


Home-based transcutaneous electrical acupoint stimulation for high-normal blood pressure: A randomized controlled trial

Yu Wang MD^{1,2} | Jing-Wen Yang MD, PhD^{1,2} | Jun-Hong Liu MD, PhD³ |
You-Sheng Qi MD, PhD³ | Jian-Feng Tu MD, PhD^{1,2} | Zhong-Xue Tian MM^{1,2} |
Guang-Xia Shi MD, PhD^{1,2} | Shi-Yan Yan MD, PhD^{1,2} | Li-Qiong Wang MD, PhD^{1,2}  |
Cun-Zhi Liu MD, PhD^{1,2}

¹International Acupuncture and Moxibustion Innovation Institute, Beijing University of Chinese Medicine, Chaoyang District, Beijing, China

²School of Acupuncture-Moxibustion and Tuina, Beijing University of Chinese Medicine, Chaoyang District, Beijing, China

³Heyi Community Health Service Center, Fengtai District, Beijing, China

Correspondence

Li-Qiong Wang, MD, PhD, International Acupuncture and Moxibustion Innovation Institute, School of Acupuncture-Moxibustion and Tuina, Beijing University of Chinese Medicine, No. 11, Bei San Huan Dong Lu, Chaoyang District, Beijing, 100029, China. Email: wangliqiongwork@163.com

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There was no racial or gender bias in the selection of participants.

Abstract

The authors investigated the effectiveness of home-based transcutaneous electrical acupoint stimulation (TEAS) combined with lifestyle modification on blood pressure (BP) control and explored the feasibility of the trial design in this prospective, randomized controlled trial. The authors recruited individuals with high-normal BP who had a systolic blood pressure (SBP) of 120–139 mm Hg and a diastolic blood pressure (DBP) of 80–89 mm Hg, or both. Participants were randomly assigned to receive either lifestyle modification combined with TEAS four times weekly for 12 weeks at home (intervention group) or solely lifestyle modification (control group). The primary outcome was the change in mean SBP at week 12 from the baseline measurement. A total of 60 participants were randomized in a 1:1 ratio, and an intention-to-treat analysis was performed on all of the outcomes. The mean difference in the change in SBP for the intervention group (compared to the control) at week 12 was -3.85 mm Hg (95% CI: -7.58 to $-.12$; $p = .043$); for the DBP, the change was -2.27 mm Hg (95% CI: -5.76 to 1.23 ; $p = .199$). There was no difference in the proportion of progression to hypertension, quality of life, body mass index (BMI) or waist circumference. In addition, two participants reported TEAS-related adverse events. The authors found a reduction in SBP control in the pragmatic, home-based intervention by using TEAS combined with lifestyle modification in adults with high-normal BP.

Trial Registration: The study was registered in the Chinese Clinical Trial Registry (ChiCTR 1900024982) on August 6, 2019.

KEYWORDS

acupuncture, high-normal blood pressure, lifestyle interventions, prehypertension, transcutaneous electrical acupoint stimulation

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1 | BACKGROUND

Elevated blood pressure (BP) is a leading preventable risk factor for many diseases and premature death throughout the world, and it causes a significant loss of quality of life.^{1–3} Adults with even a modest BP elevation (known as high-normal BP) have an increased risk of all-cause mortality.^{4,5} High-normal BP, which represents an earlier stage in the continuum of hypertension, affects 25%–50% of adults worldwide and increases the future risk of hypertension development.⁶ It also increases the risk of hypertension independently of other recognized risk factors^{7,8} and is closely associated with coronary heart disease, stroke and renal dysfunction.⁹

Prevention is considered the best strategy to lower the risk of high-normal BP progressing to hypertension and related damage to target organs¹⁰ However, due to the low awareness rate and lack of appropriate therapies, a considerable number of individuals with high-normal BP have not been effectively controlled and have progressed to hypertension.^{6,11} It remains unclear whether to initiate treatment with a medication at the high-normal BP stage.^{12,13} For low-moderate risk individuals with high-normal BP, antihypertensive drug treatment currently lacks clinical trial evidence targeting prognostic endpoints.¹⁴ Lifestyle interventions are recommended as the first choice of therapy for reducing BP for high-normal BP patients without cardiovascular comorbidity in most clinical guidelines.⁶ Nevertheless, the challenges of lifestyle modifications extend beyond counseling for physicians and patient adherence.¹⁵ Most methods of lifestyle modifications require long-term persistence; otherwise, the modifications become ineffective, which is difficult for people who judge their health as being good. Hence, there is an urgent need to find new nonpharmaceutical therapy candidates to be developed into efficient and available therapies to address the growing burden of high-normal BP.

