

## Original Article

# Effects of the Chinese heart-healthy diet (Sichuan cuisine) on lowering blood pressure in adults with hypertension: a randomized controlled feeding trial

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**Background and Objectives:** Sichuan cuisine is characterized by high salt and oil content. We aimed to evaluate the effects of the Sichuan cuisine version of Chinese heart-healthy diet (CHH diet-SC) on blood pressure reduction among hypertensive adults. **Methods and Study Design:** The Chinese heart-healthy diet (CHH) trial was a multicenter randomized controlled feeding trial among Chinese hypertensive people. We conducted a secondary analysis of the CHH trial using data from the Sichuan center in Southwest China. Fifty-three people aged 25 to 75 years with a mean systolic blood pressure (SBP) between 130 and 159 mmHg were enrolled. Eligible participants underwent a 1-week run-in period with the typical local diet and were randomized 1:1 to consume the CHH diet-SC (n=27) or typical local diet (n=26) for the next 4-week. The primary outcome was the net change in SBP, the secondary outcomes included diastolic blood pressure (DBP), mean arterial pressure (MAP), and the rate of BP control. **Results:** Compared with the control group, the CHH diet-SC decreased cooking salt, oil, and red meat content and increased inclusion of whole grains, fruits, seafood, low-fat dairy, soybean, and nuts; the SBP experienced reductions of 7.54, 8.60, 9.14, and 10.1 mmHg at the end of weeks 1 through 4; the DBP was reduced 4.01 mmHg at week 4; the MAP was significantly reduced 6.02 mmHg finally; and rate of BP control significantly increased ( $p<0.05$ ). **Conclusions:** Adoption of the CHH diet-SC for 4 weeks can significantly reduce BP and increase the rate of BP control in hypertensive adults.

**Key Words:** Sichuan cuisine, diet pattern, blood pressure, hypertension, Chinese

## INTRODUCTION

Hypertension is defined as systolic blood pressure (SBP)/diastolic blood pressure (DBP)  $\geq 140/90$  mmHg in most guidelines. It is the leading preventable risk factor for cardiovascular disease and one of the largest contributors to the global disease burden.<sup>1</sup> Hypertension affected 34% of adults and was associated with 10.8 million deaths in 2019 worldwide.<sup>2</sup> The prevalence of hypertension in Chinese adults has increased steadily in the past three decades and reached 27.5% in 2018.<sup>3</sup> Sichuan is the largest province in Southwest China, in which the prevalence of hypertension was similar to the national prevalence, but the rate of control was much lower than the national level of 9.7%, indicating a substantial disease burden related to hypertension.<sup>4</sup>

Lifestyle modifications, including salt reduction, healthy diet, weight reduction, and regular physical activity, have been proven effective in lowering blood pressure (BP).<sup>5</sup> Recently, growing evidence showed that dietary modification is effective in reducing BP, and most practical guidelines of hypertension recommend adopting a healthy diet to manage hypertension.<sup>6</sup> The Dietary Approaches to Stop Hypertension (DASH) diet, the Mediter-

ranean diet which were rich in whole grains, fruits, vegetables, low-fat dairy, and low in red meat, have been recommended as examples of dietary patterns with definite antihypertensive effects.<sup>7,8</sup> However, the diets above were designed for European and American populations, which may be difficult for Chinese to follow due to the large dietary and taste preferences differences. Therefore, it is necessary to provide effective dietary strategies that fit into traditional Chinese diet culture for hypertension management.

The Chinese diet developed into four major cuisines due to different eating habits, cultural traditions, and other factors. Sichuan cuisine is one of the most influential

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cuisines among the four major Chinese cuisines and is the first Chinese cuisine recognized by the United Nations Educational Scientific and Cultural Organization. However, data from the 2010-2012 China Health and Nutrition Survey showed that the dietary pattern in Sichuan was unbalanced, characterized by excessive intake of cooking salt, oil, and red meat but insufficient fruits, dairy, seafood, soybeans, and nuts.<sup>9</sup> Research showed it contained heavy sodium and fat but low protein, potassium, and phosphorus, which may influence the occurrence of hypertension.<sup>10</sup> In addition, takeaway food which contains excessive energy, salt, fat, and insufficient whole grain, vegetable, fruit, dairy products, and dietary fiber, has markedly increased in Sichuan and other places and also is associated with hypertension.<sup>11</sup> However, currently, no information is available on the effect of the modified Sichuan cuisine diet on BP. The Sichuan cuisine version of the Chinese heart-healthy diet (CHH diet-SC) was modified based on the traditional Sichuan cuisine referencing the Chinese Dietary Guidelines and the antihypertensive diet, including the DASH diet. We aim to investigate the effect of CHH diet-SC intervention on lowering SBP, DBP, mean arterial pressure (MAP), and rate of BP control among hypertensive adults.

## METHODS

We aimed to evaluate the effects of CHH diet-SC on blood pressure among mild hypertension adults. Our primary outcome was the difference in net changes in SBP between the intervention and control groups from baseline to the end of the 4-week follow-up period. The secondary outcome included net change in DBP, MAP, and rate of BP control.

### *Study design*

A detailed description of the study protocol has been published elsewhere.<sup>12</sup> The CHH diet study was a multicenter (Beijing, Shanghai, Chengdu, and Guangzhou) randomized controlled feeding trial among Chinese adults between March 2019 and January 2021. We conducted a secondary analysis of the CHH trial using data from the Sichuan Chengdu center in Southwest China. This trial was conducted in accordance with the Declaration of Helsinki and guidelines of Good Clinical Practice and approved by the Peking University Institutional Review Board (approval number: IRB00001052-18094). Informed consent was obtained from all subjects involved in the study.

### **Study population**

We recruited men and women aged between 25 and 75 years old with an average SBP between 130 and 159 mmHg for two screening visits. Other inclusion criteria include: living in the target communities for the past six months and without plans to relocate or go out in the next three months; ability to maintain their current medication and dosages throughout the study; willingness to consume the study diets for 5 weeks and eat at least 18 study meals per week; and willingness to sign informed consent. Detailed information about sample size and exclusion criteria have been described in the protocol.<sup>12</sup>

### **Run-in and baseline assessment**

Participants who passed the screening entered into the 1-week run-in period and consumed the typical local diet. During the run-in period, researchers adjusted the diet energy intake to a suitable level required for each subject to maintain a stable body weight. The energy intake level in both groups was maintained throughout the study to avoid significant body weight changes. Participants who failed to complete the dietary intervention or consumed less than 80% of the trial meals provided during the run-in period were excluded. At the end of the run-in period, baseline information was collected by the trained researchers using structured questionnaire items including demography, lifestyle and health behaviours, medical history, the current medication use.

