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RESEARCH ARTICLE

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Pilot randomized controlled trial of biofeedback on reducing psychological and physiological stress among persons experiencing homelessness

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Abstract

People experiencing homelessness report increased exposure to traumatic life events and higher rates of depression, anxiety, and post-traumatic stress disorder as compared with the general population. Heart rate variability-biofeedback (HRV-BF) has been shown to decrease symptoms of stress, anxiety, depression, and PTSD. However, HRV-BF has not been tested with the most vulnerable of populations, homeless adults. The purpose of this randomized controlled trial was to compare the effectiveness of an HRV-BF intervention versus a Health Promotion (HP) active control intervention focused on improving mental health symptoms among homeless adults. Guided by a community advisory board, homeless adults residing in Skid Row, Los Angeles ($n = 40$) were randomized to either the HRV-BF or an active HP control group and received eight weekly, 30-min sessions over two months, delivered by a nurse-led community health worker team. Dependent variables of HRV, mental health, anxiety, depression, and PTSD were measured at baseline, the 8-week session, and/or 2-month follow-up. All intervention sessions were completed by 90% (36/40) of participants. Both the HRV-BF and HP interventions showed significant increases in HRV from baseline to 2-month follow-up, with no significant difference between the intervention groups. The HRV-BF programme revealed a somewhat greater, although non-significant, improvement in anxiety, depression, and PTSD symptoms than the HP programme. The usefulness of both interventions, focused on emotional and physical health, warrants future studies to examine the value of a combined HRV-BF and HP intervention.

KEYWORDS

biobehavioral outcomes, biological mechanisms of stress, health psychology and stress, post-traumatic stress, psychosocial, stress coping, stress tolerance

1 | INTRODUCTION

1.1 | Stress among persons experiencing homelessness

In Los Angeles (LA) County, there are approximately 69,144 persons experiencing homelessness (PEH) on any given night, an increase of 4.1% since 2020 (Los Angeles Homeless Services Authority, 2022). PEH report high levels of stress and elevated symptoms of anxiety (Garfin et al., 2020), depression (Garfin et al., 2020; Gutwinski et al., 2021), and PTSD (Armstrong et al., 2020; Duncan et al., 2019; Garfin et al., 2022) most likely due to exposure to cumulative traumatic life events (Buhrich et al., 2000; Edalati et al., 2017), including recurrent adverse childhood experiences (Paat et al., 2019; Sundin & Baguley, 2015), adult traumatic events (Buhrich et al., 2000; Edalati et al., 2017), and unstable housing (Karadzhov et al., 2020). Indeed findings estimate the prevalence of anxiety and depression at 40% and 48%, respectively (Garfin et al., 2020); PTSD has ranged from 19% to 79% (Ayano et al., 2020; Garfin et al., 2022; Landefeld et al., 2017). PEH also experience significant disparities in chronic physical diseases (CPD) (Brown et al., 2017; Drum, 2014; Fong, 2019), including hypertension (Salem et al., 2014), arthritis (Brown et al., 2013), and diabetes, 16% (Brown et al., 2013; Cezaretto et al., 2016; Markle-Reid et al., 2018). These CPDs are exacerbated due to inadequate healthcare access and the accelerated physical decline from being chronically unhoused (Brown et al., 2017; Garibaldi et al., 2005). Further, ineffective coping modalities and inadequate self-regulation often lead to substance use and substance use disorder (SUD) (Lima et al., 2020), with SUD as high as 60% (Tsai, 2017).

There are several evidence-based psychologic interventions (i.e., cognitive behavioural therapy) (Slesnick et al., 2020) that have proven helpful in reducing symptoms of anxiety, depression, and PTSD among PEH. However, these strategies often require trained professionals to administer them. Unfortunately, these individuals are quite limited in number relative to need, particularly in areas where PEH reside (California Department of Health Care Services, 2022). These modalities also require scheduling and travel to providers, which may be out of reach financially or logistically for most PEH (Eddie et al., 2015; Wieman & Eddie, 2022). As such, interventions that can be administered by guided lay professionals in the places where PEH reside are needed to address mounting physical and health disparities.

1.2 | Chronic stress and life course trauma among PEH may lead to altered physiology and heart rate variability

It is well documented that experiences of stress lead to increased sympathetic nervous system (SNS) activity and lowered parasympathetic nervous system activity in the autonomic nervous system (Marques et al., 2010). When stressors are sustained over time, the hypothalamic-pituitary-adrenal (HPA) axis becomes dysregulated (Jones & Gwenin, 2021), and along with a lack of autonomic balance, potentially limits emotional and physiologic self-regulation to new and ongoing stress. This dysregulation leads to altered heart rate variability (HRV), a measure that reflects changes in heart rate over time, which is posited to be linked to both mental and physical disorders (Lehrer et al., 2020). Biofeedback (BF) is a process by which physiological markers, such as heart rate, respiration, and HRV, are measured and 'fed' back to the person on a computer screen (Schwartz & Andrasik, 2017).

HRV is widely accepted as a measure of autonomic balance and cardiac vagal tone. Decreased HRV is associated with decreased emotion regulation (McCraty et al., 2009) with a wide variety of mental and physical pathologies, including anxiety, depression, and PTSD (Economides et al., 2020; Goessl et al., 2017; Lehrer et al., 2020; Lin et al., 2019; Pizzoli et al., 2021). As the need for effective and sustainable strategies that will target stress, anxiety, depression, and PTSD, as well as substance use, is critical, the need for a brief, portable, and novel intervention for PEH, such as Heart Rate Variability-Biofeedback (HRV-BF) is timely as it teaches the individual to self-regulate their autonomic balance, self-manage the experiences of stress, and lower symptoms of anxiety, depression, and PTSD (Economides et al., 2020; Lehrer et al., 2020; Lin et al., 2016, 2019; Pizzoli et al., 2021).

