J Renal Inj Prev. 2025:e38681.

https://journalrip.com doi: 10.34172/jrip.2025.38681

Journal of Renal Injury Prevention

Efficacy of auricular acupuncture on blood pressure in chronic essential hypertension; a randomized, double-blinded clinical trial study

Rahim Firouzi Bostanabad[1], Haideh Mosleh[2], Sahar Kavand[3], Sara Rashki Ghalehnoo[4], Masoumeh Sadeghi[5], Mahmoud Mohammadzadeh Shabestari[6], Seyed Kazem Farahmand[1], Mohammad Hosein Ayati[7], Zahra Abbasi[2*], Hoda Azizi[1*]

[1]Department of Acupuncture, School of Persian and Complementary Medicine, Mashhad University of Medical Sciences, Mashhad, Iran
[2]Department of Otorhinolaryngology, Loghman Hakim Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran
[3]Department of Sports Medicine, School of Medicine, Loghman Hakim Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran
[4]Department of Cardiology, School of Medicine, Amir Al Momenin Hospital, Zabol University of Medical Sciences, Zabol, Iran
[5]Department of Epidemiology, Faculty of Health, Mashhad University of Medical Sciences, Mashhad, Iran
[6]Department of Cardiology, Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran
[7]Department of Traditional Medicine, School of Traditional Iranian Medicine, Tehran University of Medical Sciences, Tehran, Iran

ARTICLE INFO

Article Type:
Clinical Trial

Article History:
Received: 10 Jun. 2025
Revised: 12 Aug. 2025
Accepted: 19 Sep. 2025
Published online: 25 Oct. 2025

Keywords:
Blood pressure
Essential hypertension
Adjuvant therapy
Acupuncture
Auricular acupuncture

ABSTRACT

Introduction: Chronic hypertension is a prevalent cardiovascular disorder associated with significant morbidity and mortality. Alternative therapies such as auricular acupuncture have garnered interest as adjuncts to conventional antihypertensive management, yet robust evidence remains limited.

Objectives: To evaluate the efficacy of auricular acupuncture on blood pressure in patients with chronic essential hypertension.

Patients and Methods: This randomized clinical trial, conducted at Imam Reza hospital, enrolled 58 adult hypertensive patients (28 in the control and 30 in the acupunctural group) between August 2022 and December 2024. Informed written consent was obtained, and blood pressure was measured. The intervention consisted of applying micro-needle stickers to four selected auricular acupoints weekly for four weeks, while the control group received visually identical placebo stickers. Participants attended six sessions over eight weeks of follow-up visits. Outcomes focused on the comparison of systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) at baseline and multiple time points post-intervention between the two groups.

Results: The between-group analysis revealed no statistically significant differences in SBP, DBP, or MAP at most measurement points throughout the eight-week study period, with only one isolated significant difference observed in SBP at the second week, favoring the auricular acupuncture group. While within-group analyses demonstrated that both the auricular acupuncture and control groups experienced some significant improvements in blood pressure parameters compared to their respective baseline measurements, the differential timing and patterns of these changes suggest that the auricular acupuncture intervention did not provide clinically superior benefits over the control treatment.

Conclusion: Our results showed no clinically significant advantage of auricular acupuncture in lowering blood pressure in patients with chronic essential hypertension. While the present study found no evidence supporting the effectiveness of auricular acupuncture in reducing blood pressure among this population, the inconsistencies with prior findings warrant additional well-designed clinical trials.

Trial Registration: The trial protocol was approved by the Iranian Registry of Clinical Trials (identifier: IRCT20110809007265N13; https://irct.behdasht.gov.ir/trial/64908), and ethical code from Mashhad University of Medical Sciences (IR.MUMS.REC.1401.122; https://ethics.research.ac.ir/EthicsProposalView.php?id=268983).

Clinical Trial

***Corresponding author**: Hoda Azizi, Email: azizih@mums.ac.ir, azizi.h.md@gmail.com; Zahra Abbasi, Email: z.abbasi@sbmu.ac.ir

Implication for health policy/practice/research/medical education:
In this clinical trial study, we found that auricular acupuncture did not demonstrate a clinically significant advantage over the control placebo in lowering blood pressure among patients diagnosed with chronic essential hypertension. While these results suggest a lack of efficacy of this intervention in the studied population, it is important to recognize that previous research in this area has reported mixed outcomes, with some studies indicating potential benefits. Given the discrepancies between our findings and those documented in the existing literature, there is a clear need for further investigation. Specifically, additional rigorously designed and adequately powered clinical trials are essential to conclusively determine the effectiveness of auricular acupuncture for blood pressure management in patients with chronic essential hypertension.

Please cite this paper as: Firouzi Bostanabad R, Mosleh H, Kavand S, Rashki Ghalehnoo . Efficacy of auricular acupuncture on blood pressure in chronic essential hypertension; a randomized, double-blinded clinical trial study. J Renal Inj Prev. 2025; x(x): e38681. doi: 10.34172/jrip.2025.38681.

Introduction

Elevated blood pressure or hypertension is a leading modifiable risk factor for cardiovascular disease and mortality worldwide, with hypertension affecting approximately one in two adults globally (1,2). The relationship between blood pressure and cardiovascular outcomes is continuous and graded, with even modest reductions yielding substantial clinical benefits (3,4). Despite effective antihypertensive medications being available, a few patients achieve optimal blood pressure control with pharmacological therapy alone, highlighting the need for complementary therapeutic approaches (5).

