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Community health worker navigation to improve allostatic load: The Integrated Population Health (IPOP) study

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ABSTRACT

Background: Social determinants of health (SDOH) and cumulative stress contribute to chronic disease development. The physiological response to repeated stressors typical of lower-income environments can be measured through allostatic load – a composite measure of cardiovascular, metabolic, and immune variables. Healthcare systems have employed patient navigation for social and medical needs to improve SDOH that has demonstrated limited impact on chronic disease outcomes. This study evaluates a novel community health worker navigation intervention developed using behavioral theories to improve access to social and medical services and provide social support for poverty stressed adults.

Methods: The Integrated Population Health Study (IPOP) study is a randomized, parallel two arm study evaluating community health worker navigation in addition to an existing integrated population health program (IPOP CHW) as compared to Usual Care (population health program only, IPOP) on allostatic load and chronic disease risk factors. IPOP CHW participants receive a 10-month navigation intervention.

Results: From 381 screened individuals, a total of 202 participants (age 58.15 ± 12.03 years, 74.75 % female, 79.21 % Black/African American, 17.33 % Hispanic) were enrolled and randomized to IPOP CHW (n = 100) or IPOP Only (n = 102).

Conclusion: This study will evaluate whether CHW navigation, using a structured intervention based on health behavior theories, can effectively guide poverty stressed individuals to address social and medical needs to improve allostatic load—a composite of cumulative stress and physiological responses. Healthcare systems, nonprofit organizations, and governmental entities are interested in addressing SDOH to improve health, thus developing evidence-based interventions could have broad clinical and policy implications.

1. Introduction

In recent decades, the medical field has taken a greater interest in the social determinants of health, or the conditions in which people are born, grow, live, play, work and age that affect a wide range of health outcomes [1]. Macro-level policy decisions regarding labor, housing, land use, public safety net spending, economic development and more influence the material, behavioral and psychosocial environments of an individual. Health disparities, from this perspective, are the direct result of a stratified and imbalanced power distribution between and within societies, and experts are increasingly beginning to recognize disease as both a biological and social phenomenon [2]. The role of stress as a contributing factor to the development of chronic disease and a pathway for social determinants to impact health is a long-standing area of study.

Allostatic load is a composite index representing the bodily wear and tear inflicted by chronic stress and adaptation to stress [3,4] that often includes physiological measurements such as blood pressure, body mass index (BMI), and waist-to-hip ratio as well as biomarkers of stress

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including cortisol and C-reactive protein [5–7]. Allostatic load is associated with higher rates of type 2 diabetes, obesity, cardiovascular disease, cancer and mortality [3,8–10]. It is inversely related to income and education [11–14], but directly associated with neighborhood income- and/or race-based segregation [11,12]. Racial minorities have greater exposure to environmental stressors and exhibit higher allostatic load than their White peers [13,14], especially among individuals who report greater perceived racial or social discrimination [15].

Healthcare systems have struggled to create effective programs and interventions to address social determinants of health and improve health outcomes, particularly for chronic conditions among low-income racial and ethnic minority populations. Unaddressed social needs—such as food insecurity, unreliable transportation, or housing insecurity—increase healthcare costs and utilization [16,17]. Previous interventions have sought to connect patients with social services to address their health-related social needs with mixed results and using various iterations of case managers, such as social workers, nurse care managers, or navigators [16,18–20]. Often missing from these interventions is the integration of culturally competent staff, such as community health workers (CHWs).

CHWs have been shown to effectively reduce hospitalization rates, duration of stay, recurrent readmissions [21,22] and improve chronic disease management [23–25]—particularly within medically underserved, low-income, racial-ethnic minority communities [24–26]. CHWs have demonstrated positive effects on healthcare costs and utilization [27], with some studies demonstrating cost-effectiveness and decreased emergency care utilization based on certain conditions [25,26,28,29], and others showing cost savings offset by increased ambulatory care use. However, evidence of their effectiveness in population health models, as opposed to disease-specific interventions, remains limited [25], as does their effect on stress markers such as allostatic load.

Given the importance that allostatic load places on how external environmental stressors "get under the skin", *place* becomes an even more significant factor in health disparities. Racial/ethnic residential segregation, for instance, is a key driver of place-based health disparities, as well as disparities in allostatic load [11]. In Dallas County, these health disparities are quite stark—mortality rates for heart disease, stroke, cancer, diabetes, and all-causes are magnitudes greater in the predominantly Black and Hispanic southern portion of the county than the predominantly White northern sector [30]. The Community Needs Index—a composite index of area poverty, income, unemployment, occupation, education and language—corroborates the high level of social vulnerability and need in Southern Dallas [30]. The vast majority of ZIP codes in Southern Dallas score in the greatest need quintile for all six indicators correlated with premature death and preventable hospitalization rates [30]. The southern sector of Dallas County typifies other urban areas throughout the nation characterized by historical disinvestment, redlining, and generational poverty.

CHWs have a unique capacity to effectively navigate the social and medical needs of lower-income ethnic minority communities that can potentially reduce physiological stress responses related to worse health outcomes. The Integrated Population (IPOP) Health study will evaluate whether CHW navigation for medical and social needs improves allostatic load in a place-based population health initiative. The primary hypothesis is that the IPOP CHW intervention will lead to better improvements in allostatic load as compared to Usual Care.

