

**Prisma Health Education and research Institute Seed Grant Application Package:**  
**2025 Version HLTH 8210**

**Application Cover Page**

<b><u>Application Title:</u> Combining Plant-Based Diet and Diaphragmatic Breathing to Reduce Diastolic Blood Pressure in Older Adults with Early-Stage Hypertension: A Randomized Controlled Trial</b>	
Primary Academic Partner Investigator	Primary Academic Partner Investigator
Name: Susitra Gnanasambhandam	Name:
Title: Master's Student	Title:
Email Address: sgnanas@clemson.edu	Email Address:
Institution: Clemson University	Institution:
Academic/Clinical Department: Department of Public Health Sciences	Academic/Clinical Department:
Project Role: <input checked="" type="checkbox"/> PI <input type="checkbox"/> Co-PI <input type="checkbox"/> Co-Investigator	Project Role: <input type="checkbox"/> PI <input type="checkbox"/> Co-PI <input type="checkbox"/> Co-Investigator
Name/Title of Additional Co-Investigators	Institution and Academic/Clinical Department

## **Abstract**

Hypertension affects over two-thirds of adults aged 60 and above and is a leading cause of heart disease and stroke. While medications are common, there is increasing interest in natural strategies for blood pressure control. Plant-based diets rich in vegetables, fruits, whole grains, and legumes have shown significant effects in reducing blood pressure through improved vascular health. Separately, diaphragmatic (deep) breathing has been shown to reduce stress and autonomic imbalance, two major contributors to elevated blood pressure. This project proposes to combine these two low-cost interventions, plant-based dietary guidance and daily 20-minute diaphragmatic breathing practice, to assess their combined impact on diastolic blood pressure in older adults. Through a randomized controlled trial design over 8 weeks, participants will be assigned to either a diet advice-only group or a combined diet and breathing group. Outcomes will include changes in diastolic blood pressure, adherence to intervention routines, and stress levels measured through the Perceived Stress Scale (PSS-6). Findings from this study could lead to scalable, community-based approaches for hypertension management and support Prisma Health's strategic goals of advancing preventive care and chronic disease management in older adult populations.

## **Research Question**

In adults aged 60 years and above with early-stage hypertension, does a combined intervention of a plant-based diet and daily 20-minute diaphragmatic (deep) breathing exercises reduce diastolic blood pressure more effectively than plant-based diet advice alone over 8 weeks?

## **Specific Aims:**

- **Aim 1:** Determine whether the combined intervention results in greater diastolic blood pressure reduction compared to plant-based diet advice alone.
- **Aim 2:** Assess adherence levels to diet and breathing exercises and examine their relationship with blood pressure outcomes.
- **Aim 3:** Evaluate whether stress reduction mediates improvements in diastolic blood pressure.

## **Hypotheses:**

- **H1:** Participants receiving the combined intervention will have significantly greater reductions in diastolic blood pressure.
- **H2:** Higher adherence to the combined intervention will correlate with larger decreases in blood pressure.
- **H3:** Reduced stress levels will partially mediate blood pressure improvements.

## **Background & Significance**

- **Background**

Hypertension remains a leading risk factor for cardiovascular morbidity and mortality, especially among adults aged 60+. Plant-based diets have been shown to lower blood pressure by supplying essential nutrients like potassium and fiber while reducing inflammatory markers. Studies by Yokoyama et al. (2014), Gibbs et al. (2021), and Aljuraiban et al. (2020) demonstrate a significant decrease in both systolic and diastolic blood pressure from plant-based eating patterns.

Similarly, diaphragmatic breathing has been validated as an effective, non-pharmacological approach to improving autonomic function and lowering stress-induced elevations in blood pressure (Herawati et al., 2023; Chaddha et al., 2019; Bergeri & Daruwala, 2025). By enhancing parasympathetic activity, deep breathing offers a simple but powerful way to address stress as a blood pressure trigger.

## **Significance & Innovation**

This study addresses the need for low-cost, scalable interventions for hypertension management among older adults. Combining diet and breathing addresses two distinct yet complementary pathways: physiological and psychological contributors to high blood pressure.

