Original Article

Postural reprogramming insoles for blood pressure fall and posture misalignment in hypertensive individuals: randomized clinical trial

Palmilhas de reprogramação postural na diminuição da pressão arterial e do desalinhamento postural em indivíduos hipertensos: ensaio clínico randomizado

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ABSTRACT | OBJECTIVE: To test the hypothesis that Postural Reprogramming Insoles (PRI) improves posture and the effect of PRI on average and peaks of blood pressure (BP) in hypertensive individuals. **DESIGN:** RCT, registered at the Clinical Trials (NCT02401516), with 24 hypertensive individuals. **SETTING:** All patients underwent Ambulatory Blood Pressure Monitoring (ABPM) and posture assessment (PAS/SAPO software) at the beginning and the end of six weeks. **INTERVENTION:** intervention group (IG) used PRI and control group (CG) SHAM. **MAIN OUTCOME MEASURES:** BP averages. **SECONDARY OUTCOMES:** BP peaks, during awake and asleep periods. Improvement of posture was determined when the angle values assessed decreased or reached zero (perfect alignment). To compare BP, paired, and unpaired Student's t-tests were used, significance level of 5%. Effect size (ES) was assessed with Cohen's D. For posture assessment, Wilcoxon and Mann-Whitney were applied to analysis. Categorical variables, through Chi-square test. **RESULTS:** Baseline variables did not differ between groups. The following deltas were obtained-SBP peak in awake period (+9.3mmHgVs-7.5mmHg) (p<0.05, great ES); SBP peak during sleeping period (+2.3mmHgVs-6.8mmHg) (p<0.05, moderate ES); and DBP peak during awake period (+3.2mmHgVs-4.7mmHg) (p<0.05, great ES), in control and intervention groups, respectively. For postural angles, 33% of SBP were explained by anterior body shift. For DBP, 46% and 55% were explained by Knee and Ankle Angles, respectively. **CONCLUSIONS:** PRI reduced SBP and DBP peaks during awake period, with no effect on BP average. Even though PRI has not shown any improvement in overall posture, anterior body displacement and knee and ankle angles would solely explain 33-55% of the highest BP.

KEYWORDS: Hypertension. Insoles. Blood pressure. Posture.

RESUMO | OBJETIVO: Testar a hipótese que Palmilhas de Reprogramação Postural (PRP) melhoram a postura e podem modificar média e picos de pressão arterial (PA) em indivíduos hipertensos. **DESENHO DE ESTUDO:** ECR, registrado no *Clinical Trials* (NCT02401516), com 24 indivíduos hipertensos. **CONFIGURAÇÃO:** Todos foram submetidos à Monitorização Ambulatorial da Pressão Arterial (MAPA) e avaliação da postura (SAPO) no início e após seis semanas. **INTERVENÇÃO:** grupo intervenção (GI) utilizou PRP e grupo controle (GC) SHAM. **DESFECHO PRIMÁRIO:** Médias da PA. **DESFECHOS SECUNDÁRIOS:** Picos de PA, durante vigília e sono e ângulo posturais. A melhora da postura ocorreu quando valores angulares diminuíram ou chegaram a zero. Para comparar a PA, foram utilizados os testes t de *Student*, pareado e não-pareado, com nível de significância de 5%. O tamanho do efeito (TDE) foi avaliado com D de Cohen. Para postura, Wilcoxon e Mann-Whitney. Variáveis categóricas, através do teste do Qui-quadrado. **RESULTADOS:** As variáveis de linha de base não diferiram entre grupos. Foram obtidos os seguintes deltas: pico da PAS em vigília (+9,3mmHgVs-7,5mmHg) (p<0,05, grande TDE); pico da PAS no sono (+2,3mmHgVs-6,8mmHg) (p<0,05, TDE moderado); e pico da PAD durante vigília (+3,2mmHgVs-4,7mmHg) (p<0,05, grande TDE), GC e GI respectivamente. Para os ângulos posturais, 33% da PAS foram explicados pelo deslocamento anterior do corpo. Para a PAD, 46% e 55%, pelos ângulos de Joelho e Tornozelo, respectivamente. **CONCLUSÕES:** A PRP reduziu picos de PAS e PAD durante vigília, sem efeito na média da PA. Embora PRP não tenha mostrado melhora na postura geral, o deslocamento anterior do corpo e os ângulos de joelho e tornozelo explicaram 33-55% da PA mais alta.

PALAVRAS-CHAVE: Hipertensão arterial. Palmilhas. Pressão arterial. Postura.