Essential hypertension, accounting for approximately 90% of all hypertensive cases, is one of the most common chronic diseases of undetermined etiology (6,7). This multifactorial disorder arises from complex interactions between genetic, environmental, and behavioral factors, with a primary causal link established between chronically high dietary sodium intake and hypertension development when kidneys become unable to excrete ingested sodium unless blood pressure increases (7,8). The pathophysiology involves an abnormal renal-pressure natriuresis relationship shifted rightward, requiring higher arterial pressure for sodium equilibrium, often mediated by sympathetic nervous system dysfunction that increases renin secretion, renal tubular sodium reabsorption, and renal vasoconstriction (7). Contributing mechanisms include arterial stiffening, renin-angiotensin-aldosterone system activation, and polymorphisms affecting over 1000 blood pressure loci, and emerging factors such as intestinal microbiome alterations and epigenetic modifications (9-11). The condition represents a progressive cardiovascular syndrome with early markers often present before blood pressure elevation, leading to target organ damage, including cardiovascular, cerebrovascular, and renal complications (6,12). Current global prevalence affects 31.1% of adults (1.39 billion people) as of 2010, representing a dramatic increase from historical rates and constituting the leading cause of premature mortality worldwide (6,11,13).

Auricular acupuncture, involving stimulation of specific acupoints on the external ear, has emerged as a promising non-pharmacological intervention for hypertension based on traditional Chinese medicine principles (14). Modern research demonstrates that auricular acupuncture can modulate autonomic nervous system function through the auricular branch of the vagus nerve, increasing parasympathetic activity while reducing sympathetic outflow (15, 16). Meta-analytic evidence suggests that auricular acupressure combined with antihypertensive medications may reduce systolic blood pressure (SBP) by 5.06 mm Hg and diastolic blood pressure (DBP) by 5.30 mm Hg compared to medications alone (17). The intervention appears well-tolerated with minimal adverse effects, making it an attractive option for integration into comprehensive hypertension management protocols (14,18).

Objectives

The primary objective of this study is to evaluate the efficacy of auricular acupuncture on blood pressure parameters among adults diagnosed with chronic essential hypertension. By employing a randomized, double-blinded clinical trial design, the study aims to determine whether auricular acupuncture offers significant antihypertensive effects compared to control interventions, thereby providing robust evidence for its potential role as a complementary treatment in the management of chronic essential hypertension.

Patients and Methods

Study design and participants

This double-blind randomized clinical trial study was conducted at Imam Reza Hospital in Mashhad, Iran, under the consolidated standards of reporting trials (CONSORT) guidelines (19) to ensure methodological rigor and transparency. A total of 58 adult patients diagnosed with hypertension were enrolled between August 2022 and December 2024, with strict adherence to blinding and randomization procedures maintained throughout the recruitment and intervention phases.

Inclusion and exclusion criteria

The study included adult patients aged 18 years or older with a documented diagnosis of hypertension and controlled blood pressure, defined as a systolic pressure below 180 mm Hg and diastolic pressure below 120 mm

Hg during the preceding month. Eligible participants were registered, with the ability and willingness to provide informed consent and comply with study procedures. Exclusion criteria comprised current participation in acupuncture or other clinical trials, a history or presence of significant cardiovascular disorders such as heart failure or prior stroke, major systemic illnesses including hepatic or renal insufficiency and active malignancies, use of anticoagulant, antiepileptic, or anticancer medications, pregnancy or lactation, anticipated difficulties in attending follow-up visits or adhering to study requirements, and failure to meet any initial selection parameters during screening.

Sample size calculation

A power analysis for this randomized controlled trial was performed using G*Power software, informed by parameters obtained from prior studies. The calculation was based on detecting a minimum clinically significant difference of 3.23 mm Hg in SBP (effect size = 0.70), with a significance level (α) of 0.05 and a statistical power of 80% (β = 0.20). To accommodate an anticipated dropout rate of 10%, the required sample size was determined to be 30 participants per study arm, encompassing both the intervention and control groups.

Blinding

This single-blind clinical trial employed a pragmatic blinding approach that acknowledges the methodological challenges inherent in acupuncture research while maintaining the highest possible standards of scientific rigor. Although participants remained blinded to their group assignment throughout the study, complete blinding of practitioners was not feasible due to the physical nature of the auricular acupuncture intervention. However, the study maintained rigorous blinding protocols for outcome assessors, statistical analysts, and the safety monitoring committee, ensuring objective evaluation of results while preserving allocation concealment throughout the trial

Randomization/allocation

Participants were randomly assigned to either the treatment or control groups using a computer-generated allocation sequence developed by the epidemiology department at Mashhad University, thereby ensuring unbiased group allocation and enhancing the methodological rigor of the study. Of the 58 adult patients diagnosed with hypertension enrolled in the study, 30 were assigned to the auricular acupuncture group, while 28 were allocated to the control group.

Intervention procedure

Eligible participants were identified through electronic health records at participating clinics and subsequently contacted via telephone. A cardiologist with specialized acupuncture training, serving as the study's lead investigator, screened interested hypertensive patients for eligibility before obtaining written informed consent. Baseline assessments included comprehensive medical and medication histories, along with demographic data. Blood pressure was measured using a calibrated OMRON JPN2 digital monitor (Matsusaka, Japan) after patients were seated for a 10-minute rest; measurements were taken in both arms, and the higher reading was recorded. Four auricular acupoints, including Shenmen, superior triangular fossa, Chinese Liver, and Heart, were selected based on anatomical references, expert consensus, and previous research. The 8-week study consisted of a 4-week active treatment phase followed by a 4-week observation period. Participants attended six sessions: weekly treatments during the first four weeks, a week-5 evaluation, and a week-8 follow-up. During treatment visits, the practitioner applied either micro-needle stickers (intervention group) or visually identical placebo stickers (control group) to the four predetermined ear points after alcohol disinfection. The application alternated between ears on successive sessions (right ear on sessions 1 and 3; left ear on sessions 2 and 4). Between treatment sessions, stickers were removed, and patients underwent blood pressure measurement.

