

The Effects of Plant-Based Diet vs Non-Restrictive Diet on College-Aged Prediabetic Women With Polycystic Ovarian Syndrome: A Randomized Control Trial

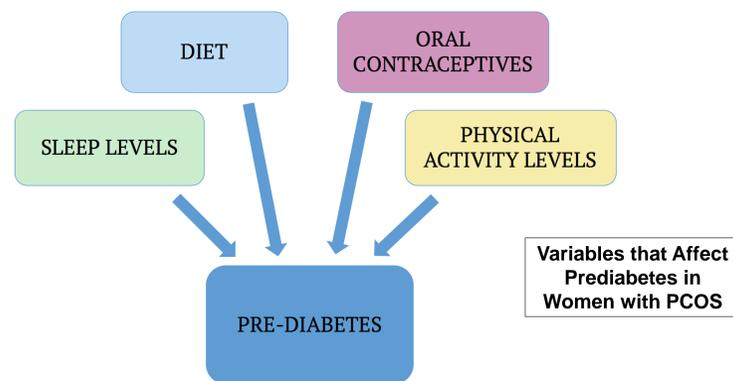


Stands For Opportunity

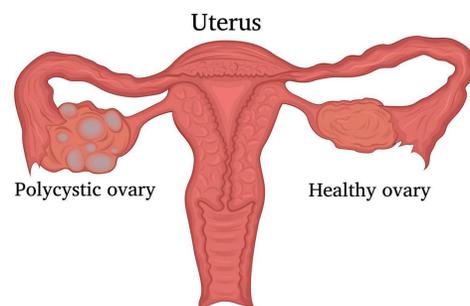
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BACKGROUND

- Polycystic ovarian syndrome (PCOS) occurs in about 10% of women of reproductive age.
- PCOS is characterized by irregular menstrual periods, excess levels of androgens, and small cysts present on the ovaries.
- More than half of women with PCOS will develop type 2 diabetes mellitus by age 40.
- Women considered prediabetic if
 - Fasting blood glucose level of 100-125 mg/dL
 - HbA1c level of 5.7% to 6.4%



Polycystic ovary



Polycystic Ovary vs Healthy Ovary

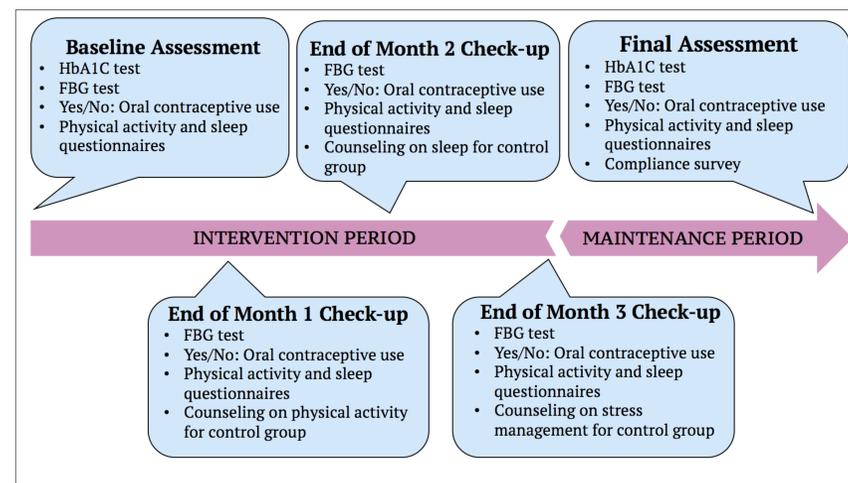
OBJECTIVES / AIMS

- To determine whether a plant-based diet will have a positive effect on the reversal of prediabetes in women with PCOS
- To assess the sustainability of the plant-based diet intervention
- To determine how the underlying factors of sleep, physical activity, and oral contraceptives impact the reversal of prediabetes

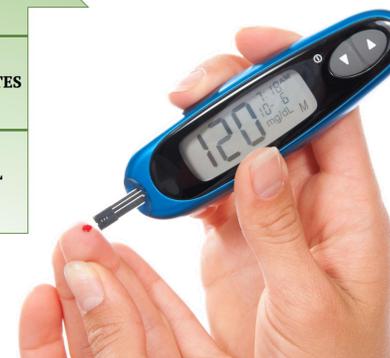
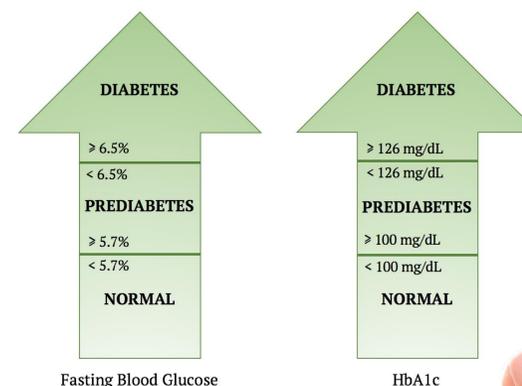
METHODS

