Original Article

Effectiveness of a two-component nutritional strategy for blood pressure control in individuals with hypertension users of a public health system: a randomized controlled clinical trial

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Objective: To evaluate the effectiveness of a nutritional strategy based on two components and adapted for the public health system on blood pressure, cardiometabolic features, self-care, qualify of life and diet quality in individuals with hypertension.

Methods: NUPRESS was an open-label, parallel-group, superiority randomized controlled clinical trial in which participants at least 21 years with hypertension and poorly controlled blood pressure were randomly assigned (1 : 1 allocation ratio) to either an individualized dietary prescription according to nutritional guidelines (control group, $n = 205$); or a two-component nutrition strategy, including a goal-directed nutritional counseling and mindfulness techniques (NUPRESS [intervention] group, $n = 205$). Primary outcomes were SBP (mmHg) after 24 weeks of follow up and blood pressure control, defined as either having SBP more than 140 mmHg at baseline and achieving 140 mmHg or less after follow-up or having SBP 140 mmHg or less at baseline and reducing the frequency of antihypertensive drugs in use after follow-up.

Results: In total, 410 participants were randomized and submitted to an intention-to-treat analysis regarding primary outcomes. Both groups decreased blood pressure, but after adjusting for baseline values, there was no significant difference between them on SBP [intervention-control difference: -0.03 (-3.01; 2.94); $P = 0.98$] nor blood pressure control [odds ratio 1.27 (0.82; 1.97); $P = 0.28$]. No differences between groups were also detected regarding secondary and tertiary outcomes.

Conclusion: There was no difference between a two-component nutritional strategy and an established dietary intervention on blood pressure in participants with hypertension.

Keywords: controlled clinical trial [Publication Type], diet, healthy, hypertension, public health, quality of life, self-care

Abbreviations: 95% CI, 95% confidence intervals; BP, blood pressure; BSC, Brazilian Society of Cardiology; COVID-19, Coronavirus disease 2019; DASH, Dietary Approach to Stop Hypertension; EAC-HI, Brazilian Self-care of Hypertension Inventory scale; IP-Hcor, Hcor Research Institute; LDL-c, low-density lipoprotein cholesterol; mAHEI, modified Alternative Healthy Eating Index; MINICHAL, Mini-Cuestionario de Calidad de Vida en la Hypertensión Arterial; SMS, short message services

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INTRODUCTION

Hypertension is the leading cause of cardiovascular disease worldwide, particularly those related to lost years of life, such as stroke and heart failure [1]. Furthermore, the economic, social, and individual health impact of inadequate blood pressure (BP) control affects developed and developing countries, with the highest rates of low adherence to antihypertensive drugs being described in low and middle-income countries and non-Western countries [2].

In addition to the proper use of antihypertensive medications, the treatment to control BP involves adherence to nonpharmacological treatment, which depends on a behavioral change. Among the components related to lifestyle change, healthy eating [such adherence to the Dietary Approach to Stop Hypertension (DASH) diet and reduction in both sodium and ultraprocessed foods intake] is the most effective nonpharmacological intervention for BP levels in individuals with hypertension [3]. In addition to BP, lifestyle changes should also focus on metabolic targets related to the occurrence of clinical outcomes associated with hypertension, such as increased body mass, impaired blood glucose, and abnormal lipid profile [4]. However, because it is a treatment based on behavioral changes, the effectiveness of nonpharmacological treatment is highly related to the individual's adherence to the recommendations and, consequently, to their self-care.

Strategies have been proposed and discussed to increase patients' perception of their health and improve treatment adherence and self-care in people with chronic diseases [5,6]. However, some elements, such as respect for local culture, the environment, and access to technology, regardless of the format, are crucial for constructing these strategies [7,8]. Patient involvement in decision-making regarding their treatment appears to increase engagement as well [9]. Despite all these points, most of the strategies that prove to be effective for BP control (especially regarding diet) were tested on more developed contexts, are not affordable, and are based exclusively on the expertise/prescription of the health professional [10–12].

