Dietary approach to hypertension based on low glycaemic index and principles of DASH (Dietary Approaches to Stop Hypertension): a randomised trial in a primary care service

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Abstract

Hypertension is one of the leading causes of morbidity and mortality in Brazil. Diet may play an important role in reducing blood pressure (BP), as has been shown for diets high in fruits, vegetables and low-fat dairy products and low in salt (Dietary Approaches to Stop Hypertension (DASH)-Na). A low-glycaemic index Brazilian diet combined with the principles of the DASH-Na diet was evaluated in a randomised study of 206 individuals who were followed for 6 months. In the control group (CG), counselling was based on standard care and mainly focused on salt intake reduction. An intention-to-treat analysis showed that, after 6 months, systolic BP was reduced by 14·4 mmHg and diastolic BP by 9·7 mmHg in the experimental group (EG), compared with 6·7 and 4·6 mmHg, respectively, in the CG. After adjusting for body weight, BP at baseline and age, these changes were 12·1 and 7·9 mmHg, respectively. Urinary Na excretion was also reduced by 43·4 mEq/24 h in the EG. Food intake was modified accordingly during the intervention with an increase in the consumption of vegetables (2·97–5·85 frequency of consumption measured in three non-consecutive days), fruits (4·09–7·18), beans (1·94–3·13) and fish (1·80–2·74) by the EG. The present study showed the feasibility of a Brazilian dietary approach to treating hypertension by reducing urinary Na excretion and BP, changes that may have a great impact on public health and promote the benefits of controlling hypertension.

Key words: Food consumption; Hypertension; Dietary Approaches to Stop Hypertension; Urinary sodium excretion

Arterial hypertension is one of the most important modifiable(1) and well-established risk factors for CVD(2) and neurocognitive dysfunction(3). In Brazil, the prevalence of hypertension reaches 23·3 % in the adult population(4) and, despite the actions of prevention and control implemented by the Ministry of Health(5), for this morbidity, less than one-third of individuals diagnosed with hypertension are able to lower their blood pressure (BP) levels adequately with the recommended treatment(6).

Trends in the Brazilian dietary pattern are consistent with the increasing prevalence of chronic disease(7) and are mainly characterised by a low intake of milk, fruits and vegetables(8). The Dietary Approaches to Stop Hypertension (DASH) diet has been shown to be an effective non-pharmacological treatment for the control of hypertension(60) and emphasises the increased consumption of fruits, vegetables and low-fat dairy products, as well as reduced salt intake (DASH-Na)(9). Diets with a low glycaemic index (GI) are also potentially effective in reducing BP, as indicated in a large randomised study(10).

Systematic reviews of the role of salt-reduced diets and weight-loss diets have shown small, long-term effects on BP. However, it would be problematic to make generalisations about the effect of the DASH diet for many different populations(11,12).

In the present study, we combined the principles of the DASH-Na diet with the ingestion of low-GI foods that are highly consumed in Brazil to design a diet that could be affordable, sustainable and culturally acceptable. Thus, the aim of the present study was to evaluate the impact of a Brazilian dietary approach to hypertension on BP levels and

Abbreviations: BP, blood pressure; CG, control group; DASH, Dietary Approaches to Stop Hypertension; DBP, diastolic blood pressure; EG, experimental group; GI, glycaemic index; SBP, systolic blood pressure.

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urinary Na and K excretion in hypertensive patients who were being monitored by primary health care providers in a poor region of Brazil.

**Methods**

The randomised trial was conducted in two primary care health units that assist hypertensive patients (Program HiperDia of the Brazilian Ministry of Health). The units were situated in the urban area of the city of São Luís, Maranhão, Brazil.

**Participants**

Participants who were at least 20 years of age were recruited between January 2010 and September 2011 from the list of participants in the Program HiperDia, a programme dedicated to the treatment of hypertensive patients located in the city of São Luís, Maranhão, Brazil. Patients with diabetes, chronic renal diseases and cancer, as well as pregnant women, were excluded from the study. Of the 673 total eligible patients, 206 individuals were randomised into either the control group (CG) or the experimental group (EG). The patient randomisation list was computer-generated by blocking. Sealed envelopes were used at the clinic to randomise the patients. The progress of the patients during the study is shown in Fig. 1. Assuming a reduction in systolic BP (SBP) of 7.1 mmHg and a standard deviation of 10 mmHg(9), with a significance level of 5 % and 80 % power, a sample size of thirty-one subjects per arm (total n 62) was required.