1.3 | Heart rate variability—Biofeedback (HRV-BF)

As stated earlier, biofeedback (BF) is a process by which physiological markers such as heart rate, respiration, and HRV are measured and 'fed' back to the person on a computer screen (Schwartz & Andrasik, 2017). Guided, paced, slowed breathing, a skill taught in HRV-BF, maximizes the natural acceleration of heart rate with inspiration and deceleration with expiration (Lehrer & Gevirtz, 2014) and produces a rhythmic stimulation of the vagus nerve, providing the basis for the overall increase in parasympathetic/vagal tone over time if practiced regularly. Strengthening of vagal tone may contribute to increased autonomic balance, thereby acting to modulate the SNS activity associated with the stress response (Lehrer & Gevirtz, 2014).

In addition to the strengthening of vagal tone, HRV-BF has also been shown to influence physiologic mechanisms which may affect emotion regulation. Thayer's Neurovisceral Integration model (Thayer et al., 2009) describes the neural networks encompassing both the autonomic nervous system and the central nervous system tied to vagally mediated HRV, particularly the influence of vagal activity on the prefrontal cortex. The influence of HRV on emotional regulation was further delineated by Mather and Thayer (Mather, 2018), linking practices that increase HRV, such as HRV-BF, to increased emotion regulation via a number of mechanisms, such as increased activity in the prefrontal cortex, and by decreasing arousal via the baroreflex stimulation, shown to be increased by HRV-BF (Lehrer et al., 2003). Thus, increased vagal tone and these altered homoeostatic mechanisms may therefore contribute to the effect of HRV-BF.

HRV-BF is thus a means to increase self-regulatory capacity (McCraty et al., 2009) and is used in training systematic self-management techniques that result in reducing anxiety (Goessl et al., 2017; Prinsloo et al., 2013) and depression (Economides et al., 2020; Lehrer et al., 2020; Lin et al., 2016, 2019; Pizzoli et al., 2021). HRV-BF could be a useful, low-cost method to improve outcomes for PEH, as it teaches the individual to self-regulate their autonomic balance, self-manage the experiences of stress, and lower symptoms of anxiety, depression, and PTSD (Economides et al., 2020; Lehrer et al., 2020; Lin et al., 2016, 2019; Pizzoli et al., 2021).

This increase in self-regulatory activity, combined with the provision of social and environmental support by lay health providers, is projected to fully encompass a whole-mind-body approach to wellness (Padgett, 2020; Tan et al., 2011).

1.4 | Nurse-led, community health worker interventions can restore balance of HRV-BF to improve mental health among PEH

In the Skid Row area of downtown LA, a shortage of psychiatric specialist physicians and nurse practitioners has been noted (California Department of Health Care Services, 2022). Community health workers (CHWs) have been utilized in low-and-middle-income countries to address health in underserved communities, decrease inequitable access to healthcare, extending the reach of primary care providers across prevention levels (Laurenzi et al., 2021). For example, nurse-led CHWs have improved latent tuberculosis (LTBI) medication adherence among LTBI positive, PEH (Nyamathi et al., 2008, 2021, 2022) and substance use and recidivism (Nyamathi et al., 2018; Nyamathi et al., 2017) among women residing in a residential drug treatment programme. Utilizing an RN/CHW-delivered intervention to implement HRV-BF is a promising approach to decreasing symptoms of anxiety, depression, PTSD, and substance use among PEH. Herein, we present results from a pilot study of HRV-BF, administered by CHW, to PEH residing on Skid Row.

1.5 | Comprehensive health seeking and coping model (CHSCP) and polyvagal theory

This pilot study draws upon two models, the CHSCP, which is a social-ecological model, and Polyvagal Theory (Porges, 2007), which focuses on a biological approach to understanding and addressing dysregulation in the ANS.

The CHSCP model (Nyamathi, 1989) served as one theoretical framework for this pilot study. Prior work using this model has focused on adherence to treatment, including latent tuberculosis chemoprophylaxis, HIV, and hepatitis risk and protective behaviours among drug-abusing and homeless adults (Nyamathi et al., 2017; Nyamathi et al., 2021; Nyamathi et al., 2017; Nyamathi et al., 2016). Based on the CHSCP, several constructs should be incorporated into models when examining community-based interventions for PEH experiencing mental health distress as they impact health outcomes. These include socio-demographic, situational, social, psychological, and behavioural factors.

Socio-Demographic Factors include age, race/ethnicity, and structural, social, and behavioural determinants of health (Boyd et al., 2020) which are associated with health equity, including structural and interpersonal racism. Situational factors include structural factors such as stable housing, which are critical to address when targeting the disproportionate burden of disease among PEH. Moreover, a less chaotic lifestyle may enable a focus on improving health needs. Social factors include social support from family/friends, which, in addition to CHWs, can act as a resource by encouraging stress reduction and Health Promotion (HP). Behavioural responses, such as drug and alcohol use, are critical to address to promote positive outcomes in PEH. Psychological factors, including emotional distress, must be lowered to reduce high-risk behaviours (Nyamathi et al., 2003).