A few randomized controlled trials were designed to test and evaluate the effectiveness of different multicomponent strategies based on lifestyle change in individuals with hypertension [13–16]. In addition, these studies primarily focus on disease-centered outcomes; however, a few address patient-centered outcomes, such as quality of life [17]. Conversely, they consider diet to be an added element to nonpharmacological treatment rather than prominently. Indeed, the way the diet is guided, whether through counseling or a more prescriptive approach, could also have a distinct effect on outcomes. Therefore, this study aimed to evaluate the effectiveness of a nutritional strategy based on two components and adapted for the public health system on BP control in individuals with hypertension. Furthermore, cardiometabolic markers, diet quality, self-care, and participants' quality of life were assessed.

MATERIALS AND METHODS

Trial design

NUPRESS was an open-label, parallel-group, superiority randomized controlled trial conducted at eight Brazilian sites between April 2019 and July 2021. We randomly assigned participants in a 1 : 1 allocation ratio and a 24-week follow-up to either an individualized dietary prescription alone, according to the Brazilian Society of Cardiology (BSC) guidelines (control group), or a two-component nutrition strategy, including a goal-directed nutritional counseling (without dietary prescription) and mindfulness techniques [NUPRESS (intervention) group]. The study coordination staff generated a permuted block randomization list with blocks of random sizes stratified by center and granted central allocation concealed via the study website using a validated software. Although participants and providers could not be blinded because of the intervention characteristics, the laboratory staff were blinded to treatment allocation.

Sites were geographically distributed across the five Brazilian regions. Hcor Research Institute (IP-Hcor, São Paulo, Brazil) coordinated the trial. The study procedures complied with the ethical human research principles established in the Declaration of Americas, and in the 466/12 resolution from Brazilian National Health Council. Hcor Institutional Review Board approved the study, as well as each participating site. Furthermore, all participants signed a consent form before inclusion in the trial, which was administered by a trained researcher. NUPRESS trial was registered in the ClinicalTrials.gov database under the identification number NCT03793881.

Participants

Each study site was responsible for disseminating the trial to promote both screening and recruitment, according to eligibility criteria and regional aspects of the population. The study was disseminated through many strategies such as social media, partnerships with health services, and cardiology, endocrinology, or nutrition outpatient clinics. Patients were invited in person or by telephone to participate in the trial, and those who volunteered were also accepted into the study. For individuals who met the inclusion criteria, a visit was scheduled with the research team in each site to confirm eligibility. All volunteers were advised to fast overnight for 12 h before the initial consultation.

In this study, we included men and women diagnosed with hypertension aged at least 21 years, with SBP at least 140 mmHg during the screening, and without a history of nutritional counseling in the past 6 months. Diagnosis of hypertension was confirmed by medical records or medication prescriptions, and participants could also confirm SBP values with both medical records and images of their home-monitoring devices. We excluded candidates previously diagnosed with resistant or secondary hypertension, severe neuropathy, autoimmune disease (or chronic use of steroids), an acute coronary syndrome in the previous 60 days or chronic heart failure, active cancer, or any neurological, cognitive, or psychiatric condition, at the researcher's discretion; with a life expectancy of less than 6 months for any reason; with a drug or alcohol addiction; who used

antipsychotic drugs; pregnant or nursing women; who presented any condition that could prevent or distort anthropometric assessments (e.g., need for a wheelchair); with BMI at least 40 kg/m^2; and who were involved in other clinical trials.

Interventions

Control group

The control group received individualized dietary prescriptions based on the BSC guidelines [18] and the DASH diet principles (to increase the intake of foods that are rich in potassium, calcium, and magnesium, such as fruits, vegetables, whole grains, low-fat dairy, nuts, and seeds; and to limit the intake of foods that are rich in sodium, saturated fats and added sugars, including meats and ultra-processed foods) [10]. Furthermore, we introduced the concepts of the "10 Steps to Healthy Eating" proposed by the Brazilian Ministry of Health to be used in the context of the publica health system in Brazil (Supplementary Material, Methods 1, http://links.lww.com/HJH/C423).

