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Protocol

Official Study Title:

ReCLaiMeD: Using community healthcare workers to improve blood pressure control among food insecure hypertensive adults: Aim 2

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Protocol

1. Project Title

ReCLaiMeD: Using community healthcare workers to improve blood pressure control among food insecure hypertensive adults: Aim 2

2. Investigator(s):

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3. Abstract:

Each year, hypertension causes 10 million deaths worldwide. Controlling blood pressure (BP) among individuals with hypertension can dramatically reduce risk of stroke, heart attack, cardiovascular disease, and kidney damage. In the United States, 1 in 2 adults has hypertension, and 3 in 7 are aware of their disease yet do not have their BP controlled. Basic behavioral strategies including eating healthy diets rich in fruits and vegetables can improve BP control. While dietary changes are difficult in general, individuals experiencing food insecurity face additional barriers. Tailored strategies that address these barriers to improve dietary intake are critically needed to reduce BP among hypertensive individuals with socioeconomic vulnerabilities. In close collaboration with community partners, this pilot project will feasibility test a community health worker (CHW)-administered education implementation strategy with and without an enhanced CHW-navigation component designed to improve fruit and vegetable intake and BP control among individuals experiencing food insecurity and hypertension while living in East Gainesville. Once our pilot is complete, we will be prepared to submit a competitive NIH R01 proposal to evaluate the effectiveness of the implementation strategies.

4. Background:

Uncontrolled high BP is the major predictor of cardiovascular diseases including stroke and heart failure causing the greatest number of premature deaths in the United States (US).^{1,2} Due to the overwhelming evidence of an association between diet and cardiovascular disease,³ guidelines to reduce and control BP include recommendations to eat diets rich in fruits and vegetables.^{4,5} Consumption of fruits and vegetables are associated with significant reductions in BP and can resemble the effectiveness of monotherapies for mild hypertension with decreases of up to 8 mmHg systolic and 4 mmHg diastolic.^{6,7}

Recommending healthy diets without reducing barriers to nutritional lifestyle changes has modest effectiveness on cardiovascular health due to food insecurity, nutritional skills gaps, and socioeconomic vulnerability.⁸⁻¹² Participation in federal nutrition assistance programs aimed at improving food security, such as the Supplemental Nutrition Assistance Program (SNAP), can increase food access and

decrease consumption of unhealthy foods.¹³ However, improving food security alone has limited effectiveness because individuals may increase intake of a less healthy foods, be unable to reach stores that accept SNAP and have healthy foods, be unable to identify eligible healthy foods, or have the skills to create culturally relevant and healthy meals.^{8,9,14,15} While federal nutrition education programs such as SNAP-ED and the Expanded Food and Nutrition Education Program have shown success in addressing the nutrition educational gap,¹⁶⁻¹⁸ the programs' effectiveness may be reduced by limited access to healthy foods within vulnerable communities and limited community reach due to funding restrictions.¹⁹

We will evaluate the feasibility, acceptability, and appropriateness of a nested series of tailored implementation strategies designed to educate individuals about available food Resources, provide culturally relevant Cooking recipes, help individuals Learn to use their resources, Motivate individuals to take control of their BP, and Drive individuals to local grocery stores (entitled ReCLaiMeD to represent individuals' ability to reclaim control of their BP). We chose to address hypertension and food insecurity including transportation barriers due to local needs assessments indicating community interest and need.²⁰⁻²³ To increase the likelihood of success, all components of our implementation strategies will be adapted from evidence-based programs in increasing food access, healthy diets, or healthy behaviors including registering individuals for SNAP, providing education on managing food resources, and transportation assistance.²⁴⁻²⁷ Finally, following other successful strategies to address food insecurity and knowledge,^{28,29} a CHW will implement the strategies to bridge community members with the health resources.^{28,30}