Transcutaneous electric acupoint stimulation (TEAS) is a novel therapy combining acupuncture and transcutaneous electric nerve stimulation techniques.¹⁶ It is considered a nonpharmaceutical, inexpensive and safe form of treatment that replaces acupuncture needles with surface electrodes. TEAS is widely used in gastrointestinal diseases and for perioperative and nonsurgical analgesia.¹⁷ It has been consistently shown to enhance vagal activity and inhibit sympathetic hyperexcitability,^{18–21} thereby potentially affecting BP. Previous studies using transcutaneous electrical stimulation have demonstrated a reduction in BP.^{22–26} This approach has the advantages of being easy to use, being more “user friendly,” requiring minimal training for physicians and patients and being convenient for clinical application at a health facility or at home.²⁷ With the miniaturization of transcutaneous nerve stimulators, the use of TEAS treatment at home has become a clinical reality and would further reduce the time and transportation costs of travel to the hospital. Although TEAS has been shown to lower BP in several studies,^{22–25} few rigorous and long-term clinical trials addressing the intervention have been integrated within real-world practice settings to have sustainable, widespread applications among high-normal BP individuals. In this study, we investigated the effectiveness and safety of home-based TEAS combined

with lifestyle modification in the treatment of high-normal BP and explored the feasibility of a trial design.

2 | METHODS

This study was a prospective, randomized and parallel design clinical trial conducted in China. The trial was conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines for the presentation of clinical trials²⁸ and the principles of the Declaration of Helsinki. The protocol was approved by the Ethics Committee of Beijing University of Chinese Medicine (2019BZHLYL0208). In addition, the study was registered in the Chinese Clinical Trial Registry (ChiCTR 1900024982) on August 6, 2019. Details of the trial's design and analysis plan have been previously published.²⁹

Participants were recruited at a large public-sector clinic in Beijing, China, from September 2019 to February 2020. They were screened for eligibility after written informed consent was obtained. Adults 35–65 years of age with a clinic-based systolic and/or diastolic BP of 120–139 mmHg and diastolic blood pressure (DBP) of 80–89 mmHg (from at least three separate visits) were enrolled. The individuals had to be able to completely answer the questionnaire and did not receive antihypertensive drugs or other drugs that affected BP over the previous 2 months. Pregnant women and people with contraindications for the use of electrostimulation, secondary hypertension, uncontrolled diabetes, drug abuse, alcohol abuse or participation in another research trial were excluded.

Eligible participants were randomly assigned (1:1) to the intervention group or the control group by using the block random method, and the block size was 6. The randomization sequence was prepared with SAS software (version 9.3, SAS Inc., Cary, NC, USA) by a professional statistician who was not involved in the assessment, treatment or analysis of the study to ensure the balance in baseline BP across the groups. Participants and study investigators who taught participants how to locate acupoints and use the TEAS instrument were not blinded. However, outcome assessors and statisticians were blinded to the group allocations. The automatic mode of the sphygmomanometer was used to measure BP without the need for intervention by the assessors, other than to place the cuff and to switch the device on.

2.1 | Intervention

Following randomization, all of the study participants received an assessment at baseline by trained study investigators. The assessment consisted of a series of questionnaires to evaluate sociodemographic characteristics, medical history, alcohol intake, smoking habits and quality of life.

All of the participants received advice for lifestyle modification from the study investigators. Information about weight control, increased physical activity, healthy eating, dietary sodium reduction, smoking abatement and limitation of alcohol consumption was sent to the