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Introduction

High Blood Pressure (HBP) is a major modifiable risk factor for cardiovascular diseases[1,2]. It is estimated that around 17 million deaths/year worldwide are caused by diseases of the circulatory system, and of these, 55.3% are related to elevated blood pressure (BP)[3]. Excessive activation of the sympathetic nervous system (SNS) seems to play an important role in the maintenance of HBP[4-6], being considered the final system of integration in function regulation[7]. Most vascular nerves of the SNS cause vasoconstriction; its main transmitter is noradrenaline and it suffers interference from the musculoskeletal[7], vestibular, cutaneous[7], respiratory[8], renal[9], endocrine[9] and somatosensory systems[10].

Posture can be defined as the form that the body acquires at a given moment to counteract the gravitational force applied to each body segment, maintaining stable segment position[11]. Posturology treats postural misalignment and is based on insole use to restore proper posture to individuals. The postural reprogramming insole (PRI) is composed of a central device in the middle of the foot, consisting of two crossed polarizing processes formed by ferromagnetic macromolecules, which are hot-rolled and generate eletromagnetic currents and cause vibrations[12]. Despite of not knowing exactly how this device truly works, it seems that the current stimulates, through the autonomous system, the Postural Tonic System (PTS)[13], to promote adequate posture[14-18].

Also, a study developed by this group found a possible pattern of postural misalignment between hypertensive individuals: anterior trunk shift, posterior body shift, flexing hip, knee and ankle. Alterations of these angles caused greater pressure loads at Ambulatory Blood Pressure Monitoring (ABPM), for total, during awake or asleep periods, and lower blood pressure variations between awake/asleep period, for both systolic and diastolic blood pressure. These findings suggest an association between postural misalignment and BP alteration[19].

The pathways used by the Autonomic Nervous System (ANS) to control BP[9] appear to be similar to those used for posture control, which are also used by PRI for postural adjustment[13]. Due to this similarity in the areas of activation, PRI may have some effect on BP. Thus, it is important to analyse the possible influence of PRI on BP in hypertensive individuals.

Thus, the aim of this study was to evaluate the effect of PRI on BP fall and on postural misalignment in hypertensive individuals.

Methods

Trial design: This is an exploratory randomized, triple-blinded, controlled clinical trial conducted with hypertensive individuals followed at an outpatient clinic that was linked to an educational institution and primary health care centre throughout the 20-month period.

Participants: Inclusion criteria for the study were: previous hypertension diagnosis, i.e. SBP≥140mmHg and/or DBP≥90 mmHg, for at least two months, participants of both sexes, aged between 30-60 years old with a body mass index (BMI) of up to 34.9 kg/m2, and clinical stability. All participants were instructed to maintain dietary pattern and prescribed medications.

Participants with history of cerebrovascular disease and previous cardiovascular events (myocardial infarction, heart failure, unstable angina), diagnosed renal or peripheral arterial disease, neurological diseases, mental illness, pregnancy, diabetes mellitus, and participants who did not perform ABPM after intervention and those who were on medication for glycaemic control were excluded.

This protocol was approved by Ethics Committee of Bahiana School of Medicine and Public Health (EBMSP), according to the ethical guidelines of the 1975 Declaration of Helsinki. The project design was based on the determinations of the CONSORT Statement[20]. The identification of this study on the ClinicalTrials.gov website is NCT02401516.

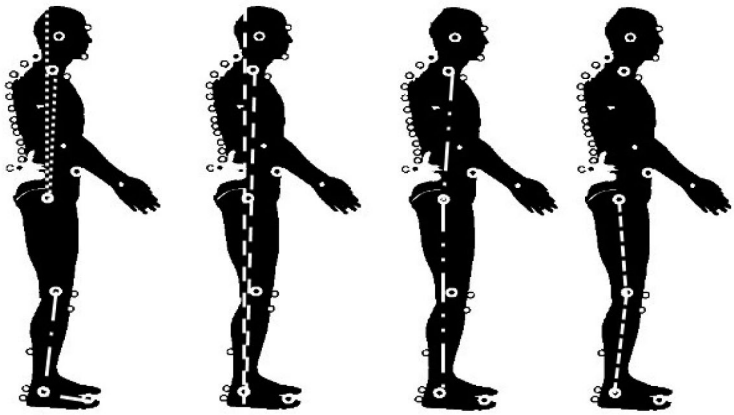
Intervention and Randomization: Participants were divided into two groups by simple randomization: intervention group (IG) and control group (CG). Both groups used insoles, and in the IG, the PRI contained the resonator that emits the electromagnetic current, whereas the CG insole contained a device with dimensions and size similar to resonator but made of cork. The participants were instructed to use the insole for at least 12 hours a day for 6 weeks.