5. Specific Aims:

The overall objective of this project is to assess the feasibility, acceptability, and appropriateness of adapted community health worker (CHW)-led implementation strategies designed to improve intake of fruits and vegetables and reduce BP among patients with hypertension experiencing food insecurity. Guided by the Integrated Behavioral Model, this pilot study will adapt CHW education (personalized information and assistance with food benefit programs, healthy eating strategies and motivation to reduce hypertension) with and without navigation/personalized implementation strategies (transportation to grocery stores/\$10 gas card, culturally adapted hypertension-tailored recipes, and asynchronous online demonstrations of cooking healthier meals). The project will target East Gainesville communities characterized by high rates of cardiovascular disease deaths, food insecurity, and socioeconomic vulnerability.

Aim. Evaluate the feasibility, acceptability, and appropriateness of CHW-led implementation strategies designed to improve consumption of healthy foods and ultimately reduce BP.

Among hypertensive adults experiencing food insecurity and living in East Gainesville, we will conduct a three-arm, individually randomized feasibility trial assigning participants equally to: (1) A CHW-assisted educational program, (2) A CHW-assisted educational program with navigation/personalized implementation strategies, or (3) no strategy.

The results of this feasibility study will provide the preliminary evidence to justify the need for efficacy testing this novel personalized and precisely targeted implementation strategy to prevent cardiovascular deaths within our most vulnerable communities.

6. Research Plan:

6.1 Study Design

We will evaluate the feasibility of the implementation strategies with a three-arm individually randomized controlled trial of 75 participants in which participants are equally randomized to no strategy, CHW education, or CHW education and navigation (Figure 1). Prior to data collection, and once a CHW is identified, they will be added to the study team.

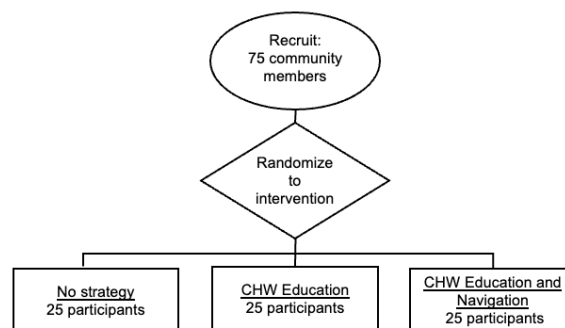


Figure 1. ReCLaimMeD Study Design

6.2 Study population

Participants who have self-reported diagnosed hypertension, BP between 130 to 179 mm Hg systolic or 80 to 119 mm Hg diastolic, experience food insecurity (defined by the 10-question US Adult Food Security Survey Module), live in 32609, 32601, or 32641, are between 18 and 69 years old, and did not participate in our developmental focus groups (IRB202202859) are eligible for this study. We chose our BP eligibility to be consistent with guidelines from the American Heart Association and American College of Cardiology for hypertension that does not indicate a medical crisis.^{31,32} We chose to focus on the zip codes 32609, 32601, and 32641 due to extensive vulnerability for hypertension, food insecurity, and poverty (Table 1). Compared to Florida, the targeted zip codes have more disparate measures of CVD-related deaths, limited care for hypertension, hypertension-related emergency care, and social vulnerability as indicated by the red font in Table 1.³³⁻³⁸ Within Gainesville, the city that encompasses our targeted zip codes, a greater percentage of households (11%) do not have a vehicle compared to the US average (9%).³⁹ The surrounding county, Alachua, has medium to high transportation vulnerability (score =0.7 on scale of 0 lowest to 1 highest vulnerability).⁴⁰

Table 1. Vulnerability of the Population within East Gainesville Zip Codes compared to Florida and the US