A diagnosis of hypertension, as proposed by the Ministry of Health of Brazil and adopted by the HiperDia Program, was made for individuals with a SBP $\geq 140$ mmHg and/or diastolic BP (DBP) $\geq 90$ mmHg(1) who are not using antihypertensive medication(5). The present study was conducted according to the guidelines laid down in the Declaration of Helsinki, and all procedures involving human subjects/patients were approved by the Ethics Committee of the University Hospital of Federal University of Maranhão (protocol no. 312/09) and the trial was registered at the Brazilian Register Clinical Trials of the Ministry of Health of Brazil (no. RBR8ztcv9). Written informed consent was obtained from all subjects/patients.

**Intervention.** Both groups (EG and CG) received standard care focused on salt intake reduction and hypertension control. The EG, in addition to standard care, also received monthly nutritional counselling provided by a nutritionist, which was based on the principles of the DASH(13) and the glycaemic levels of common foods(14). These recommendations were focused on foods with a low to moderate GI (GI <70), with glucose as the reference standard and using the foods listed in the ‘International Tables of Glycemic Index and Glycemic Load Values’(15).

Compared with regular diets, the one proposed in the present study encouraged increased intake of fruits, vegetables, low-fat dairy products, beans and manioc products, while discouraging excess consumption of salt, meats and meat products and sugar-sweetened beverages. Food item choices were also adapted to the local production and eating habits (Fig. 2).

The CG received standard care focused on reducing Na intake, according to assistance provided by the health unit. At the end of the study, an adapted Brazilian diet was also recommended for implementation by the CG.

**Data collection**

Subjects answered a questionnaire on sociodemographic data, co-morbidities and lifestyle factors. Physical activity level was measured by a validated questionnaire that included leisure, occupational, commuting and housework activities(16). Weight was measured using an electronic digital scale (Líder®), and height was measured using a portable stadiometer (Alturexata®). BMI was calculated as weight in kg divided by the square of height in m (kg/m²). BMI were classified according to the WHO standards, which are defined as follows: $<25.0$ kg/m²; $25.0–29.9$ kg/m²; $\geq 30.0$ kg/m²(17).

Dietary intake was estimated by three non-consecutive 24 h records, including two weekdays and one weekend day, in

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**Fig. 1. Progress of the participants during the study.**
which all foods and beverages consumed, their time of consumption, the quantity consumed (in units of household measurements), the form of food preparation and the location of preparation were recorded. For more detailed information, a form with instructions about how to report food consumption was provided to the participants.

Nutritional analysis was performed using BRASIL-NUTRI software, which was developed by Instituto Brasileiro de Geografia e Estatística and has been utilised by national surveys (18).

BP was measured using an electronic sphygmomanometer (HEM-742INT; Omron), in accordance with the procedures recommended by the American Heart Association (19). Overall, three measurements were taken, and the mean was calculated.

A 24 h urinary Na and K excretion test was performed. Patients received appropriate bottles and were carefully instructed to collect all urine produced during the 24 h period, to continue drinking water normally throughout the day and to discard the first urine in the morning of the initial collection day (20). Urinary Na excretion was measured spectrophotometrically and converted to mEq/l. Na intake was estimated by assuming that approximately 86% of the total Na intake of the day is excreted in the urine (21).

Nutritional counselling

During the 6-month follow-up study, BP and anthropometric measures were recorded monthly, and food consumption evaluation took place both in the third month and at the end of the study. On the evening of the day before the appointment, patients were contacted to either confirm their clinical appointment or reschedule it.