Data collection

Before any intervention, written informed consent was obtained from all participants. Demographic information, including age, gender, and comorbid conditions, was collected through participant interviews. Blood pressure measurements, including SBP, DBP, and mean arterial pressure (MAP), were conducted following established clinical guidelines using a calibrated OMRON JPN2 digital monitor (Matsusaka, Japan), a device validated for clinical accuracy in hypertension assessment. Participants were seated for a standardized 10-minute rest period before each measurement to ensure stability. Blood pressure readings were recorded at baseline (before study initiation) and subsequently at weeks 1, 2, 3, 4, and 8 following the commencement of the intervention.

Outcomes

The study outcomes comprised comparisons of blood pressure parameters, including SBP, DBP, and MAP, measured at baseline (before intervention) and at weeks 1, 2, 3, 4, and 8 post-intervention. These comparisons were conducted both between the intervention and control groups and within each group over time to evaluate the efficacy of the auricular acupuncture treatment.

Data analysis

Data analysis was performed using SPSS software version 27. Continuous variables were summarized as mean ± standard deviation (SD), whereas categorical variables were reported as frequencies and percentages. The Kolmogorov-Smirnov test was applied to evaluate data

normality, and Levene's test assessed the homogeneity of variances. Comparisons of categorical variables, including gender, were carried out using the Chi-square test, while Fisher's exact test was applied for variables such as underlying diseases between the control and auricular acupuncture groups. Independent samples t-tests were used to compare mean values of age, SBP, DBP, and MAP between groups, and paired t-tests assessed within-group changes over time. A *P* value less than 0.05 was regarded as statistically significant.

Results

A total of 71 participants were assessed for eligibility in this study. Of these, 11 individuals were excluded; 8 because they did not meet the inclusion criteria, and 3 who declined to participate. Sixty participants were then randomized into two equal groups: 30 were allocated to the auricular acupuncture group and 30 to the control group. All participants in both groups received their respective assigned interventions. During the follow-up period, none in the acupuncture group were lost, whereas 2 participants from the control group were lost to follow-up. For analysis, data from all 30 participants in the acupuncture group were included, with no exclusions, while for the control group, only 28 participants were analyzed, as none were excluded, but 2 were lost to follow-up (Figure 1).

The analysis of the frequency distribution of baseline characteristics between the auricular acupuncture and control groups revealed no statistically significant differences in terms of gender, underlying disease status, or age. Specifically, the gender distribution showed no significant difference. Similarly, comparisons across various health conditions such as diabetes, cardiovascular disease, and hypothyroidism showed no significant difference between the groups. Additionally, the comparison of mean ages between the two groups did not reach statistical significance. These findings indicate that the demographic factors and clinical data were comparably distributed between the intervention and control groups at baseline (Table 1).

The comparative analysis of blood pressure parameters, including SBP, DBP, and MAP, between the auricular acupuncture and control groups throughout the study demonstrated no statistically significant differences at any measurement point. All SBP measurements across baseline, first, second, third, fourth, and eighth weeks remained nonsignificant, indicating no meaningful differences between groups. Similarly, DBP comparisons showed non-significant values at all time points, with the closest approach to significance occurring at the first and eighth weeks, though remaining above the significant threshold.

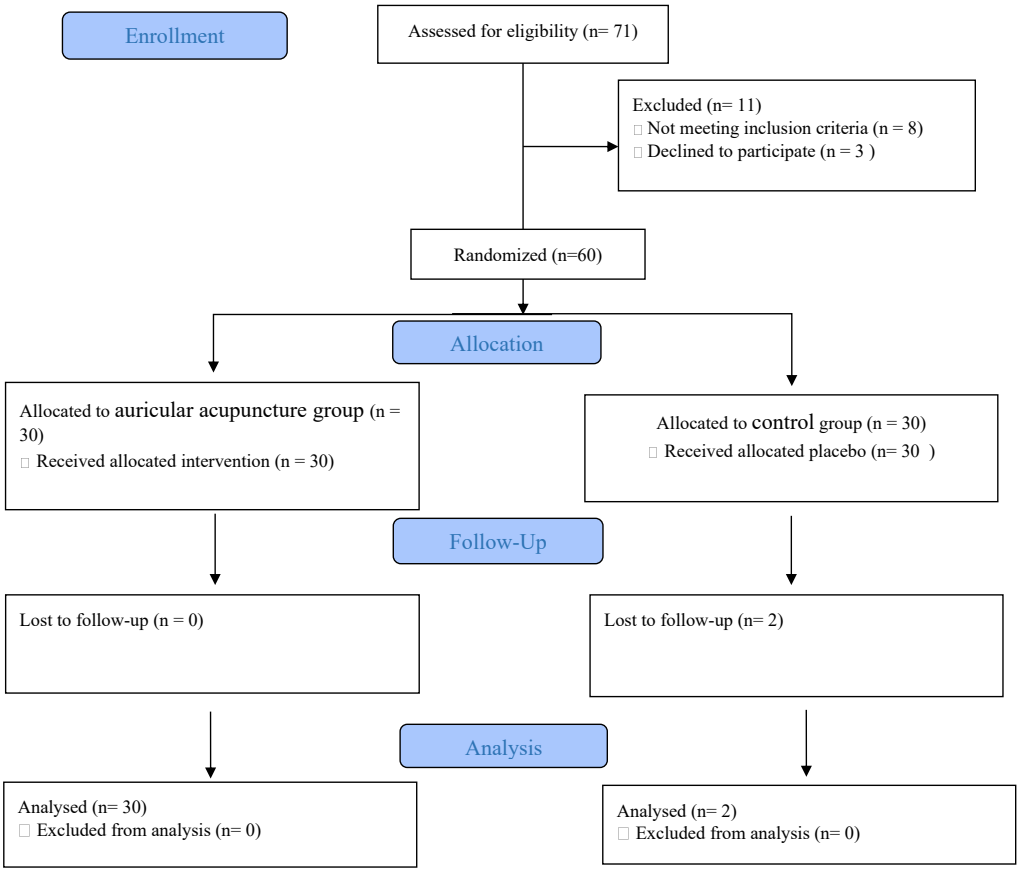

Figure 1. CONSORT flow diagram of the study.