2. Methods

2.1. Study aims

The primary aim of the IPOP study is to determine whether CHW navigation for medical and social needs in addition to an existing population health model improves allostatic load as compared to usual care (access to population health model without navigation) at 6-months. Secondary aims include changes in diet, physical activity, stress, psychosocial and physiological variables, and utilization of health care services.

2.2. Study design

The IPOP study is a single center, randomized, parallel two arm study evaluating the impact of CHW navigation in addition to an integrated population health program (IPOP CHW) on allostatic load in 202 adults. Participants were randomized to one of two 10-month interventions: 1) IPOP plus CHW navigation (IPOP CHW) or 2) IPOP Only (Usual Care). Beginning in May 2021, participants were recruited and enrolled on a rolling basis. A total of seven cohorts of participants (n = 20–30 per cohort) were recruited between May 2021 and August 2022. Participants completed informed consent prior to enrollment, and the Institutional Review Board of Baylor Scott & White Research Institute approved the study.

2.3. Recruitment

Study recruitment was guided by a Resident Advisory Council (RAC). The RAC was comprised of 10 residents from six designated ZIP codes in the southern sector of Dallas located within 10 miles of the Baylor Scott & White Health and Wellness Center (BSW HWC). Two additional residents who work and run organizations in these ZIP codes also participated in the RAC. The RAC was formed in January 2021 and met virtually due to the COVID-19 pandemic. Their primary role was to guide study recruitment and disseminate study information to local communities.

Participants were recruited through flyers, word of mouth, and community events with the assistance of the RAC and BSW HWC outreach and community partners. Recruitment locations were within the six primary ZIP codes for the study including churches, recreation centers, and housing complexes. Additionally, participants who had been screened for and/or enrolled in previous studies were contacted.

Interested individuals were screened for eligibility using a questionnaire and invited to baseline measures. Eligibility criteria included: 1) living within six designated zip codes or within 10 miles of the BSW HWC; 2) not utilizing BSW HWC programs within the past twelve months; 3) 18 years of age or older; 4) able to alter diet and/or physical activity; 5) willing to participate in a 10-month study; 6) willing to meet with a CHW once a month if necessary; 7) willing to be called or texted about the study; and 8) not planning to move outside the area for the next 10 months.

2.4. Study groups

2.4.1. IPOP only (usual care)

Participants assigned to Usual Care are referred to BSW HWC's membership program, a place-based population health model that provides access to wellness and prevention programs and routine health screening for no charge. BSW HWC has an onsite clinic that provides primary care to low-income uninsured and insured community members. However, only approximately 30% of BSW HWC members are also primary care clinic patients. It is co-located with a city recreation center that provides a low-cost gym with exercise equipment. Free exercise and nutrition classes are offered such as Zumba, yoga, Medical Nutrition Therapy, and the Diabetes Prevention Program [31]. BSW HWC also has a weekly farm stand that provides low-cost fresh produce. The BSW HWC population model has demonstrated improvements in health outcomes and reductions in emergency healthcare use [32]. Members are provided free health screens (i.e., blood pressure, lipids) every 6 months but are not provided an individual CHW or navigation to services. After completion of the study (i.e., completion of 10-month measures), usual care participants are offered one abbreviated CHW navigation session with referrals.

Table 1
Facilitator session guides.

Session	Title	Content, Tools, or Activities	Core Theoretical Constructs
Session 1	Welcome to the I-POP Health Program	- Get to know participant - Build rapport - Set expectations - Complete Participant Intake form	Motivational Interviewing Social support (SCT)
Session 2	Prepare to Take Action	- Reflection with Wellness Wheel - Intake form score review - Develop Wellness Plan - Tools: Wellness Wheel, Wellness Plan, SMART goal worksheet	Motivational Interviewing Social support (SCT)
Session 3	Taking Action	- Mindful Reflection - Goal-setting (Set 3 goals) - Services and referrals	Motivational Interviewing Self-efficacy (SCT) Social support (SCT)
Session 4	Integration of Usual Care	- Mindful Reflection - Review progress toward goals - Provide Navigation - Introduce/Review Membership at the Health and Wellness Center	Motivational Interviewing Self-efficacy (SCT) Social support (SCT)
Session 5	Progress Check: Stay in the Game	- Review progress toward goals - Provide Navigation - Introduce Habit Tracker (to assist with goal monitoring)	Motivational Interviewing Self-efficacy (SCT) Social support (SCT)
Session 6	SMART-ER Goals	- Progress and Habit Tracker Review - SMART-ER Goals- evaluate (E) and reassess (R)	Motivational Interviewing Self-efficacy (SCT) Social support (SCT)
Session 7	Post-Measures Progress Check-In	- Measures Review (mid-point review) - Goal-setting - Habit Tracking review - Review progress and provide navigation/ referrals	Motivational Interviewing Self-efficacy (SCT) Social support (SCT)
Session 8	Where am I? Cycle of Change Self-Assessment	- Introduce Stages of Change model - Cycle of Change activity - Goal progress review and navigation	Motivational Interviewing Self-efficacy (SCT) Social support (SCT) TTM
Session 9	Strengths to Sustain Change	- Identify participant strengths to make/sustain change - Review goals and Wellness Plan	Motivational Interviewing Self-efficacy (SCT) Social support (SCT) TTM
Session 10	Celebrate and Look Forward	- Mapping your Milestones - Planning for the Future (Review of and reflect on goals and progress) - Certificate of achievement	Motivational Interviewing Self-efficacy (SCT) Social support (SCT) TTM

SCT = Social Cognitive Theory, TTM = Transtheoretical Model.

