Proposal Title:	Effect of Short-term Vitamin D supplementation on Blood Pressure in Vitamin D deficient Hypertensive African Americans.
Group Members: Group 19	[redacted]
Class/Section:	[redacted]
Class Semester (Year):	[redacted]
Data Collection:	Primary

Abstract

Background: Hypertension (HTN) increases the risk for cardiovascular diseases, stroke, and renal failure. Several studies have indicated an inverse correlation between blood pressure (BP) and 25-hydroxyvitamin D (25[OH]D) levels. Most studies have analyzed the effect of vitamin D supplementation on hypertensive Caucasian subjects however, this inverse association has never been replicated in African American population using a randomized control trial.

Purpose Statement: This study aims to determine the oral vitamin D supplementation effects on BP in hypertensive African American adults.

Methods: An 8-week randomized clinical trial will be designed between November-March period. The sample will comprise African American adults (age ≥40 years). Eligible subjects will be randomized into treatment or control groups following physical examination. Participants will self-administer a daily dose of 800 IU oral vitamin D (treatment) or a placebo (control) pill. Physical activity and compliance will be self-reported. BMI will be calculated at the study entry. Blood analysis for 25[OH]D level and blood pressure (BP) measurement will be performed at each visit. The change in systolic/diastolic BP will be compared between the two groups.

Hypothesis: We hypothesize that the daily intake of 800 IU oral vitamin D will increase the concentration of serum 25[OH]D in the treatment group improving the systolic/diastolic BP however no change is expected in the control group.

Future Implications: This study can introduce a safe, inexpensive and widely available preventive/interventional measure to reduce the risks of HTN (and its associated diseases) in at-risk populations. However, further experimental studies covering wider geographical areas are required to ensure generalizability and reproducibility of the results.

Keywords: Vitamin D, African American, hypertension, blood pressure, at-risk populations, randomized control trial

Effect of Vit. D Supplementation on Blood Pressure in Hypertensive African American population

Introduction:

High blood pressure is a major risk factor for heart diseases and stroke, the first and the fourth leading causes of death for all Americans. It contributes to approximately 1,000 deaths/day and one in three U.S. adults- or about 75 million people- suffer from hypertension. The annual estimated cost associated with hypertension is $51 billion. Currently, around a third of people with hypertension are undiagnosed and the World Health Organization estimates that it causes deaths of at least nine million people globally every year, directly or indirectly[1]. Management and treatment of hypertension is highly essential for significantly reducing the risk of subsequent cardiovascular diseases (CVD), cerebrovascular attack (CVA), peripheral artery disease (PAD), and end-stage renal disease (ESRD).

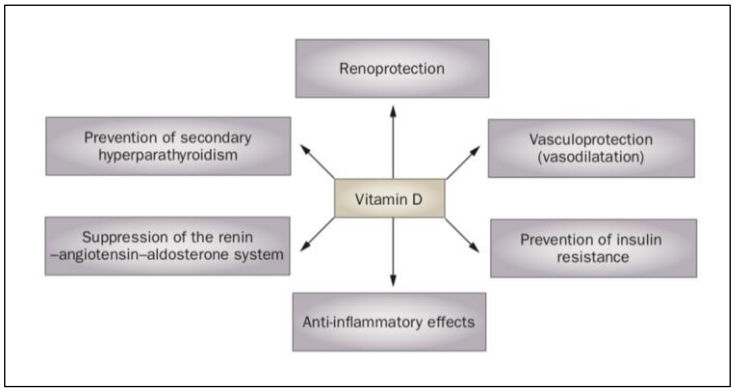

Figure 1: Anti-hypertensive effects of Vitamin D [2].

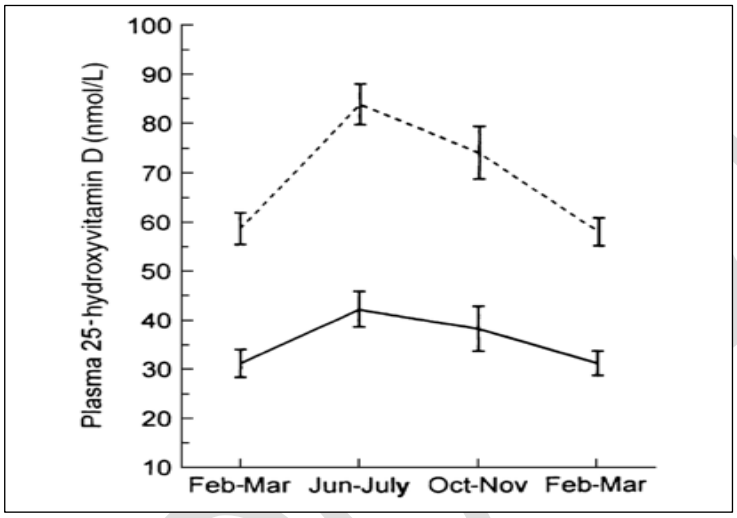

Figure 2: Mean seasonal change in 25(OH)D concentrations of 51 African American (solid) and 39 Caucasian women (dashed)[3].

Several cross-sectional studies have suggested an association between Vitamin D deficiency and hypertension (Figure 1). The third National Health and Nutritional Examination Survey (NHANES-III) showed that systolic blood pressure was inversely and significantly correlated with 25(OH)D levels among 12,244 participants. Additionally, reduced serum 25(OH)D levels were consistent with the prevalence of hypertension in the 4,030 participants of the German National Interview and Examination Survey, in 6,810 participants of the 1958 British Cohort, and in other study populations[2].