### **Randomization and blinding**

Eligible participants who completed the run-in period were randomly allocated 1:1 to the intervention group (the CHH diet-SC) or the control group (the typical local diet) using a computer-generated random-number sequence by the statistician in Peking University Clinical Research Institute. This was a single-blind trial in which subjects were masked to the diet assignment. Similar ingredients were used for the same meal in both groups and eating places were different between groups to ensure the successful implementation of single blinding. BP was measured and assessed by researchers who were blinded to the group assignment.

### **Dietary intervention**

For the 4-week intervention period, the intervention group (n=27) consumed the CHH diet-SC, and the control group (n=26) consumed the typical local diet. All diets were prepared and provided to participants throughout the study. The lunch and dinner meals were centralized supplied in the community and breakfast was taken back by the subjects the day before and consumed the next morning. Researchers and nutritionists developed the recipes. The dietary recipes were designed according to the Chinese Dietary Guidelines (2016), the Chinese Dietary Reference Intakes (2013), the China Food Composition Tables (2018 and 2019), the Dietary Consumption Survey of the Sichuan area, and the DASH diet study. The recipe of CHH diet-SC was carefully designed and modified based on traditional Sichuan cuisine to retain the original flavour and taste and improve the compliance of participants. Professional chefs were responsible for the diet preparation to ensure the flavour of the dishes.

For the CHH diet-SC, the targeted macronutrient distributions were 55-60 energy (E)% from carbohydrates, 17-19 E% from protein, and 25-27 E% from fat. Dietary sodium intake was estimated to be restricted to 2000 mg/d, and dietary potassium, calcium, magnesium, and fiber increased to 3700 mg/d, 1200 mg/d, 500 mg/d, and 30 g/d, respectively. To achieve the targeted nutrient goal, food groups including whole grains, vegetables, fruit, low-fat dairy, lean meat, seafood, soybean, and nuts were emphasized in the CHH diet-SC. In addition, low-sodium salt and vegetable oil were used for cooking in the CHH diet-SC.

The control group consumed the typical local diet with targeted macronutrient distributions of 50-55% carbohydrate, 32-34% fats, and 10-12% protein. The sodium content of the control diet was estimated to be 4700 mg/d and slightly lower than the mean intake level of Sichuan residents. The control diet provided potassium, calcium, magnesium, and fiber at levels close to those of the average Sichuan diet.

### **Outcomes measurements**

#### **Dietary intake of foods and nutrients**

All the foods consumed by participants during the 4-week intervention period were recorded exactly. First, the raw food materials used for cooking the trial meal were weighed after cleaning and before cooking. In addition, the weight of every trial meal provided to participants was recorded twice: once before eating and again afterward. Moreover, information about the food that participants consumed that was not provided by the researchers during the trial was also collected. The average intake of nutrients was calculated using the China Food Composition Tables (2018 and 2019), and the United States Department of Agriculture National Nutrient Database was used to complete partial fatty acid data. The food classification referenced the Chinese Dietary Guidelines (2022) and the China Food Composition Tables (2018 and 2019). The food variety data only accounted for consumed food items of >10 g/d that participants consumed during the intervention period, and condiments were excluded.

#### **Blood pressure measurements**

The average SBP and DBP of each subject were measured weekly by trained researchers using an electronic manometer (Omron HEM-713) throughout the study. At baseline and at the end of the 4-week intervention, the SBP and DBP of each subject were measured at 3 separate time points: in the morning (8:00 to 10:00 am), afternoon (2:00 and 4:00 pm), and evening (6:00 to 8:00 pm). At each time point, 3 BP measurements were taken with a one-minute interval between measurements. At weeks 1 to 3, BP was measured 3 times in the morning, and the mean of 3 measurements was taken. MAP is the time-averaged BP within the arterial circuit and was calculated as  $2/3\text{DBP} + 1/3\text{SBP}$ .<sup>13</sup> The controlled BP level was defined as both SBP < 140 mmHg and DBP < 90 mmHg, and the rate was equal to the percentage of people with controlled BP within the group.

#### **Body weight measurements**

Body weight was measured using the Tanita HD-366 digital weight scale at the end day of every week. Participants' energy intakes were estimated to maintain their body weight within 2 kg. If the body weight of the subject changed more than 2 kg from baseline, researchers slightly adjusted the energy intake to keep the weight at a stable level.

#### **Food preference score assessment**

Participants were required to score their preference for the trial meal weekly. The food preference score was assessed on a visual analog scale ranging from 0 to 10, in which 10 means preferred the most. At the same time, we

also regularly collected their opinions about the meal at the scene.

#### **Laboratory measurement**

We collected the second-morning fasting midstream urine sample of all participants at baseline and the end. Participants were instructed about the method of spot urine sample collection, and disposable urinary catheters and cups were provided. The collected urine samples were preserved at the -80 ° refrigerator, and the urinary sodium content was tested by the Roche Cobas c501 automatic biochemistry analyzer with the ion selective electrode method.

Twenty-four-hour urine collection is considered the gold standard to assess dietary sodium intake, which is difficult to obtain.<sup>14</sup> We adopted the method developed in the China Salt Substitute and Stroke Study to estimate the 24-hour urinary sodium, which was equal to the 24-hour mean urine volume multiplied by spot urine sodium concentrations.<sup>15</sup> The mean volume (2.5 L) of 24-hour urine samples in the first batch of 8 participants in the Beijing study center was used in this study.

#### **Statistical analysis**

We used SPSS statistical software for Windows (IBM, version 24.0; IBM, Armonk, NY, USA) for analyses. Details of sample size can be found in our protocol.<sup>12</sup> Primary analyses were performed in accordance with the full analysis set (FAS), including all patients eligible for the study and completed randomization. A per-protocol analysis (PPS) was performed as a sensitivity analysis, which excluded participants who consumed <80% of the study meals, had their medications (medications to control blood pressure, glucose, or serum lipids) changed, or had body weight change >2 kg during the intervention period. Missing values were managed with multiple imputations. Baseline characteristics were presented in randomly assigned treatment groups. Continuous variables were summarized by the mean (standard deviation) or 95% confidence interval and categorical variables were described by the frequency or proportion of participants in each category. Continuous variables were analyzed by the independent samples t-test, or Mann-Whitney U test between groups, two-sample t-test or Wilcoxon signed-rank test within the group.