The Polyvagal Theory frames autonomic function in terms of functional differences between evolutionarily distinct parts of the vagus nerve—the 'newer' unmyelinated vagus (dorsal vagal complex), the sympathetic adrenal system, and the 'oldest' myelinated vagus (ventral vagal complex). Each component plays a role in behavioural responses to various contexts ranging from safe to life-threatening (Porges, 2007). By focussing on practices that build tone in the newer, myelinated vagus (vagal "brake"), HRV-BF fosters the acquisition of self-regulation skills and the development of the 'social engagement system,' improving emotional and behavioural health outcomes (McCraty & Shaffer, 2015). This theory provides a linkage between the techniques used in HRV-BF, which focus on increasing HRV/vagal tone via physiologic mechanisms and improving behavioural health outcomes.

The integration of the CHSCP model and the Polyvagal Theory results in an intervention that adapts known HRV-BF interventions to the uniqueness of the PEH population with the purpose of accessibility, relevance, and adherence.

1.6 | Purpose

The purpose of the present study was to assess the preliminary efficacy of HRV-BF intervention, delivered by RN/CHW teams, for reducing psychological and physiological stress among PEH as compared to an active attention control programme, a HP programme. We hypothesised that the HRV-BF intervention would lead to improvements in HRV and mental health, as well as a reduction in symptoms of anxiety, depression, and PTSD, as compared with the HP active control.

1.7 | Design

In this pilot randomized controlled trial, conducted over one year, beginning in April 2021, 40 PEH were recruited from a larger sample of 97 PEH that were participating in a survey on COVID-19. Our outcomes were HRV and symptoms of anxiety, depression, and PTSD.

Prior to the intervention, a Community Advisory Board (CAB) met to assess the feasibility and acceptability of the HRV-BF programme, which was presented in a theatre-style approach (Wingood & DiClemente, 2008). The CAB, composed of 6 PEH and 3 healthcare providers, spoke quite favourably about the programme and provided exceptional feedback in terms of acceptability and feasibility in delivery logistics and cultural sensitivity. PEH shared the high levels of stress and anxiety they were experiencing, how helpful they perceived the programme to be, the best timing for delivery, the length of time for the intervention (under 60 min), and how to minimize attrition.

1.8 | Sample and setting

The sample was stratified on the following before randomisation: (1) verified as being infected with SARS-CoV-2 versus not infected; (2) high, moderate, and low/no depression; and (3) high, moderate, and low/no levels of substance use before randomization to a group. Inclusion Criteria: (1) age 18 and older; (2) self-reported as residing in a homeless living condition during the previous night; and (3) self-reported having used illicit substances or alcohol during the past year. Exclusionary Criteria included persons who: (1) exclusively spoke languages other than English or Spanish; (2) were unable to understand informed consent; and (3) had a cardiac deficiency, arrhythmias, or pacemakers or who took medications affecting autonomic function. Two homeless shelters in Skid Row served as recruitment sites. Each of these sites provided healthcare and social services for homeless adults.

1.9 | Procedure

In our original COVID-19 study completed in July 2021, trained staff handed out flyers that featured the COVID study and provided informational sessions in two homeless shelters. If interested, a confidential meeting was arranged to hear more information about the study, and if interest continued, a questionnaire was administered and other aspects of the study completed. In total, 97 participants were recruited.

In the current study, these trained research staff returned to the original shelters and other nearby shelters and provided flyers to 42 of the original 97 participants, intending to locate and invite 40 participants to enroll in the HRV-BF study. Among those interested, our trained research staff similarly provided a brief presentation in a private area and answered any questions. If interested, informed consent was obtained. After informed consent, the research staff administered the baseline questionnaire to eligible participants, and thereafter, they were stratified on select variables and randomly allocated to one of two study arms in a 1:1 ratio. The project biostatistician created a randomization table before study initiation. This table was uploaded to the REDCAP Randomization Module, which assigns participants to the study arms. HRV-BF and HP participants were paid $10 for each intervention session, $20 for the baseline, and $30 for the 2-month assessment. Completers of all aspects of the study received up to $60 in cash over the 2 months.

A team of nurse-guided CHWs was trained. Recruitment was continuous so that each CHW was delivering the intervention to 7-8 homeless adults in a given period. To promote fidelity, the research staff followed a procedural and resource manual for each intervention that outlined the procedures that the trained staff followed. The RN/CHW handed out referrals as needed (i.e., drug issues, housing, mental health, etc). The specific role of the RN was to provide weekly case conferences with the CHW, including fidelity checks. In addition, the RN helped explain, in simple terms to their enroled PEH, more of the physiologic concepts related to the impact of stress on anxiety/depressive symptoms or chronic disease, respectively.

1.10 | HRV-BF intervention

The HRV-BF was delivered over 8 weeks in 30-min weekly, individual, in-person settings by our RN/CHW team trained to deliver videos and scripted material created by a trained BF practitioner on our study team. The weekly sessions included the use of a tablet device to share a 10-min video that teaches the basic techniques and breathing practices of HRV-BF. The weekly videos began by teaching basic diaphragmatic breathing, techniques for slowing the breath, and, eventually, slow-paced breathing. Video content also included simple educational content on stress and the effects of stress on the body, as well as content designed to guide participants regarding day-to-day applications of the HRV-BF techniques. Following the viewing of the video, the RN/CHW team used scripted material to guide the participant through a 20-min HRV-BF practice, using the paced breathing technique with an on-screen pacer while watching their heart rate data in real time. The EmWave Pro (HeartMath) (Edwards, 2015) device with a photoplethysmograph sensor was used in the HRV-BF training.