- Source population: female students ages 18-35 at the University of Florida, the University of South Florida, and the University of Central Florida
- Sample population: 100 participants among all three universities who meet the inclusion criteria
- Parallel group randomized control trial: Participants randomized using clustered stratification
- Intervention group will receive a minimally processed vegetarian plant-based diet. Control group will receive an attention control of health counseling on physical activity, sleep, and stress management.

Timeline of the Intervention and Maintenance Period of this Study



Diagnostic Criteria for Diabetes and Prediabetes

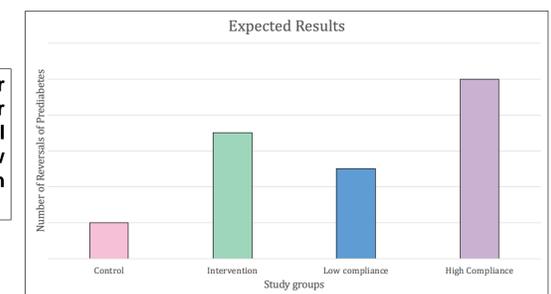


Glucometer: Instrument Used to Measure FBG

EXPECTED/HYPOTHESIZED FINDINGS

- The intervention group will experience more of a reversal in their prediabetes than the control group will experience.
- Those in the intervention group who have the highest compliance to the diet during the maintenance phase will have the best results overall.

Expected results for the number of women who will reverse their prediabetes among the control group, intervention group, low compliance group, and high compliance group



LIMITATIONS

- Recall bias and obtaining self-reported data regarding health behavior and intervention compliance.
- Other factors that may impact prediabetes (e.g. genetics, socioeconomic status, etc.)
- Inclusion of only one region of Florida which limits external validity

IMPLICATIONS

- May prompt more research on the effects of plant-based diets on other health conditions
- May shift the research focus from tertiary to preventive care for type 2 diabetes
- May influence colleges to construct programs for PCOS management

KEY REFERENCES

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- Kazemi M, McBreaity LE, Chizen DR, Pierson RA, Chilibeck PD, Zello GA. A Comparison of a Pulse-Based Diet and the Therapeutic Lifestyle Changes Diet in Combination with Exercise and Health Counseling on the Cardio-Metabolic Risk Profile in Women with Polycystic Ovary Syndrome: A Randomized Controlled Trial. *Nutrients*. 2018;10(10)

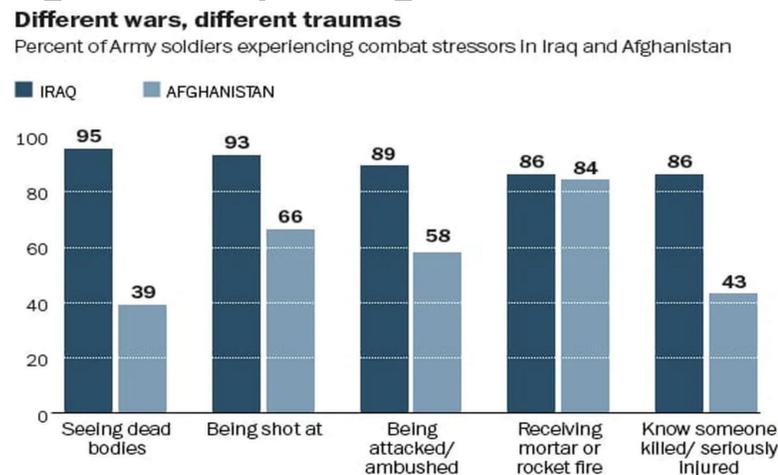
Cognitive behavioral therapy combined with physical exercise treatments for PTSD in veterans.

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BACKGROUND

- Post traumatic stress disorder is a psychiatric condition that occurs due to life threatening events, natural disasters, or sexual assaults. Soldiers are more likely to experience traumatic situations triggering PTSD.
- PTSD affects about 11 percent of veterans of the war in Afghanistan, and 20 percent of veterans who served in Iraq. This presents a total of 31 percent for both wars, and this number continues to increase as veterans discover PTSD at different rates (See Figure 1).
- We intend to compare the effectiveness of cognitive behavioral therapy versus exercise and when combined in treatment. Through this combination of treatment, we hope to reduce the symptoms of PTSD by a greater extent.