The MAP measurements also consistently yielded non-significant results across all assessment periods, with the eighth week showing a borderline value while still failing to reach statistical significance. These findings collectively indicate that the auricular acupuncture intervention did not produce statistically significant changes in any blood pressure parameter compared to the control group throughout the study (Table 2 and Figure 2).

The within-group analysis of blood pressure parameter changes from baseline throughout the study period revealed differential patterns of statistical significance between the auricular acupuncture and control groups. In the control group, SBP showed no statistically significant changes at any time point. Conversely, the auricular acupuncture group demonstrated statistically significant reductions in SBP at the second and fourth weeks, while other time points did not reach significance. For DBP, the control group exhibited significant decreases at the first, fourth, and eighth weeks, whereas the auricular acupuncture group showed significant reductions only at the third and fourth weeks. The MAP analysis revealed significant decreases in the control group at the first and fourth weeks, while the auricular acupuncture group demonstrated significant reductions at the second, third, and fourth weeks. These findings indicate that both groups experienced some statistically significant improvements in blood pressure parameters compared to their respective baseline measurements, though the timing and pattern of significance varied between the intervention and control groups throughout the study duration (Table 3).

The statistical analysis of blood pressure parameter changes from baseline between the auricular acupuncture and control groups revealed predominantly non-significant differences across the study duration. For

Table 1. Frequency distribution of participants' baseline characteristics between the two intervention and control groups

Variable		Group				*P* value
		Control		Intervention		
		N	%	N	%	
Gender	Female n = 37	18	48.6	19	51.4	0.940*
	Male n = 21	10	47.6	11	52.4	
Underlying disease	Diabetes n = 18	9	50	9	50	0.826**
	CVD n= 5	2	40	3	60	
	Hypothyroid n = 3	1	33.3	2	66.7	
	No disease n = 32	16	50	16	50	
Variable		**Mean**	**SD**	**Mean**	**SD**	***P* value**
Age (year)		58.32	7.62	56.66	10.46	0.516***

CVD, Cardiac vascular disease; N, Number; SD, Standard deviation. *Chi-square, **Fisher Exact test, ***Independent T-test.

Table 2. Comparative analysis of blood pressure parameters between intervention and control groups throughout the study

Parameters		Group				Difference		*P* Value*
		Control		Intervention				
		Mean	SD	Mean	SD	Mean	Std. Error	
SBP (mm Hg)	Baseline	140.53	19.08	146.16	20.66	5.63	5.23	0.287
	First week	136.96	13.42	140.80	18.25	3.83	4.23	0.369
	Second week	141.57	13.09	137.36	16.49	4.20	3.92	0.289
	Third week	137.50	13.63	139.20	16.31	1.70	4.45	0.704
	Fourth week	136.10	12.65	138.50	17.49	2.39	3.99	0.556
	Eighth week	138.35	13.49	143.73	17.67	5.37	4.15	0.201
DBP (mm Hg)	Baseline	85.67	11.41	88.03	12.60	2.35	3.16	0.460
	First week	79.60	9.84	85.10	13.47	5.49	3.11	0.084
	Second week	84.32	12.68	84.33	14.92	0.01	3.64	0.997
	Third week	81.53	12.31	82.66	10.15	1.13	2.95	0.703
	Fourth week	80.39	9.36	82.33	12.97	1.94	2.98	0.519
	Eighth week	80.75	8.99	85.56	11.83	4.81	2.74	0.088
MAP (mm Hg)	Baseline	103.96	13.48	107.41	14.83	3.44	3.73	0.360
	First week	98.72	8.96	103.66	13.76	4.94	3.07	0.114
	Second week	103.40	10.64	102.01	14.16	1.39	3.30	0.675
	Third week	100.190	12.16	101.51	10.30	1.32	2.95	0.657
	Fourth week	98.96	9.44	101.05	12.85	2.09	2.98	0.481
	Eighth week	99.95	8.23	104.95	12.40	5.00	2.78	0.078

SBP, Systolic blood pressure; DBP, Diastolic blood pressure; MAP, Mean arterial pressure; SD, Standard deviation. *Independent T-test