In humans, the primary source of Vitamin D is ultraviolet B (UVB) induced synthesis in the skin with only 10-20 % from dietary sources such as fish, or eggs. Vitamin D is hydroxylated in the liver to 25-hydroxyvitamin D [25 (OH)D]-the main circulating metabolite which is used to classify vitamin D status: vitamin D sufficient (25[OH]D>75 nmol/l), insufficient (25[OH]D 50-75 nmol/l) and deficient (25[OH]D < 50 nmol/l)[2]. Vitamin D insufficiency affects almost 50 % of the population worldwide and can be attributed to lifestyle (reduced outdoor activities) and/or environment (air pollution) which reduces exposure to sunlight essential for UVB induced Vitamin D synthesis in the skin. Vitamin D insufficiency is more prevalent among African American population and most young, healthy African Americans do not achieve optimal [25(OH)D] levels at any time of the year (Figure 2)[3]. This is primarily due to the fact that African Americans have darker skin pigmentation, which acts as a natural sunscreen and decreases the absorption of UVB to ultimately reduce the synthesis of [25(OH)D]. The prevalence of high blood pressure in African Americans in the United States is among the highest in the world (Figure 3). More than 40 % of non-Hispanic African American population has hypertension[4]. Additionally, hypertension develops earlier in this population with higher severity. The inverse association of Vitamin D status with hypertension may explain this ethnic variation in hypertension. Additionally, some observational studies have exhibited an increased prevalence of hypertension during the winter season and in geographic locations which are further away from the equator. This can be attributed to the decline in exposure to ultraviolet (UV) radiation which decreases the skin's capacity to synthesize Vitamin D[5].

Several interventional studies have examined the effects of Vitamin D supplementation, or ultraviolet-B (UVB) radiation (to increase Vitamin D) on hypertensive subjects. Accumulating evidence from molecular mechanism studies and outcomes of randomized trials favor the hypothesis that vitamin D deficiency is associated with arterial hypertension, however further data is required on this topic. A double-blind, randomized control trial conducted by Pfeiffer *et al.* enrolled 148 elderly women (aged 70 years or older) with hypovitaminosis (25[OH]D levels < 25 ng/ml). The subjects either received a daily dose of 1,200 mg of calcium and 800 IU Vitamin D

(treatment) or only 1,200 mg of calcium (control). After 8 weeks of treatment, both groups exhibited significant reduction in blood pressure however the reduction in systolic blood pressure was greater in the treatment group by 7.4 mmHg compared to the control (P=0.02)[6]. The results of the study conducted by Krause *et al.* supported these findings by showing an association between UVB-induced increase in 25(OH)D levels and lowering in blood pressure. In another study, a cohort of 34 Vitamin D deficient patients with type 2 diabetes were randomly assigned to receive a single dose of 100,000 IU Vitamin D or placebo. At the end of 8 week-period, the mean office systolic blood pressure was 14 mm Hg lower in the treatment group compared to the control (P=0.001) however this study had an extremely low study population[7].

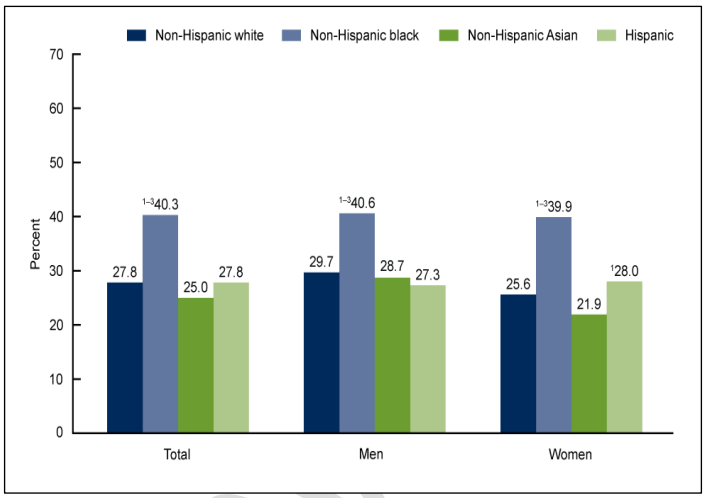

Figure 3: Ethnic variation of hypertension in men and women in the United States[4].

In the largest trial in this field-the Women's Health Initiative (WHI)- 36,282 postmenopausal women were randomly assigned to receive either 400 IU Vitamin D plus 1,000 mg calcium daily or placebo. During the average 7 years of follow-up, the results exhibited no significant changes in systolic and diastolic blood pressure or the frequency of incident hypertension between the treatment and control group. This null finding was confirmed in various subgroup analyses[8]. Several explanations are available for these findings such as the extremely low dose of Vitamin D supplementation used in the study which was insufficient to increase the 25(OH)D levels to clinically effective limits. Also, the baseline or post-treatment serum 25(OH)D levels were not measured in any of the study participants. All study subjects (treatment and control group) were permitted home Vitamin D supplementation. Additionally, adherence to treatment-defined as use of 80 % or more of the assigned medication- was only 60-63% in the first three years of follow-up which reduced to 59 % at the end of the trial[2]. Therefore, it can be concluded that the results of clinical studies largely, but not consistently, favor the hypothesis that optimal Vitamin D levels promote lowering of arterial blood pressure. Also, these findings have been based mainly on Caucasian population and the antihypertensive effect of Vitamin D is yet to be determined in the African American population. An observational study evaluated the association of serum 25(OH)D levels with high blood pressure in 1,334 African Americans and Hispanic participants. An increment of 10 units in 25(OH)D was associated with statistically significant reduction of systolic and diastolic blood pressure by 2.05 and 1.35mm Hg respectively[9]. The inverse association between Vitamin D and blood pressure has never been replicated in the African American population using a randomized, placebo-controlled trial. This study design is greatly needed to evaluate the effect of Vitamin D supplementation on African American subjects to prove the antihypertensive effects of Vitamin D in this population[10]. As previously mentioned, this population has the highest prevalence of hypertension and Vitamin D insufficiency and could greatly benefit from maintaining sufficient levels of Vitamin D levels either by supplementation or increased sun exposure.