2.4.2. IPOP CHW navigation (IPOP CHW)

The IPOP CHW intervention was based on previously published navigation models and health behavior theory including social cognitive theory, the transtheoretical model, and motivational interviewing to develop a structured CHW navigation intervention that guides participants to identify their top medical and social needs, set goals, refer them to resources, and provide follow-up and support (see Table 1). Participants are provided BSW HWC membership and randomly assigned to a CHW with whom they meet monthly for 10 months. CHWs were chosen to be navigators due to their ability to provide cultural mediation between health care, social services, and the community. CHWs are trusted community members with a close understanding of the ethnicity, language, socio-economic status, and life experiences of the community served.

Motivational Interviewing (MI) is a method of communication or counseling that promotes intrinsic motivation for change [33]. Communication using MI guides participants through evoking reasons and ideas for change; collaboration where participant and interviewer share ideas that influence actions toward change; promoting autonomy by emphasizing personal control and choice; and showing empathy through deep understanding of participant perspectives [33]. The Transtheoretical model (TTM) suggests various stages of change when adopting health behaviors, and provides categories for moving through a behavior change from precontemplation to action to relapse [34]. Social cognitive theory (SCT) posits that behaviors develop from the interplay of individual, behavioral and environmental aspects, and emphasizes the development of self-efficacy and provision of social support as key factors that assist in promoting change [35].

CHWs assist with navigation and are a liaison to navigate systems and structures that participants need to access to improve their health. Individual participants also engage in their health through decision-making about health priorities and taking action to fulfill their health goals. The ten facilitator guides assist CHWs with applying core aspects of MI, TTM, and SCT to promote participant trust, engagement, and autonomy while providing support, education, and connections to essential resources connected to participant health needs and goals (see Table 1).

Facilitator guides for all ten sessions assist CHWs by providing techniques and tools to 1) build a strong relationship between the CHW and the participant to better identify the participant's needs, and 2) connect participants to primary care providers, health information, health screening, financial assistance, transportation, or other resources within the local community that best fit the needs identified by the participant, and 3) provide ongoing support and reevaluation of needs.

Briefly, Session 1 includes an in-person session at BSW HWC to complete a needs assessment. Session 2 develops an individualized, participant-led health and wellness plan. Sessions 3–10 involve assessments of participant progress with delivery of needed resources, education, referrals, and completion of membership to BSW HWC. CHWs complete intermittent check-ins with participants by phone in between scheduled monthly visits. Sessions 2–10 can be completed in-person, by phone, or virtually depending upon participant preference and availability. Individuals can request additional sessions for urgent needs or additional support. All CHW activities are tracked in a database, and process evaluations grade fidelity (e.g., how well tasks are completed) on a random schedule.

CHW Training. Texas state certified CHWs employed by BSW HWC will implement the intervention including several who are bilingual in Spanish and English (n = 9, 100 % female, 44 % Hispanic, 56 % African American). CHWs complete 7 h of didactic MI training and 8 h of facilitator training covering topics related to research study design, skills in building rapport, active listening, practicing MI techniques, virtual technology training to provide virtual sessions, goal-setting skills related to SMART (Specific, Measurable, Achievable, Realistic, and Time-Bound) goals, and orientation to each of the ten facilitator guides, session tools and handouts. Additionally, CHWs complete required human subjects training. A 1-h booster training for MI is provided midway through the study period, and periodic MI activities are incorporated into weekly CHW meetings. To ensure that participants are receiving similar content across sessions, facilitator guides were developed to assist CHWs with reminders of MI skills, sample questions and content to

Table 2
Study measures.