The EG received a diet plan with a food equivalency list and schedules in which food groups and servings were distributed according to and between the main meals. This plan was reinforced in each visit beginning with the first appointment. The foods included in dietary recommendations were based on the DASH diet (13), with the reduction of salt intake and the inclusion of low-GI food items (14). Thus, increased consumption of fruits, vegetables, fish, whole grains, parboiled rice, beans and natural spices (such as pepper, garlic, chives, green scent and oregano) was emphasised to reduce Na intake. The diet was therefore also high in K, Mg and fibre, as well as being lower in saturated fat, total fat, cholesterol, refined grains, Na and sweets. Encouraged foods are outlined in Fig. 2.

The recommendations included daily consumption of the following: three servings of low-fat milk; three to five servings of fruits; four to five servings of vegetables; one serving of legumes; five to nine servings of grains, roots and tubers; one to two servings of meat, mainly fish. Additionally, all food consumption was to be distributed over five to six meals a day (22).

In the follow-up appointments, the diet plan was adjusted and nutrition education was discussed. Conversations focused on patient difficulties and the importance of healthy eating habits. At the end of the study, the groups underwent a new 24 h urine collection.

Fig. 2. Food groups included in the basic menu.

- Breakfast and snacks
  - Milk products: skimmed milk, creamed curd, white low-fat cheese and low-fat yogurt
  - Bread: whole bread, French bread, oat (oat bran), maize or rice, couscous maize or preparation of maize, cassava, whole or water cracker
  - Fruits: avocado, pineapple, acerola, count fruit, banana, hog-plum, cashew, star fruit, guava, jackfruit, orange, lemon, apple, mango, papaya, passion fruit, watermelon, melon, pear, pitomba, sapodilla, tangerine, grape
- Lunch and dinner
  - Cereals (every day): parboiled/coarse rice, rice with vinegar or other greens and pasta
  - Beans (every day): bean and soya
  - Green vegetables: cabbage leaf, lettuce and vinegar
  - Others vegetables: carrots, cabbage, cassava, cucumber, eggplant, gherkin, onion, okra, pepper, pumpkin, tomato, sweet potato/potatoes and pod
  - Meats, eggs and fish: lean meat, beef liver, bovine viscera, eggs (egg white), fishes, skinless chicken, sardine fish, tuna fish, shrimp and mussels
  - Desserts: fruits, jelly fruit and jam
  - Soups: vegetables and beans without rice or pasta
  - Oils: olive oil and soyabean oil
  - Spices: garlic, bay leaf, chive, coriander, oregano, parsley leaf and pepper
Analysis
Age was categorised into <60 and ≥60 years. The family monthly income was also categorised into multiples of minimum wage (which in Brazil was approximately US$ 283-00): ≤2; 3–5; ≥6. Participants were classified as white or non-white according to their skin colour. Educational level was assessed in years of schooling: <4; 4–8; ≥8. Participants were classified as smokers or non-smokers, as well as alcohol consumers or non-alcohol consumers. Patients were considered physically active if they performed at least 150 min of weekly physical activity.

All statistical analyses were performed using SAS software (version 9.1; SAS Institute, Inc.). Initially, raw data were tested for normality using the Shapiro–Wilk test. The baseline characteristics of the two groups were compared using Student's *t* test if the variables were continuous or Fisher's exact test if the data were categorical. A paired *t* test was used to compare changes in urinary Na and K excretion from baseline to post-intervention. Repeated-measures regression analyses were performed for measurements of BP and weight using mixed models. Data were adjusted for baseline values of BP and weight, weight change, age and duration of intervention. Results were considered as statistically significant if the *P* value of the *t* test was precisely at a one-tailed level of 0.05.

Results
Of the 206 individuals randomised in the study, 156 completed the data collection (Fig. 1). The baseline characteristics of the participants in the two groups are shown in Table 1. No significant differences in any of the characteristics were observed between the groups, except for age.

All patients received essential drugs for hypertension treatment monthly. Antihypertensive medications provided by the Ministry of Health and taken by the subjects consisted of angiotensin-converting enzyme inhibitors, β-blockers and the diuretic hydrochlorothiazide. A total of one, two or three antihypertensive agents were used by 64, 33 and 3% of the subjects, respectively.

Fig. 3 shows BP changes observed during the follow-up. Patients who underwent the dietary intervention had a statistically significant reduction in both SBP and DBP in comparison with CG patients (*P*=0.02, *P*=0.04, respectively). The mean of both SBP and DBP decreased by 14.4 and 9.7 mmHg, respectively, in the EG, compared with 6.7 and 4.6 mmHg in the CG.