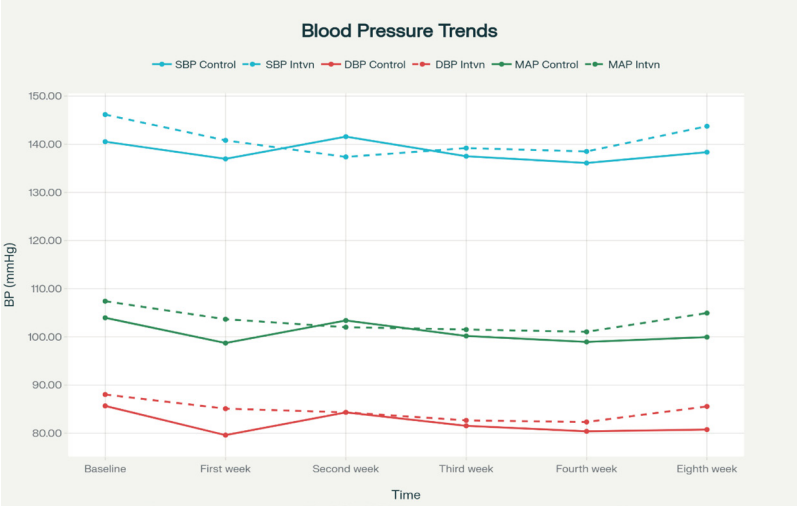

Figure 2. Trends of blood pressure parameters in both the control and intervention groups, across all measured time points. SBP, Systolic blood pressure; DBP, Diastolic blood pressure; MAP, Mean arterial pressure; BP, Blood pressure; Ctrl, Control; Intv, Intervention.

Table 3. Comparison of changes in blood pressure parameters within the intervention and control groups throughout the study period, compared to baseline measurements

Group	Time	Difference		95% CI		*P* Value*
		Mean	Std. Error	Lower	Upper	
		SBP (mm Hg)				
Control	First week	-3.57	3.69	-11.15	4.00	0.342
	Second week	1.03	3.38	-5.91	7.98	0.762
	Third week	-3.03	4.10	-11.46	3.39	0.466
	Fourth week	-4.42	3.12	-10.83	1.97	0.168
	Eighth week	-2.17	3.62	-9.61	5.26	0.553
Intervention	First week	-5.36	2.95	-11.41	0.67	0.080
	Second week	-8.80	3.04	-15.03	2.56	0.007
	Third week	-6.96	4.08	-15.31	1.37	0.098
	Fourth week	-7.66	2.67	-13.13	2.19	0.008
	Eighth week	-2.34	2.87	-8.30	3.43	0.404
		DBP (mm Hg)				
Control	First week	-6.07	23.4	-10.87	-1.26	0.015
	Second week	-1.35	2.52	-6.53	3.82	0.595
	Third week	-4.14	2.23	-8.72	0.44	0.075
	Fourth week	-5.28	1.82	-9.03	-1.53	0.007
	Eighth week	-4.92	2.32	-9.69	-0.15	0.043
Intervention	First week	-2.93	2.45	-7.94	2.08	0.241
	Second week	-3.70	2.40	-8.61	1.21	0.135
	Third week	-5.36	2.24	-9.96	-0.76	0.024
	Fourth week	-5.70	1.87	-9.54	-1.85	0.005
	Eighth week	-2.46	2.14	-6.84	1.91	0.259
		MAP (mm Hg)				
Control	First week	-5.23	2.49	-10.53	-0.12	0.045
	Second week	-0.55	2.44	-5.56	4.44	0.820
	Third week	-3.77	2.46	-8.83	1.28	0.137
	Fourth week	-5.00	2.03	-9.18	-0.81	0.021
	Eighth week	-4.01	2.46	-9.07	1.04	0.115
Intervention	First week	-3.74	2.40	-8.66	1.17	0.131
	Second week	-5.40	2.26	-10.02	-0.77	0.021
	Third week	-5.90	2.68	-11.38	0.41	0.036
	Fourth week	-6.35	1.84	-10.13	-2.57	0.002
	Eighth week	-2.45	2.14	6.83	1.92	0.261

SBP, Systolic blood pressure; DBP, Diastolic blood pressure; MAP, Mean arterial pressure; CI, Confidence interval. *Paired-samples T-test

SBP measurements, only the second week demonstrated a statistically significant difference between groups, while all other time points, including the first, third, fourth, and eighth weeks, showed non-significant results. The DBP comparisons consistently yielded non-significant results across all measurement periods, indicating no statistically meaningful differences between the auricular acupuncture and control groups at any time point throughout the study duration. Similarly, MAP analyses showed no statistically significant differences between groups at any of the assessed time points across the first, second, third, fourth, and eighth weeks. These findings suggest that while both groups may have experienced changes in blood pressure parameters compared to their respective baselines, the magnitude of change did not differ significantly between the auricular acupuncture intervention and control groups for the majority of measurements, with only one significant reduction observed in SBP at the second week assessment in the auricular acupuncture group compared to the control (Table 4 and Figure 3).

Discussion

Our findings collectively indicated that auricular acupuncture did not demonstrate meaningful efficacy in reducing blood pressure compared to the control intervention, suggesting limited therapeutic value for this specific approach in managing chronic essential hypertension under the study conditions examined. The present finding that auricular acupuncture did not demonstrate meaningful efficacy in reducing blood pressure compared to placebo control is consistent with several recent high-quality systematic reviews and meta-analyses. Most notably, a systematic review and meta-analysis of 78 trials of auricular stimulation, including auricular acupuncture, acupressure, and vagus-nerve electrostimulation, found significant slowing of heart rate but no statistically significant change in either systolic or DBP when compared with sham procedures (20). This aligns closely with the Cochrane systematic review by Yang et al, which concluded that there was no evidence for a sustained BP lowering effect of acupuncture and that the short-term effects of acupuncture are uncertain due to the very low quality of evidence (21). Similarly, Chen et al in their systematic review and meta-analysis stated that there is inadequate high-quality evidence that acupuncture therapy is useful in treating hypertension, as the exact effect and safety of acupuncture therapy for hypertension are still unclear (22). These findings collectively suggest that the null results observed in the current study reflect a broader pattern of limited efficacy rather than an isolated finding.