Measure	Time point (months)	Instrument	Description	Validity	Reliability
Waist circumference	0, 6, 10	Tape Measure	Measured twice with inelastic tape to the nearest 0.1 cm using NIH Guidelines [36].	When measured at umbilicus, iliac crest, midpoint, and minimal waist, r = 0.95 to 0.99 for women and r = 0.98 to 1.00 for men [37].	For women ICC = 0.98 to 0.99 for intra-observer and ICC = 0.96 to 0.98 for inter-observer reliability when measured at umbilicus, iliac crest, midpoint, and minimal waist. For men, ICC = 0.99 to 1.00 and 0.98 to 0.99 for intra- and inter-observer [37].
Hip circumference	0, 6, 10	Tape measure	Hip circumference measured around the widest portion of the buttocks, tape parallel to the floor. Measured twice with inelastic tape to the nearest 0.1 cm based on WHO Guidelines [38].		For hip measurement, technical error to be 1.23 cm from intra-measurer error and 1.38 from inter-measurer error [39].
Lipids (HDL, LDL, Total cholesterol, Triglycerides)	0, 6, 10	Alere Cholestech LDX System	Measures fasting blood lipids and glucose profiles from blood samples collected via finger stick.	For all four lipids, r = 0.86 to 0.93 when compared with a hospital reference laboratory [40].	ICC >0.75 for all four lipids when compared with a hospital reference laboratory [41].
Hemoglobin A1C (HbA1c)	0, 6, 10	Siemens DCA Vantage Analyzer	HbA1c measure collected via finger stick.	Mean bias = −0.09, −0.11, −0.21 for reference value of 5.30, 6.14, and 8.05, respectively, when compared with laboratory values [42].	CV = 2.3 %, 2.5 %, 2.7 % for reference value of 5.30, 6.14, and 8.05, respectively [42].
Blood Pressure	0, 6, 10	Omron Digital Blood Pressure Monitor (HEM-907XL)	Measured twice to the nearest 1 mm Hg, averaged.	R = 0.94 for systolic and 0.83 for diastolic BP when compared with mercury sphygmomanometer (HgS) [43].	Cohen's kappa = 0.68 for hypertension when compared HEM-907XL and HgS [43].
Urine albumin/ creatinine ratio (ACR)	0	McKesson Consult Diagnostics 120 Urine Analyzer	Measured once via test strip dipped in urine sample and put in analyzer. Urine sample collected in cup.	Agreement between the Bayer Clinitek 500 Urine Chemistry Analyzer (CM) and the McKesson Consult® 120 Urine Analyzer (WM) is 86.3 % with 95 % CI.	
Cortisol	0, 6	75 μL Saliva, ELISA method	Fasting morning saliva sent to Salimetrics laboratory to measure cortisol using ELISA method.	R = 0.81 when measured by EIA and compared with serum sample [44]. r = 0.98 when compared between EIA and LC-MS methods [45].	CV < 6 % for both intra and inter-assay [44]. Sensitivity: <0.007 μg/dL Assay Range: 0.012–3.000 μg/dL
C-reactive protein (CRP)	0, 6	225 μL Saliva, ELISA method	Fasting morning saliva sent to laboratory to measure CRP using ELISA method.	Salivary CRP significantly correlated with plasma levels (r = 0.73, p < 0.01) [46].	Sensitivity: 9.72 pg/mL Assay Range: 25 pg/mL1600 pg/mL
Diet	0, 6, 10	NHANES – Dietary Screener Questionnaire 2009–2010	The Dietary Screener Questionnaire (DSQ) is a 28-item questionnaire from the National Health and Nutrition Examination Survey (NHANES) [47].	In comparison with 24h-recall, difference in means were <2 % and difference in prevalence were <16 % [47]. Used in African American and Hispanic populations [48–50].	–
Physical activity – Neighborhood Environment	0, 6, 10	Physical activity neighborhood environment survey	7-item questionnaire with one question about residential density but all other questions use a Likert scale [51].	–	ICC ranged from 0.64 for free or low-cost recreation facilities to 0.84 for sidewalks on most streets [51].
Physical activity	0, 6, 10	Past weeks physical activity questionnaire – short form	Records frequency and duration of different levels of PA, developed to optimize applicability and appropriateness in assessing PA in various age and population groups [52].	PWMAQ was significantly associated with averaged accelerometer data: ρ = 0.33–0.76 [52].	ICC = 0.77 [52].
Resiliency	0, 6, 10	Brief resilience scale (BRS)	A self-administered questionnaire with six Likert-style items [53].	Survey demonstrates construct validity [54].	Cronbach's α ranges from 0.70 to 0.95 for internal reliability [54]. ICC of 0.69 and 0.62 for samples n = 48 and n = 61, respectively [54].
Social support	0, 6, 10	The Medical Outcomes Study Social Support (MOSSS) Survey (PhenX Toolkit)	Likert-style 19 items across four functional support subscales: emotional/informational support (8 items), tangible/instrumental support (4 items), affectionate support (3 items), and positive social interaction (3 items) [55,56].	Available at: https://www.phenxtoolkit.org/protocols/view/630501?origin=search	Internal consistency (Cronbach's α) of >0.70 across 33 out of 35 studies [55,56]. ICC varies from 0.50-0.97.
Mood	0, 6, 10	Hospital anxiety and depression scale (HADS)	14-item questionnaire to assess anxiety and depressive symptoms in a general medical population [57].	Compared to commonly used depression and anxiety measures correlations with the HADS-D and HADS-A ranged from 0.60 (good) and 0.80 (very good) [57].	Cronbach's α ranges from 0.78 to 0.93 for the HADS-A and from 0.82 to 0.90 for the HADS-D [57].