Figure 1: Iraq vs. Afghanistan Traumas



SOURCE: U.S. Dept. of Veteran's Affairs. Data from 2003.
GRAPHIC: The Washington Post. Published April 3, 2014

OBJECTIVES / AIMS

- **Aim 1:** Improve the quality of life for veterans, decrease the severity of PTSD symptoms, and decrease the number of incidents.
- **Aim 2:** Determine which form of treatment had a greater effect (CBT, physical exercise, or combination).
- **Aim 3:** To examine how effective cognitive behavioral therapy and exercise are individually used as PTSD treatment options.

METHODS

- We will be conducting a primary study design over the course of 6 months. This study will use a randomized control trial to give optimal results.
- Patients will be pooled from the 9,000 Iraq/Afghanistan U.S. veterans living in Durham, North Carolina.
- The control group will be receiving the standard of care, CBT, while our experimental groups include: 1. Exercise alone, 2. CBT and Exercise (See Figure 4).
- PTSD symptoms will be assessed by a licensed clinician using the CAPS scale at the start of study, midway point, end, and at a 6 month follow up (See figure 3).

Figure 2: PTSD Diagnostic Criteria

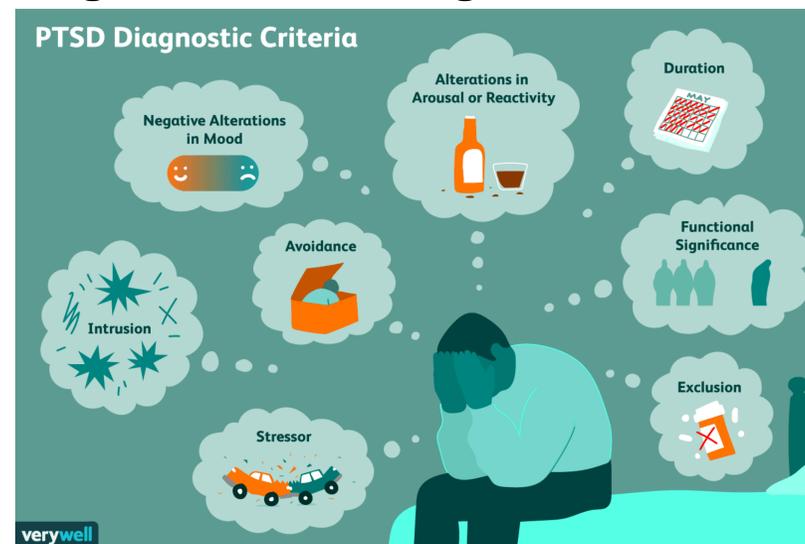


Figure 3: CAPS-5 Scoring

CAPS-Score	Category of PTSD
0-10	Asymptomatic
11-22	Mild
23-34	Moderate
35-46	Severe
47+	Extreme

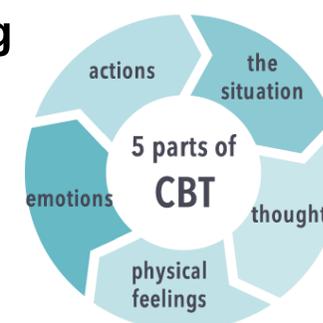
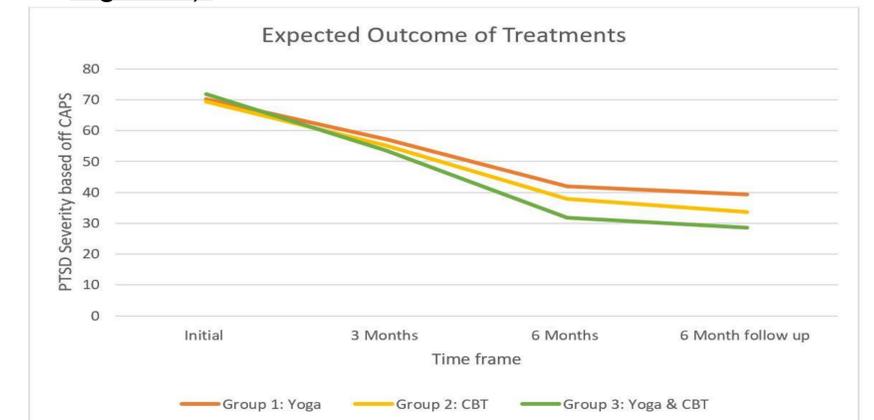


Figure 4: Parts of CBT

EXPECTED/HYPOTHESIZED FINDINGS

- We expect to find that the combination treatment of CBT along with exercise treatment will be the most effective treatment for those suffering with PTSD (See Figure 5).