The linear mixed model (LMM) with covariance structure compound symmetry was used to calculate net differences in BP changes between groups, participants were assumed to be random effects, while intervention group, time, and interaction were assumed to be fixed effects. The generalized estimating equations (GEEs) was used to analyze the hypertension control rate. Possible confounders including age, sex, antihypertension medication use, and weight change from baseline were adjusted in all models. The same analysis was repeated in PPS for Sensitivity analyses. Statistical significance was defined using a 2-sided significance level of  $\alpha=0.05$ .

## **RESULTS**

### **Baseline characteristics of all participants**

The enrollment and retention of study participants are presented in Figure 1. Totally 53 participants signed in-

formed consent and were randomly assigned to the CHH diet-SC group (n=27) and control group (n=26). All 53 participants were included in the FAS, and 41 were included in the PPS. Ultimately, 50 (94.3%) participants completed the trial. The mean age was 60.2 years old, and 52.8% were men. The average SBP, DBP, and MAP were 140/88.2/105 mmHg, respectively. Baseline characteristics were well balanced between the groups (Table 1).

#### **Average nutrient and food group intake during the intervention period**

The average daily nutrient and food group intake are described in Tables 2 and 3. Overall, the CHH diet-SC group consumed significantly more protein, carbohydrate, polyunsaturated fatty acids (PUFAs), cholesterol, and dietary fiber but less saturated fatty acids (SFAs) and monounsaturated fatty acids (MUFAs). Regarding mineral and vitamin intake, the CHH diet-SC group consumed less sodium but more potassium, calcium, magnesium, phosphorus, zinc, selenium, and antioxidative vitamins, including vitamin A, vitamin E, vitamin C, and folate ( $p<0.001$ , respectively).

Overall, the food variety of the CHH diet-SC group was higher than that of the control group ( $p<0.001$ ), the consumption of whole grains, fruits, poultry, seafood, eggs, low-fat dairy, soybean, and nuts was significantly increased but red meat, cooking oil, and salt were decreased compared with the control ( $p<0.001$ ). No signifi-

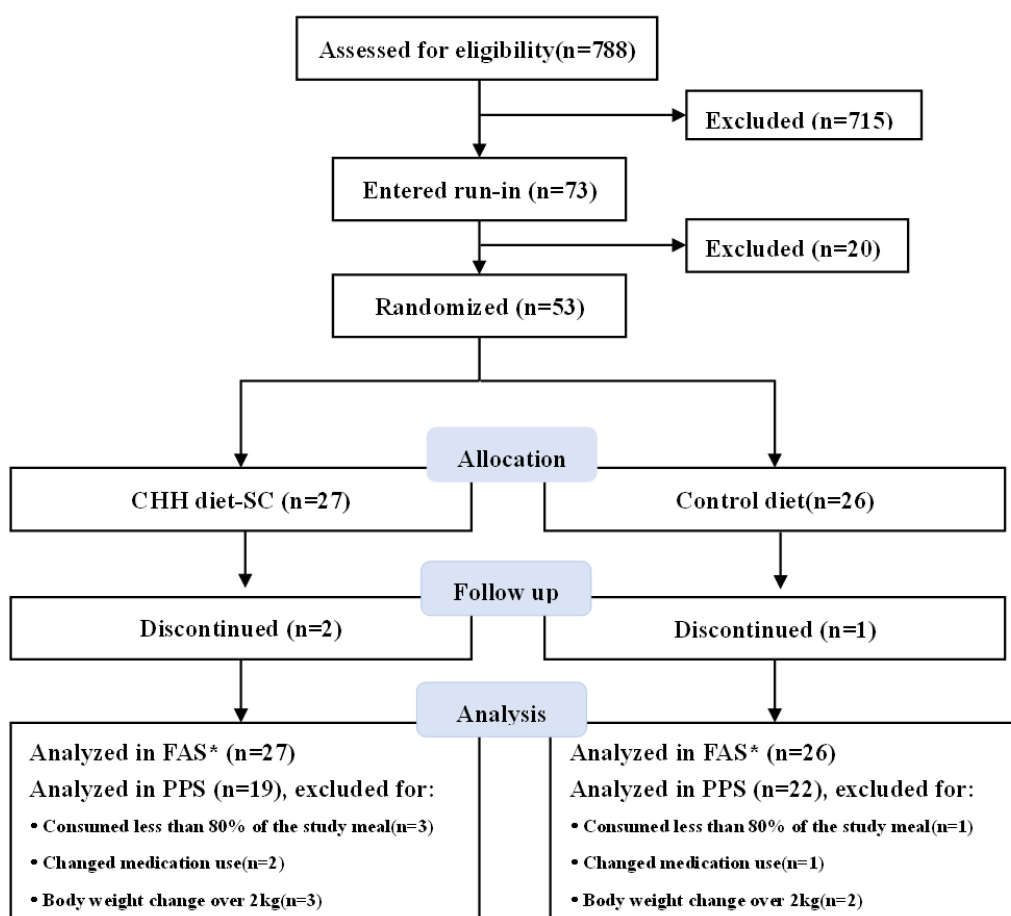
cant difference was found in vegetable consumption on between groups ( $p=0.333$ ).

#### **Compliance with the dietary intervention of study participants**

The dietary compliance assessment for participants is presented in Supplementary Table 1. Consistent with dietary sodium intake changes, the estimated 24-hour urinary sodium decreased substantially from baseline to the end of the study in the CHH diet-SC group but had no significant change in the control group. The mean body weight changes from baseline to the final were -1.13/-0.43 kg in the CHH diet-SC and control groups, respectively, which were relatively stable. The mean food preference scores in the two groups were similar at baseline and increased conspicuously to approach 10 at the end, indicating that participants accepted and enjoyed the trial diet.