(continued on next page)

Table 2 (*continued*)

Measure	Time point (months)	Instrument	Description	Validity	Reliability
Quality of life	0, 6, 10	CDC HRQOL–14 "Healthy Days Measure"	This 14-item questionnaire includes four core questions, and ten additional questions on health-related quality of life.	Good and acceptable construct validity [58,59].	Retest reliability of 0.75 or higher [58,60].
Stress	0, 6, 10	Perceived Stress Scale (PSS-10)	10 items, measures the degree of stress perception [61].	PSS provided better predictions than life-event scale of psychological symptoms, physical symptoms, and utilization of health services [61].	Internal reliability (Cronbach's α = 0.78) [61].
Racial discrimination	0, 6, 10	Everyday Racism – 9 questions. Lifetime Racism – 3 questions	Two measures of race-related stress including discrimination and everyday discrimination based on unfairness instead of in the context of race [62].	–	Everyday racism: Cronbach's α = .88 [62]. Reliability: Kappa = 0.54–0.73 [63].
Food insecurity	0, 6, 10	U.S. Household Food Security Survey Module [64]	Five self-administered questions pertaining to food insecurity [64].	–	High sensitivity and minimal specificity bias: Cronbach's α = 0.83 [64].
Self-efficacy	0, 6, 10	'General Self-Efficacy – Adult'	A 10-item survey using a four-point Likert scale [65].	–	Cronbach's α ranging from 0.76 to 0.90 in 23 nations [65,66].

guide sessions, and to encourage an approach to each session that is participant-focused and generation of health goals are participant-led. Lastly, CHWs participate in weekly meetings with a certified CHW supervisor to discuss participant needs, successes, and process evaluation findings.

2.5. Measures

Measures are conducted at BSW HWC at baseline, 6-, and 10-months by trained and blinded research staff. Participants are asked to fast and take needed medications prior to attending measures. At baseline, participants complete informed consent, have biometrics taken and answer self-report surveys including demographics, medical history and medication use, diet, physical activity, and psychosocial variables (see Table 2). Participants receive a gift card at each measurement event ($20 at baseline, $30 at 6 months, and $40 at 10 months), food, and a passport with point of care biometric data. Descriptions of study measures including reliability and validity are shown in Table 2.

Allostatic load. Allostatic load (AL) score, the primary outcome measured at baseline and 6-months only, is a composite of the following 10 variables: body mass index (BMI), waist to hip ratio (W/H), high-density lipoprotein (HDL), total cholesterol/HDL ratio, triglycerides, glycosylated hemoglobin A1c (HbA1c), systolic blood pressure (SBP), diastolic blood pressure (DBP), C-reactive protein (CRP) and salivary cortisol [9]. For each biomarker, a value of 1 is assigned if the biomarker belongs to the 3rd quartile (≥Q3), otherwise a value of 0 is assigned. Since cortisol wanes throughout the day, it will be transformed to correspond to the level of cortisol at time of waking using the method proposed by Miller et al. [67]. For HDL, a value of 1 is assigned if it falls in the 1st quartile (≤Q1) whereas a value of 0 is assigned if HDL is above Q1. A participant is assigned a value of 1 for the corresponding biomarker if currently using medication for hypertension, hypercholesterolemia, or diabetes—irrespective of the actual measurement of the corresponding biomarker [13]. Finally, AL score is calculated by summing the assigned values (i.e., 1 or 0) derived from each biomarker. Scores range from 0 to 10, with higher scores indicating worse AL.

Anthropometrics. Height and weight are measured using a Health-*O*-Meter ® Professional 500 KL digital scale with stadiometer. Height is measured to the nearest 0.125 inch. Weight is measured to the nearest 0.1 lbs. Each measurement will be taken twice and reported as an average. The average height and average weight will be used to calculate the body mass index (BMI = (weight/(height2)) x 703). Waist and hip circumferences are measured with a tape measure to calculate waist-to-hip ratio (WHR = waist/hip).

Biometrics. All blood lab values are measured via a blood sample collected by finger stick. HDL, LDL, total cholesterol, and triglycerides are measured by the Alere Cholestech LDX machine, and HbA1c is measured by the Siemens DCA Vantage Analyzer. Blood samples are collected after fasting for at least 8 h.

Blood pressure is measured using the Omron Digital Blood Pressure Monitor (HEM-907XL). Each participant will rest for 5 min before the first measurement and will rest for 2 min between the first and second measurements. The machine is automatically set to take two measurements with a 2-min rest between measurements. If the two measurements are more than 10 mmHg apart, a third reading will be taken after an additional 2-min rest.

Urine is self-collected in a sterile urine cup. The McKesson Consult Diagnostics 120 Urine Analyzer is used to measure the albumin and creatinine values to calculate albumin to creatinine ratio at baseline only.

Cortisol and CRP are measured by collecting 1.0 mL of saliva by passive drool approximately 1–4 h after awakening. Each vial of saliva will be frozen at −80 °C until shipped to Salimetrics, where both cortisol and CRP will be measured by the ELISA (enzyme-linked immunosorbent assay) method - a plate-based assay technique to detect and quantify soluble substances.

Psychosocial Health Survey. Survey information including reliability and validity are detailed in Table 2. Briefly, basic demographics are collected including mailing address, date of birth, preferred language, gender, ethnicity and racial background, marital status/living situation, education level, household background, and total family income (from NIH Phen X Toolkit). Reliable and valid surveys also capture healthcare access, health information, and medication use [68]. Health information focuses on diabetes, hypercholesterolemia, hypertension, and obesity due to their effects on allostatic load. Smoking and alcohol consumption habits are also collected, along with questions pertaining to diagnosis and hospitalization-related to COVID-19 positive testing, vaccination barriers, access, and hesitation.