This intervention combines two evidence-based strategies into a single, cohesive approach aimed at improving health outcomes. It specifically targets early-stage hypertensive older adults to promote timely and effective management of hypertension. To better understand how the intervention works, it incorporates stress assessment and adherence tracking, allowing for insight into the underlying mechanisms influencing its effectiveness.

## **Alignment with Prisma Health Priorities**

Supports community health by offering affordable, home-based lifestyle interventions aimed at chronic disease prevention among vulnerable older adult populations.

## Approach:

### Strategy

The overall strategy of this project is to conduct a randomized controlled trial (RCT) with two parallel arms to rigorously assess the efficacy of the intervention. Participants will be randomly assigned to either:

- Control Group: Plant-based diet advice only.
- Intervention Group: Plant-based diet advice plus daily 20-minute diaphragmatic breathing exercises.

This strategy allows for a clear evaluation of the individual and combined effects of the interventions on diastolic blood pressure (DBP) among older adults.

### Methodologies

Participants will be recruited through Prisma Health community networks and affiliated clinics. Eligibility criteria include adults aged 60 and above with early-stage hypertension (systolic BP 130–139 mmHg or diastolic BP 80–89 mmHg). Following informed consent, baseline data will be collected, including blood pressure measurements and the Perceived Stress Scale-6 (PSS-6).

Participants in the intervention group will receive training on diaphragmatic breathing techniques either in-person or through telehealth sessions. All participants will receive structured counseling and printed materials about following a healthy plant-based diet.

Participants will maintain daily logs tracking their adherence to the dietary advice and, if applicable, to the breathing exercises. Follow-up assessments, including blood pressure measurements and the PSS-6, will occur at the midpoint (week 4) and final endpoint (week 8).

### Measures

#### **Outcome(s)/Dependent Variable(s):**

The primary outcome is **diastolic blood pressure (DBP)**, measured at baseline, week 4 (midpoint), and week 8 (final). Blood pressure will be assessed using calibrated automatic clinical BP monitors at Prisma Health facilities.

#### **Predictor(s)/Independent Variable(s):**

The main independent variable is **intervention group assignment**:

- Control Group: Plant-based diet advice only
- Intervention Group: Plant-based diet advice plus diaphragmatic breathing

Adherence to the intervention will be tracked through daily self-reported logs recording diet and breathing practice.

#### **Management of Co-Interventions and Confounding Variables:**

Information on potential confounders, such as changes in medications, significant lifestyle modifications, or medical events during the study period, will be collected through follow-up questionnaires. Participants will be instructed to maintain their usual activities and medication regimens unless medically advised otherwise.

### Analysis Plan

Primary analysis will involve **independent samples t-tests** to compare changes in diastolic blood pressure between the control and intervention groups.

Secondary analyses will include **Pearson correlation** to assess associations between adherence levels and blood pressure

changes.

A **mediation analysis** will be conducted to determine whether reductions in perceived stress, as measured by the PSS-6, mediate the relationship between the intervention and blood pressure outcomes.

All analyses will follow an **intention-to-treat** approach, preserving the benefits of randomization.

### **Feasibility**

This study is feasible within the Prisma Health setting due to access to the target population and the availability of clinical infrastructure for blood pressure monitoring. Telehealth and remote monitoring reduce participant burden and ensure flexibility, confidentiality, and minimal disruption to clinical operations. The Principal Investigator has completed training in clinical research methods, intervention design, and statistical analysis, supporting the successful execution of the project within the proposed timeline and budget.

### **Capacity of Investigators**

The Principal Investigator (PI) is a master's student in Biomedical Data Science and Informatics with foundational training in clinical research design, health intervention development, and statistical analysis. Although early in their career, the PI has a strong commitment to translational research and is guided by faculty mentorship throughout the study process, ensuring successful completion of the project.