During the HRV-BF practice, participants were encouraged to follow the breath pacer and modify their breathing in order to maximise the wave-like properties of their heart rhythm, as captured and displayed as the 'coherence score'. Coherence is a quantitative score that reflects how stable, regular, and repeating the user's heart rhythm is, calculated by a mathematical algorithm internal to the software app according to the formula formulated as: (Peak Power/[Total Power − Peak Power]) (McCraty & Shaffer, 2015). Coherence is the means by which individuals are cued to their performance within the EmWave app, thus creating the 'feedback' to the user and contributing to the learning—for easy interpretation, feedback is coded as green, blue and red, with green being highest coherence scores.

Due to the limitations of the session timing, kept brief and tailored specifically for the PEH population, and for maximised fidelity of the sessions delivered by the RN/CHW teams, resonance frequency was not tested. While a version of resonance frequency can be performed on the EmWave device, for above reasons we instead chose to train participants at 6 breaths/minute (0.1 Hz) using a 1:1 inhalation to exhalation ratio, a generally accepted 'preset' pace at which HRV amplitude is maximised (Lehrer & Gevirtz, 2014), an easier and more economical method for applying HRV-BF (Lalanza et al., 2023). Completion of 30 min guided sessions were tracked by RN/CHW teams. Outside of the structured, weekly HRV-BF session guided by RN/CHW, participants were also asked to complete daily breathing practices on their own, without the HRV-BF device but using a breath pacer for 10 min, twice a day, to reinforce topics and skills taught in videos and weekly sessions. Practices logged by the participant were collected weekly by the CHW, and referrals to resources were provided (See Table 1).

1.11 | Health promotion (HP) intervention

The HP active control group was delivered over 30 min, once weekly for 8 weeks, by our RN/CHW team, trained to deliver scripted materialised content created. The HP programme was originally developed utilising community-based participatory research elements, including the establishment of a CAB with community stakeholders, social service providers, and academicians (Salem, Kwon, J., Ames, M., 2017; B. E. Salem, Ma-Pham, J., Chen, S., Brecht, M.L., Antonio, A.L., Ames, M., 2017; Salem & Ma-Pham, 2015) and a manualized programme was developed for the HP programme. As stated, formative research by a CAB helped to refine an 8-week programme, focused on the most common physical chronic diseases PEH experience, and included discussions of hypertension, diabetes, heart disease, and arthritis; a total over 8 weeks, along with full discussion and referrals provided based on needs expressed by PEH. Only those in the HP active control group received the HP programme; those in the HRV-BF group were not offered the HP content.

For both measures, fidelity was measured on a weekly basis by the RN/CHW team. In particular, the research team tracked participant session completion weekly and assessed reasons for non-completion.

1.12 | Measures

The following measures, as guided by the CHSCP and standards for HRV measures, were collected at baseline and 8 weeks-follow-up (LaBorde et al., 2017). These assessments took approximately 30 min and were administered by the research staff. All non-HRV measures have been utilised with PEH previously and have supported psychometrics (Nyamathi et al., 2012, 2016a, 2016b). All baseline and follow-up measures were administered by the research team.

2 | DEPENDENT VARIABLES

2.1 | Heart rate variability measures

Heart Rate Variability (HRV) was assessed during the resting 5-min period at week 1 and week 8 sessions by the RN/CHW teams using commercially available, medical grade photodetector (photoplethysmography or PPG) sensor (Vescio et al., 2018) and accompanying HRV-BF software application (EmWave Pro Plus, HeartMath) to collect interbeat interval data to produce standard measures of HRV (Laborde et al., 2017) including time-domain measures: SDNN (standard deviation of N-to-N intervals); RMSSD (Root mean square of successive differences between normal heart

TABLE 1 HRV-BF Intervention 8-week intervention delivered via weekly contact with the RN/CHW.

Week	Topic	Key points	Homework
1	Stress and your body	Teach basic stress physiology; build awareness of impact and somatic experience of stress	Keep awareness log
2	Belly breathing	Teach diaphragmatic breathing.	Diaphragmatic breathing recording daily
3	Paced breathing	Introduce paced diaphragmatic breathing	Paced breathing—use breathing pacer app or you Tube
4	Introduction to self-regulation	Introduce concept of 'self-regulation'; orient to HRV-BF device	Paced breathing—use breathing pacer app or you Tube
5	Heart rate variability	HRV-BF; discuss applications of HRV-BF	Paced breathing—use breathing pacer app or you Tube; additional recording links.
6	Self-regulation strategies: Part 2	HRV-BF and additional tools; discuss application of tools in real life situations.	Paced breathing—use breathing pacer app or you Tube; additional recording links.
7	Self-regulation strategies: Part 3	HRV-BF and additional tools; discuss application of tools in real life situations.	Paced breathing—use breathing pacer app or you Tube; additional recording links.
8	Wrapping up/moving forward	Complete exit questionnaires; formulate plan for continued practice.	Continued practice and use of self-regulation tools.