After signing the informed consent form, participants attended the Laboratory of Cardiovascular Research-EBMSP for placement of ABPM, according to the V Brazilian Guideline for the use of ABPM[21]. ABPM was performed one day before PRI placement to define BP values, considered as baseline, and a new evaluation was performed six weeks after insole use. Subjects were oriented to complete a diary of activities with data about symptoms and other situations that could modify BP during the period under intervention[21].

Postural Assessment: Styrofoam hemispheres of 25mm diameter were glued on the main osseous accidents with double sided tape (brand 3M), according with PAS/SAPO protocol. Feet were positioned in 30° abduction for alignment and image standardization. Subjects dressed in shorts and tops (women) and shorts (men) were positioned upon meter paper sheet measuring 1m² in area, near the plumb line attached to the ceiling and marked 10cm long for image calibration purposes in the software. Images were caught by Sony Cybershot digital still camera (DSC-W570, 16,1 Megapixels), supported on a tripod, placed three meters away from the individuals and on half their heights.

The software engenders report in the Right Side View was raffled. The angles were described as: 1)Vertical Alignment of Trunk (VAT), angle formed between acromion, greater trochanter and vertical line; 2)Vertical Alignment of Body (VAB), angle formed between acromion, lateral malleolus and vertical line; 3)Hip Angle (HA), formed between acromion, greater trochanter and lateral malleolus; 4)Knee Ankle (KA), formed between major trochanter, lateral joint line of the knee and lateral malleolus and 5)Ankle Angle (AA), formed by lateral joint line of the knee and the lateral and horizontal lines of the lateral malleolus (Figure 1).

Figure 1. Angles used in the study at Right Side View



Primary Outcomes

Average of systolic and diastolic BP.

Secondary Outcome

Peak of systolic and diastolic BP, during awake and asleep periods. Posture angles.

After exam validation, a survey containing sociodemographic, life habit, and health information was filled out. Weight and height were evaluated by the Welmy® brand hand scale (Santa Bárbara D'Oeste, SP). Outpatient BP was measured according to the VII Brazilian Hypertension Guideline[2], using an automatic arm digital device, model HEM-742, of the Omron brand (Omron Healthcare Inc., Lake Forest, IL, USA). Three measurements were performed with a one-minute interval between them and arithmetic mean was calculated.

To evaluate PRI immediate effects, measurements of systolic and diastolic BP (SBP and DBP) in outpatients were performed one, five, and ten minutes after the insoles were placed for both groups and the late effects were evaluated with measurements of average and peaks of BP, during awake and asleep periods, and were performed after six weeks of continuous use of the insoles, with new ABPM.

For posture, the following angles were assessed: VAT and VAB were categorized as posterior shift (when angular values are negative) and anterior (positive values); HA, categorized as increased (when angular values are negative, featuring extension) and decreased (positive values, featuring flexion); KA, categorized as increased (when angular values are negative, featuring hyperextension or geno recurvatum) and decreased (positive values featuring semiflexion). AA, categorized as increased (angular values over 90°, featuring plantiflexion) and decreased (values under 90°, featuring dorsiflexion).

Improvement was determined when the angle value decreased or reached zero (perfect alignment). It was considered worse when values increased or were reversed (changing between positive and negative).

Intention-to-treat analysis could not be performed, because the study protocol considered not performing ABPM after intervention as exclusion criteria, once we had a short time period to realize the exam. We tried to schedule the exam twice in 10 days period. If the participant did not appear, it was excluded from the study. However, even after application of this protocol, the randomization was not compromised.

Sample size: Considering the metanalysis developed by Lin[22] in which dietary control and physical activity within a period of 12 months caused decrease in BP around 2.29mmHg, it was decided to consider the standard deviation of the mean BP in 3mmHg for both groups, to detect a difference between the means of BP of 3mmHg, a significance level of 5%, 80% test power, in a two-tailed hypothesis, totalling 32 participants, with 16 in each group. The WinPepi calculator was used and the data were organized and analysed in SPSS 14.0 program for Windows.

Blinding: All ABPM exams were reported by a cardiologist with experience in the analysis of this method and who were blinded to the participants' allocation. Evaluations of outpatient BP were performed by a blinded and trained researcher for this purpose. Participants did not know in which group they were allocated. Only one person of the team had knowledge about PRI distribution and that person did not participated of data collection.