### **Overall Impact**

If successful, this project could offer an affordable, sustainable, and accessible strategy for hypertension management in older adults. The combination of dietary intervention and stress reduction aligns with Prisma Health's mission of improving community health through preventive care. Positive findings could lead to integration into community health programs, rural clinics, and senior wellness initiatives, thereby expanding the impact beyond the immediate study participants.

## References

1. Aljuraiban, G., Chan, Q., Gibson, R., Stamler, J., Daviglus, M. L., Miura, K., ... & Griep, L. M. O. (2020). Association between plant-based diets and blood pressure in the INTERMAP study. *BMJ Nutrition, Prevention & Health*, 3(2), 133–142. <https://doi.org/10.1136/bmjnp-2020-000077>
2. Bergeri, A. S., & Daruwala, S. (2025). Effectiveness of Abdominal Deep Breathing Exercises in Managing Blood Pressure Among Hypertensive Patients. *Cureus*, 17(2), e78393. <https://doi.org/10.7759/cureus.78393>
3. Chaddha, A., Eagle, K. A., Braverman, A. C., & Messerli, F. H. (2019). Nonpharmacologic therapy for hypertension: What is the evidence? *Current Hypertension Reports*, 21(2), 14. <https://doi.org/10.1007/s11906-019-0915-2>
4. Gibbs, J., Gaskin, E., Ji, C., Miller, M. A., & Cappuccio, F. P. (2021). The effect of plant-based dietary patterns on blood pressure: A systematic review and meta-analysis. *Journal of Hypertension*, 39(1), 23–37. <https://doi.org/10.1097/HJH.0000000000002604>
5. Herawati, I., Mat Ludin, A. F., Mutalazimah, M., Ishak, I., & Farah, N. M. F. (2023). Breathing exercise for hypertensive patients: A scoping review. *Frontiers in Physiology*, 14, 1048338. <https://doi.org/10.3389/fphys.2023.1048338>
6. Joshi, S., & Ettinger, L. (2019). Plant-Based Diets and Hypertension. *American Journal of Lifestyle Medicine*, 13(6), 486–493. <https://doi.org/10.1177/1559827619875411>
7. Satija, A., Bhupathiraju, S. N., Spiegelman, D., et al. (2016). Healthful and unhealthful plant-based diets and coronary heart disease risk. *Journal of the American College of Cardiology*, 70(4), 411–422. <https://doi.org/10.1016/j.jacc.2017.05.047>
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9. Yokoyama, Y., Nishimura, K., & Barnard, N. D. (2014). Vegetarian diets and blood pressure: A meta-analysis. *JAMA Internal Medicine*, 174(4), 577–587. <https://doi.org/10.1001/jamainternmed.2013.14547>
10. Zaccaro, A., Piarulli, A., Laurino, M., Garbella, E., Menicucci, D., Neri, B., & Gemignani, A. (2018). Psycho-physiological correlates of slow breathing: A systematic review. *Frontiers in Human Neuroscience*, 12, 353. <https://doi.org/10.3389/fnhum.2018.00353>

## Biographical Sketch

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 01/31/2026)

### BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.

Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Susitra Gnanasambhandam

eRA COMMONS USER NAME (credential, e.g., agency login): N/A

POSITION TITLE: Graduate Student/ Principal Investigator

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	Completion Date MM/YYYY	FIELD OF STUDY
SRIHER, Chennai, India	B.Sc. (Hons.)	06/2024	Biomedical Sciences
Clemson University	M.S.	In Progress	Biomedical Data Science and Informatics

### A. Personal Statement

I am a master's student passionate about applying data science and public health research to real-world challenges. With training in statistical modeling, clinical data analysis, and intervention design, I am leading this seed grant project to explore a combined lifestyle approach, plant-based diet and deep breathing, to reduce hypertension in older adults. This work is aligned with Prisma Health's goals of promoting non-pharmacological, community-based interventions. My prior research and healthcare exposure position me well to manage this project effectively.