Participants assessed as overweight or with obesity (BMI $>$ 25 kg/m^2) were advised to follow a 20–25 kcal/kg/day prescription diet, and those eutrophic (BMI 19–24.9 kg/m^2) were informed to follow a 25–30 kcal/kg/day prescription diet for body weight maintenance. Dietary plans ranged from 1400 to 2400 kcal/day, categorized into portions of foods. In addition to the calorie and portion recommendations, participants received a list of equivalent foods to make substitutions. Dietitians were responsible for dietary prescriptions. During follow-ups, participants were reassessed once a month, in person or by web meetings, and each visit lasted approximately 30–45 min; the last visit was longer due to blood sample collection, lasting about 1 h30 min. Therefore, the total energy value was recalculated when necessary, and the recommendations were adapted. An illustrative diet plan considering 2000 kcal/day, including macronutrient distribution and suggested meals, is presented in the Supplementary Material (Methods 2 and 3, http://links.lww.com/HJH/C423). We made no specific recommendations regarding physical activity levels.

All participants received a validated personal BP monitoring home device to be used during the study (digital sphygmomanometer G-Tech model BP3BK1–3; Shenzhen, China) and a personal booklet to record self-monitoring pressure values twice a week at prespecified dates and times. This booklet was to be brought in for staff checkups at every follow-up visit and returned to the research team at the end of the study.

NUPRESS group

Participants in the NUPRESS group received a two-component nutrition strategy based on goal-directed nutritional counseling and mindfulness strategies [including short message services (SMS)] rather than dietary prescription. We made no specific recommendations regarding physical activity levels and dietitians were responsible for delivering the intervention. During monthly follow-ups, participants were reassessed, in person or by web meetings, and each visit lasted approximately 30–45 min; the last visit was longer due to blood sample collection, lasting about 1 h30 min.

Goal-directed nutrition counseling

We predefined 11 goals for nutritional counseling according to previous studies and the American Heart Association's healthy diet score (all based on foods/nutrients related to the DASH diet or in those to promote cardiovascular health): at least two portions of 170 g/day of fruits; at least six portions of 30 g/day of vegetables; at least two portions of 100 g/week of fish and seafood; less than two portions of 100 g/week of red meat; less than 1 l/week of sweetened sugar beverages; at least three portions of 30 g/day of whole cereals; $\geq$ 1 portion of 80 g/day of legumes; $\geq$ 3 portions of 30 g/week of nuts; $\leq$ 3 portions of 30 g/week of processed meat; at least one portion of 250 g/day of dairy; less than 4 portions/day of ultra-processed foods [19,20].

The baseline assessment of eating behaviors and choice of goals in each visit was completely patient-oriented and always discussed and supported by the registered dietitian. In each follow-up visit, the participant could reassess their improvement and subsequently readjust up to five goals based on what they deemed feasible. We introduced the same concepts of "10 Steps to Healthy Eating" proposed by the Brazilian Ministry of Health to their counseling (Supplementary Material, Methods 1, http://links.lww.com/HJH/C423) as the control group; however, it was adapted to a mindful approach. All discussions were based on this semi-quantitative approach (number of portions for each type of food).

Mindfulness and mindfulness-based text messages

We invited participants to attend a group meeting (2–10 participants) with a duration of approximately 90 min to apply the mindful-based intervention 30 days from baseline (second study visit). During this session, trained researchers on mindfulness moderated a discussion on hunger signals and how to identify them and a meditation session focused on conscious breathing (one strategy based on mindful-eating and the other based on mindfulness protocols). The standardized scripts used in these groups are presented in Supplementary Material (Methods 4, http://links.lww.com/HJH/C423). After the group meeting, we shared guided audio with the participants with the same mindful content. We encouraged them to practice both mindful strategies (identification of hunger signals and guided breathing) at least twice a week at their discretion. Furthermore, during each subsequent study visit, the researchers emphasized the significance of incorporating these practices.

We sent monthly SMS to all participants to remind them to practice both mindfulness strategies. The list of all forwarded messages is presented in Supplementary Material (Methods 5, http://links.lww.com/HJH/C423).

Participants in the NUPRESS group also received the personal BP monitoring home device and booklet and were encouraged to monitoring their BP and to document it and the frequency of their mindfulness practices.

Study procedures

We trained all researchers (in person or remotely) according to the standard operating manual created for this trial at each investigation site, with a particular emphasis on variables that may deviate due to inter and intra-observer variations, including anthropometric and food consumption

measurements. All research information was obtained using a standardized case report form.