Hence, the primary aim of this study is to ascertain the effect of short-term oral Vitamin D supplementation on blood pressure in Vitamin D deficient hypertensive African American population. To our knowledge, this will be the first randomized, placebo-controlled, and double-blinded clinical trial investigating the role of vitamin D supplementation on blood pressure in this specific population. Study participants will be recruited based upon inclusion/exclusion criteria and will be randomly assigned to either take a daily dose of 800 IU Vitamin D supplement or the placebo. At the end of the eight-week intervention period, blood pressure will be measured to test the effect of Vitamin D supplementation. The levels of serum 25(OH)D will be checked by blood sample analysis. The mean difference in blood pressure between the treatment and control group will be analyzed using the independent t-test. The effect of physical activity, compliance and BMI on the blood pressure will also be determined using multiple linear regression analysis.

Methods[6,7]:

The study design is a randomized, placebo-controlled, and double-blinded clinical trial for an 8-week period which is a gold standard for assessing causality.

Subjects: We will study African American individuals (40 years or older) between November 2020 and March 2021. We have chosen the winter period as there is a higher tendency to have Vit D insufficiency due to the lack

of sunlight (short winter days). The inclusion criteria will be stable medications for 8-week study period, Vitamin D serum level < 50nmol/L and systolic blood pressure ≥ 130 mm Hg and/or diastolic blood pressure ≥ 80 mm Hg. Subjects will be excluded if taking Vitamin D supplements, antihypertensive medications, have chronic renal failure (serum creatine > 20% of the upper limit of the reference range; 200 mmol/l), liver function tests (bilirubin, aminotransferases and alkaline phosphatase) > 3 times upper limit of normal, history of alcohol or drug abuse, nicotine abuse (>20 cigarettes/day), drink more than seven cups of coffee daily, therapy with Vitamin D or its metabolites, scheduled holiday along the geographic longitude during the study period, diabetes mellitus, or severe cardiovascular diseases (myocardial infarction, or stroke).

Study design and protocol: All baseline and outcome measurement visits will be performed at the Department of Clinical Pharmacology, Downtown Orlando. The study will have several phases (Figure 4):

A. Recruitment: Week 1 of November '20

Subjects will be recruited from 10 locations of Advent Health Hospital (See Appendix A).

1. The director of nursing of each hospital location and the medical employees such as doctors and nurses will be briefed about our study and consent will be obtained.
2. If the healthcare providers encounter a patient with the following criteria: African American (40 years or older), systolic blood pressure ≥ 130 mm Hg and/or diastolic blood pressure ≥ 80 mm Hg, and not taking any medication for hypertension, then the patient will be asked if they want to participate in the study. Also, an information flyer will be handed to the patient with more study details to encourage enrollment (see Appendix B).
3. Upon patient's consent, their name and phone number will be documented and provided to the researchers.

B. Telephone Screening: Week 2 of November '20

The interested participants will be contacted through telephone calls for initial screening and will be asked a series of questions to determine eligibility. Patients will be included if they are African American (40 years or older) and have hypertension. Patients will be excluded if they are taking antihypertensive medications, Vitamin D supplements, have chronic renal failure, abnormal liver function, history of alcohol or drug abuse, nicotine abuse (>20 cigarettes/day), drink more than seven cups of coffee daily, therapy with Vitamin D or its metabolites, scheduled holiday along the geographic longitude during the study period, diabetes mellitus, or severe cardiovascular diseases (myocardial infarction, or stroke). Based upon this, we will invite 150 participants to the first baseline measurement day. Verbal consent will be taken to participate in the study. Oversampling will be done to account for attrition.