	32601	32609	32641	Florida	US
Age-adjusted CVD-Related Deaths per 100,000 ^a	145	159	185	146	162
% Adults who have taken medication for high blood pressure ^b	58%	71%	75%	77%	79%
Adults with ER visits for hypertension per 10,000 ^c	63.9	61.8	93.5	52.1	--
Area Deprivation Index Percentile ^d	64%	78%	83%	52%	50%
% Households Utilizing SNAP ^e	13%	25%	26%	16%	14%
% Adults Aged 18-64 Living in Poverty ^e	48%	22%	27%	12%	12%
Food Insecurity Index Percentile ^f	71%	88%	95%	-	50%
% Population Non-Hispanic Black	17%	36%	67%	15%	12%

6.3 Study Procedures

6.3.1 Recruitment and Consent

We will attend community events to inform community members about the study. At these events, we will distribute recruitment flyers. One of the main places we will inform community members about the project is at food distribution

Table 2. Activities by Cohort at each of the Four Food Distribution Events

	Event 1	Event 2	Event 3	Event 4
Recruitment and Baseline	Cohort 1	Cohort 2	Cohort 3	
Post-implementation measurements		Cohort 1	Cohort 2	Cohort 3

events hosted by Pastor Duncan at his Food is Medicine program (see letter of support). The recruitment flyer includes a QR code that links to our study REDCap eligibility survey (see REDCap eligibility survey). During events, we will assist interested community members in accessing and completing the REDCap eligibility survey. When appropriate study staff and equipment are available, we will enroll eligible and interested persons during the community events. If not all materials or staff are available, we will offer interested and eligible persons opportunities approximately 4 weeks apart to enroll (Table 2). We will also use these opportunities to have participants return for post-implementation measurements. We plan to have three cohorts of approximately 25 participants for a total of 75 participants.

Interested community members will be assessed for eligibility in two steps. First, community members will be invited to complete the REDCap screening survey that includes questions on our criteria: self-reported diagnosed hypertension, food insecurity status (defined by the 2-question US Adult Food Security Survey Module), live in 32609, 32601, or 32641, are 18-69 years old, and did not participate in our developmental focus groups (see REDCap eligibility survey). Participants who are eligible by the REDCap screener survey will be directed to choose either complete the second step of eligibility at the same time (when available) or select a future date. We will call eligible participants to remind them about their events that they have chosen to attend (See reminder script).

Second, for community members that are eligible by the screening questions, CHWs or study team member will measure their BP with an appropriately sized cuff in duplicate, averaged for the visit, according to current standards specified by the American Heart Association.⁴¹ CHWs or study team member will use a single validated monitor for all measurements to minimize device-related variability in BP, and will use the same arm at both measurement time points (determined on baseline measurement). CHWs or study team member will give community members a record of their blood pressure measurement, a page showing where their BP falls on the diagnostic scale (normal, elevated, hypertensive stage 1, hypertensive stage 2, or hypertensive crisis), and a list of Gainesville primary care practices that accept Medicaid or provide free care, with contact information. Community members with BP between 130 to 179 mm Hg systolic or 80 to 119 mm Hg diastolic will be invited to participate.

A study team member will explain the consent to the potential participant. The consent will be explained at the event in an area as private as possible given the setting. We will retain the screening information for the consented participants and delete the information for those who do not qualify or consent.

6.3.2 Evaluation Data

Community members who consent, i.e., participants, will be invited to complete the baseline data collection, randomly assigned to a study group, and receive instructions on the next steps. When possible, this collection will happen on the same day as screening. Otherwise, participants will sign up to complete this data collection at specified times. The baseline data collection includes a brief behavior survey (See pre-intervention survey) and baseline biometrics. The baseline survey includes questions about fruit and vegetable intake, intent to increase fruit and vegetable intake, knowledge/skills about available food programs, co-morbid factors, and self-reported demographics. Regarding biometrics, in addition to BP, will measure fruit and vegetable

intake with self-report (National Institutes of Health Eating at America's Table survey) and a biologic marker of skin carotenoid – the Veggie Meter.⁴² The Veggie Meter is an FDA-approved instrument that uses resonance Raman spectroscopy to reliably, effectively, and non-invasively measure fruit and vegetable consumption in a community setting.⁴³ Similar to Dr. Shelnutt's prior research, a trained research staff will direct participants to place one of their index fingers on a lens on the top of the Veggie Meter. A lever will be lowered to apply gentle pressure to blanch the skin temporarily and measure the skin carotenoid. The participants will be provided with a veggie meter educational sheet with a record of their veggie meter score (please see miscellaneous attachment Veggie Meter Educational Sheet).