However, some studies have reported modest benefits for acupuncture in hypertension management, though with important caveats regarding study quality and clinical significance. An overview by Fan et al examining 14 systematic reviews concluded that acupuncture may be an effective and safe treatment for essential hypertension,

Table 4. Comparison of changes in blood pressure parameters compared to baseline between intervention and control groups throughout the study

Time		Group				Difference		*P* value*
		Control		Intervention				
		Mean	Std. Error	Mean	SD	Mean	Std. Error	
SBP (mm Hg)								
Baseline	First week	-3.57	3.69	-5.36	2.95	1.79	4.69	0.704
	Second week	1.03	3.38	-8.80	3.04	9.83	4.54	0.035
	Third week	-3.03	4.10	-6.96	4.08	3.93	5.79	0.500
	Fourth week	-4.42	3.12	-7.66	2.67	3.23	4.11	0.432
	Eighth week	-2.17	3.62	-2.43	2.87	0.26	4.59	0.956
DBP (mm Hg)								
Baseline	First week	-6.07	2.34	-2.93	2.45	3.13	3.39	0.360
	Second week	-1.35	2.52	-3.70	2.40	2.34	3.48	0.504
	Third week	-4.14	2.23	-5.36	2.24	1.22	3.17	0.701
	Fourth week	-5.28	1.82	-5.70	1.87	0.41	2.62	0.875
	Eighth week	-4.92	2.32	-2.46	2.14	2.46	3.15	0.438
MAP (mm Hg)								
Baseline	First week	-5.23	2.49	-3.74	2.40	1.49	3.46	0.668
	Second week	-0.55	2.44	-5.40	2.26	4.84	3.32	0.151
	Third week	-3.77	2.46	-5.90	2.68	2.12	3.65	0.536
	Fourth week	-5.00	2.03	-6.35	1.84	1.35	2.74	0.623
	Eighth week	-4.01	2.46	-2.45	2.14	1.55	3.25	0.634

SBP, Systolic blood pressure; DBP, Diastolic blood pressure; MAP, Mean arterial pressure; SD, Standard deviation. *Independent T-test.

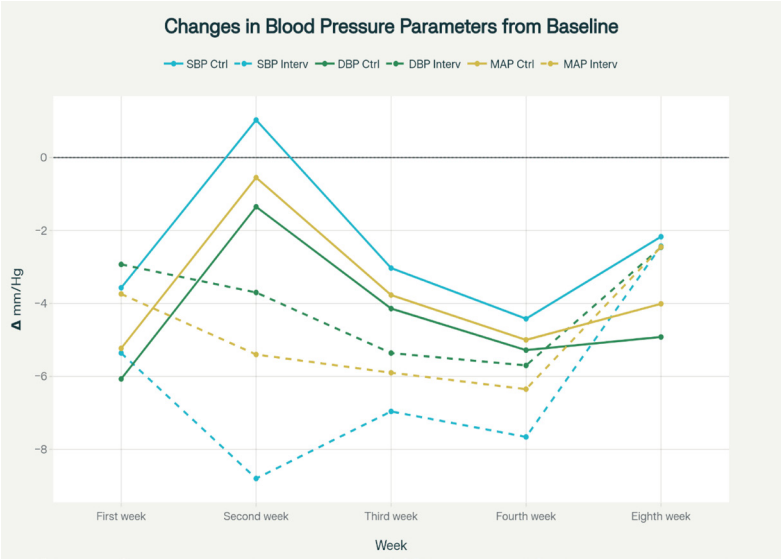

Figure 3. Changes in blood pressure parameters from baseline values for both control and intervention groups throughout the study period. SBP, Systolic blood pressure; DBP, Diastolic blood pressure; MAP, Mean arterial pressure; BP, Blood pressure; Ctrl, Control; Intv, Intervention.

but critically noted that the quality of evidence is low, and caution should be exercised when applying this evidence in clinical practice (23). A systematic review on acupuncture for insomnia symptoms in hypertensive patients reported blood pressure reductions (SBP: MD = −10.31 mm Hg, DBP: MD = −5.71 mm Hg), but this study focused on a specific comorbid population and combined acupuncture with conventional treatment rather than examining auricular acupuncture as a standalone intervention (24). The discrepancy between these modestly positive findings and the current study's null results can be largely attributed to differences in study populations, acupuncture protocols, and, most importantly, the methodological rigor of the control groups employed.

The current findings suggest that the mechanistic prerequisites for durable blood-pressure lowering, robust afferent signaling to central autonomic nuclei, and downstream modulation of sympathetic vasomotor tone are not reliably engaged by auricular stimulation alone. Although modest short-term decreases have been reported when auricular acupressure is combined with antihypertensive drugs (17), these effects vanish under rigorous blinding and sham control, implying a probable placebo or co-intervention contribution rather than a direct physiological action. By contrast, somatic electroacupuncture at forearm–leg neurovascular bundles elicits measurable sympathoinhibition and renin–aldosterone suppression that translate into clinically meaningful falls in ambulatory blood pressure (25). The divergence highlights the heterogeneity within acupuncture modalities and cautions against extrapolating benefits from body points to auricular protocols. Furthermore, the consistently low methodological quality, high risk of allocation and detection bias, inadequate sham designs, and small sample sizes continue to obscure the true treatment signal in auricular acupuncture trials (17,20).

Overall, current high-quality evidence does not support auricular acupuncture as an effective stand-alone therapy for lowering blood pressure in essential hypertension. Our placebo-controlled data reinforce a growing consensus that, unlike selected somatic electroacupuncture paradigms, auricular needling fails to achieve meaningful antihypertensive effects in randomized settings (17). Future research should prioritize large, rigorously blinded trials that incorporate continuous ambulatory blood-pressure monitoring and mechanistic biomarkers if auricular approaches are to be reconsidered; until such data emerge, clinicians should rely on interventions with proven cardiovascular benefit and regard auricular acupuncture as no more than an investigational adjunct (17,25).