Statistical Methods

Descriptive and inferential analysis: sociodemographic variables: Age (years old), skin colour (Black/White/ Yellow/Indigenous), education (up to 4 years of education, 5-8 years, 9-11 years, and 12 or more years), marital status (Married-Stable Union/Single/ Widowed/ Separated-Divorced). Anthropometric and lifestyle habits and health: BMI (kg/m2), smoking (never smoked/smoker/former smoker), consumption of alcoholic beverage (dichotomic), regular use of medication (dichotomous), type of medication (categorical). Posture: posture angles. Clinical: BP peaks during the awake and sleeping periods (mmHg), mean BP (mmHg), and SBP, DBP, and HR in outpatients measurements.

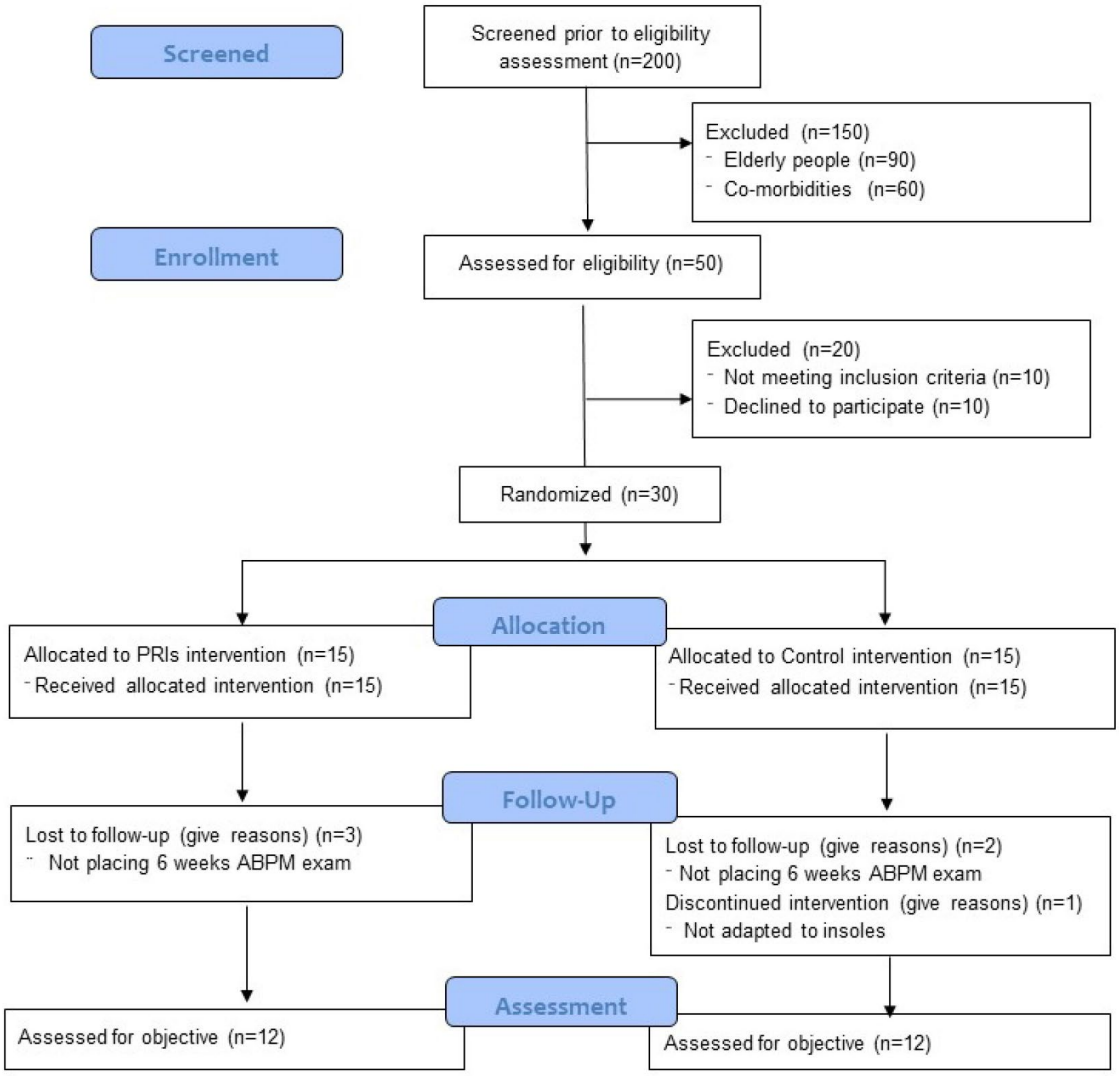
Mean and standard deviation were used for descriptive analysis of the quantitative variables. For categorical variables, absolute number and proportion were used. To identify immediate effects of the insole, the differences in SBP and DBP means were compared at the different estimated times (resting, one, five and 10 minutes) using the ANOVA test for repeated measures and Bonferroni post-test.