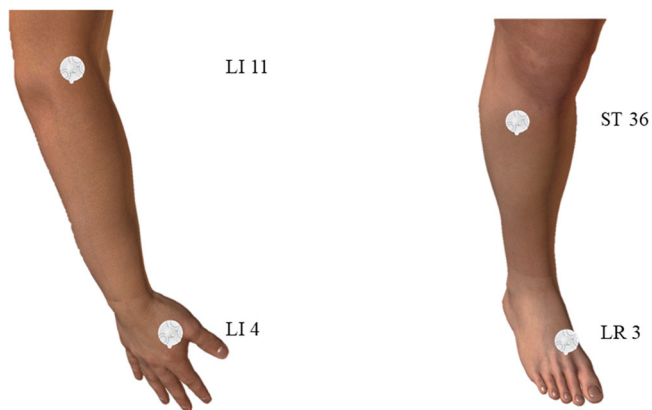


FIGURE 1 Locations of the acupoints

participants on a weekly basis via a social network app (WeChat, Tencent, Shenzhen, China). A previous study validated the use of the WeChat-based self-management intervention to control BP.³⁰

The intervention group received the TEAS intervention, whereas the control group received no TEAS. The TEAS intervention was delivered via domestic equipment (SDP-330; Yuwell, Suzhou Medical Appliances Co., Ltd., Suzhou, China) by participants themselves in their home settings. The intervention lasted for 12 weeks, and follow-up lasted until 36 weeks after the initiation of treatment.

Before the start of the first treatment, a stimulator (with written instructions) and a participants' manual were distributed to the participants, and they were taught how to properly perform the TEAS treatment at home. The study investigators instructed participants on how to locate the acupoints and to accurately use the stimulator. Pictures and videos of acupoints and operation demonstrations were distributed to help participants further familiarize themselves with the TEAS. The transcutaneous nerve stimulator has two 100-Hz output channels, and the intensity of the stimulation can be adjusted. The suitable intensity should be gradually increased to trigger the maximum sensory threshold without discomfort or pain. The self-adhesive electrodes were placed on the skin surface of the following bilateral acupoints: *Hegu* (LI4), *Quchi* (LI11), *Zusanli* (ST36), and *Taichong* (LR3) (Figure 1). The four acupoints were considered to have BP-lowering effects according to traditional Chinese medicine concepts, and the choice of the above acupoints was supported by previous studies that used TEAS to treat LI4 and LI11 on the forearm or acupuncture at ST36 and LR3 on the foreleg, with the acupoints demonstrating a significant reduction in BP.^{24,25,31} Participants in the intervention group were required to have undergone TEAS at LI4 and LI11 on the same arm for 15 min, followed by the same acupoints on the opposite arm for 15 min as the first TEAS treatment. One day later, the second TEAS was applied at ST36 and LR3 on the same leg for 15 min, followed by the same acupoints on the opposite leg for 15 min. Each TEAS treatment lasted a total of 30 min, and participants were asked to alternate the treatment location on alternate days to guarantee that they received four TEAS treatments per week for 12 weeks. In addition, participants were asked to take photos to provide feedback to the investigators during the initial treatment to ensure that they had a comprehensive

understanding of the TEAS treatment operation. After 12 weeks of treatment, the participants were not required to continue the TEAS intervention. However, we could not determine whether the participants voluntarily continued with the intervention; however, due to the fact that we did not provide any more bespoke self-adhesive electrodes, the participants were unlikely to use the equipment for too long without the electrodes.

2.2 | Measures

The primary outcome was the change in mean systolic blood pressure (SBP) measured at baseline and week 12. Other secondary BP outcomes included measures of changes in mean SBP from baseline to 4, 8, 24, and 36 weeks and mean DBP from baseline to 4, 8, 12, 24, and 36 weeks. Additional secondary outcomes measured at weeks 12, 24, and 36 were the proportion of participants developing hypertension (a mean SBP greater than 140 mmHg and/or a mean DBP greater than 90 mmHg), quality of life measured with the 12-item Short Form Health Survey (SF-12), body mass index (BMI) and waist circumference (Supplementary figure).

The process of measuring BP was performed according to a standard protocol recommended by the 2018 Chinese Guidelines for Prevention and Treatment of Hypertension.¹⁴ BP was measured with participants in a seated position after 5 min of rest by an assessor using a digital BP monitor (HEM-7136, OMRON Corporation, Kyoto, Japan) with a suitable cuff size in a standardized fashion. Participants were required to avoid exercise, alcohol, cigarettes and coffee/tea for at least 30 min before the BP measurement was performed. The assessor recorded three sequential BP readings at 5-min intervals, and the final BP was calculated by removing the initial reading and calculating the mean from the two remaining readings. Participants recorded adverse events during the study, and feedback was provided to the investigators in a timely manner.