Abbreviations: HRV-BF, Heart rate variability – biofeedback; RN/CHW, Registered-nurse/community health worker.

beats); and frequency-based measures: (HF) High Frequency; LF: Low Frequency; and LF/HF: Low Frequencies to High Frequencies ratio. RMSSD is most reflective of vagal tone and is free from respiratory influences (Laborde et al., 2017), and thus is our primary outcome measure. While HRV time-based variables are age-dependent, with older individuals having lower HRV (Sangha et al., 2003), the analysis focuses on change in HRV, thus, this decline with age is less relevant. HRV statistical analysis was conducted by members of the research team.

2.2 | Psychological factors

Mental Health Status was assessed by the Mental Health Inventory-5, which has well-demonstrated reliability for detecting psychological disorders (Berwick et al., 1991) with reliabilities of 0.77 and 0.71 for women/men, respectively (Leake et al., 1997).

Anxiety Symptoms were measured by the Generalised Anxiety Disorder −7, a self-report 7-item measure (Spitzer et al., 2006). Example items include 'worrying too much about different things' and 'trouble relaxing' (Endpoints 0 = not at all; 3 = nearly every day). Scores are summed. The severity of anxiety was determined with cut-off scores of 5 (mild anxiety), 10 (moderate anxiety), and 15 (severe anxiety). Reliability $\alpha = 0.87$.

Depressive Symptoms were assessed by the Patient Health Questionnaire-9 (PHQ-9) (Kroenke et al., 2001). The PHQ-9 is a brief, 9-question depression module from the full 26-item PHQ. Each of the 9 items addresses DSM diagnostic criteria, rating them from '0' (not at all) to '3' (nearly every day). Patient Health Questionnaire-9 not only makes criteria-based diagnoses of depressive disorders but also can determine severity, with scoring cut-offs for minimal (1–4), mild (5–9), moderate (10–14), moderately severe (15–19) and severe (20–27) depression. The reliability of the PHQ-9 is $\alpha = 0.89$.

PTSD was measured using the PCL-C (McDonald & Calhoun, 2010), a 17-item screener for PTSD with cut points for symptomatic versus non-symptomatic; scores correlate highly with the Clinician-Administered PTSD scale, $r = 0.93$ (Forbes et al., 2001). The PCL-C has high levels of validity (Wilkins et al., 2011), test-retest reliability ($r = 0.96$), and high internal consistency ($\alpha = 0.97$). The self-report rating scale is 0–4 for each symptom: 'Not at All' to 'Extremely' (0–80). A 5-point change is a minimum threshold for determining a treatment response, while a 10-point change is a minimum threshold for determining a clinically meaningful treatment response (McDonald & Calhoun, 2010; Weathers et al., 2013).

2.3 | Behavioural factors

Drug and Alcohol Use was assessed by the *TCU Drug History Form* (Simpson & Chatham, 1995). It records the frequency of use of 16 drugs used over 12 months, such as heroin and other opiates, street methadone, cocaine, crack, meth, etc. Yes/No to each drug was assessed for use versus dependency. The total score ranges from 0 to 11; higher scores (≥3) correspond to the DSM 4 drug dependence diagnosis. Urinalysis: In addition, we conducted a urine assay which measures cannabis, methamphetamine, cocaine, and amphetamines (Pharmatech Laboratories and Diagnostics, 2015). A five-panel Food and Drug Administration-approved urine test cup (Pharmatech Laboratories and Diagnostics, 2015) was used at baseline and 8-week follow-up. The test cup screened for metabolites of Amphetamines (1000 ng/ml), Cocaine (300 ng/ml), Methamphetamines/MDMA (500 ng/ml), Opiates (2000 ng/ml), and THC (50 ng/ml).

2.4 | Physical disease

Physical Diseases was assessed by the self-reported comorbidity index (SCQ) for medical problem, treatment, and limitations (Sangha et al., 2003). PEH were asked to respond if they have chronic health conditions (e.g., heart disease, high blood pressure, diabetes, osteoarthritis; Sangha et al., 2003). Responses include 'yes or no' (Sangha et al., 2003). In a previous PEH sample ($N = 150$), Cronbach's $\alpha = 0.91$ (Salem et al., 2013).

2.5 | Sociodemographic factors

These factors included age, race/ethnicity, personal health, county of origin, literacy level, and history of physical and mental illness. We used self-identified race/ethnicity categories as a proxy for experience of racism in interpersonal and structural forms (Boyd et al., 2020).

2.6 | Situational factors

Shelter Stability was assessed by length of time residing in a shelter versus elsewhere at baseline and 2-month follow-up.

2.7 | Social factors

Social support was measured by the Medical Outcome Study (MOS) Social Support Survey (Sherbourne & Stewart, 1991). The MOS is a 19-item instrument and includes four subscales: emotional and informational support; tangible support; positive social interaction; and affectionate support. The MOS uses a Likert scale, with endpoints 1 (none of the time) to 5 (all of the time), that assesses the availability of social support, with higher scores indicating more social support. An overall support index was also calculated.

2.8 | Data management

Data were collected and maintained on REDCap (Research Electronic Data Capture; http://project-redcap.org/), which was only accessible to the research team. REDCap is a web-based system maintained by UCI Health Information Services on a secured encrypted server. Data collection instruments were created and designed for real-time data entry by research staff using electronic tablet devices during the interview. Study data was exported (i.e., SPSS, SAS, Stata, R/S-Plus), and data quality was reviewed on an ongoing basis. REDCap is flexible and provides an intuitive user interface for database design and data entry.