To identify the differences in averages and peaks of SBP and DBP between IG and CG, the unpaired Student's t-test was used. The paired Student's t-test was used for intragroup variables. In order to identify the effects of PRI in posture, the Wilcoxon test was used in the intragroup analysis whereas the Chi-square test was used in the intergroup analysis. Pearson's Correlation test was used to associate posture angles with pressure variables. All tests were considered with a significance level of 5%. In the intergroup comparisons, the Effect Size (ES) was calculated using Cohen's D test and values of up to 0.2 were considered as small effect, between 0.21-0.8, moderate effect and values above 0.81 of great effect[23]. The Cohen's D test was calculated using the RStats Effect Size Calculator for t-Tests[24]. We also calculated the difference between the final and initial values of each BP variable, called delta and Student's t-test was used. Data were organized in SPSS 14.0 for Windows program for further analysis.

Results

During the previous screening assessment of eligibility, 200 possible participants met criteria. Of these, 150 were excluded: age above 60 years old (90) and presenting co-morbidities such as diabetes mellitus, metabolic syndrome and target-organ lesion (60). Of 50 evaluated for eligibility, 20 were excluded: they did not fit the criteria for eligibility (10) and declined to participate in the research(10). Of the 30 who agreed to participate in the study, 15 participants were allocated to each group and all have received the proposed intervention. There was a loss of follow-up of 3 (20%) participants in each group. In the intervention group, they did not attend for assessment of ABPM after six weeks and in control, two participants did not appear to last evaluation and one did not adapt to the insole. (Figure 2)

Figure 2. Elegibility CONSORT flow diagram



Foram incluídos 24 participantes, com média de idade de 49±6,6 anos, IMC de 30±4,2 Kg/m2. Ser do sexo feminino (83,3%), casada (54,2%), com 12 ou mais anos de estudo (66,7%) e cor da pele preta ou parda (45,8% para cada) foram as características mais frequentes. A maioria nunca fumou (70,8%), não consumia bebida alcóolica (58,3%), estava em uso regular de medicamento anti-hipertensivo (83,3%). O medicamento mais frequente foi o bloqueador de receptores de angiotensina II (58,3%) e a hipertensão estava controlada (70,8%) (Tabela 1).

Tabela 1. Distribuição dos participantes de acordo com as características sociodemográficas e de estilo de vida. 2020. (n=24)

	Control (n = 12)	**Intervention (n = 12)**	**Total (n=24)**	**p-value**
Variables	**X ±SD**	**X ±SD**	**X ±SD**	
Age (years)	47.8±7.5	50.3±5.6	49±6.6	0.4$
BMI (Kg/m²)	30.4±3.4	29.5±4.9	30±4.2	0.6$
Sex	**n(%)**	**n(%)**		1.0$
Female	10(83)	10(83)	20(83)	
Marital Status				0.34**
Married/Stable relationship	5(41.7)	8(66.7)	13(54)	
Single	4(33.3)	2(16.7)	6(25)	
Separated/Divorced	2(16.7)	1(8.3)	3(12.5)	
Widowed	1(8.3)	1(8.3)	2(8.5)	
Educational Status (years)				0.33**
Until 4	1(8.3)	---	1(4.2)	
5 - 8	----	2(16.7)	2(8.4)	
9 - 11	1(8.3)	4(33.3)	5(20.8)	
12 or more	**10(83.3)**	**6(50)**	16(66.6)	
Skin Color				0.59**
Black	**7(58.3)**	4(33.3)	11(45.8)	
Brown	4(33.3)	**7(58.3)**	11(45.8)	
White	----	1(8.3)	1(4.2)	
Yellow	1(8.3)	----	1(4.2)	
Smoking				1.0**
Never	9(75)	8(66.7)	17(71)	
Former smoker	3(25)	4(33.3)	7(29)	
Alcohol consumption				0.11**
No	5(41.7)	9(75)	14(58)	
Use of antihypertensive medication				0.59**
Yes	9(75)	11(91.7)	20(83)	
Types of medication				
Thiazide diuretic (n=7)	2(16.7)	5(41.7)	7(29)	0.37**
Beta-blocker (n=10)	3(25)	7(58.3)	10(42)	0.21**
ACE inhibitor (n=1)*	1(8.3)	----	1(4.2)	1.0**
ARB‡ (n=15)	8(66.7)	6(50)	14(58)	0.68**
Calcium channel blockers (n=3)	3(25)	1(8.3)	4(17)	0.59**
BP classification				
Controled	7(58.3)	10(83.3)	17(71)	0.37**