After adjusting for baseline values of BP and weight, age and duration of intervention, there was a 7.9 mmHg DBP and a 1.7 kg weight reduction in the EG. For both analyses, the variable time × intervention, which tests changes over time related to the intervention, was statistically significant (Table 2).

Table 3 reports the 24 h urinary Na and K excretion in all patients. At baseline, the mean urinary Na in the EG was 151 mEq/24 h. At the 5-month follow-up, the mean urinary Na dropped to 106 mEq/24 h. This 43.4 (95% CI 99, 114) mEq/24 h reduction was statistically significant (*P*<0.01). In the CG, urinary Na increased by 2.5 mEq/24 h, which was not significantly different (*P*=0.77). The 24 h urinary K increased by 3.4 mEq/24 h in the EG and decreased by 4.1 mEq/24 h in the CG, but the changes were not statistically significant (*P*=0.13 and *P*=0.07).

Food intake at baseline and follow-up (first-wave follow-up) and at the last month of the follow-up (second-wave follow-up) are shown in Table 4. In the EG, a gradual increased intake of the encouraged foods that the patients were counselled to eat was observed throughout the intervention period.

Changes over time in dietary intake were associated with a greater and statistically significant change in the GL of the intervention group compared with the CG. A 9.6 reduction in the intervention group compared with the CG was observed, but this change was mostly related to a reduction in carbohydrate intake with almost no change in the GL. A statistically significant reduction in lipids in the intervention compared with the CG was also observed (Table 5).

Discussion
The present study showed that individuals diagnosed with hypertension who were being treated by a primary health care provider and who were advised to follow a low GI and DASH diet showed a reduction in both BP and urinary Na excretion.

The hypotensive effect of the experimental diet when compared with the control, based mainly on salt reduction, was 12.1 mmHg for SBP and 7.9 mmHg for DBP, values that are of high clinical significance. The levelling effect on BP observed at 3 months was probably contributed to the initial expectations...
of the patient related to his/her participation in a study for hypertension treatment and the type of assistance provided, which led patients to achieve greater self-care and feel more assisted by the health team. However, this effect was not maintained until the end of the experiment; the nutritional intervention was received by the CG only after the completion of the study.

The reductions observed in the present study were greater than those observed in the studies of salt reduction alone. Meta-analyses of randomised controlled trials showed that the effects of reduced Na intake on BP in hypertensive patients are about half of those observed in the present study, but also showed a greater effect on SBP reduction. Thus, Horvath et al.\(^{(12)}\) noted a significant reduction in SBP and DBP (6·26 and 3·41 mmHg, respectively). Similarly, Graudal et al.\(^{(23)}\) reported a reduction in SBP and DBP levels of by 3·5%. However, another meta-analysis conducted by Taylor et al.\(^{(24)}\) showed modest SBP and DBP reductions that were not statistically significant.

The results of studies using only the DASH diet vary in the magnitude of its effect. The results of long follow-up studies such as the one in this study are much smaller than those observed in this study. The original DASH study\(^{(13)}\), conducted among 133 hypertensive patients, compared the effects of a traditional American diet with one enriched by fruits and vegetables. Notably, both diets contained 3000 mg/d of Na. At an 8-week follow-up, an 11·4 mmHg reduction in SBP and a 5·5 mmHg reduction in DBP were observed. In a subsequent clinical trial, the effects of a traditional American diet and a DASH diet on BP levels were compared using three levels of Na intake. The lower Na content (1500 mg) DASH diet exhibited an 11·9 mmHg SBP reduction when compared with a traditional American diet with a higher Na content (3000 mg)\(^{(19)}\).

