2020	• End of the project monitor. Implement the PDSA cycle.

APPENDIX G: Plan-Do-Study-Act (PDSA) cycle (White & Zaccagnini, 2017)