Scales are also included to assess food insecurity [64], Health Related Quality of Life [69,70], environmental factors that impact physical activity participation [71–73], and race-related stress and racial discrimination [62]. Other psychosocial measures include the Perceived Stress Scale (PSS-10) [61], anxiety and depressive symptoms [57] from the Hospital Anxiety and Depression Scale (HADS) [69], resiliency using a Brief Resilience Scale (BRS) [53], and social support from the Medical Outcomes Study (MOS) Social Support Survey [74].

Diet and Physical Activity. Questions to understand eating and dietary habits were included from the National Health and Nutrition Examination Survey (NHANES) – Dietary Screener Questionnaire (2009–2010 series) [47]. To assess physical activity of participants

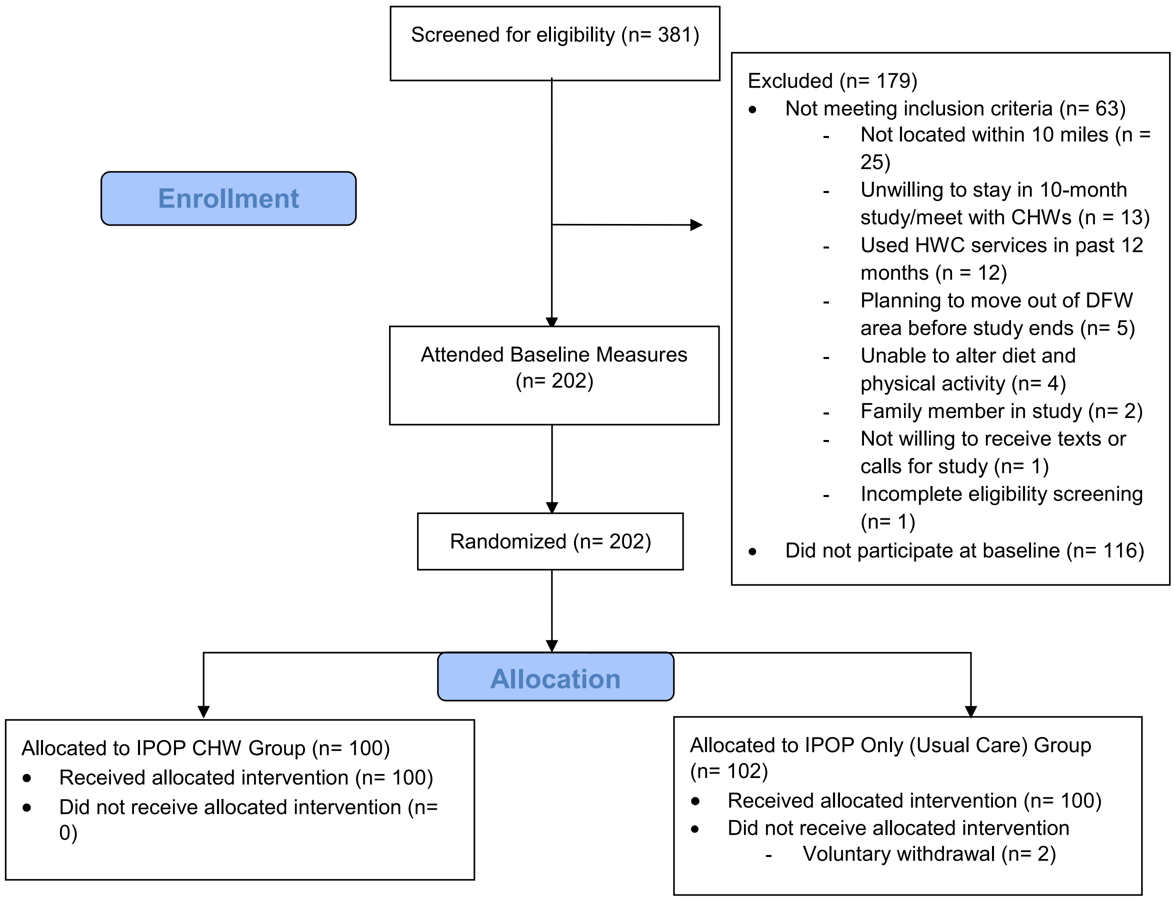

Fig. 1. CONSORT diagram.

outside of work, minutes of physical activity (PA), sedentary time, and frequency of physical activity were evaluated by the Past Week Modifiable Activity Questionnaire (PWMAQ), which focuses on exercise behaviors within the last seven days [52].

Process Evaluation. Process evaluation is integral to understanding the context of a program's implementation and the impact on outcomes [75]. Research staff will evaluate select audio recordings of CHW and participant sessions from each cohort with a quantitative checklist. The checklist will assess fidelity and dose of the navigation intervention. Dose related items, including the CHWs' adherence to the patient navigation curriculum and session delivery, will be scored 0 or 1. Items scored as 1 will indicate the intervention component was done as planned. Fidelity related items will include the community health worker's motivational interviewing strategies, communication skills with participants, and behavioral skills such as supporting participant's SMART goals to aid in patient navigation. These items will be scored on a scale of 1–4, with 4 representing an item is always incorporated in the session. Additionally, participant satisfaction using a brief survey will be collected at the end of the study.