The multicentre PREMIER study (Trial of Lifestyle Interventions for Blood Pressure Control) tested several 6-month follow-up dietary interventions, including the DASH, as part of an intervention using general behaviour modification to reduce BP\(^{(25)}\). The DASH group exhibited a 14·2 mmHg reduction in SBP and a 7·4 mmHg reduction in DBP, which were statistically significant. Similarly, Huggins et al.\(^{(26)}\) evaluated the effect of the DASH diet intervention in hypertensive patients in a 4-week follow-up study, and observed a 16·7 mmHg reduction in SBP and a 10·3 mmHg reduction in DBP. Modest but significant results have been reported by Hsieh et al.\(^{(27)}\), who achieved reductions in SBP (5·9 mmHg) and DBP (3·7 mmHg) in a 6-month follow-up study using a community nutritional education programme to decrease BP. On the other hand, a study conducted by Charlton et al.\(^{(28)}\) showed BP reduction after the first 4 weeks that was not observed throughout the entire follow-up period (8 weeks).

Compared with randomised studies\(^{(15,25,28)}\) and meta-analyses\(^{(12,23)}\), combining salt reduction and dietary changes in a free-living population, in which dietary changes were based only on counselling, exhibited a significant reduction in BP. This indicates that the combination of DASH-Na with

![Fig. 3. (a) Systolic blood pressure and (b) diastolic blood pressure according to intervention. Values are means, with their standard errors represented by vertical bars. Mean values were significantly different for the experimental (n 105, •) and control (n 101, ○) groups (P < 0·05).](https://www.cambridge.org/core/doi/10.1017/S0007114513000718)

Table 2. Blood pressure and weight changes during the follow-up according to intervention*

<table>
<thead>
<tr>
<th>Follow-up (months)</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>Time × intervention P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic (mmHg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0·08</td>
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<tr>
<td>Experimental</td>
<td>143·8</td>
<td>141·0</td>
<td>137·4</td>
<td>135·5</td>
<td>133·5</td>
<td>131·7</td>
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<tr>
<td>Control</td>
<td>142·9</td>
<td>144·0</td>
<td>143·3</td>
<td>141·7</td>
<td>140·9</td>
<td>140·0</td>
<td></td>
</tr>
<tr>
<td>Diastolic (mmHg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt;0·01</td>
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<tr>
<td>Experimental</td>
<td>84·6</td>
<td>83·1</td>
<td>80·6</td>
<td>79·2</td>
<td>77·9</td>
<td>76·7</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>82·7</td>
<td>82·8</td>
<td>82·6</td>
<td>81·9</td>
<td>81·5</td>
<td>81·0</td>
<td></td>
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<tr>
<td>Weight (kg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt;0·01</td>
</tr>
<tr>
<td>Experimental</td>
<td>65·7</td>
<td>65·3</td>
<td>65·0</td>
<td>64·7</td>
<td>64·3</td>
<td>64·0</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>64·5</td>
<td>64·4</td>
<td>64·4</td>
<td>64·4</td>
<td>64·4</td>
<td>64·3</td>
<td></td>
</tr>
</tbody>
</table>

* The PROC MIXED model included weight, weight change, age, blood pressure at baseline, time and time × intervention (variable that measures changes over time).
A low-GI diet is an effective approach to reduce hypertension in the clinical setting. Changes in BP were also attributed to the weight reduction observed in the present study. While weight change did not explain the overall reduction in both SBP and DBP, as indicated in the analysis adjusted for BMI at baseline and the change in BMI, it was also a positive effect of dietary intervention. Weight change could not be easily maintained in longer follow-ups (9, 14), but the effect on BP was independent of weight change.

The results from randomised controlled trials examining the association between GI and CVD risk factors including BP and weight loss have not been consistent (29–32). The PREMIER study examined these associations, but GI changes were not associated with changes in any risk factors at 6 months (33). A low-GI diet is easy to follow in Brazil because beans and manioc are staple foods of very low glycaemic index (14). The present results suggest a role for this approach combined with the DASH diet.

Recently, the Institute of Medicine Committee has recommended a level of Na intake no higher than 1500 mg/d (65 mEq/d) (34). However, accomplishing this recommendation is not easy. A reasonable recommendation is the upper limit of 2300 mg/d (100 mEq/d), which is similar to previous recommendations for the prevention and treatment of hypertension (6, 35).