*ACE inhibitor: Angiotensin-converting-enzyme inhibitors; ‡ARB: angiotensin II receptor blocker; $Student T test; **Fisher Exact test;

For ABPM pressure variables, mean values of 154±19mmHg, 134±19mmHg and 125±16mmHg were the peaks during the awake and sleeping periods and mean SBP, respectively. In addition, a mean of 105±11mmHg, 91±13mmHg and 82±10mmHg for peak during the awake and sleeping periods and mean DBP were observed, respectively. Considering outpatients measures, the average was 152±21mmHg, 92±16mmHg and 77±12bpm for SBP, DBP, and HR, respectively. Most participants did not present pressure decrease during sleep, at 58.3% in the CG and 66.7% in the IG. The initial values of the pressure variables did not present differences between the groups (Table 2).

Table 2. Sample characteristics according to Blood Pressure Variables (ABPM). 2020. (n=24)

Variables	Control (n = 12)	Intervention (n = 12)	Total (n=24)	p-value*
Systolic Blood Pressure (SBP) (mmHg)	**X ±SD**	**X ±SD**	**X ±SD**	
Awake period Peak	156.6±15.7	152.3±22.8	154±19	0.59
Sleep period Peak	132.8±12.6	135.9±24.4	134±19	0.71
Average	126.8±13.5	122.8±19.3	125±16	0.56
Diastolic Blood Pressure (DBP) (mmHg)				
Awake period Peak	106.8±12.3	103.2±8.5	105±11	0.41
Sleep period Peak	91.4±14.4	90.8±12.3	91±13	0.92
Average	85.1±11.7	79.6±8.6	82±10	0.20
Absence of nocturnal dipping (n=15)				
Yes	7(58.3%)	8(66.7%)	15(62.5)	0.50+

*Student T test; +Fisher Exact test.

PRI did not show immediate effect on BP decrease between the times studied for the IG or CG (p>0.05). In the intragroup comparison of CG, no pressure variable reached a significant difference, showing that there was little change in the variables during the six weeks of study intervention. In the comparison of IG, the SBP peak during sleep presented a difference between baseline and post-intervention levels, with a mean of 135.8±24.4 mmHg in the baseline period and 129.1±25.2 mmHg after PRI (p<0.05)

When comparing deltas, we found that SBP delta peak during the awake period was +9.3mmHg for CG and -7.5mmHg for IG (p<0.05), with a difference of 16.8mmHg between groups and an ES of 1.10. The delta peak SBP during the sleep period was +2.3mmHg for CG and -6.8mmHg for IG (p<0.05), whose difference between groups was 9.1mmHg and ES of 0.3 and the delta peak of DBP during awake was +3.2mmHg in the CG and -4.7mmHg in the IG (p<0.05), with a difference of 7.9mmHg and an ES of 1.12 (Table 3).

Table 3. Inter-group comparison of BP delta variables (ABPM). 2020. (n=24)

Variables	Control (n = 12)	Intervention (n = 16)	p-value*
Systolic Blood Pressure (SBP) (mmHg)	Dif(Post-Pre)	Dif(Post-Pre)	
Δ Awake period Peak	+9.3	-7.5	0.04
Δ Sleep period Peak	+2.3	-6.8	0.03
Δ Average	+3.0	-3.8	0.20
Diastolic Blood Pressure (DBP) (mmHg)			
Δ Awake period Peak	+3.2	-4.7	0.04
Δ Sleep period Peak	-1.3	-3.8	0.52
Δ Average	+0.1	-0.6	0.82

*Student T test.

For posture analysis, 30 participants were enrolled, maintaining the similar frequency characteristics. For basal values of posture parameters, the participants presented posterior trunk shift, anterior body shift, increased hip and knee angles and decreased ankle angle, with no difference between groups (p>0.05) (Table 4). In both intragroup and intergroup comparisons, baseline parameters were maintained for CG and IG, with no statistical difference. After recategorization, similar improvement was observed between the two groups, with no statistical difference (p>0.05).