2.6. Data analysis

Descriptive statistics using means and standard deviation for continuous variables and frequencies and percentages for categorical variables will be calculated. At baseline, to compare possible group differences, a *t*-test will be used for continuous variables and a chi-square test will be used for categorical variables. Appropriate non-parametric tests will be used when the assumption for parametric tests is violated.

Analysis of primary outcome variable. A generalized mixed effect model will be fitted to test the significant difference of AL score between groups (IPOP CHW vs. IPOP Only/Usual Care) from baseline to 6-months. The model will use a log link function where the conditional mean from the link function follows a Poisson distribution as the AL score is a count variable. In the presence of over-dispersion, Poisson distribution will be replaced by a negative binomial distribution. A random intercept will be used in the mixed model to account for within subject variation over time. Age, sex, and race will be included in the model as covariates. A negative estimate of the coefficient of Time-xGroup interaction term will indicate effectiveness of the intervention in reducing AL score at 6-months where usual care group and baseline time-point comprises the reference group in the model. The proposed model can be presented as follows:

Level 1 (between subject effects):

$$\log\left(E\left(Y_{ij}\middle|\boldsymbol{X}\right)\right)=\beta_{0j}+\beta_1 Time_{ij}+\beta_2 Group_i+\beta_3 Time_{ij}\times Group_i + \sum \beta_k Covariates_i$$

Level 2 (within subject effects):

$$\beta_{oj}=\gamma+\mu_{0j}$$

Here, Y_{ij} is the AL score for ith subject at jth time; β_{0j} is the random intercept term at time j and can be expressed as $\gamma+\mu_{0j}, j=$ baseline, 6-month. The intercept γ may vary from subject to subject due to the random term $\mu_{0j}, \mu_{0j}\sim N(0,\sigma_\mu)$; $Time_{ij}$ represents time-point (baseline and 6-months) for ith subject; $Group_i$ represents groups (IPOP CHW and IPOP Only) for the ith subject; $Covariates_i$ represents age, sex, and race for the ith subject; and $\beta_1, \beta_2, \ldots$ represents the parameter of the corresponding variables in the model. The term $\log(E(Y_{ij}|\boldsymbol{X}))$ is the link function where $Y_{ij}\sim Poisson(E(Y_{ij}|\boldsymbol{X}))$ and the bold-faced X represent the covariates in the model.

Table 3
Baseline demographic, socio-economic, and biometric characteristics by group (IPOP CHW and Usual Care).

Variable	All	IPOP CHW	Usual Care	P-value
N	202	100	102	
Age, mean (SD)	58.15 (12.03)	57.56 (12.86)	58.73 (11.18)	0.49
Sex, n (%)				0.29
Female	151 (74.75)	78 (78.00)	73 (71.57)	
Male	51 (25.25)	22 (22.00)	29 (28.43)	
Race/Ethnicity, n (%)				
White	6 (2.97)	4 (4.00)	2 (1.96)	0.50
Black or African American	160 (79.21)	81 (81.00)	79 (77.45)	
Hispanic	35 (17.33)	15 (15.00)	20 (19.61)	
Other	1 (0.5)	–	1 (0.98)	
Income, n (%)				0.30
$0 to less than $20,000	105 (51.98)	57 (57.00)	48 (47.06)	
$20,000 to less than $35,000	50 (24.75)	19 (19.00)	31 (30.39)	
$35,000 to less than $50,000	27 (13.37)	14 (14.00)	13 (12.75)	
$50,000 or more	20 (9.9)	10 (10.00)	10 (9.8)	
Education, n (%)				0.31
Less than 9th grade	14 (6.93)	7 (7.00)	7 (6.86)	
9th to 12th grade, no diploma	34 (16.83)	18 (18.00)	16 (15.69)	
High school graduate	46 (22.77)	25 (25.00)	21 (20.59)	
Some college, no degree	51 (25.25)	26 (26.00)	25 (24.51)	
Associate's degree	21 (10.4)	13 (13.00)	8 (7.84)	
Bachelor's degree	29 (14.36)	9 (9.00)	20 (19.61)	
Graduate or professional degree	7 (3.47)	2 (2.00)	5 (4.9)	
Marital status, n (%)				0.08
Married	46 (22.77)	19 (19.00)	27 (26.47)	
Divorced	58 (28.71)	33 (33.00)	25 (24.51)	
Widowed	23 (11.39)	12 (12.00)	11 (10.78)	
Separated	12 (5.94)	8 (8.00)	4 (3.92)	
Never married	52 (25.74)	20 (20.00)	32 (31.37)	
Have a health insurance, n (%)				0.70
Yes	147 (72.77)	74 (74.00)	73 (71.57)	
No	55 (27.23)	26 (26.00)	29 (28.43)	
Weight (lbs.), mean (SD)	212.48 (55.71)	217.4 (64.12)	207.66 (45.82)	0.22
BMI (kg/m^2), mean (SD)	36.02 (9.37)	36.55 (10.27)	35.5 (8.41)	0.43
Waist to hip ratio, mean (SD)	0.9 (0.09)	0.9 (0.08)	0.9 (0.09)	0.77
SBP (mmHg), mean (SD)	129.58 (18.21)	131.21 (19.71)	127.98 (16.55)	0.21
DBP (mmHg), mean (SD)	79.71 (11.46)	79.67 (12.4)	79.75 (10.53)	0.96
HDL (mg/dL), mean (SD)	50.21 (16.77)	50.44 (16.18)	49.98 (17.41)	0.85
LDL (mg/dL), mean (SD)	99.18 (39.71)	100.34 (35.59)	98 (43.64)	0.68
Triglycerides (mg/dL), mean (SD)	126.6 (83.86)	118.76 (65.73)	134.36 (98.31)	0.19
HbA1c (%), mean (SD)	6.58 (1.7)	6.54 (1.54)	6.63 (1.85)	0.69