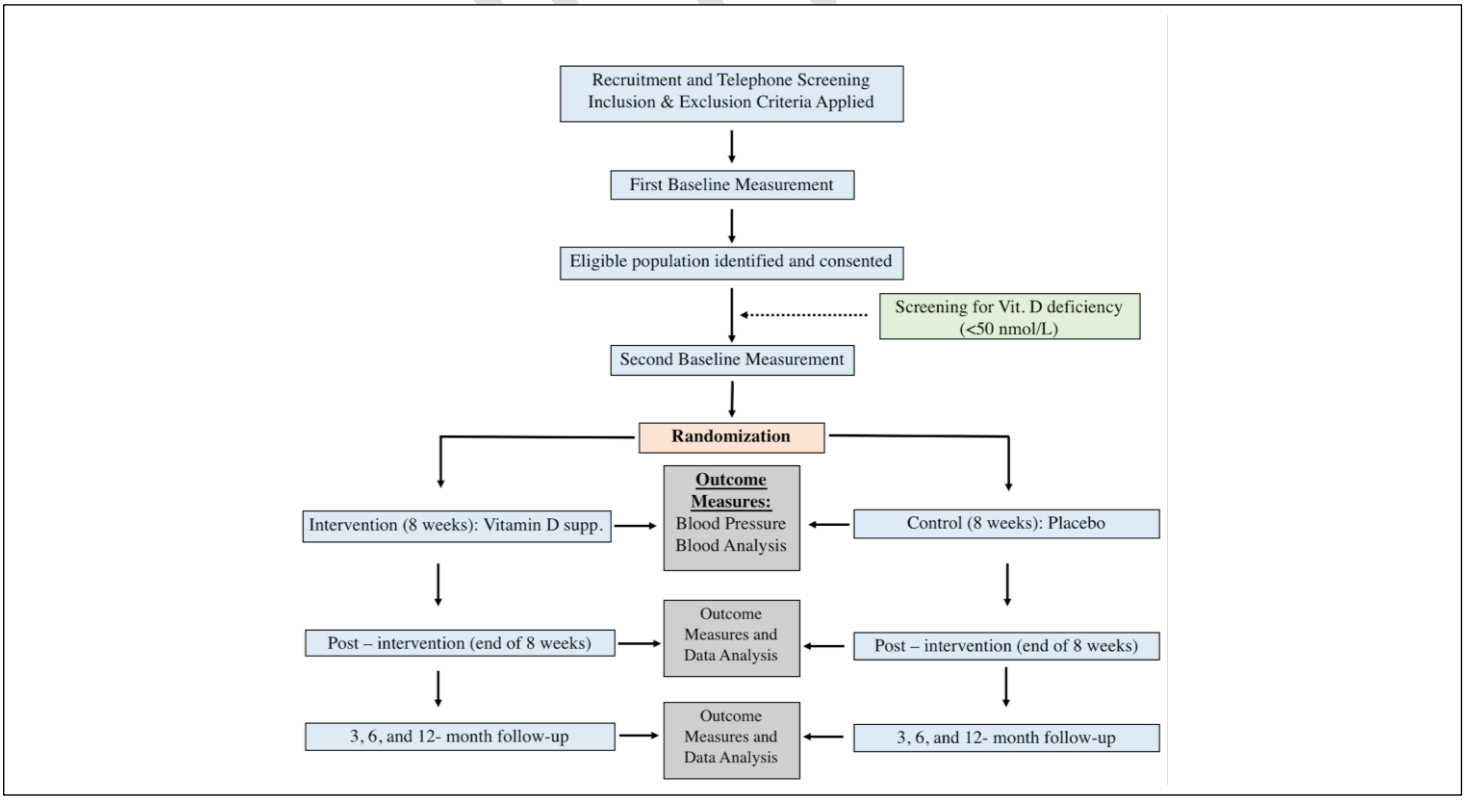

Figure 4: Study design and protocol.

Effect of Vit. D Supplementation on Blood Pressure in Hypertensive African American population

C. First Baseline Measurement: Week 3 of November '20

At study entry, a complete physical examination and assessment of each subject's age, gender, body mass index, pulse, and blood pressure will be performed. Medical history, smoking status and physical activity will be self-reported and obtained through questionnaires and written consent will be obtained (see Appendix C). The Vitamin D status, renal and hepatic function will be determined by obtaining and analyzing blood samples by trained clinicians. The subjects will be instructed to maintain their usual diet and avoid home supplementation of Vitamin D. Based on the blood analysis results, subjects with Vitamin D serum < 50nmol/L and systolic blood pressure ≥ 130 mm Hg and/or diastolic blood pressure ≥ 80 will qualify to proceed in the study and be invited to the second baseline measurement day.

D. Second Baseline Measurement: Week 4 of November '20

Blood pressure will be measured, and blood samples will be drawn by trained clinicians for analysis. The participants will be randomized into treatment and control groups. The study participants will be given the bottles with the Vitamin D supplement or the placebo to take home with them and instructed to begin taking the dose on the first day of December.

E. Intervention: Week 1 of December '20-Week 4 of January '21

The intervention duration will be 8 weeks with 100 participants. The mid-intervention outcome measurement will be performed after one month of intervention. The post-intervention outcome measurement will be performed at the end of 8 weeks period. Blood pressure will be assessed non-invasively by sphygmomanometer. Vitamin D levels will be measured by blood analysis.

F. Follow-up

The follow-up outcome measurement will be performed at after three, six, and twelve months from the day of intervention commencement.

Groups: Doses will be contained in sequentially numbered bottles with treatment codes generated from computerized random number tables. These codes will be concealed from the researchers until after the completion of the study. The pills will be identical in shape, size, color and all other aspects. Participants will have two visits for baseline measurements, one visit for mid-intervention outcome measurement, one visit for post-intervention outcome measurement and three follow-up visits resulting in a total of seven visits. Each supplement pill given to the treatment group will contain 400 IU Vitamin D. Subjects will be instructed to take one pill every day at breakfast and dinner with meals resulting in total of 800 IU of Vitamin D each day. Control group subjects will take one placebo tablet at breakfast and dinner with meals. All subjects will receive a text message every morning throughout the intervention period as a reminder to take the prescribed dose. Adherence will be determined by self-reported usage of pills. The subjects will receive a text message at the end of each week asking the number of days they were compliant in taking the supplements to track adherence.