Conclusion

In conclusion, this randomized, double-blinded clinical trial demonstrated that auricular acupuncture did not produce clinically superior effects on blood pressure reduction compared to the control intervention in patients with chronic essential hypertension. While both the auricular acupuncture and control groups exhibited statistically significant improvements in various blood pressure parameters compared to their respective baseline measurements at different time points throughout the study, the between-group comparisons revealed no consistent or sustained differences in SBP, DBP, or MAP across statistically significant difference observed in SBP at the second week represents an isolated finding that was not maintained at subsequent assessments, suggesting it may be attributable to random variation rather than a true therapeutic effect. These findings indicate that auricular

acupuncture, as implemented in this study protocol, does not provide additional blood pressure-lowering benefits beyond those achieved through standard care approaches. The observed within-group improvements in both treatment arms suggest that factors common to both interventions, such as increased medical attention, regular monitoring, or placebo effects, may have contributed to the blood pressure reductions noted throughout the study period. Despite the lack of observed efficacy of auricular acupuncture on blood pressure reduction in this study of patients with chronic essential hypertension, contrasting results reported in earlier studies suggest that further clinical trials are necessary.

Limitations of the study

First, while participant blinding was maintained, complete practitioner blinding was not feasible due to the physical nature of auricular acupuncture interventions; this inherent limitation could introduce performance bias. Second, the relatively modest sample size of 58 participants, though adequately powered based on prior effect size estimates, may limit the generalizability of the findings to broader hypertensive populations, particularly given the strict inclusion criteria that excluded patients with complex comorbidities or more severe hypertension. Third, the intervention duration comprised a 4-week treatment phase followed by a 4-week observation period, which may be insufficient to capture long-term effects and the sustainability of blood pressure reductions attributable to auricular acupuncture. Fourth, the use of micro-needle stickers as the intervention and visually identical placebo stickers as controls, while carefully designed, may not fully replicate the physiological or sensory experience of true acupuncture, potentially affecting participant perception and placebo effects. Additionally, blood pressure measurements, though standardized and conducted with validated digital monitors, were limited to clinic visits; ambulatory or home blood pressure monitoring could provide a more comprehensive assessment of circadian and daily variations. Lastly, participant recruitment from a single center and a relatively homogenous population in Mashhad, Iran, may constrain the external validity of the results across different ethnic or geographic groups. Future studies should consider larger, multi-center trials with longer follow-up periods and incorporation of ambulatory monitoring to address these limitations.

Acknowledgments

The authors extend their sincere gratitude to Imam Reza Hospital and Mashhad University of Medical Sciences for providing research facilities, infrastructure, and institutional resources that were instrumental in conducting this clinical trial.

Authors' contribution

Conceptualization: Rahim Firouzi Bostanabad, Zahra Abbasi, and Hoda Azizi.
Data curation: Rahim Firouzi Bostanabad, Masoumeh Sadeghi, and Hoda Azizi.
Formal analysis: Sahar Kavand and Seyed Kazem Farahmand.
Investigation: Zahra Abbasi, Mohammad Hosein Ayati, and Sara Rashki Ghalehnoo.
Methodology: Haideh Mosleh and Sahar Kavand.
Project management: Hoda Azizi and Zahra Abbasi.
Resources: All authors.
Supervision: All authors.
Validation: Mahmoud Mohammadzadeh Shabestari and Masoumeh Sadeghi.
Writing–original draft: All authors.
Writing–review and editing: All authors.

Ethical issues

The research was conducted in accordance with the principles of the Declaration of Helsinki. This study took place at Imam Reza Hospital and originated from the thesis of Rahim Firouzi Boston Abad (Thesis #4010368), with the ethical code (IR.MUMS.REC.1401.122; https://ethics.research.ac.ir/EthicsProposalView.php?id=268983) approved by Mashhad University of Medical Sciences, Mashhad, Iran. The study protocol was also registered as a clinical trial at the Iranian Registry of Clinical Trials (identifier: IRCT20110809007265N13; https://irct.behdasht.gov.ir/trial/64908). Accordingly, written informed consent was obtained from all participants before any intervention. Furthermore, the authors have adhered to ethical standards, including avoiding plagiarism, data fabrication, and double publication.

Conflicts of interest

The authors declare that they have no competing interests.

Data availability statement

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declaration of generative artificial intelligence (AI) and AI-assisted technologies in the writing process

While preparing this work, the authors utilized AI (Perplexity.ai and Grammarly.com) to refine grammar points and language style. Subsequently, they thoroughly reviewed and edited the content as necessary, assuming full responsibility for the publication's content.

Funding/Support

The funding was supported by the Mashhad University of Medical Sciences (Grant#4010368).