2.3 | Sample size

In this pilot study, we aimed to assess the effectiveness and safety of TEAS combined with lifestyle modification for high-normal BP and determine the feasibility of a further large clinical trial. As a feasibility pilot study, our trial was not subject to a formal sample size estimation. The data collected in this trial will allow us to refine our sample size estimates for the primary trial. We chose 30 participants in each group (which is the most frequently prescribed sample size for pilot studies in the literature³²) as a suitable sample size for the comparisons. This was determined to be a sufficiently large sample size to confirm the feasibility of the trial design.

2.4 | Statistical analysis

The analysis was performed on an intention-to-treat (ITT) basis by using SPSS 23.0 statistical software (IBM SPSS Statistics, New York,

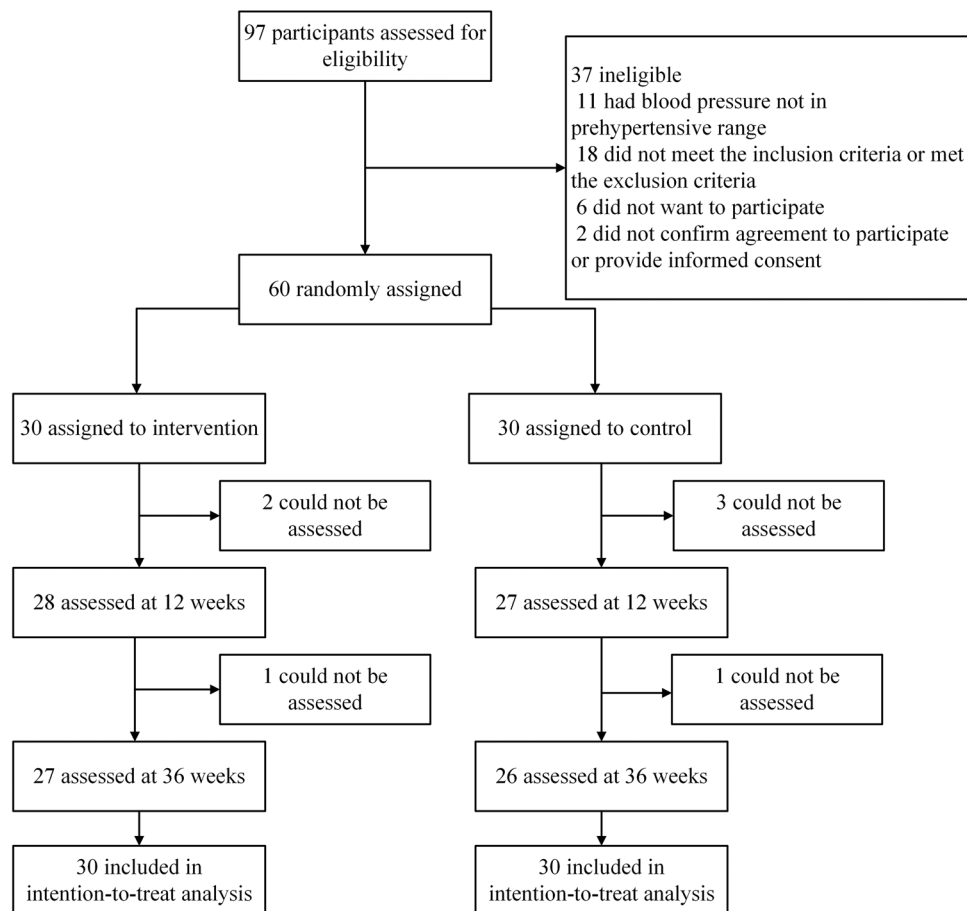


FIGURE 2 Trial profile

USA), with a two-sided p -value of $<.05$ indicating statistical significance. Continuous variables conforming to a normal distribution were compared by using a Student's t -test, whereas those that were non-normally distributed were tested by using the Mann-Whitney U-test. Differences in proportions and binary variables were compared by using the Chi-square test or Fisher's exact test. Missing data were imputed by using the last observation carried forward. Even if participants dropped out of the study, we still needed to include them in the statistical analysis according to the predesigned ITT definition. The baseline data were used as the last observation when no follow-up data was available.