### B. Positions, Scientific Appointments, and Honors

- Intern, Brigham and Women's Hospital, Harvard Medical School (Apr–Oct 2023)
- Class Representative, SRIHER

### C. Contributions to Science

- Contributed to research on infertility diagnostics using deep learning and microfluidics.
- Led a molecular docking study on mutations in the PAH gene related to PKU.
- Developed Power BI dashboards for healthcare analytics and e-commerce monitoring.
- Designed a project on combining diet and deep breathing to manage hypertension, with plans to conduct an RCT as part of Health Research coursework.

## Budget

Seed Grant Detailed Budget					Start Date 01/01/2026	End Date 06/30/2027
<b>Personnel</b> – Key Personnel salary/fringe is unallowable. Other Personnel may be requested if necessary to complete the project.					<i>*Specify which academic partner will incur the costs.</i>	
Name or TBD	Role	Percent Effort	Salary Requested	Fringe Benefits	Total (Salary + Fringe)	Academic Partner*
Susitra Gnanasambhandam	Principal Investigator	45%	\$0	\$0	\$0	Clemson University
Subtotal Personnel						
Materials and Supplies					\$700	\$0
Equipment (over \$5,000 per unit)						\$0
Travel					\$4,500	\$0
Consultants/Contractors						\$0
Patient Care Costs					\$6,000	\$0
Other – Participant Incentives – For ClinCards include the card and load fees.					\$5,000	\$0
Other – Miscellaneous					\$650	\$0
Other Expenses – Publication / Dissemination					\$500	\$0
Subtotal Prisma Health					\$15,500	\$0
Subtotal Academic Partner					1,850	\$0
Total Budget					\$17,500	\$0



## **Budget Justification**

### **Materials and Supplies (\$700):**

Funds are requested for printing participant questionnaires (including PSS-6 stress scales), consent forms, dietary education materials, and breathing exercise guides. Additional supplies such as pens, folders, and data collection sheets will also be purchased. Costs were estimated based on approximately \$7 per participant for materials (100 participants). All material costs will be incurred by the student investigator through general academic supplies and printing services.

### **Travel (\$4,500):**

Participants will be reimbursed \$15 per visit for travel costs to Prisma Health locations for blood pressure measurements. Each participant will make three visits (baseline, midpoint, final), totaling \$45 per participant.

$\$45 \times 100 \text{ participants} = \$4,500.$

Travel reimbursements will be issued via ClinCard or equivalent system administered by Prisma Health.

### **Patient Care Costs (\$6,000):**

Blood pressure measurements will be conducted at Prisma Health sites. A flat fee of \$20 per BP check is allocated to cover clinical staff time, equipment use, and clinic space for a total of three BP checks per participant:

$\$20 \times 3 \text{ visits} \times 100 \text{ participants} = \$6,000.$

All patient care costs will be incurred at Prisma Health facilities.

### **Participant Incentives (\$5,000 + \$300 card fees):**

Each participant will receive a \$50 incentive through a prepaid gift card (ClinCard) after completing the final study visit.

$\$50 \times 100 \text{ participants} = \$5,000.$

An additional ~\$3 per participant (\$300 total) covers ClinCard purchase and load fees.

Participant incentives will be distributed by Prisma Health's financial services team.

### **Other Direct Costs – Miscellaneous (\$500):**

Miscellaneous costs include study logistics such as Zoom subscriptions for virtual check-ins, small snacks or refreshments during participant visits, thank-you notes, and any additional incidental supplies required for participant engagement.

All miscellaneous costs will be managed by the student investigator through standard academic purchasing.

**Publication and Dissemination (\$500):**

Funds are allocated for poster printing and dissemination of study findings at Clemson University research day events. Printing a high-quality academic poster is estimated at \$250, with an additional \$250 reserved for creating educational infographics summarizing results for participants and Prisma Health community outreach.

**Cost Allocation Statement:**

All costs related to patient care (blood pressure checks), participant travel reimbursements, and incentive distributions will be incurred at Prisma Health. All remaining costs, such as printing, educational materials, and miscellaneous supplies, will be managed by the student investigator and processed through Clemson University. No partner institution awards are required. Prisma Health will retain funding for all expenses incurred on-site, including participant-related clinical costs and travel reimbursements.