LIMITATIONS

- Large age range of 18 to 60
- Environmental influence during video calls
- Not applicable to a general population
- Inability for participants to attend all yoga sessions

IMPLICATIONS

- The outcomes will be measured based on the decrease in severity of PTSD and how each participant responds to cognitive behavioral therapy and exercise therapy. A drop in those affected leads to a positive impact, in which public health and clinical practices can make these treatments more common.
- An existing research gap that can be filled by additional research includes the use of these treatments of female participants. This can advance our knowledge on cognitive behavioral therapy and exercise therapy on treating all sexes or PTSD

KEY REFERENCES

1. Jak AJ, Aupperle R, Rodgers CS, et al. Evaluation of a hybrid treatment for Veterans with comorbid traumatic brain injury and posttraumatic stress disorder: Study protocol for a randomized controlled trial. 2015;45:210-216.
2. Galea S, Basham K, Culpepper L, et al. Treatment for posttraumatic stress disorder in military and veteran populations: Initial assessment. 2012.
3. Cushing RE, Braun KL, Alden C-I, Susan W, Katz ARJMM. Military-tailored yoga for veterans with post-traumatic stress disorder. 2018;183(5-6):e223-e231.

Effect of Short-term Vitamin D Supplementation on Blood Pressure in Vitamin D-deficient Hypertensive African American Adults

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BACKGROUND

- Management/treatment of hypertension (HTN) is highly essential (Fig. 1) with the highest prevalence in the African American population (Fig. 2).
- Recent studies have exhibited the therapeutic effect of Vit. D supplementation on blood pressure reduction (Fig. 3).
- Vit. D insufficiency is more prevalent among the African Americans (Fig. 4) however, the inverse relationship between Vit. D level and blood pressure using a randomized controlled trial is yet to be analyzed in this population.

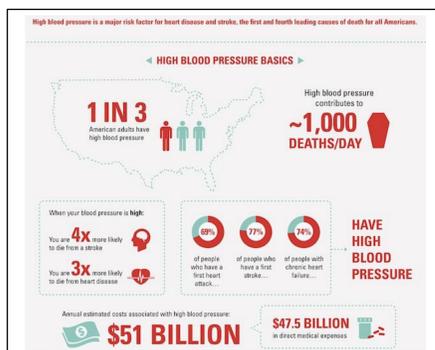


Figure 1: Hypertension in the U.S.[1]

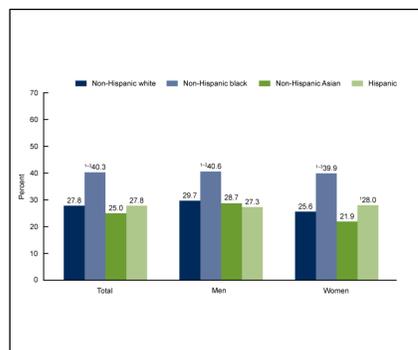


Figure 2: Ethnic Variation of HTN in the U.S.[2]

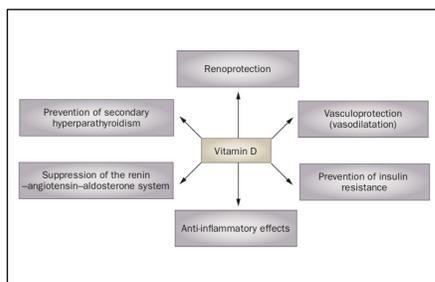


Figure 3: Anti-hypertensive effects of Vit. D.

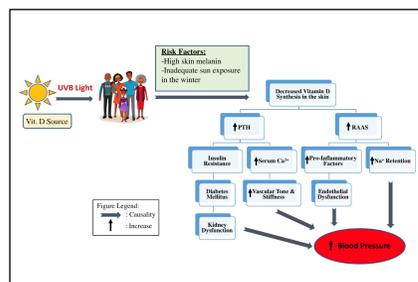


Figure 4: Proposed Role of Vitamin D Deficiency in causing Hypertension in African Americans.

OBJECTIVES

- The primary aim of this study is to determine the effect of short-term oral vitamin D supplementation on blood pressure in Vitamin D deficient hypertensive African American population.
- The effect of treatment compliance, physical activity, and body-mass index (BMI) of the subjects on blood pressure reduction will also be evaluated.