2.9 | Statistical analysis

Descriptive statistics were conducted to analyse continuous and categorical variables. To assess whether non-parametric methods or transformations were needed, histograms of continuous variables were examined. The histogram of RMSDD suggested that the original data were highly skewed, but as the log-transformed data followed approximately normal distributions, all subsequent analyses were based on the log-transformed data.

The outcome data were naturally paired, as each variable was measured both pre- and post-intervention. The mean, standard deviations and effect sizes (Cohen's d) of the changes were reported. Given the small sample sizes and the non-Gaussian distribution of the outcome variables, Wilcoxon's signed-rank test was used to examine whether there was a significant change. Since both interventions were expected to improve outcomes, one-sided p-values were reported. To compare whether the changes due to the two arms were significantly different from each other, a two-sample t-test and its non-parametric version, namely the Mann-Whitney-Wilcoxon test were used, analysing the ranked difference scores.

3 | RESULTS

3.1 | Sample characteristics

The baseline sample for this study consisted of 40 PEH. Among the 42 screened, one was unable to participate, and the second reported a cardiac arrhythmia which was an exclusion criterion. Among the 40 enrolled, 36 (90%) completed all sessions within their assigned group, 17 of whom were assigned to the HRV-BF intervention, while 19 were assigned to the HP control intervention. Adherence to practice sessions was high, with 65% of participants in the HRV-BF group practicing between weekly sessions for at least 6–8 weeks.

The sample was predominantly male (80.6%) and had an average age of 53.7 (SD 11.8); about one-third (29.2%) were over 60 years old, and the age range was from 34 to 80. The majority (97.1%) lived in shelter housing. Latinx individuals comprised 36.1% of the sample, and over two-thirds were either Black (33.3%) or unknown race (38.9%). This sample was largely representative of the population in the Skid Row area.

3.2 | HRV

Among all participants, there were significant increases in HRV, with 72% of participants (76% among HRV-BF and 68% among HP) showing an increase in HRV, using paired t-test with natural log-transformed variables, $p = 0.01$, and by signed rank test, $p = 0.01$. The increase in HRV was significant in each group, with signed rank test $p = 0.05$ for HRV-BF and $p = 0.01$ for HP, with medium effect sizes (Cohen's d = 0.37 and 0.55) were found in improved HRV for the HRV-BF and HP programs, respectively. No statistically significant differences were observed for HRV improvement between HP and HRV groups (using Fisher's Exact test, $p > 0.05$). See Figure 1 for the violin plot of the log-transformed RMSSD pre- and post-intervention. For each subject, the pre (Before) and post (After) intervention observations were connected using a straight line.

Among the participants who did not do daily breathing exercises, the reasons included having multiple jobs, forgetting to do the breathing, or being in crowded shelters with too many people around. The participants mentioned that they valued HRV-BF because it was an easy-to-use technique when experiencing a stressful situation. It was very helpful in calming stressful emotions and helped deal with interpersonal conflict, and was able to de-escalate emotions.

3.3 | Depression symptoms

The PHQ-9 decreased an average of 0.88 ± 4.7 (Cohen's d 0.187) in the HRV-BF group as compared to a decrease of 0.42 ± 5.3 (Cohen's d 0.079) in the HP group. Intervention effects were not statistically

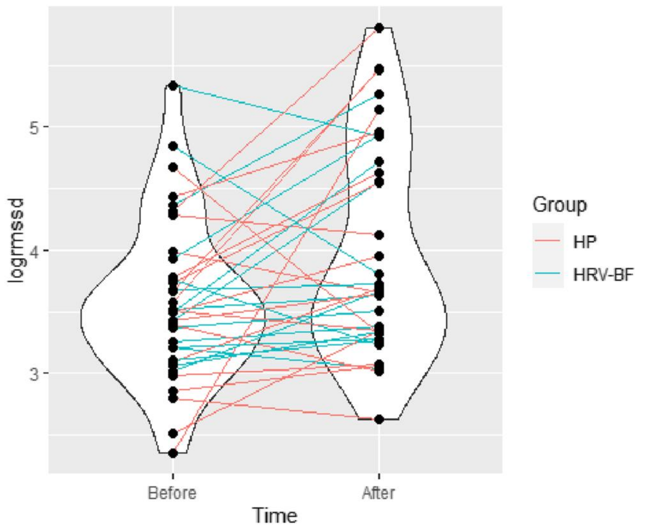

FIGURE 1 Violin plot 'before' and 'after' intervention of log-transformed RMSSD on heart rate variability. HP, health promotion; HRV-BF, heart rate variability-biofeedback; RMSSD, Root mean square of successive differences.

significant across time in any of the two groups. See Table 2 for all mental health change scores and levels of significance.

3.4 | Anxiety symptoms

Similarly, as reflected in the General Anxiety Disorder-7, anxiety scores decreased to a greater degree in the HRV-BF group, with an average decrease of 0.4 + 3.9 (Cohen's d 0.105) as compared to the HP group, revealing an average increase in anxiety of 0.63 ± 4.7 (Cohen's d 0.134). No significant differences were found across time for both programs.

3.5 | Mental health inventory

Analysis showed the HRV-BF group had improved MHI scores at 8 weeks, with an average increase in score of 0.71 ± 10.1 (Cohen's d 0.070) while the HP participants revealed lowered mental health wellness, as reflected in a decrease of 0.84 ± 11 (Cohen's d 0.076). Regardless, no statistically significant pre-post differences were noted.