3 | RESULTS

A total of 97 participants were screened, of whom 60 participants were randomly assigned to the trial (Figure 2). The main reason for exclusion was not meeting the diagnostic criteria of high-normal BP. The disease characteristics of all of the randomized participants at baseline were similar between the two groups (Table 1). After randomization, seven (12%) participants were lost to follow-up (three participants in the intervention group and four participants in the control group; $p = 1.0$, χ^2 -test). The average number of TEAS treatments for each participant

in the intervention group was 44.32 ± 6.18 times, which showed that the compliance of the participants was good.

SBP was significantly reduced from 129.38 ± 8.04 at baseline to 124.28 ± 9.62 mmHg (-5.10 ± 5.93 mmHg) at week 12 in the intervention group and reduced from 129.05 ± 9.57 to 127.80 ± 9.54 mmHg (-1.25 ± 8.30 mmHg) in the control group (Table 2, Figure 3). DBP was reduced from 82.25 ± 7.06 to 78.83 ± 7.74 mmHg (-3.42 ± 7.72 mmHg) in the intervention group and from 80.85 ± 7.48 to 79.70 ± 7.01 mmHg (-1.15 ± 5.65 mmHg) in the control group. The mean difference in the change in SBP for the intervention group compared to the control group at week 12 was -3.85 mmHg (-7.58 to $-.12$, $p = .043$); for DBP, the mean difference in the change was -2.27 mmHg (-5.76 to 1.23 , $p = .199$) (Table 2). The mean decreases in SBP and DBP in the intervention group were -5.10 ± 5.93 mmHg ($p < .001$) and -3.42 ± 7.72 mmHg ($p = .022$), respectively, compared with the baseline values; however, no changes were observed in the control group (Table 3).

Quality of life, as measured by the SF-12, was not significantly different between each group at the week 12–36 follow-up (Table 4). Similarly, BMI and waist circumference were not significantly different between baseline and follow-up in the intervention group, compared with the control group (Table 4). The proportion of progression to hypertension was not significantly lower in the intervention groups at

TABLE 1 Baseline characteristics

	Intervention group (n = 30)	Control group (n = 30)	p-Value
Sex, n (%)			
Female	20 (66.7)	18 (60.0)	.789
Male	10 (33.3)	12 (40.0)	
Age, in years	54.13 ± 7.59	53.57 ± 9.21	.796
BMI, kg/m ²	26.00 ± 3.07	25.57 ± 3.25	.597
Waist circumference (cm)	89.57 ± 10.02	86.27 ± 12.28	.259
Systolic blood pressure, mmHg	129.38 ± 8.04	129.05 ± 9.57	.884
Diastolic blood pressure, mmHg	82.25 ± 7.06	80.85 ± 7.48	.459
12-item short form health survey			
Physical score	49.79 ± 5.83	47.99 ± 6.48	.262
Mental score	52.18 ± 7.31	52.74 ± 9.04	.794

Note: Values are means (standard deviation) or percentages.

Abbreviation: BMI, body mass index.

TABLE 2 Mean systolic blood pressure outcomes (including primary outcome)

Variable	Intervention group (n = 30)	Control group (n = 30)	Difference in mean change (95% CI) Intervention group versus control group	p-Value
Systolic blood pressure (mm Hg)				
Baseline	129.38 ± 8.04	129.05 ± 9.57	-	-
Week 12	124.28 ± 9.62	127.80 ± 9.54	-3.85 (-7.58 to -.12)	.043
Week 24	123.58 ± 8.90	126.73 ± 8.57	-3.48 (-7.57 to .61)	.093
Week 36	123.32 ± 8.72	125.53 ± 9.57	-2.55 (-7.10 to 2.00)	.266
Diastolic blood pressure (mm Hg)				
Baseline	82.25 ± 7.06	80.85 ± 7.48	-	-
Week 12	78.83 ± 7.74	79.70 ± 7.01	-2.27 (-5.76 to 1.23)	.199
Week 24	77.98 ± 6.28	78.83 ± 7.34	-2.25 (-6.07 to 1.57)	.243
Week 36	78.02 ± 7.03	78.32 ± 6.92	-1.70 (-5.53 to 2.13)	.378

Note: Values are means (standard deviation).

Abbreviations: 95% CI, 95% confidence interval; BMI, body mass index.