References

1. Faraci FM, Scheer F. Hypertension: Causes and Consequences of Circadian Rhythms in Blood Pressure. Circ

Res. 2024;134:810–32. doi: 10.1161/circresaha.124.323515.
2. Khamissi FZ, Sun L, Johnson P, Shah S, Benjamin IJ. Machine Learning and Artificial Intelligence for Research on Hypertension. Am J Hypertens. 2025. doi: 10.1093/ajh/hpaf051.
3. Elfassy T, German CA, Muntner P, Choi E, Contreras G, Shimbo D, et al. Blood Pressure and Cardiovascular Disease Mortality Among US Adults: A Sex-Stratified Analysis, 1999-2019. Hypertension. 2023;80:1452–62. doi: 10.1161/hypertensionaha.123.21228.
4. Wu CY, Hu HY, Chou YJ, Huang N, Chou YC, Li CP. High Blood Pressure and All-Cause and Cardiovascular Disease Mortalities in Community-Dwelling Older Adults. Medicine (Baltimore). 2015;94:e2160. doi: 10.1097/md.0000000000002160.
5. Hong D, Shan W. Improvement in Hypertension Management with Pharmacological and Non-Pharmacological Approaches: Current Perspectives. Curr Pharm Des. 2021;27:548–55. doi: 10.2174/1381612826666200922153045.
6. Carretero OA, Oparil S. Essential hypertension. Part I: definition and etiology. Circulation. 2000;101:329–35. doi: 10.1161/01.cir.101.3.329.
7. Bolívar JJ. Essential hypertension: an approach to its etiology and neurogenic pathophysiology. Int J Hypertens. 2013;2013:547809. doi: 10.1155/2013/547809.
8. Jose PA, Yang Z, Zeng C, Felder RA. The importance of the gastrorenal axis in the control of body sodium homeostasis. Exp Physiol. 2016;101:465–70. doi: 10.1113/ep085286.
9. Maamor NH, Ismail J, Malek KA, Yusoff K, Boon-Peng H. AGT, CYP11B2 & ADRB2 gene polymorphism & essential hypertension (HT): A meta-analysis. Indian J Med Res. 2024;159:619–26. doi: 10.25259/ijmr_520_23.
10. Miao Q, Zhang J, Yun Y, Wu W, Luo C. Association between copper intake and essential hypertension: dual evidence from Mendelian randomization analysis and the NHANES database. Front Nutr. 2024;11:1454669. doi: 10.3389/fnut.2024.1454669.
11. Qi S, Luo X, Liu S, Ling B, Si M, Jin H. Effect of vitamin B(2), vitamin C, vitamin D, vitamin E and folic acid in adults with essential hypertension: a systematic review and network meta-analysis. BMJ Open. 2024;14:e074511. doi: 10.1136/bmjopen-2023-074511.
12. Borozan S, Kamrul-Hasan ABM, Shetty S, Pappachan JM. Approach to Endocrine Hypertension: A Case-Based Discussion. Curr Hypertens Rep. 2025;27:8. doi: 10.1007/s11906-025-01323-w.
13. Moiz A, Zolotarova T, Eisenberg MJ. Outpatient management of essential hypertension: a review based on the latest clinical guidelines. Ann Med. 2024;56:2338242. doi: 10.1080/07853890.2024.2338242.
14. Kim JH, Jung HJ, Kim TH, Lee S, Kim JE, Kang KW, et al. Auricular acupuncture for prehypertension and stage 1 hypertension: study protocol for a pilot multicentre randomised controlled trial. Trials. 2013;14:303. doi: 10.1186/1745-6215-14-303.
15. He W, Wang X, Shi H, Shang H, Li L, Jing X, et al. Auricular acupuncture and vagal regulation. Evid Based Complement Alternat Med. 2012;2012:786839. doi: 10.1155/2012/786839.
16. Gao XY, Wang L, Gaischek I, Michenthaler Y, Zhu B, Litscher G. Brain-modulated effects of auricular acupressure on the regulation of autonomic function in healthy volunteers. Evid Based Complement Alternat Med. 2012;2012:714391. doi: 10.1155/2012/714391.
17. Gao J, Chen G, He H, Liu C, He Q, Li J, et al. The effect of auricular therapy on blood pressure: A systematic review and meta-analysis. Eur J Cardiovasc Nurs. 2020;19:20–30. doi: 10.1177/1474515119876778.
18. Kim B, Park H. The effects of auricular acupressure on blood pressure, stress, and sleep in elders with essential hypertension: a randomized single-blind sham-controlled trial. Eur J Cardiovasc Nurs. 2023;22:610–9. doi: 10.1093/eurjcn/zvad005.
19. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c332. doi: 10.1136/bmj.c332.
20. Hua K, Cummings M, Bernatik M, Brinkhaus B, Usichenko T, Dietzel J. Cardiovascular effects of auricular stimulation -a systematic review and meta-analysis of randomized controlled clinical trials. Front Neurosci. 2023;17:1227858. doi: 10.3389/fnins.2023.1227858.
21. Yang J, Chen J, Yang M, Yu S, Ying L, Liu GJ, et al. Acupuncture for hypertension. Cochrane Database Syst Rev. 2018;11:Cd008821. doi: 10.1002/14651858.CD008821.pub2.
22. Chen H, Shen FE, Tan XD, Jiang WB, Gu YH. Efficacy and Safety of Acupuncture for Essential Hypertension: A Meta-Analysis. Med Sci Monit. 2018;24:2946–69. doi: 10.12659/msm.909995.
23. Fan M, Dai G, Li R, Wu X. Efficacy of Acupuncture in the Treatment of Essential Hypertension: An Overview of Systematic Reviews and Meta-Analyses. Cardiovasc Ther. 2023;2023:2722727. doi: 10.1155/2023/2722727.
24. Zhang J, Zhou X, Jiang H, Zhu W, Chi H, Jiang L, et al. Acupuncture for insomnia symptoms in hypertensive patients: a systematic review and meta-analysis. Front Neurol. 2024;15:1329132. doi: 10.3389/fneur.2024.1329132.
25. Li P, Tjen ALSC, Cheng L, Liu D, Painovich J, Vinjamury S, et al. Long-Lasting Reduction of Blood Pressure by Electroacupuncture in Patients with Hypertension: Randomized Controlled Trial. Med Acupunct. 2015;27:253–66. doi: 10.1089/acu.2015.1106.