In Brazil, Na intake is approximately 4500 mg/d and largely exceeds the maximum recommendation (36). In the present study, EG patients achieved the minimum mean values of 106 mEq/d in urinary Na excretion after the dietary intervention, with a 43·4 mEq/d reduction that was statistically significant. This finding does not quite match the amount recommended by the Institute of Medicine Committee (34), it is close to other reasonable recommendations (6, 35).

A Meta-Analysis of Healthful Diet Trials, Salt Reduction Counselling (37) demonstrated a statistically significant decrease in urinary Na excretion. Another meta-analysis, conducted by Taylor et al. (24), showed that a reduction in dietary salt intake was able to decrease urinary Na excretion by 39·1 mEq/24 h, although this result was not statistically significant. In clinical trials, Nowson et al. (38) and Huggins et al. (26) observed a 43·1 and 36·1 mEq/d reduction in urinary Na excretion, respectively, after 4 weeks of the DASH diet intervention. However, the multicentre PREMIER study noted a 32·6 mEq/d reduction in urinary Na excretion of the DASH diet intervention group that did not reach statistical significance (25).

Minor reductions in urinary Na excretion were found in the original DASH study (13), which showed a 10·1 mEq/d reduction with a diet enriched with fruits and vegetables and a 3·2 mEq/d reduction with the DASH diet. In another study, Robare et al. (39) evaluated the effects of a DASH low-Na diet in 115 hypertensive patients in the USA using a 6-month follow-up study and observed a small decrease in urinary Na excretion (6 mEq/d). On the other hand, Charlton et al. (28) noted a greater reduction

### Table 3. Urinary sodium and potassium excretion of the participants according to intervention (Mean values and 95% confidence intervals)

<table>
<thead>
<tr>
<th>Urinary excretion (mEq/24 h)</th>
<th>Change from baseline (mEq/24 h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental group</td>
<td>Control group</td>
</tr>
<tr>
<td>Mean</td>
<td>95% CI</td>
</tr>
<tr>
<td>Baseline (n 206)</td>
<td></td>
</tr>
<tr>
<td>Na (mEq/24 h)</td>
<td>151·0</td>
</tr>
<tr>
<td>K (mEq/24 h)</td>
<td>42·0</td>
</tr>
<tr>
<td>Post-intervention (n 156)</td>
<td></td>
</tr>
<tr>
<td>Na (mEq/24 h)</td>
<td>106·0</td>
</tr>
<tr>
<td>K (mEq/24 h)</td>
<td>45·0</td>
</tr>
</tbody>
</table>

* P calculated using a paired t test of the change in urinary Na from baseline to post-intervention.
in urinary Na excretion (14.6 mEq/d) over a shorter follow-up period (8 weeks) after a low-Na diet intervention in hypertensive patients in South Africa.

The present findings on the reduction in urinary Na excretion are similar to those of randomised controlled trials (27,38) and meta-analyses (37), again supporting the feasibility of dietary intervention in reducing Na in primary health care settings by tailoring changes in the diet to the habits of the population.

The current trend in Brazilian eating habits is characterised by a reduced consumption of fruits and vegetables (40), which are good sources of K, and the dietary intervention conducted in this study promoted an increased intake of all food groups for the EG. Although we observed an increase in food intake after the intervention, there was no significant difference in K excretion in the urine at 24 h after the intervention. One potential explanation for this finding may be the tendency for certain patients to overestimate their records of consumed foods considered beneficial to their treatment.

Furthermore, although our dietary counselling focused on changes in carbohydrate composition beyond changes in the lipid content of the diet, the most important changes observed were related to a lower load of carbohydrates in the EG, followed by a reduction in the fat content of the diet.

One positive aspect of the present study was that the monitoring of patients emphasised actively promoting compliance with keeping appointments and rescheduling missed appointments based on convenience and patient availability. Another positive point involves the methodology applied: a longitudinal 24-week follow-up study; analysis of Na and K intakes conducted by a 24 h urinary excretion test; detailed 24 h food records documented on three different occasions during the intervention. This method allowed for greater knowledge of the patients’ eating habits, which may be reflected in the results. On the other hand, a limitation of the present study was that the hypertensive population was mainly composed of female and elderly patients at primary health care facilities.

In conclusion, dietary intervention to reduce BP tailored according to eating habits may have a major effect on BP reduction.

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