3.6 | PTSD

Similar improvement was found with the PCL-C with both HRV-BF and HP, with averages of −0.29 ± 10.7 (Cohen's d −0.027) and −1.21 ± 13.1 (Cohen's d 0.092), respectively. The findings were not statistically significant.

3.7 | Chronic physical disease

Chronic physical disease was found to be higher in HRV-BF (65%) than in HP (82%), although the difference is not statistically significant at 0.05 level ($p = 0.09$).

For participants enroled in the HRV-BF group, the most frequently reported chronic diseases included depression (38.9%), high blood pressure (16.7%), and HCV (11.1%). For the HP programme participants, the most frequently reported chronic diseases included depression (31.8%), high blood pressure (18.2%), diabetes (13.6%), osteoarthritis/degenerative arthritis (9.1%), and heart disease (4.6%).

3.8 | Substance use

Self-report perception of general health varied among the participants. Drug and alcohol use was mixed: 2.9% ($n = 1$) reported mild/moderate drug use, and 5.7% ($n = 2$) reported severe drug use. Further, nearly one-third (30%) reported problematic alcohol use. No statistically significant differences were between the HP and HRV-BF groups for these outcomes.

4 | DISCUSSION

People experiencing homelessness (PEH) report high levels of mental health symptoms; yet have limited resources to help mitigate these disorders. In this pilot study, we assessed the effect of an HRV-BF versus an HP programme on outcomes of HRV and symptoms of anxiety, depression, and PTSD, as well as mental health. Our findings revealed significant increases in HRV in both the HRV-BF and HP programs, with no between-group differences. Further, while we noted some improvement in symptoms of anxiety, depression, mental health, and PTSD in the HRV-BF programme as compared to the HP programme; moreover, differences were not statistically significant.

While we expected to see greater gains in HRV accompanied by improvements in anxiety, depression, PTSD, and mental health in the HRV-BF arm versus an active control HP programme, both interventions showed improved regulation of the ANS (vis a vis RMMSD). Although we intended the HP intervention to be an active control group, we postulate that the HP intervention may have helped the participants who received that intervention to increase self-efficacy in managing chronic physical and mental health conditions.

Self-efficacy, defined as the perceived ability to perform specific actions required to achieve concrete goals (Bandura, 1997), is based on the Bandura Social Cognitive Theory. Bandura (1986) contends that the ability to self-regulate is related to personal, environmental,

TABLE 2 Changes (post vs. pre) of outcomes.

	HRV-BF			HP		
	Mean (SD)	Effect size (Cohen's d)	*p*	Mean (SD)	Effect size (Cohen's d)	*p*
PCL-CI	−0.29 (10.7)	−0.027	0.525	−1.21 (13.1)	−0.092	0.347
PHQ9	−0.88 (4.7)	0.187	0.285	−0.42 (5.3)	−0.079	0.443
GAD-7	−0.410 (3.9)	−0.105	0.36	0.63 (4.7)	0.134	0.612
MHI-5	0.71 (10.1)	0.070	0.389	−0.84 (11)	−0.076	0.437

Note: *p*-values are one-signed based on Wilcoxon's signed rank test.

Abbreviations: GAD-7, General Anxiety Disorder-7; HP, Health Promotion; HRV-BF, Heart Rate Variability-Biofeedback; MHI-5, Mental Health Inventory-5; PCL-CI, PTSD CheckList—Civilian Version; PHQ-9, Patient Health Questionnaire-9.

and behavioural factors that act separately and inter-dependently to prevent unhealthy consequences of illness and restore health through self-directed activities that manage symptoms of chronic disease. Thus, it is reasonable to consider that integrating self-efficacy training in a combined Mind-Body programme will strengthen our intervention. Moreover, as self-efficacy beliefs can be enhanced through modelling and reinterpretation of physiological symptoms, the integration of the nurse-led CHW plays a vital role in this activity, thus leading to improved behaviours, motivation, thinking patterns, and emotional well-being (Bandura, 1997). Across several studies, self-efficacy was correlated with lower PTSD scores (Blackburn & Owens, 2015; Samuelson et al., 2017), as well as reduced smoking (Al Thani et al., 2022; Ma et al., 2020) and improved emotional distress (Caprara et al., 2022).

Implications for a future RCT should also address the challenges the participants reported. These included sending reminders to their phone so that forgetting to do the exercise may be mitigated. Furthermore, securing quiet space for residents to do their breathing may be helpful when overcrowding in the sleeping quarters is a reality.

Finally, ensuring the breathing skills taught in the sessions can be applied to real-life situations as a means to increase self-regulation can be practiced as part of the training. While the video content in later sessions of the intervention does address this topic of application, making it more concrete may be helpful to promote the practice as well as further influence the outcomes. Creating a means to definitively guide participants in a step-by-step 'protocol' of how to implement the HRV-BF tools during a stressful event could help with this, to make the skills more relevant and easy to remember/implement.

Another finding was that there were varying levels of chronic disease between groups (65% - HRV-BF and 37% - HP). It is also possible that providing information on chronic diseases to participants in the HP programme may have improved their HRV balance and mental health symptoms. This may have occurred by improving their self-efficacy in managing CPD. Further research is of high importance in understanding how the mechanism of action differs between HRV-BF and HP. The findings of Lehrer et al. in a 2020 meta-analysis (Lehrer et al., 2020) show that HRV-BF is effective for many conditions, including anxiety, but not more effective than other interventions. Our findings suggest that a combination of the HRV-BF and HP programs may be an even more powerful approach to improving the mental health outcomes of PEH. Future studies are needed to assess the combination of the HRV-BF and HP programs; namely, a Mind-Body programme, delivered by nurse-led CHW teams would not only deliver the HRV-BF and HP sessions but also help navigate social service referrals, housing, and healthcare referrals.