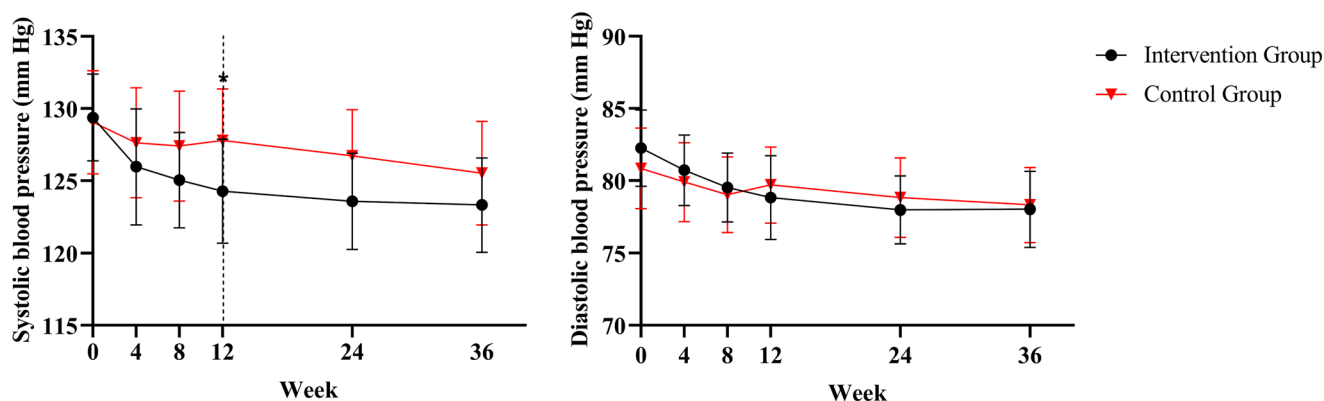


FIGURE 3 Mean blood pressure during trial follow-up in the intervention and control groups. Note: Systolic blood pressure (left) and diastolic blood pressure (right). The point estimates are mean blood pressure and error bars represent 95% CIs. * $p < .05$, mean between-group differences in the changes in blood pressure from baseline

TABLE 3 Mean difference change relative to baseline

Variable	Intervention group (n = 30)	p-Value	Control group (n = 30)	p-Value
Systolic blood pressure (mmHg)				
Week 12	-5.10 ± 5.93	<.001	-1.25 ± 8.30	.416
Week 24	-5.80 ± 7.98	<.001	-2.32 ± 7.84	.116
Week 36	-6.07 ± 8.33	<.001	-3.52 ± 9.24	.046
Diastolic blood pressure (mmHg)				
Week 12	-3.42 ± 7.72	.022	-1.15 ± 5.65	.274
Week 24	-4.27 ± 7.68	.005	-2.02 ± 7.09	.130
Week 36	-4.23 ± 8.66	.012	-2.53 ± 5.90	.026

Note: Values are means (SD).

TABLE 4 Secondary outcomes at 12, 24, and 36 weeks

Variable	Intervention group (n = 30)	Control group (n = 30)	Intervention group versus control group (95% CI)	p-Value
The 12-item Short Form Survey (SF-12)				
Physical score week 12	51.17 ± 5.25	49.74 ± 5.63	1.43 (-1.39 to 4.24)	.736
Mental score week 12	52.61 ± 5.74	53.25 ± 7.98	-.64 (-4.23 to 2.96)	.320
Physical score week 24	50.67 ± 4.03	49.84 ± 4.90	.84 (-1.48 to 3.15)	.472
Mental score week 24	53.83 ± 6.67	53.08 ± 7.30	.74 (-2.87 to 4.36)	.683
Physical score week 36	52.84 ± 4.69	51.72 ± 4.70	1.12 (-1.31 to 3.55)	.360
Mental score week 36	53.42 ± 3.81	52.98 ± 5.43	.44 (-1.98 to 2.86)	.717
BMI (kg/m ²)				
Week 12	25.87 ± 3.26	25.35 ± 3.20	.52 (-1.15 to 2.18)	.538
Week 24	25.28 ± 2.97	24.96 ± 3.14	.32 (-1.26 to 1.90)	.686
Week 36	25.25 ± 2.77	24.88 ± 3.31	.36 (-1.21 to 1.94)	.645
Waist circumference (cm)				
Week 12	88.73 ± 10.55	85.67 ± 12.35	3.07 (-2.87 to 9.00)	.305
Week 24	87.20 ± 9.84	84.70 ± 11.80	2.50 (-3.11 to 8.11)	.376
Week 36	86.87 ± 9.72	84.17 ± 11.84	2.70 (-2.90 to 8.30)	.338

Note: Values are means (standard deviation).