Instrumentation and Analytical Plan:

Timeline of Major Events	Nov '20	Dec '20-Jan '21		Feb '21-Dec '21		
	Pre-Intervention Period	Intervention Period		Post-intervention and Follow-Up Period		
	Month					
	1	2	3	4	7	13
Recruitment & Telephone Screening	x					
Study Entry & First Baseline Measurement	x					
Second Baseline Measurement & Randomization	x					
Intervention		x	x			
Outcome Measurement: Blood Analysis and Blood Pressure		x	x	x	x	x
Data Analysis			x	x	x	x

Figure 6: Timeline of Major Events.

Effect of Vit. D Supplementation on Blood Pressure in Hypertensive African American population

The five measures which will be collected are blood analysis for measurement of serum Vitamin D [25(OH)D], blood pressure, body mass index (BMI), compliance, and physical activity. Physical activity will be determined by questionnaire (see Appendix C). Height will be measured using a stadiometer, and weight will be determined using a digital scale. BMI will be calculated as weight/height^2 (kg/m^2). Physical activity and BMI will be measured at the study entry. Blood pressure measurement and blood analysis will be performed at each outcome visit[6] (Figure 5).

Measurement of blood pressure[7]: Blood pressure and pulse will be measured non-invasively after at least 5 minutes of supine rest in a quiet room using a mercury sphygmomanometer with an appropriate cuff. Resting seated blood pressure will be measured three times at a single study visit by trained clinicians using identical equipment. Systolic and diastolic blood pressures will be taken at Korotkov sounds I and V. The mean of the last two readings will be used to calculate the blood pressure.

Measurement of serum Vitamin D [25(OH)D] levels:[11] Blood will be drawn between 0800-0900 h after the subjects have fasted for at least 8 h. Subjects will be instructed not to exercise, smoke, or consume caffeine for 4 h prior to testing. Measurement will involve 2-step process including rapid extraction of 25(OH)D from plasma and radioimmunoassay with 25(OH)D-specific antibody. The blood draw and analysis will be performed by trained medical staff and technicians.

Measurement of Compliance: Compliance will be self-reported by all the subjects in the form of text message sent at the end of each week during the intervention period.

Data handling and cleaning: The main outcome of interest and the primary dependent variable is reduction in systolic and diastolic blood pressure (ratio variable). The primary independent variable is whether the subjects received Vitamin D (1) or placebo (0) and covariates are physical activity, compliance and BMI. Based on the median split, physical activity levels will be dichotomized as High (1) vs Low (0). Subjects with BMI<30 will be categorized as Not Obese (1) and subjects with BMI≥30 will be categorized as Obese (0). Additionally, at the end of each week, all subjects will receive a score out of 14 which corresponds to the number of pills taken in that week. The compliance will be calculated by adding the scores received for the eight-week period. The minimum score which can be received is 0 (not compliant on any day) and the maximum is 112 (compliant on all days). Based on this, the compliance variable will be dichotomized. Participants who receive a full score of 112 will be deemed as fully compliant (1). Subjects with score < 112 will be declared as partially/not compliant (0).

Covariates	Binomal Categories	
Body Mass Index	Not Obese **(1)** (BMI <30)	Obese **(0)** (BMI ≥30)
Physical Activity	High **(1)**	Low **(0)**
Compliance	Fully Compliant **(1)** (100 %)	Partially/ Not Compliant **(0)**

Figure 6: List of covariates.

Data Analysis: Prior to data entry, a codebook will be created to describe each outcome measure. The name of each variable and its type will be entered in the codebook. All the results of the clinical assessment will be entered into an excel spreadsheet using Microsoft Excel. We are performing a bivariate analysis. The mean of the change in systolic and diastolic blood pressure will be calculated and compared in both groups and reported along with the standard deviation. The change in vitamin D levels with time in both the groups will be plotted using a line diagram. After ensuring that data is normally distributed, independent t-test will be used to compare the change in blood pressure between the treatment and control group. Separate multiple linear regression analysis will be performed to observe the effect of physical activity, BMI, and compliance on systolic and diastolic blood pressure reduction in both treatment and control groups. All data will be analyzed as intent-to-treat.

Expected Results: The primary aim of this study is to test the effect of oral Vitamin D supplementation on Vit D deficient African American adults with hypertension. The proposed hypothesis is that 8 weeks of 800 IU daily supplementation of oral Vitamin D would increase the concentration of serum Vitamin D in the treatment group and contribute to improvement in systolic and diastolic blood pressure, however no change in blood pressure would be observed in the placebo group (Figure 6). We expect subjects who are fully compliant with the treatment with high level of physical activity and not obese to show the best outcome (Figure 7).

Study Limitations: This study suffers from some limitations such as ensuring 100 % compliance in the treatment group however text reminders and self-reported usage will likely remedy it. Also, the study examines only the short-term effect of Vitamin D supplementation on blood pressure. The study has a small sample size of 100 people in the Orlando region which affects the generalizability of the results. The blood pressure measurement

will only be performed during the outcome visits and a mean of two readings will be taken which will provide a crude estimate and is susceptible to artifacts. Diet and physical activity data of all subjects will be self-reported which can pose as potential confounders as these parameters can change over the course of the intervention and affect the results of the study.