#### **Intervention effects on blood pressure**

The intervention effects on BP are presented in Table 4 and Figure 2. In both the CHH diet-SC group and control group, the level of SBP, DBP, and MAP was significantly reduced at the end in comparison to the baseline value ( $p<0.05$ ). With regard to the CHH diet-SC group compared with the control diet, the net SBP changes were -7.54, -8.60, -9.14, and -10.1 mmHg at the end of weeks 1 through 4, respectively, with differences first observed at week 1 which continuously improved through week 4 ( $p$ -



**Figure 1.** Participants enrolment and treatment assignment in the trial. \*Participant who discontinued the intervention but had blood pressure measured at the withdrawal was included in FAS.

**Table 1.** Baseline characteristics of study participants

Characteristic	CHH diet-SC group (n=27)		Control group (n=26)		Overall (n=53)	
	Number	%	Number	%	Number	%
Sex						
Men	11	40.7	17	65.4	28	52.8
Women	16	59.3	9	34.6	25	47.2
Age <sup>†</sup>	59.8	9.48	60.7	9.25	60.2	9.29
30~59	13	48.1	14	53.8	27	50.9
≥60	14	51.9	12	46.2	26	40.1
Body Weight (kg) <sup>†</sup>	63.7	8.64	64.5	7.88	64.1	8.20
BMI (kg/m <sup>2</sup> ) <sup>†</sup>	26.0	2.09	25.9	2.25	26	2.14
< 24	4	14.8	5	19.2	9	17.0
≥ 24	23	85.2	21	80.8	44	83.0
Educational level						
College and above	2	7.41	5	19.2	7	13.2
High school	7	25.9	4	7.7	11	20.8
Middle school and below	18	66.7	17	65.4	35	66.0
Occupation						
Labor	15	55.6	15	57.7	30	56.6
Housework	11	40.7	9	34.6	20	37.7
Others	1	3.70	2	7.69	3	5.66
Monthly household income						
> 1450\$	9	33.3	7	26.9	16	30.2
725-1450\$	12	44.4	11	42.3	23	43.4
< 725\$	6	22.2	8	30.8	14	26.4
Marriage status						
Married	23	85.2	21	80.8	44	83.0
Others	4	14.8	5	19.2	9	17.0
Currently drinking	2	7.40	5	19.2	7	13.2
Currently smoking	4	14.8	6	23.1	10	18.9
Antihypertension medication use	15	55.6	12	46.2	27	50.9
Blood pressure (mmHg) <sup>†</sup>						
SBP	140	8.28	140	6.70	140	7.47
DBP	88.0	8.56	88.4	7.66	88.2	8.06
MAP	105	7.30	105	5.60	105	6.50
Diabetes	0	0	6	23.1	6	11.3
Hypercholesterolemia	4	14.8	3	11.5	7	13.2

BMI, body mass index; BP, blood pressure; SBP, systolic blood pressure; DBP, diastolic blood pressure; MAP, mean arterial pressure.

<sup>†</sup>Continuous variables are summarized by mean and SD.

**Table 2.** The average nutrients intake of participants during intervention

Nutrients	CHH diet-SC group (n=27)	Control group (n=26)	<i>p</i> value
Energy (kcal)	2253±145	2400±144	<0.001
Protein (E%)	17.9 (17.1, 18.9)	12.6 (12.2, 13.4)	<0.001
Plant protein (%)	9.36 (8.73, 10.3)	7.06 (6.67, 7.74)	<0.001
Animal protein (%)	8.36±1.14	5.41±1.17	<0.001
Fat (%)	24.8±2.11	34.4±3.86	<0.001
SFAs (%)	6.17±0.86	8.85±1.91	<0.001
MUFAs (%)	7.21±0.78	11.8±2.75	<0.001
PUFAs (%)	8.96±0.86	8.22±1.64	0.001
Carbohydrate (%)	57.3±2.47	52.7±3.67	<0.001
Fiber (g)	29.3 (27.1, 29.3)	12.6 (11.3, 14.2)	<0.001
Cholesterol (mg)	439 (257, 502)	327 (195, 476)	0.026
Sodium (mg)	2471 (2261, 2727)	5569 (5152, 5975)	<0.001
Potassium (mg)	4055 (3805, 4415)	2129 (1878, 2404)	<0.001
Calcium (mg)	983 (903, 1037)	412 (293, 524)	<0.001
Magnesium (mg)	534 (494, 595)	299 (280, 332)	<0.001
Phosphorus (mg)	1676 (1588, 1766)	1054 (933, 1174)	<0.001
Zinc (mg)	14.5 (13.8, 15.9)	9.69 (9.06, 10.7)	<0.001
Selenium (mg)	42.4 (38.3, 59.5)	35.1 (30.8, 38.5)	<0.001
Vitamin A (µg RAE)	645 (577, 879)	403 (288, 542)	<0.001
Vitamin E (mg)	45.7 (41.4, 51.7)	39.6 (33.7, 45.5)	<0.001
Vitamin C (mg)	150 (132, 176)	111 (72.9, 153)	<0.001
Folate (µg)	244 (186, 325)	156 (127, 218)	<0.001

SFAs, saturated fatty acids; MUFAs, monounsaturated fatty acids; PUFAs, polyunsaturated fatty acids.