Missing values range from 0 % to 6 %. BMI = body mass index, SBP = systolic blood pressure, DBP = diastolic blood pressure, HDL = high-density lipoprotein, LDL = low-density lipoprotein, HbA1c = hemoglobin A1c.

Other primary outcome variables in this study are cortisol, CRP, BMI, W/H, HbA1c, lipids and blood pressure. Similar mixed effect models will be fitted for each primary outcome variable to evaluate the effect of the intervention. These outcome variables are continuous; therefore, Gaussian mixed models will be fitted. In cases where the normality assumption is violated, transformation (e.g., log transformation) will be applied to the dependent variable to achieve normality. Except AL, cortisol and CRP, the remaining outcome variables are assessed at baseline, 6-months and 10-months so the proposed model will be extended for three time points.

Secondary outcomes. Secondary outcome variables in this study are changes in dietary intake, physical activity, service utilization, psychosocial variables, social determinants of health, and medication use. Data are collected at three time-points (i.e., baseline, 6-months, and 10 months). A mixed-effects model as described above will be fitted to estimate the effect of the intervention.

Analysis for missing data. The patterns of missing-ness (i.e., missing at random or missing completely at random) will be evaluated for the primary and secondary outcome variables using Little's test [76]. Missing data will be imputed using fully conditional specification imputation method to avoid case-wise deletion. A total of 20 imputed datasets will be generated and used in the adjusted models. Adjusted models will also be fitted using original data and compared with the outputs found from imputed data analysis. However, both findings will be presented if the inferences are not aligned from imputed data analysis and original data analysis. Conclusions will be drawn from the analysis of imputed data.

Power analysis. Power analysis was conducted assuming 30 % reduction in AL score in the IPOP CHW group compared to the IPOP Only group at 6-months. Considering 5 % level of significance (type I error rate) and 10 % attrition, the required sample size is 202 (101 participants in each group) to achieve ≥80 % power to observe a statistically significant effect of the intervention for the GroupXTime interaction term.

3. Results

Fig. 1 displays the CONSORT diagram of participant engagement for the IPOP study. A total of 381 individuals were initially screened for eligibility. Of these 381 individuals, 63 were ineligible and excluded according to inclusion criteria, and 116 were eligible but did not attend baseline measures. A total of 202 participants enrolled in the study, completed baseline measurements, and were randomized by the study statistician to either IPOP CHW or IPOP Only. 100 participants were randomized to the IPOP CHW group and 102 participants were randomized to IPOP Only.

Table 3 shows the baseline characteristics of enrolled participants in the IPOP study. Average (standard deviation [SD]) age of the participants was 58.15 years (12.03), 74.75 % were female, and 79.21 % were Black/African American. Fifty-two percent of the participants had an annual household income of less than $20,000, 25.25 % had some college education without any degree, and 72.77 % had health insurance. Self-report data indicated that 37.1 % were diagnosed with type 2 diabetes, 52.5 % with dyslipidemia, 69.3 % with hypertension, and 59.4 % with overweight/obesity by a health care provider. Baseline biometric characteristics which include weight, BMI, waist-to-hip ratio, SBP, DBP, HDL, LDL, triglycerides, and HbA1c are reported in Table 3. There were no significant baseline differences between IPOP CHW and Usual Care groups.

4. Study implications

This study will evaluate whether CHW navigation, using a structured intervention based on health behavior theories, can effectively guide poverty stressed individuals from historically marginalized communities to address social and medical needs to improve allostatic load—a composite of cumulative stress and physiological responses. Healthcare systems, nonprofit organizations, and governmental entities are interested in addressing SDOH, yet previous health system interventions to address SDOH have had mixed results [16,18–20]. Due to their cultural competency and knowledge of local resources, CHWs may improve access and use of existing resources to address social and medical needs. Further, MI and social support variables integrated into the IPOP CHW intervention may improve stress responses that increase chronic disease risk and worsen health outcomes. Involvement of CHWs in health promotion has grown exponentially and is often not evaluated or published in scientific literature. This study provides an opportunity to rigorously evaluate a CHW navigation model to guide best practices and evaluate the integral role of stress on health in historically marginalized communities.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

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