Strengths and Limitations of the Study. To our knowledge, this is the first test of HRV-BF among PEH, a medically underserved population with high rates of anxiety, depression, PTSD (Armstrong et al., 2020; Duncan et al., 2019; Farhoudian et al., 2020; Garfin et al., 2020; Gutwinski et al., 2021) and chronic disease (Brown et al., 2017; Fazel et al., 2014; Fong, 2019). The HRV-BF intervention, adapted for this specific study population in both content and delivery, was shown not only to be both feasible and acceptable but had an excellent completion rate, suggesting that even among a highly transient population, it can be implemented effectively.

In order to adapt the HRV-BF intervention to the target population using our chosen delivery method, we opted to use methods which were easily replicable and easily delivered with greatest fidelity by the RN/CHW teams. As alluded to above, instead of completing a resonant frequency (RF) protocol or modified RF protocol, we instead chose to train participants using the biofeedback device at the consistent rate of 6 breaths/minute. There are studies showing that breathing at RF plays a key role in the effect that HRV-BF has on measures such as mood and blood pressure (compared to RF rate plus 1 breath/min) (Steffen et al., 2017). On the other hand, there is also evidence that using slow paced breathing with or without HRV-BF positively affects mood, emotion regulation, and HRV (RMSSD) (Laborde et al., 2022), and that there are not necessarily additional benefits of RF breathing over slow paced breathing (Lehrer et al., 2020).

Average RF is often assumed as 6 breaths/minute among the general population (Lehrer & Gevirtz, 2014) and examined as such in numerous studies, though later studies point to 5.5 breaths/minute as the average RF (Vaschillo et al., 2006). Our protocol integrates the above evidence, incorporating HRV-BF with EmWave during weekly sessions as well as slow paced breathing at 6 breaths/min in a blend adapted to the study population. Forgoing RF assessment but incorporating HRV-BF may be a necessary adaptation to make the intervention accessible to this severely underserved population. In future studies we may consider incorporating RF assessment to test the feasibility of including this step in the HRV-BF protocol with this population.

While HRV-BF showed promise in improving mental health symptoms and HRV, gaps in this pilot study included a small sample size. Further, self-reported measures may have contributed to measurement error (Bernard & Bernard, 2013); however, this limitation is partially addressed by the collection of biomarkers such as HRV. HRV is influenced widely by age as well as by the effect of specific substances (both prescribed and recreational), though the analysis of mean change in HRV measures (via delta, pre-post) accounts for this. Further, the findings may not be generalisable to PEH living in rural or other urban areas. Future studies point to the necessity of assessing the synergy between improving mental health and physical health via a combined Mind Body programme and including the assessment of key moderators such as self-efficacy for managing CPD and substance use disorder.

Despite the limitations of this pilot study, the positive impact on mental health and HRV combined with the ease of delivery and positive safety profile make this intervention a highly accessible intervention that warrants further investigation in large-scale efficacy trials.

AUTHORS' CONTRIBUTIONS

Adeline Nyamathi is Principal Investigator of the funded grant and collaborated with key co-authors on conceptualization and implementation of the grant, conceptualisation of the manuscript, data analysis, writing major components of the manuscript, and final review. **Benissa E. Salem** collaborated on grant conceptualization, training of staff, implementation of the study, contributed select sections to the manuscript, and final manuscript review. **Lillian Gelberg** assisted in the grant operationalisation, and reviewed the final manuscript. **Dana Rose Garfin** assisted in manuscript conceptualisation, data analysis and manuscript review. **Kate Wolitsky-Taylor** strengthened the psychological aspects of the manuscript in the final review prior to submission. **Sanghyuk S. Shin** collaborated on grant conceptualization, development of the statistical plan, statistical analysis, and manuscript review. **Zhaoxia Yu** assisted in data analysis, writing select portions of the manuscript, and final review of the manuscript. **Angela Hudson** assisted in strengthening the HP aspects in the final review of the manuscript. **Kartik Yadav** assisted in the grant development, funding acquisition, and data collection, and final review of the manuscript. **Richard Clarke** assisted in the delivery of the intervention and review of the manuscript prior to submission. **Mitra Alikhani** served as Dr. Nyamathi research assistant, helped in the operationalisation of the grant, and assisted in writing the manuscript and final review. **Emily Van Cise** helped in the operationalisation of data collection and final review of the manuscript. **Darlene Lee** conceptualized and operationalised the delivery of the Heart Rate Variability-Biobeedback, significantly involved in working with the staff in delivery of the intervention, wrote sections of the manuscript, and final review.

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CONFLICT OF INTEREST STATEMENT

The authors declare that they have no competing interests.

DATA AVAILABILITY STATEMENT

The datasets generated during and/or analysed during the current study are available by email request to the corresponding author at anyamath@uci.edu.

ETHICS STATEMENT

Our study was approved by the Human Subjects Protection Committee at the University of California, Irvine and the University of California, LA.

CONSENT TO PARTICIPATE

All study participants provided informed consent prior to enrolling in the study.

CONSENT FOR PUBLICATION

No personally identifying information is provided in this study.

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