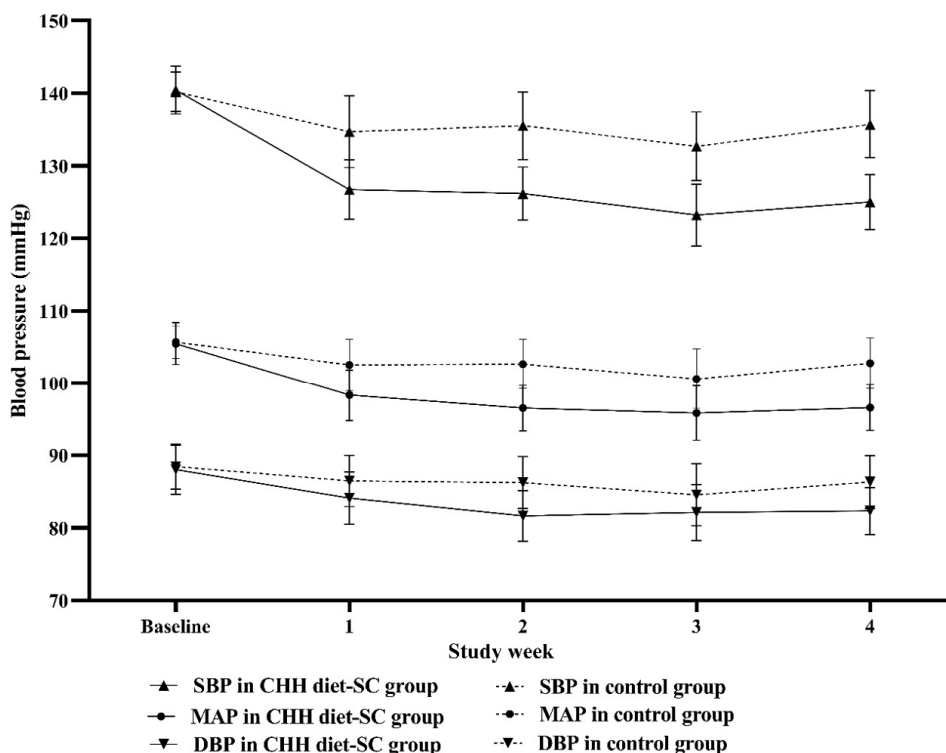
Data are expressed as mean ± SD or median (IQR).

**Table 3.** The average food groups intake of participants during intervention

Food groups	CHH diet-SC group (n=27)	Control group (n=26)	<i>p</i> value
Grains	371 (323, 433)	365 (324, 407)	0.332
Whole grains	133.2±60.4	31.9±45.6	<0.001
Tubers	17.6±44.0	46.2±55.2	<0.001
Vegetables	443 (390, 483)	441 (394, 525)	0.333
Fruits	250 (169, 319)	49.8 (21.5, 149)	<0.001
Meat	201 (178, 227)	200 (187, 225)	0.894
Poultry	49.7 (34.4, 55.8)	40.6 (3.98, 51.0)	0.005
Red meat	80.4 (68.8, 110)	130 (121, 146)	<0.001
Seafood	28.9±33.7	9.4±23.3	<0.001
Eggs	42.6±28.8	29.0±28.7	<0.001
Dairy	269±23.6	75.6±113	<0.001
Low-fat dairy	254±21.5	0.25±2.13	<0.001
Regular-fat dairy	14.6±18.3	75.3±114.0	<0.001
Soybean and nuts	39.4 (29.9, 54.6)	16.4 (5.00, 30.2)	<0.001
Soybean	32.4 (17.6, 39.5)	3.80 (0.08, 22.4)	<0.001
Nuts	11.7 (5.00, 16.2)	2.60 (0.00, 8.08)	<0.001
Cooking oil	25.9 (23.7, 27.7)	41.3 (37.7, 47.9)	<0.001
Animal oil	0	11.03±4.94	<0.001
Vegetable oil	25.9 (23.7, 27.7)	29.6 (26.1, 35.7)	<0.001
Cooking salt	3.98±1.10	7.05±1.26	<0.001
Food variety <sup>†</sup>	20.2±1.98	15.3±2.10	<0.001

Data are expressed as mean ± SD or median (IQR).

<sup>†</sup>Food variety only account for food items with >10 g/d which participants consumed during intervention period and excluded condiments.

**Figure 2.** Mean blood pressure at baseline and during each intervention week according to assigned groups.

The error bars represent 95% CI; SBP, systolic blood pressure; MAP, mean arterial pressure; DBP, diastolic blood pressure.

interaction<0.001). At week 2, a significant difference in the change of DBP was found between the 2 groups (-4.77 mmHg,  $p=0.038$ ). However, the reduction in DBP was 4.01 mmHg at the end between groups, with no significant difference ( $p>0.05$ ). The net difference in MAP change occurred by week 2 (-6.03 mmHg,  $p=0.010$ ) and achieved a similar effect at week 4 (-6.02 mmHg,  $p=0.009$ ). The pattern of MAP change over time was significantly different between groups ( $p$ -interaction=0.006).

The effects of CHH-SC on BP were more obvious in the sensitivity analysis (Supplementary Table 2).

The rates of BP control were similar between groups at baseline. After the 4-week intervention, the rate of BP control significantly increased to 88.9% in the CHH diet-SC group and higher than that in the control group ( $p=0.005$ , Table 5 and Supplementary Table 3).

**Table 4.** The mean BP change from baseline during intervention

	CHH diet-SC group (n=27)			Control group (n=26)			CHH diet-SC versus Control group	
	Mean ± SD	Mean differences (95% CI)	<i>p</i> value <sup>†</sup>	Mean ± SD	Mean differences (95% CI)	<i>p</i> value <sup>†</sup>	Mean differences (95% CI)	<i>p</i> value <sup>‡</sup>
<b>SBP</b>								
Baseline	140±8.28	—	—	140±6.70	—	—	—	—
Week 1	127±10.3	-13.7 (-16.8, -10.7)	<0.001	134±12.2	-5.49 (-9.46, -1.52)	0.007	-7.54 (-13.2, -1.83)	0.010
Week 2	126±9.31	-14.3 (-17.7, -10.8)	<0.001	135±11.5	-4.67 (-8.63, -0.70)	0.021	-8.60 (-14.4, -2.76)	0.004
Week 3	123±10.8	-17.2 (-21.0, -13.4)	<0.001	132±11.7	-7.49 (-12.2, -2.80)	0.002	-9.14 (-14.9, -3.35)	0.002
Week 4	125±9.63	-15.4 (-18.5, -12.4)	<0.001	135±11.4	-4.47 (-8.36, -0.60)	0.024	-10.1 (-15.8, -4.34)	0.001
<b>DBP</b>								
Baseline	88.0±8.56	—	—	88.4±7.66	—	—	—	—
Week 1	84.1±9.12	-3.91 (-5.67, -2.15)	<0.001	86.5±8.70	-1.99 (-3.71, -0.27)	0.023	-2.20 (-6.63, 2.23)	0.326
Week 2	81.6±8.75	-6.35 (-8.22, -4.48)	<0.001	86.2±8.84	-2.21 (-4.07, -0.36)	0.019	-4.77 (-9.26, -0.29)	0.038
Week 3	82.1±9.72	-5.88 (-7.73, -4.03)	<0.001	84.6±10.6	-3.89 (-6.40, -1.37)	0.002	-2.49 (-6.96, 1.99)	0.272
Week 4	82.3±8.16	-5.67 (-7.14, -4.20)	<0.001	86.3±9.0	-2.15 (-4.27, -0.02)	0.048	-4.01 (-8.45, 0.43)	0.076
<b>MAP</b>								
Baseline	105±7.30	—	—	105±5.63	—	—	—	—
Week 1	98.3±8.92	-7.17 (-9.21, -5.14)	<0.001	102±8.86	-3.16 (-5.55, -0.76)	0.010	-3.97 (-8.45, 0.51)	0.081
Week 2	96.5±7.93	-8.98 (-11.2, -6.82)	<0.001	102±8.50	-3.03 (-5.47, -0.59)	0.015	-6.03 (-10.6, -1.47)	0.010
Week 3	95.8±9.51	-9.66 (-12.0, -7.27)	<0.001	100±10.2	-5.08 (-8.23, -1.95)	0.002	-4.69 (-9.22, -0.16)	0.043
Week 4	96.6±8.03	-8.92 (-10.7, -7.17)	<0.001	102±8.79	-2.92 (-5.51, -0.33)	0.027	-6.02 (-10.5, -1.53)	0.009