Upon enrollment, participants will be invited to attend the event in 4 weeks to complete their post intervention assessments. Participants will receive \$25 for completing baseline measurement and \$50 for completing the post-implementation strategy measurements. Post-implementation strategy measures will be identical to the pre-implementation measurements with the addition of self-reported use of the offered services and the validated and reliability tested four-item scales to measure Acceptability of Intervention (AIM), Feasibility of Intervention (FIM), and Appropriateness (IAM).⁴⁴

6.3.3 Intervention Assignment and Components

After the completion of the baseline data, participants will randomly be assigned to one of the three arms: (1) no strategy (n=25 participants), (2) CHW education (n=25 participants), (3) CHW Education and Navigation (n=25 participants). Each participant will be in the study for the following 4 weeks.

The implementation strategies will be conducted by a trained CHW from within the East Gainesville community. Our partner organization, *ComHIT*, will provide certified training to the CHW (see letter of support). The elective courses for the CHW will include training on: (1) measuring BP, providing dietary education, and behavior change support led by co-investigator, Dr. Harrell; (2) consent procedures and rigor for data collection led by MPI Dr. Staras, and (3) communication approaches to maximize impact led by co-investigator Dr. Bylund. The communication approaches will be grounded in principles of patient-centered communication which have been shown to be linked to important patient outcomes.⁴⁵ CHW training will follow best practices for communication skills training including an explanation of the concepts, modeling of the communication approaches, and practice.⁴⁶

The participants assigned to **no strategy** will be provided a color copy of the NIH's Healthy Blood Pressure for Healthy Hearts: Small Steps to Take Control Flyer available at: <https://www.nhlbi.nih.gov/health-topics/education-and-awareness/high-blood-pressure/publications-patients>.

The **CHW Education arm** participants will be invited to meet with the CHW to learn about eating healthier to reduce blood pressure and enhance quantity and quality of life. The CHW will register individuals for SNAP benefits and educate them on how to use their benefits locally. As other resources exist, including food pantries and food distribution events, the CHW will provide information on these services. The CHW will also provide a brief motivational educational session about eating healthier to reduce BP and enhance quantity and quality of life. The CHW will meet once for up to one hour with each participant. Meeting will occur at a negotiated time and place between the CHW and

the participant including, but not limited to the participant's home, public locations, the mobile outreach clinic, and the Food is Medicine conference rooms.

The **CHW Education and Navigation arm** participants will be invited to complete all the CHW education arm material and be offered a menu of optional services for personalization including: (1) transportation to the grocery store (weekly for 4 weeks provided by MyHealthDriv see support letter) or \$10 gas card, (2) culturally adapted hypertension-tailored cooking recipes, and (3) access to UF IFAS's online library of healthy food cooking videos.. The CHW will aim to complete the first meeting regarding education within one week of enrollment. At the education meeting, the CHW will explain the options available to the participant, gather interest in each activity, and schedule grocery store transportation or provide a \$10 gas card. The CHW will attempt contact by phone or in-person with education and navigation arm participants. Meetings between the CHW and participant will occur at a negotiated time and place between the CHW and the participant including, but not limited to the participant's home, public locations, the mobile outreach clinic, and the Faith Ministries conference rooms.