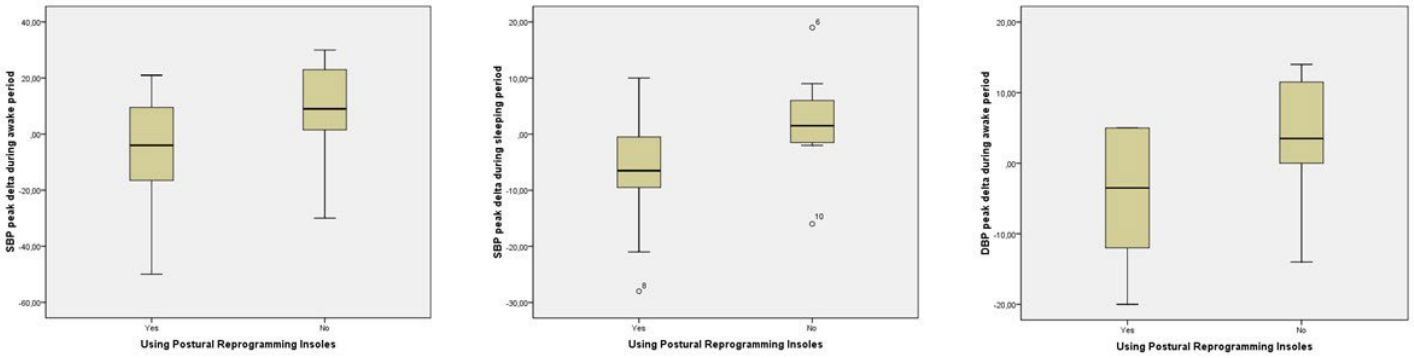
Table 4. Basal characteristics according to Angles Posture (PAS/SAPO). 2020. (n=30)

Variables	Control (n = 15)	Intervention (n = 15)	p-value[+]
	Med[IQ25-75][*]	**Med[IQ25-75] [*]**	
Vertical Alignment of Trunk (VAT)	-1.7[-3.4 – 2.4]	-1,5[-3.4 – 2.1]	0.78
Vertical Alignment of Body (VAB)	2.5[1.4 – 3.0]	2,1[1.1 – 3.2]	1.0
Hip Angle (HA)	-6.5[-12.4 – -0.4]	-5,5[-11.2 – -1.6]	0.94
Knee Angle (KA)	-0.7[-3.6 – 2.0]	-1,7[-3.8 – 4.2]	1.0
Ankle Angle (AA)	85.4[84.3 – 87.5]	85,9[83.3 – 86.9]	0.94

*Median[Interquartil Interval]; [+]Mann-Whitney

For IG, anterior body shift presented a moderate positive correlation for SBP (r=0.57, p=0.03), 33% of SBP explained by anterior displacement of the body. Knee angle with moderate positive correlation for DBP (r=0.68, p<0.01), and ankle angle with moderate negative correlation for DBP (r=-0.75, p<0.01), with 46% and 55% of the DBP defined by the angles, respectively. (Figure 3). No correlations between specific posture parameters and BP were found, considering the initial values in the two groups and the final GC values.

Figure 3. Inter-group comparison of deltas peak of awake and sleep periods of BP variables (ABPM)



Discussion

This research aimed to verify the PRI effect on BP fall in hypertensive individuals, and after six weeks of PRI usage, there was no effect of PRI on average BP, a great effect in reducing SBP peak was observed during the awake period, a moderate effect in reducing SBP peak during the sleep period, and a great effect in reducing peak of DBP during the awake period. The electromagnetic current caused by the artifact of the insoles has action on the adjacent muscles (deep somatosensory system)[13], and in the plasma properties of fluids[25,26].

It is possible that the position of the foot device caused direct myotatic reflex of the muscle receiving stimulus[13]. Studies that correlated Muscle Sympathetic Nerve Activity (MSNA) and hypertension mostly demonstrated an increase in MSNA at rest in muscles[4,6], favouring increased systemic sympathetic activity, with release of circulating noradrenaline and glutamate, activation of β-adrenoceptors, which will increase vascular tone and peripheral vascular resistance (PVR)[4,6,27,28].

In this study, it was possible to observe that there was a decrease in pressure peaks[21]. Pressure peaks are associated with adrenergic discharges, secondary to sympathetic stimulation. Once pressure peaks declined for SBP in awake and sleeping periods and DBP in awake, around 17mmHg, 9mmHg and 8mmHg, respectively, with a magnitude effect of moderate or large, it may be suggested that there was inhibition of the sympathetic stimulus.

It is important to emphasize the effect sizes produced by the PRI. In a systematic review and meta-analysis of 13 published studies combining dietary interventions and medium-to-high intensity physical activity, with most participants taking antihypertensive drugs, mean baseline SBP/DBP of 127-162/71-96mmHg for individuals using medication and 144/87mmHg in the non-drug group and duration of intervention between 12-24 months showed a reduction of SBP and DBP for a period of <12 months of 2.29 (3.82-0.76) mmHg and of 1.22 (2.53 to 0.08) mmHg, respectively[22]. The present study showed a peak SBP decrease of at least 9mmHg and DBP around 8mmHg.