Abbreviations: 95% CI, 95% confidence interval; BMI, body mass index.

TABLE 5 The proportion of participants achieving hypertension^a

Variable	Intervention group (n = 30)	Control group (n = 30)	p-Value
Week 12, n (%)	3 (10.0)	5 (16.7)	.704
Week 24, n (%)	1 (3.3)	2 (6.7)	1.0
Week 36, n (%)	1 (3.3)	2 (6.7)	1.0

^aThe proportion of participants achieving hypertension was defined as the proportion of patients with a mean SBP greater than 140 mmHg and/or a mean DBP greater than 90 mmHg.

week 12 (three participants [10.0%] in the intervention group vs. five participants [16.7%] in the control group, $p = .704$ for the comparison; Table 5).

In the intervention group, 2 (7.7%) participants reported at least one TEAS-related adverse event compared with no participants in

the control group. None of the participants withdrew from the study because of an adverse event. All of the adverse events occurred only once and resolved spontaneously. No serious adverse events were reported by any of the participants in either group (Table 6).

TABLE 6 Adverse events^a

	Intervention group (n = 30)	Control group (n = 30)
Overall	2	0
Severe adverse events	0	0
Fatigue	1	0
Muscular soreness	1	0

^aAdverse events were analyzed in all participants. Adverse events were counted by frequency in patients. For example, an adverse event with two occurrences in a single patient was defined as two adverse events.

4 | DISCUSSION

To the best of our knowledge, this was the first randomized controlled clinical trial to investigate the effectiveness of TEAS combined with lifestyle modification in individuals with high-normal BP. This pilot trial indicated that a home-based multicomponent intervention was effective in reducing SBP. The results indicate that the design is safe and feasible, which justifies the need for a larger trial in the future.

A recent study showed that 18 sessions of electroacupuncture during a 6-weeks time period caused an 8-mmHg reduction in SBP for patients with mild hypertension, and the effect on SBP reduction lasted for another 6 week after the acupuncture treatment was terminated.²⁹ In this trial, we found that TEAS combined with lifestyle modification lowered the mean SBP by 5 mmHg and lowered the mean DBP by 3 mmHg. One possible reason for the discrepancies may be the differences in the therapeutic schedule. Another reason could be that patients with higher baseline BP have more capacity for lowering BP. A mean SBP of 130 mmHg at baseline without comorbidities generally represents acceptable control; hence, aiming for even better BP control in this context may have been challenging.³³

The preliminary results of the BPLTTC trial showed that for patients with different BP stages, each 5-mmHg SBP reduction can reduce the risk of stroke, ischemic heart disease, heart failure and death by 13%, 7%, 14%, and 5%, respectively.³⁴ A prospective cohort study involving over .5 million adults from 10 areas of China showed that, with normal adults as the reference, adults with high-normal BP had a higher risk of cerebrovascular disease and hemorrhagic stroke, and they were associated with the increased mortality of overall cardiovascular disease and its subtypes.³⁵ Intensive BP control can reduce the risk of stroke in individuals with increased cardiovascular risk, even in the ranges of high normal and normal BP.³⁶ In our trial, the target population was BP in the high-normal range because such individuals not only have increased BP but also have an increased prevalence of being overweight and obesity, which places them at greater cardiometabolic risk than people in the general population.³⁷ Despite this pilot study not having enough power to detect cardiovascular outcomes, our findings still have significant clinical implications and provide support for interventions to improve BP control in individuals with high-normal BP. However, the results of weight and waist circumference evaluations showed that the effect of recommendations for lifestyle modification was not satisfactory. One possible explanation for this phenomenon is that people were under lockdown because of the viral pandemic. In this

scenario, they were sheltered at home and in self-isolation to limit the spread of the virus during the COVID-19 pandemic period. This restriction of activities may be a potential cause for the poor effect of lifestyle modification. Although we provided healthy nutrition education and encouragement for physical activity, a targeted diet and weight-loss strategy were not provided. In this study, the extent of BP reduction may not yet be sufficient to affect quality of life, and the sample size was relatively small, which may be insufficient to observe differences in the progression to hypertension.