Ethical Principles: The research will be conducted in a clinical setting at the Department of Clinical Pharmacology in Downtown Orlando. Trained clinicians and technicians will be conducting the lab work and informed consent will be obtained from each participant to ensure safety. All paper documents will be safely stored in a locked room. All researchers and staff will ensure they are HIPAA compliant[12] and all protected health information (PHI) will be kept confidential. The excel file containing patient data will be password encrypted and a limited number of people will have access to it. Two separate files linked by unique study identification number will be maintained. One will contain the participants' name and contact information and the other will contain the study data. Everyone on the research team will be required to complete CITI training, which will cover the basics of ethical principles in research. To ensure these ethics are being upheld, the research will be reviewed by the IRB. To improve patient compliance, we will be using incentives. The subjects will be given a $50 gift card at each baseline visit and $100 gift card at every outcome measurement visit.

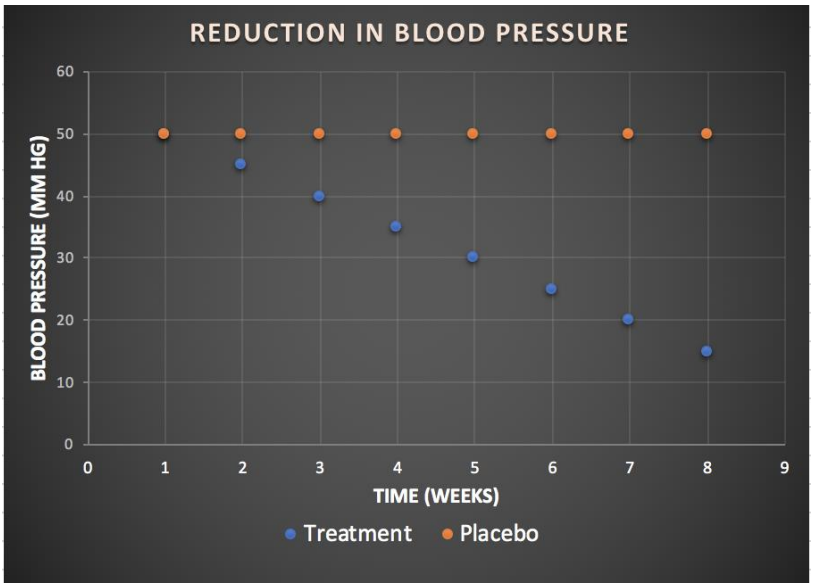

Figure 6: Expected decrease in blood pressure with time.

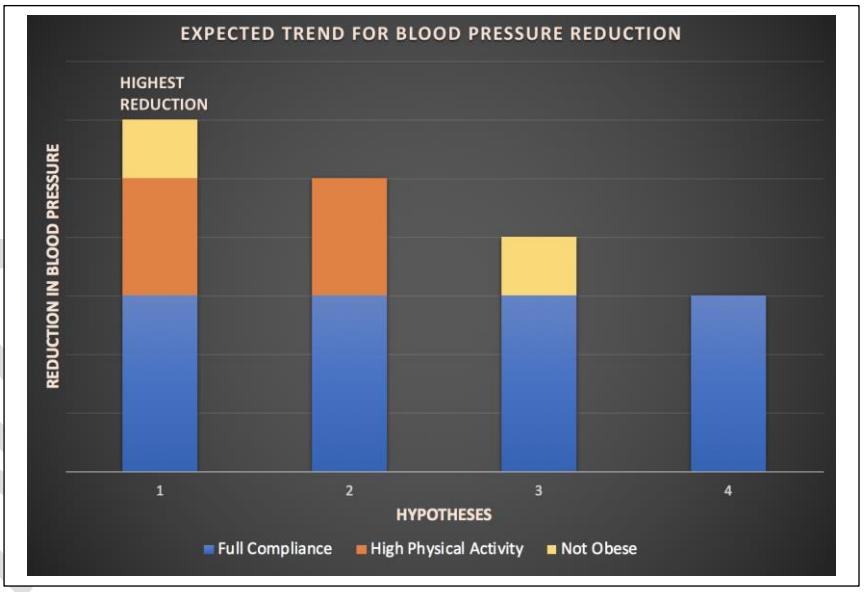

Figure 7: Expected decrease in blood pressure with high compliance, high physical activity and low BMI.

Future Implications: If our study hypothesis is confirmed, Vitamin D supplementation would be a safe, cheap and widely available alternative for preventing and managing hypertension. However, additional experimental studies are required to ensure generalizability and reproducibility of the results. A study could be done with a larger sample size covering a wider geographical area. More interventional studies are required to establish optimum dose and frequency of vitamin D supplementation to achieve clinically relevant results. The complex pharmacological kinetics of Vitamin D results in unclear strategy for optimal supplementation. More studies are required to evaluate the clinical efficacy of oral supplementation versus UVB exposure. Interventional studies can be conducted using the ambulatory blood pressure monitoring (ABPM) method which is considered the gold standard for blood pressure measurement to provide better and more accurate information about the average blood pressure in daily life of the study participants. Qualitative studies can be conducted to study the impact of text reminders on compliance in the treatment group which would ultimately reflect the success of the treatment.