At baseline, all participants were administered a standardized questionnaire for demographic, clinical, and lifestyle data collection. Socioeconomic and education data were evaluated based on the Brazilian Criteria for Economics Classification [21]. Physical activity levels were assessed according to the International Physical Activity Questionnaire short version, translated and validated into Portuguese [22]; low levels of physical activity were considered if the participant reported less than 600 metabolic equivalent of task/week. Quality of life was evaluated using the *Mini-Cuestionario de Calidad de Vida en la Hypertensión Arterial* (MINICHAL) questionnaire [23], which was specific for hypertension and validated in Portuguese. Furthermore, Self-care was assessed using the Brazilian Self-care of Hypertension Inventory scale (EAC-HI) [24], specific for hypertension and validated in Portuguese; self-care was considered adequate for scores at least 70 points.

Dietary habits were evaluated using 24-h food recalls, and a food frequency questionnaire [25] adapted to capture ultra-processed food intake. In addition, a photo album containing images of standardized food portion sizes was used to assist in food intake evaluation. Diet quality was assessed by the modified Alternative Healthy Eating Index (mAHEI) [26], and all dietary data were recorded in a specific software suite (*Sistema Vivanda de Alimentação*, São Paulo, Brazil), which prioritizes the use of Brazilian and American food composition tables [27,28].

SBP and DBP were assessed using an automatic electronic BP monitor (Omron model HEM-705CP; Kyoto Head Office, Japan) calibrated and validated according to the BSC guidelines [18]. BP was measured three times after 3–5 min of rest between the measures. Baseline BP was measured during a single face-to-face office visit, and the outcome BP was assessed at a subsequent face-to-face follow-up after six-months.

Anthropometric and biochemical data were collected according to standardized procedures described in Supplemental Material (Methods 6, http://links.lww.com/HJH/C423).

All procedures performed in each study visit are described in the Supplementary Material (Table S1, http://links.lww.com/HJH/C423).

Coronavirus disease 2019 (COVID-19)-related protocol amendments

Because the follow-up of this study occurred during the COVID-19 pandemic, adaptations to the protocol were necessary both to ensure participant safety and to facilitate the study's follow-up [29]. The major change was replacing the face-to-face follow-up visit with the remote follow-up visit (by phone or video call). In addition, the laboratory tests previously performed in the hospital's clinical laboratory also started to rely on home collection. Similarly, both recruitment and consent became virtual.

Because of this change in the protocol, we emphasized that our primary outcome (SBP) on many occasions was measured by the participants at home and referred to during the remote contact. Another necessary adaptation refers to the holding of group meetings, which was part of the two-component intervention proposal. These group meetings ceased to exist, and the topics that would have been discussed in a group were discussed individually with each participant remotely. The remote format included telephone contact. As this intervention is more associated with changing the participant's behavior, we understand that telephone contact (without seeing the person) may not be the best alternative. However, it is essential to emphasize that NUPRESS study participants were from the Brazilian public health service, mostly individuals without resources and access to video calling programs or other contact possibilities.

Outcomes

Our primary outcomes were changes in SBP (in mmHg) and BP control at 6-month follow-up. BP control was defined as if the participant had SBP more than 140 mmHg at baseline and achieved SBP 140 mmHg or less after follow-up; or if the participant had SBP 140 mmHg or less in both baseline and after follow-up but reduced the frequency of antihypertensive drugs in use.

Secondary outcomes were, in a 6-month follow-up, changes in DPB, quality of life, self-care, anthropometric measures, biochemical parameters, and diet quality. As tertiary outcomes, we evaluated at 6 months the frequency/type of antihypertensive drugs in use and the percentage of participants who reached the following target therapeutic goals: SBP/DBP less than 140/90 mmHg, fasting glucose less than 100 mg/dl; low-density lipoprotein cholesterol (LDL-c) less than 100 mg/dl; BMI less than 25 kg/m^2 or weight loss more than 5%.