The main intervention involved transcutaneous electrical stimulation, which solely involves skin-contact stimulation and does not penetrate the skin, similar to acupuncture. We provided information on lifestyle modification for participants via smartphones and social media, which is widely used in community chronic disease management.^{38,39} Due to the pragmatic nature of the study, we integrated these interventions into real-world settings, and a multi-component intervention was conducted via participants' self-management at home to further reduce the costs of treatment. A more self-determined and flexible time may be a particular advantage. Such an approach represents substantial savings in cost and time to outpatient care, compared with traditional acupuncture. One of the goals of this pilot study was to determine the feasibility of using home-based interventions. To the best of our knowledge, our participants were able to adequately perform the trial intervention at home, and TEAS treatment appeared to be reliably and safely performed. The recruitment and follow-up rates in the study were acceptable, and the desired BP control results were achieved. Hence, the results of this trial support the feasibility of conducting a large randomized trial in the future. A total of 296 patients will be required for an adequately powered future trial, based upon our results.

4.1 | Limitations

The present study had some limitations to be considered. For example, this study was performed in an unblinded fashion. We did not employ a sham control because it was difficult to blind the participants so that they could tell whether the instrument was on. However, due to the automatic mode of the sphygmomanometer that was used, it is unlikely that this objective outcome was influenced by the unblinded nature of the intervention. Second, the optimal frequency of electrical stimulation of TEAS could not be elucidated in this study. Third, although we

used a diary to record the usage frequency of TEAS, it is better to use a more accurate system for real-time uploading of data in the future. Fourth, the small sample size limited the power of the trial to a certain extent, although it was believed that this would be a large enough sample to confirm the feasibility of the trial design. Finally, there was no comprehensive analysis of cost-effectiveness in the present study because modeling requires extensive assumptions that were beyond the scope of this trial.

5 | CONCLUSIONS

In this prospective, randomized controlled study, lifestyle modification combined with home-based TEAS modestly decreased BP at week 12 in a population of adults with high-normal BP, compared to the sole use of lifestyle modification. Although the clinical significance of these findings remains to be further confirmed, our trial shows the potential of a pragmatic, nonpharmaceutical, home-based intervention for BP control, especially under lockdown during the COVID-19 pandemic period. The results of this trial support the feasibility of conducting a larger randomized trial in the future.

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CONSENT FOR PUBLICATION

Not applicable.

CONFLICT OF INTEREST

None declared.

AUTHOR CONTRIBUTIONS

Concept and design: Yu Wang, Zhong-Xue Tian, Li-Qiong Wang, Jing-Wen Yang, Jian-Feng Tu, Guang-Xia Shi and Cun-Zhi Liu; Acquisition of data: Zhong-Xue Tian, Jun-Hong Liu, You-Sheng Qi and Jian-Feng Tu; Statistical analysis: Yu Wang, Shi-Yan Yan; Interpretation of results: Yu Wang, Jing-Wen Yang, Guang-Xia Shi, Li-Qiong Wang and Cun-Zhi Liu; Drafting of the manuscript: Yu Wang and Li-Qiong Wang; Critical revision of the manuscript for important intellectual content: Yu Wang, Li-Qiong Wang, Jing-Wen Yang, Jian-Feng Tu, Guang-Xia Shi, Shi-Yan Yan and Cun-Zhi Liu; Administrative: Jun-Hong Liu and You-Sheng Qi.

AUTHOR STATEMENT

Yu Wang: concept and design; statistical analysis; interpretation of results; drafting of the manuscript; critical revision of the manuscript for important intellectual content. Jing-Wen Yang: concept and design; interpretation of results; critical revision of the manuscript for important intellectual content. Jun-Hong Liu: acquisition of data; administrative. You-Sheng Qi: acquisition of data; administrative. Jian-Feng Tu: concept and design; acquisition of data; critical revision of the manuscript for important intellectual content. Zhong-Xue Tian: concept and design; acquisition of data. Guang-Xia Shi: concept and design; interpretation of results; critical revision of the manuscript for important intellectual content. Shi-Yan Yan: statistical analysis; critical revision of the manuscript for important intellectual content. Li-Qiong Wang: concept and design; interpretation of results; drafting of the manuscript; critical revision of the manuscript for important intellectual content. Cun-Zhi Liu: concept and design; interpretation of results; critical revision of the manuscript for important intellectual content.

ORCID

Li-Qiong Wang MD, PhD  <https://orcid.org/0000-0003-1222-7715>

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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