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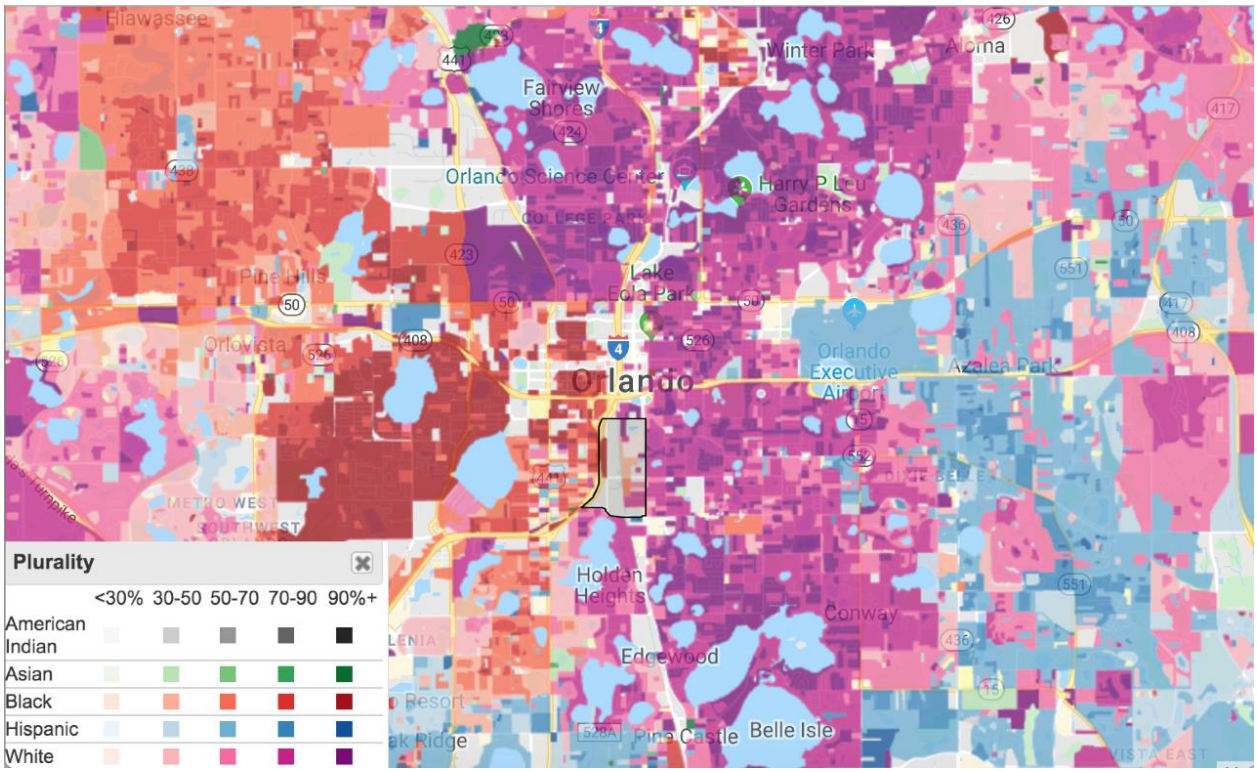
Appendix A: AdventHealth Hospital Locations



AdventHealth Orlando 601 E Rollins St, Orlando, FL 32801	AdventHealth East Orlando 7727 Lake Underhill Rd, Orlando, FL 32822
AdventHealth Orlando System Nutritional Services 221 NE Ivanhoe Blvd, Orlando, FL 32804	AdventHealth Home Care Services 600 Courtland St, Orlando, FL 32804
AdventHealth Care Center Orlando North 730 Courtland St, Orlando, FL 32804	AdventHealth Medical Group Family Medicine at Orlando, 1723 S Lucerne Terrace, Orlando, FL 32806
AdventHealth Sports Med & Rehab Pelvic 2520 N Orange Ave Suite 100, Orlando, FL 32804	AdventHealth Medical Group Urology at Orlando 1812 N Mills Ave, Orlando, FL 32803
AdventHealth Medical Group Family Medicine at RDV 8701 Maitland Summit Blvd, Orlando, FL 32810	AdventHealth Medical Group Vascular Surgery at Orlando 2415 N Orange Ave Suite 302, Orlando, FL 32804

Figure 1: Subjects will be recruited from 10 locations of Advent Health in the Orlando area. The locations were selected from the red area on the map where there is a high African American population.