Another hypothesis to understand the results, it can also be suggested that the electromagnetic current produced by the PRI, may be involved in regulating systemic sympathetic activity. The resonator purpose is to cause depolarization of neurons in the region close to the location of the device, generating potentials of action, wich will be driven to the brain[29]. Although this theory seems to be feasible, there is no certainty of its functioning for PRI. PRI characteristics are considered of being a low-frequency current with a constant electron flux[12].

Studies that applied transcutaneous vagus nerve stimulation (tVNS), with electrodes placed on tragus showed that resting heart rate decreased and cardiac baroreflex sensitivity increased, regulating autonomic modulation[30]. Also, tVNS can alter cardiovascular autonomic control in healthy humans, with a shift in cardiac autonomic balance toward parasympathetic/vagal dominance (tVNS significantly decreased LF/HF ratio), and decrease in MSNA[31]. Transcutaneous electrical nerve stimulation (TENS) improves blood flow[32]. Low-frequency TENS decreases sympathetic and increases parasympathetic nervous system activities when applied on the paravertebral ganglionar region in hypertensive patients[33].

Considering posture improvement, after six weeks of PRI use, little change in posture was noted, with maintenance of initial postural patterns, for both groups. This study observed that anterior body shift revealed a moderate and positive association to SBP (the greater the projection of the body forward, the greater the BP value).

In a previous study, postural misalignments showed association with ABPM elements: anterior trunk shift presented a lower wake/sleep variation for SBP (14.7%Vs25.3%, p=0.01), flexed hip presented higher pressure load (29.4%Vs18.3% p=0.02) for DBP(19). Differences on posture angles alterations can lead to different associations with BP variables, but the assumption that postural misalignments may modify BP regulation becomes more consistent.

Decrease in anterior displacement of the body and consequent improvement of distribution of center of mass can impact the intensity of muscular contraction of the whole posterior chain, that contracts so that people can keep themselves against gravity. Decrease of muscle contraction may decrease MSNA, with a potential decrease of systemic sympathetic activity, with a consequent decrease in BP[4,6].

The knee and ankle angles are proportional in standing position: the smaller the knee angle (more flexion), the lower the ankle angle (more dorsiflexion). The decrease in angles caused an increase in DBP. The aforementioned angles generate eccentric stretching of the posterior muscles of the leg, mainly gastrocnemius and soleus, altering the state of muscle tension, with sustained mechanical vessel compressions and mechanoreceptor stimulus[34]. This constant state of tension of the posterior muscles of leg causes loss of calf pump mechanism. This pump has an important role on venous return and on the interaction of cardio-postural-musculoskeletal systems[35].

PRI did not affect the posture correction, but it improved the anterior shift of the body, which favored an SBP decrease. The maintenance of knee flexion and ankle dorsiflexion impacted on DBP increase. It is important to stress that the device should not be the only correction to be performed on the insole for complete postural correction: shims are usually used to correct dysmetria of lower limbs, flat and valgus feet[13], what could have impacted on improving

posture. However, the main objective of this study was to verify the effect of the device, singly, on the posture of hypertensive individuals and to ascertain if the change on posture could affect BP.

As limitations this study did not reach the number estimated by sample size calculation and the need to consider participants who did not undertake ABPM at the end of six weeks of intervention as an exclusion criterion. A large number of hypertensive patients presented obesity, metabolic syndrome and diabetes mellitus, all exclusion criteria of the study. These clinical conditions affect neuroendocrine system and are considered, for these studies, outcome modifiers, because it interferes in the neurophysiological mechanisms that potentially explain the intervention results. Considering the importance of ABPM to the main outcome and because this is an exploratory study, the examination data were necessary to understand the real action of the insole on this population. However, it is important to note that this study used adequate design of randomized clinical trial to test the effect of PRI.

The originality of this study was to propose an innovative way to produce electromagnetic current through the combination of metals in an insole, with action focused on the cardiovascular system. Considering the positive results, it is important to encourage the use of this tool in a larger population, with less control of the intervening variables, to identify the behaviour of PRI against these conditions. From the findings, it is possible to consider that PRI may be a complementary treatment for individuals with arterial hypertension to reduce peaks pressure of SBP and DBP during the awake period.

Author contributions

Góes ALB participated in the conception, design, search and statistical analysis of research data, interpretation of results and writing of the scientific article. Barbosa ASM, Araújo BGV, Barbosa CC, Barbalho GMOG, Lago VC, Souza LAP participated in the collection and interpretation of the research data. Ladeia AMT participated in the conception, design, search and statistical analysis of the research data, interpretation of results, writing and editing of the scientific article.

Competing interests

No financial, legal or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

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