6.3.4 Data Analysis Plan

We will produce descriptive statistics of baseline characteristics for study participants in each arm and test for balanced randomization. We will perform regression analyses, ANOVA estimations, and non-parametric statistical tests for pre-post differences in BP and carotenoid levels within and between treatment arms. Assuming a baseline systolic mean of 140 mmHg, standard deviation of 10, 25 participants/arm, and alpha 0.05, we will have 82% power to detect a 8 mmHg difference in both active arms vs. control, similar to prior dietary studies ($\geq 71\%$ power if one arm achieves only 4 mmHg difference).^{7,47,48} Average scores of ≥ 3 on the 0-5 scale for AIM, FIM, and IAM will indicate success.⁴⁹

7. Possible Discomforts and Risks:

The proposed research does not present risk greater than minimal risk defined by 45 CFR 46 as no greater than those encountered during routine clinical examinations or psychological examinations. There are no physical risks to the participants posed by this study. There is a slight risk that information provided could be revealed inappropriately or accidentally. Depending on the nature of the information revealed, such a release could upset or embarrass participants. There is no known risk associated with participation in the behavioral surveys, BP or Veggie Meter monitoring, or receiving educational material.

To minimize this risk of accidental disclosure of information, we will take extensive security precautions during data collection, data storage, and communication with participants. Data collection will occur via RECap. All data will be kept confidential, stored on secure servers, identifiers will be destroyed as soon as possible, and access to data will be limited to the minimum staff necessary. Individual information will not be released to anyone outside the project and will only be accessible to the principal investigator and the research team.

University of Florida (UF) information technology (IT) Security Office is responsible for the development and maintenance of the Health Science Center (HSC) Information Security Program. The UF-HSC IT Department is responsible for adapting, supplementing as necessary and implementing the Information Security Program for ICHP. Each component is reviewed internally at least biannually (every two years) or as necessary due to environmental, operational, or Information Security Program changes.

ICHP is able to maintain optimal security practices through the use of the services and expertise of the UF-HSC IT Department to maintain optimal security practices. Specifically, the UF-HSC IT Department has experts on protection of health data and HIPAA compliance across multiple platforms, systems and applications. The servers supporting the ICHP computing environment are connected to a Cisco based IP network, protected by a Palo Alto high-performance firewall which provides both application and port-based security. The firewall provides connectivity to the AHC enterprise network. The UF-HSC IT Security Office and the overall UF IT Security Office conduct audits and perform network and vulnerability scanning and alerting. The University of Florida has a campus-wide Intrusion Detection Service that monitors all traffic leaving the University. Network sweeps are performed using Nessus to look for vulnerabilities to address in cooperation with HSC system administrators. Risk assessments are performed on an ongoing and scheduled basis following a process outlined in the IS Audit Methodology document. Each server is individually protected by a host-based firewall that provides local-port based access control. The configuration of all host-based firewalls is managed centrally through either Active Directory GPOs or through Trend's Deep Security Console. A VPN encrypts data between remote devices and the secure network. A site-to-site VPN and Globalscape Secure FTP architecture provides security for bulk data transfers. Physical access to the HSC Data Center is monitored 24/7 via a video recording security system. Full motion video for all data center cameras is retained for 15 days. Data Center personnel administer and audit physical access using the University of Florida's enterprise LENEL access management system. Wiring closets have key specific locks and all equipment is protected by software that only allows devices approved and maintained by the institution to access the network. Trend Office Scan protects ICHP Windows servers from viruses and spyware. Workstations are protected from viruses and malware via TrendMicro's Corporate Edition OfficeScan Agent. Lumension Endpoint Management and Security Suite software provides automated deployment of Windows Security updates and auditing of server patch compliance. The Linux server patching process utilizes a combination of Puppet configuration management software and shell scripts to download a list of pending patches per system.

8. Possible Benefits:

There is potential of direct benefit to community members from participating. Participants may benefit from learning their blood pressure, receiving education about how to control their blood pressure, and learning strategies of how to obtain and use more fruits and vegetables. Participants may lower their blood pressure.

9. Conflict of Interest:

No conflicts of interest to report.

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