Appendix B: Recruitment Flyer

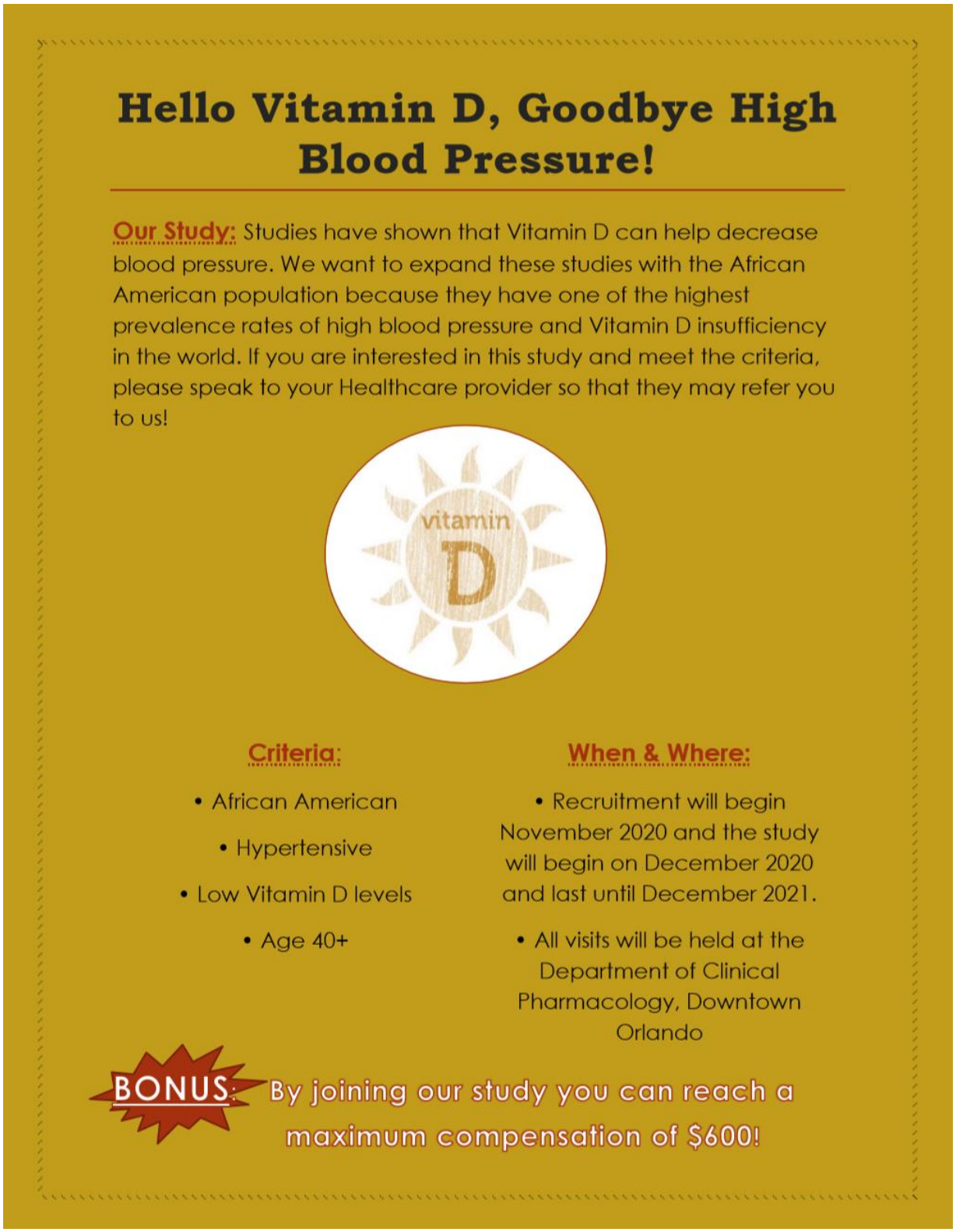


Figure 2: Information flyer which will be given to the patients at the initial recruitment stage.

Appendix C: Patient Questionnaire

Filled by Survey Conductors) Respondent ID Number:

Respondent ID:

QUESTIONNAIRE

All questions contained in this questionnaire are strictly confidential.

Name: ☐ M ☐ F	**Date:**
Marital status: ☐ Single ☐ Partnered ☐ Married ☐ Divorced ☐ Widowed	

Ethnicity: (Circle all that applies)	White/ Caucasian Hispanic/ Latino Black/African American Native American Asian Other: _____	**Age Group:** (Circle one)	19 and under 20-29 30-39 40-49 50-59 60+
Which of these bests describe you? (Circle all that applies)	Full-time employed Part-Time employed Not employed Caregiver Student Other	**Education Status:** (Circle one)	Highschool or Equivalent Vocational/ Technical School Some of College College degree Masters or higher

PART ONE: MEDICAL HISTORY

Baseline Markers: Height: _____ Weight: _____ BMI: _____		
Have you had or is currently experiencing any of the following? (Check all that applies)	☐ High Blood Pressure	☐ Heart Failure
	☐ High Cholesterol	☐ Cancer
	☐ Stroke	☐ Diabetes Type 1 Or Type 2

List any medical problems that other doctors have diagnosed

Surgeries ☐**Yes** ☐**No** **If no, skip to next question.**		
Year	Reason	Hospital

Other hospitalizations ☐**NONE** **If none, skip to next question.**		
Year	Reason	Hospital

Have you had a blood transfusion in the last 6 months?	☐ Yes	☐ No

Please turn to next page

List your prescribed drugs and over-the-counter drugs, such as vitamins and inhalers		
Name the Drug	Strength	Frequency Taken

PART TWO: PHYSICAL ACITIVITY

ALL QUESTIONS CONTAINED IN THIS QUESTIONNAIRE WILL BE KEPT STRICTLY CONFIDENTIAL.	
Does your current occupation require you to spend time outside, exposed to the sun?	☐ Yes
	☐ No
	If yes, How long? ☐ <1hour ☐ 1 hour ☐ 1 ½ hour ☐ 2 hour ☐ 2 ½ hour ☐ 3+
How active are you on a daily basis?	Approximately, how many minutes of physical activity (Jogging, Running, Gym Work Outs) do you perform on a weekly basis? _____ minutes

PART THREE: SMOKING, DRUG AND ALCOHOL CONSUMPTION

Smoking	Do you currently use nicotine products?		☐ Yes	☐ No
	If yes, how often do you use them?	☐ Packs - #/day	☐ Vape - #/day	☐ Cigars - #/day
	☐ # of years using nicotine products	☐ If you've quit smoking, what year did you quit?		
Drug	Do you currently use recreational or street drugs?		☐ Yes	☐ No
	If yes, How many times per week?	☐ <1 ☐ 1 ☐ 1 ½ ☐ 2 ☐ 2 ½ r ☐ 3+		
Alcohol	Do you drink alcohol?		☐ Yes	☐ No
	If yes, How many drinks per week? ☐ <1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6+			
	Do you have a history of drinking alcohol?		☐ Yes	☐ No

Figure 3: Medical History and Physical Activity Questionnaire to be completed at the study entry.