BP, blood pressure; SBP, systolic blood pressure; DBP, diastolic blood pressure; MAP, mean arterial pressure.

<sup>†</sup>Comparison of BP change from baseline within group.

<sup>‡</sup>Comparison of BP change from baseline between groups, which were adjusted age, sex, antihypertension medication use, and weight change using the linear mixed model.

**Table 5.** Change of blood pressure control rate during intervention

Time	CHH diet-SC group (n=27)		Control group (n=26)		CHH diet-SC versus control group	
	n/total n (%) <sup>†</sup>	<i>p</i> value <sup>‡</sup>	n/total n (%) <sup>†</sup>	<i>p</i> value <sup>‡</sup>	<i>p</i> value <sup>§</sup>	<i>p</i> value <sup>§</sup>
Baseline	8/27 (29.6)	-	8/26 (30.8)	-	-	-
Week 1	19/27 (70.4)	<0.001	13/26 (50.0)	0.048	0.177	0.177
Week 2	22/27 (81.5)	<0.001	14/26 (53.8)	0.048	0.074	0.074
Week 3	21/27 (77.8)	<0.001	14/26 (53.8)	0.048	0.177	0.177
Week 4	24/27 (88.9)	<0.001	13/26 (50.0)	0.086	0.010	0.010

<sup>†</sup>n/total n (%) means the percent of subjects with SBP <140 and DBP <90 mmHg within group.

<sup>‡</sup>Comparison of BP control rate change from baseline within group.

<sup>§</sup>Comparison of BP control rate change from baseline between groups, which were adjusted age, sex, antihypertension medication use, and weight change using the generalized estimating equations.

## DISCUSSION

The CHH diet-SC, which was based on the traditional Sichuan cuisine and retained the original flavor, featured a large reduction in oil and salt content and increased inclusion of whole grains, fruits, seafood, low-fat dairy, soybean, and nuts. We conducted a 4-week randomized controlled-feeding trial among people with elevated BP, which showed that CHH diet-SC can lower SBP/DBP/MAP by 10.1/4.01/6.02 mmHg, respectively, more than the control group. We also found that the reduction in SBP started within 1 week and continuously improved for the next three weeks. Furthermore, the rate of BP control was significantly increased after the 4-week CHH diet-SC intervention.

The significant decrease in BP reported in our study was consistent with several RCTs that examined the effect of diet patterns on BP. The magnitude of BP reduction observed in this study corresponded to that of the DASH-sodium study, in which sodium intake restriction (2300 mg/d) combined with the DASH diet for 8 weeks reduced SBP/DBP by 11.4/5.50 mmHg in hypertension participants.<sup>16</sup> This may result from the similar composition of key dietary nutrients between the DASH-sodium diet and CHH-diet SC. The DASH-JUMP diet was a modified DASH diet tailored to the Japanese food culture with similar nutrients as the original DASH diet. However, the 2-month DASH-JUMP intervention observed a larger hypotensive effect than ours, in which the SBP/DBP decreased 23.5/11.8 mmHg among people with baseline BP levels of 153/91 mmHg.<sup>17</sup> This difference may be explained by the different baseline BP and study duration. Evidence found that trials conducted among people with higher baseline BP can obtain greater BP change.<sup>18</sup> Interestingly, although Mediterranean diets were regarded as having cardioprotective and BP-lowering effects, the NU-AGE study found that a one-year Mediterranean diet intervention achieved a significant but relatively small BP reduction (SBP/DBP -5.50/-1.70 mmHg) among healthy older people.<sup>19</sup> Analogously, the SYSDIET study found that 12 weeks of the Nordic diet can decrease ambulatory SBP/DBP/MAP by 3.50/4.40/4.2 mmHg in hypertension subjects, which was smaller than those in our results.<sup>20</sup> One explanation for the superiority of the CHH diet-SC compared to the Mediterranean diet and Nordic diet was the recommendation to lower sodium intake.

Notably, we found that when comparing the CHH diet-SC with the control diet, BP reduction occurred within one week and was further reduced for the next 3 weeks. Most likely, the full effect of CHH diet-SC may not be completely achieved within 4 weeks of intervention. This finding was partially consistent with evidence from previous studies. The DASH-sodium study documented that the effect of salt reduction may not be entirely achieved within one month, whereas the DASH diet achieved the largest BP-lowering effects within one week and was maintained throughout the study.<sup>21</sup> The hypotensive effects of the DASH-JUMP diet were observed from 3 to 7 days after the intervention, but they stabilized once a normal BP was achieved.<sup>17</sup> Few studies have reported the time course of BP change after dietary intervention, but