METHODS

Study Design: Randomized, placebo-controlled, double-blinded clinical trial with an eight-week intervention period (Figs. 5 & 6). Treatment group will be administered 800 IU oral Vit. D daily.

Sample and Inclusion Criteria:

- Study will be performed with African American subjects (40 years or older) during winter period (November - March).
- The inclusion criteria will be Vit. D serum level < 50 nmol/L, systolic BP \geq 130 mm Hg and/or diastolic BP \geq 80 mm Hg, and no usage of anti-hypertensive medications.

Collected Measures:

- Physical activity and compliance will be self-reported.
- BMI (kg/m^2) will be calculated at the study entry.
- Blood analysis for measurement of serum Vit. D level and blood pressure will be collected at each outcome visit.

Data Analysis: Change in blood pressure between treatment and control group will be examined using the independent t-test. Separate multiple linear regression analysis will be performed to observe the effect of physical activity, BMI, and compliance on blood pressure reduction.

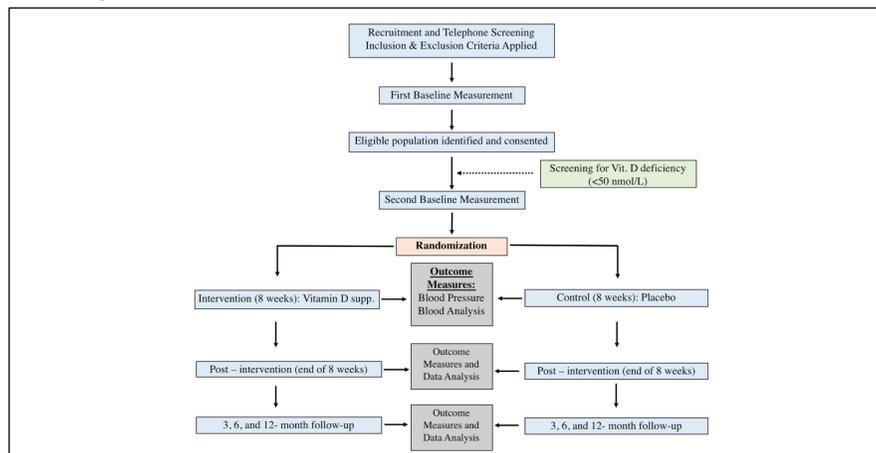


Figure 5: Study design exhibiting the recruitment, screening, and randomization process.

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 During the Study Period.

EXPECTED RESULTS

- We expect that 800 IU daily oral Vit. D supplementation would increase its serum concentration in the treatment group leading to blood pressure reduction (Fig. 7).
- We also expect that subjects who are fully compliant with the treatment with high physical activity and low BMI to exhibit the best outcome (Fig. 8).

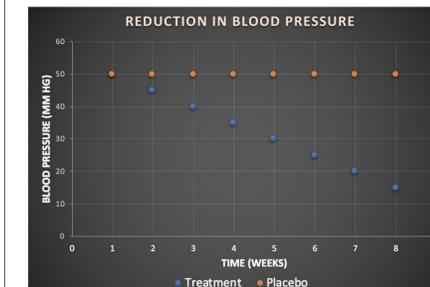


Figure 7: Expected reduction trend in blood pressure with Vit. D supplementation.

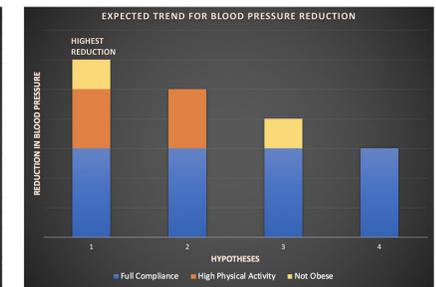


Figure 8: Expected decrease in blood pressure with high compliance, high physical activity, and low BMI.

LIMITATIONS

- Ensuring 100% compliance.
- Short-term study.
- Small sample size of 100 people in the Orlando region affects the generalizability of the results.
- Self-reported physical activity and diet =potential confounders

IMPLICATIONS

- Vitamin D has multiple health benefits. Its supplementation is easy, safe, and inexpensive.
- Vit. D supplementation can be incorporated into public health strategies to prevent/manage hypertension in the African American population however, additional experimental studies are required to ensure generalizability/ reproducibility.

KEY REFERENCES

1. Prevention CfDCA. *High Blood Pressure Facts*. National Center for Chronic Disease Prevention and Health Promotion; 2016.
2. Fryar CD OY, Hales CM, Zhang G, Kruszon-Moran D. Hypertension prevalence and control among adults: United States. In: Statistics NCfH, ed2017.