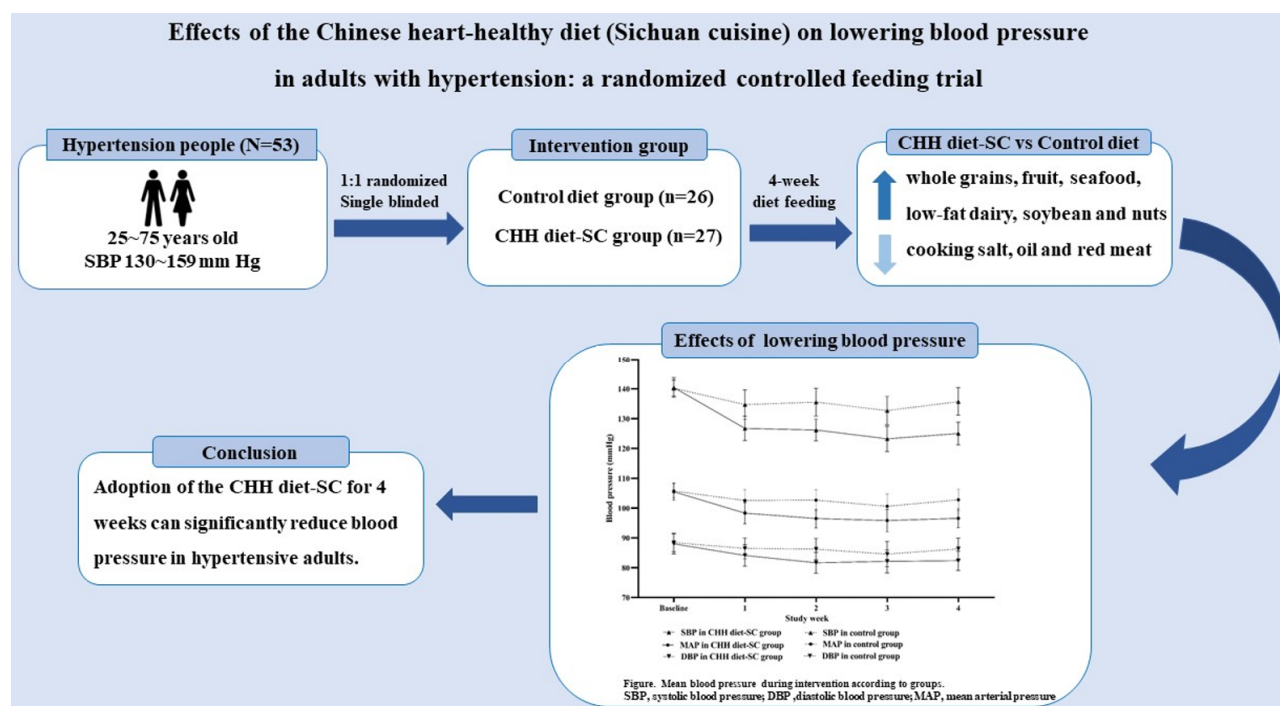
the information is useful when patients are consulted on the expected benefits of the diet.

The hypotensive effects of CHH diet-SC may be partially attributed to its inclusion of less edible salt and oil compared with that of the control diet. On the one hand, by using low-sodium salt, limiting sodium-laden condiments, and improving cooking methods, the CHH diet-SC reduced sodium to 2.47 g. Strong evidence has documented that reducing sodium intake can decrease BP.<sup>22</sup> Recently, a meta-analysis of 133 RCTs found that each reduction of 2.30 g sodium decreased SBP/DBP by 7.70/3.00 mmHg in hypertensive individuals.<sup>23</sup> Thus, the low-sodium characteristics of the CHH diet-SC could explain a large part of the BP reduction in our study. On the other hand, the high content of edible oil is a distinctive feature of traditional Sichuan cuisine that may influence BP. Conversely, the CHH diet-SC limited the edible oil to 26.0 g/d and mainly used vegetable oil (soybean oil and sesame oil) for cooking. Compared with animal oil, vegetable oil contains fewer SFAs but abundant PUFAs and antioxidants, which can reduce BP due to their strong anti-inflammatory effects.<sup>24, 25</sup>

In addition, the CHH diet-SC contained adequate whole grains and fruits and vegetables (FV), moderate red meat, seafood, low-fat dairy, soybean, and nuts, which may also result in BP reduction. In contrast with refined grains, whole grains provide a wider range of nutrients beneficial for BP, including potassium, magnesium, folate, and dietary fiber.<sup>26</sup> A network meta-analysis showed that whole grains were more effective at reducing SBP than refined grains.<sup>27</sup> FV are an important component of healthy diets that can provide abundant dietary fiber, minerals and vitamins with antihypertensive properties. Evidence from RCTs found that diets rich in FVs can reduce BP well.<sup>28</sup> In contrast to the local diet, the CHH diet-SC reduced red meat (mainly unprocessed lean red meat) intake and increased seafood intake. Antihypertensive diets including the DASH and Mediterranean diet limited red meat consumption, but advancing evidence showed that moderate unprocessed lean red meat could be adopted into a healthy diet and result in lower BP.<sup>29, 30</sup> Seafood is considered an effective food component in the Mediterranean diet that may improve endothelial function, and regular seafood intake may be beneficial to BP.<sup>31, 32</sup> In addition, moderate evidence supported that dairy consumption, particularly low-fat dairy, has beneficial effects on BP in adults, which may contribute to the major nutrients including calcium, potassium, protein, magnesium, and vitamin D.<sup>33</sup> Thus, the CHH diet-SC provided participants with 254.9 g of low-fat dairy per day may partially contribute to the BP-lowering effects.

Our study had several strengths. First, this was the first high-quality randomized controlled feeding trial in Southwest China to explore the effect of a complete dietary pattern on BP. Study meals were provided to participants, and all the food consumed by participants during the trial was rigorously recorded. Second, the percentage of participants who completed the intervention phase was 94.34%, and the food preference score was close to 10, which means that participants showed high dietary adherence to the trial. Third, BP was measured weekly using standardized methodologies and multiple readings. We





#### Graphical abstract.

measured BP 3 times within a day and 3 readings each time at baseline and final. For other visits, BP was only measured in the morning to reduce the burden on participants. Limitations should also be considered. First, due to the 2019 novel coronavirus pneumonia, relatively few participants were included in this study, and the statistical power of the study may be low. Second, the 4-week intervention duration was relatively short, and the largest effect of the CHH diet-SC may not have been observed. Third, body weight may affect BP, but the change in body weight was significantly different between groups. According to a previous study, for 1 kg in body weight, SBP and DBP were reduced by 1.05 and 0.92 mmHg, respectively.<sup>34</sup> Thus, the influence of body weight loss on BP was minimal in our study.

#### Conclusions

In conclusion, the present study showed that the CHH diet-SC, which contained reduced cooking salt, oil, and red meat, adequate whole grains, vegetables, and fruits, moderate seafood, low-fat dairy, soybean, and nuts, can reduce BP and increase the rate of BP control among hypertensive adults, suggesting the beneficial effect of CHH diet-SC on BP. More efforts are needed to further promote the adoption of the CHH diet-SC in larger populations.

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#### CONFLICT OF INTEREST AND FUNDING DISCLOSURES

The authors declare no conflict of interest.

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## Supplementary Tables

Supplementary Table 1. Dietary compliance assessment of study participants

Variables	CHH diet-SC group (n=27)	$p^{\dagger}$	Control group (n=26)	$p^{\dagger}$	$p^{\ddagger}$
24-hour urinary sodium (mg/d)					
Baseline	6863±2835		7107±2549		
Final	4689±2384		7364±2631		
Change	-2172 (-3118, -1230)	<0.001	256 (-947, 1460)	0.665	0.002
Body weight (kg)					
Baseline	63.5±8.56		64.2±7.70		
Final	62.4±8.64		63.8±7.52		
Change	-1.13 (-1.51, -0.75)	<0.001	-0.43 (-0.82, -0.04)	0.031	0.011
Food preference score					
Baseline	9.70±0.48		9.62±0.53		
Final	10.0±0.00		9.92±0.23		
Change	0.30 (0.11, 0.49)	0.006	0.30 (0.10, 0.51)	0.008	0.925

<sup>†</sup>Comparison of variable change from baseline within groups.

<sup>‡</sup>Comparison of variable change from baseline between groups.

**Supplementary Table 2.** Sensitivity analysis of mean BP change during intervention

	CHH diet-SC group (n=19)			Control group (n=22)			CHH diet-SC versus Control group	
	Mean ± SD	Mean differences (95%CI)	<i>p</i> value <sup>†</sup>	Mean ± SD	Mean differences (95%CI)	<i>p</i> value <sup>†</sup>	Mean differences (95%CI)	<i>p</i> value <sup>‡</sup>
<b>SBP</b>								
Baseline	140±8.28	—	—	139±6.99	—	—	—	—
Week 1	127±10.3	-13.7 (-16.8, -10.7)	<0.001	135±12.3	-3.92 (-8.07, 0.24)	0.065	-8.70 (-15.1, -2.27)	0.009
Week 2	126±9.31	-14.3 (-17.7, -10.8)	<0.001	135±12.5	-4.05 (-8.65, 0.55)	0.084	-8.13 (-14.6, -1.62)	0.015
Week 3	123±10.8	-17.2 (-21.0, -13.4)	<0.001	133±11.5	-6.11 (-11.1, -1.16)	0.016	-10.2 (-16.7, -3.76)	0.002
Week 4	125±9.63	-15.4 (-18.5, -12.4)	<0.001	135±11.9	-4.17 (-8.48, 0.14)	0.058	-10.7 (-17.2, -4.22)	0.001
<b>DBP</b>								
Baseline	88.0±8.56	—	—	88.3±8.13	—	—	—	—
Week 1	84.1±9.12	-3.91 (-5.67, -2.15)	<0.001	87.2±8.71	-1.08 (-2.73, -0.58)	0.202	-2.84 (-7.88, 2.20)	0.264
Week 2	81.6±8.75	-6.35 (-8.22, -4.48)	<0.001	86.7±9.36	-1.62 (-3.67, 0.43)	0.121	-5.62 (-10.7, -0.55)	0.030
Week 3	82.1±9.72	-5.88 (-7.73, -4.03)	<0.001	85.4±10.9	-2.92 (-5.60, 0.25)	0.032	-3.71 (-8.77, 1.35)	0.148
Week 4	82.3±8.16	-5.67 (-7.14, -4.20)	<0.001	86.4±9.14	-1.89 (-4.11, 0.33)	0.095	-4.30 (-9.36, -0.76)	0.094
<b>MAP</b>								
Baseline	105±7.30	—	—	105±6.00	—	—	—	—
Week 1	98.3±8.92	-7.17 (-9.21, -5.14)	<0.001	103±8.80	-2.02 (-4.42, 0.38)	0.099	-4.79 (-9.8, 0.21)	0.060
Week 2	96.5±7.93	-8.98 (-11.2, -6.82)	<0.001	103±9.13	-2.43 (-5.21, 0.35)	0.087	-6.45 (-11.5, -1.41)	0.013
Week 3	95.8±9.51	-9.66 (-12.0, -7.27)	<0.001	101±10.2	-3.99 (-7.32, -0.65)	0.019	-5.88 (-10.9, -0.86)	0.022
Week 4	96.6±8.03	-8.92 (-10.7, -7.17)	<0.001	102±8.91	-2.65 (-5.42, 0.12)	0.061	-6.42 (-11.4, -1.41)	0.013

BP, blood pressure; SBP, systolic blood pressure; DBP, diastolic blood pressure; MAP, mean arterial pressure.

<sup>†</sup>BP change from baseline within group.

<sup>‡</sup>BP change from baseline between groups, which were adjusted for age, sex, antihypertension medication use, and weight change using the linear mixed model.

**Supplementary Table 3.** Sensitivity analysis of blood pressure control rate during intervention

Time	CHH diet-SC group (n=19)		Control group (n=22)		CHH diet-SC versus control group
	n/total n (%) <sup>†</sup>	<i>p</i> value <sup>‡</sup>	n/total n (%) <sup>†</sup>	<i>p</i> value <sup>‡</sup>	<i>p</i> value <sup>§</sup>
Baseline	6/19 (31.6)	—	7/22 (31.81)	—	—
Week 1	14/19 (73.7)	0.001	10/22 (45.5)	0.167	0.154
Week 2	16/19 (84.2)	0.002	10/22 (45.5)	0.167	0.029
Week 3	16/19 (84.2)	<0.001	11/22 (50.0)	0.089	0.059
Week 4	18/19 (95.7)	0.001	10/22 (45.5)	0.249	0.017

<sup>†</sup>n/total n (%) means the percent of subjects with SBP <140 and DBP <90 mmHg within group.

<sup>‡</sup>Comparison of BP control rate change from baseline within group.

<sup>§</sup>Comparison of BP control rate change from baseline within group using the generalized estimating equations.