Sample size

Three hundred and fourteen participants would be needed for a power of 80% to detect a difference of 6 mmHg between-groups (intervention vs. control groups) under a standard deviation of 19 mmHg and an alpha of 0.05 [30]. Therefore, considering that loss to follow-up is common in lifestyle and nutrition trials, we enrolled 30% more participants, with a final sample size of 410 individuals. More considerations about sample size calculation and study power were described in the Supplementary Material (Methods 7, http://links.lww.com/HJH/C423).

Statistical analysis

All analyses followed the intention-to-treat principle. Demographic and clinical data were described as means and standard deviations, medians and interquartile ranges, or absolute and relative frequencies, as appropriate. SBP, secondary outcomes presented as continuous variables, and self-care at 6 months were analyzed using generalized estimating equations considering gamma distribution. Treatment effects were expressed as the mean difference with their respective 95% confidence intervals (95% CIs). Dichotomous variables were analyzed using generalized estimating equations considering binomial distribution and treatment effects expressed as odds ratios with their respective 95% CI. The use of types of antihypertensive drugs at 6 months was analyzed using Fisher's exact test. The quality of life through the MINICHAL questionnaire was assessed

using the Mann–Whitney *U* test. Diet quality was analyzed using generalized estimating equations considering gaussian distribution. Missing data regarding primary and secondary outcomes were imputed with the multiple imputation technique by Gibbs sampling with the chain equation method (100 replications) [31], according to the number of antihypertensive medications and BP observed at baseline, duration of hypertension, age, and sex; in this case, both means and proportions estimated were presented with their respective 95% CI and estimated median values were presented with interquartile range.

A sensitivity analysis of the primary and secondary outcomes was performed using only patients with SBP and DBP information at follow-up and no withdrawal. The models used for these analyses were the same as the main analysis.

A two-tailed alpha of 5% was considered as statistical significance, and all analyses were performed using the R statistical software. Adjustments for multiple testing were not made for secondary outcomes; in this sense, interpretation of *P* values and 95% CI regarding these results should be considered as exploratory.

RESULTS

Recruitment and participant characteristics

Overall, 952 individuals were screened between April 2019 and January 2021. Of these, 542 were excluded because they did not meet the inclusion criteria, were not interested in participating in the study, or were eligible but not randomized (Fig. 1). Overall, 410 men and women with hypertension were enrolled into the study at the eight participating centers from five Brazilian regions (South, Southeast, Middle-west, Northeast, and North), of which 205 were randomized to the control group and 205 to the intervention group.

Table 1 summarizes the participants' characteristics at the study's baseline. Women (62.2%) and white (48.5%) individuals predominated; 65% of participants were classified in lower socioeconomic strata, representing a family income between US$ 134.00 and US$ 560.00 per month. The mean age was 52.3 ± 11 years, the mean time since hypertension diagnosis was 10.4 ± 9 years, and the mean SBP and DBP were 138.5 ± 19 and 89.8 ± 12 mmHg, respectively. Generally, the characteristics were balanced between both groups; however, a higher proportion of women was allocated to the NUPRESS group, as well as smokers, more physically active, and those using dietary supplements.

Retention and adherence

The control group had 40 follow-up losses (13 withdrawals due to eligibility breaches - these individuals followed the protocol, 25 dropouts, and two changed cities). The NUPRESS group had 48 follow-up losses (12 withdrawals due to eligibility breaches - these individuals followed the protocol, 34 dropouts, and two changed cities). Therefore, 165 (80%) patients in the control group and 157 (77%) patients in the intervention group completed follow-up. All participants were included in the final analysis of the primary outcomes by intention to treat. Figure 1 shows the study flowchart.

No difference was observed in baseline characteristics between participants who completed the study and those who did not (Supplementary Material Table S2, http://links.lww.com/HJH/C423). However, among patients who did not complete the protocol, a higher proportion of individuals with higher levels of physical activity was observed in the NUPRESS group than in the control group ($P = 0.026$) (Supplementary Material Table S3, http://links.lww.com/HJH/C423).

BP home monitoring rates were 85.1 and 86.7% in the control and intervention groups, respectively ($P = 0.8$). Concerning attendance at study visits, no statistical differences were observed between groups (control vs. intervention). Specifically, for visit 2, attendance rates were 88.8 and 89.3%, for visit 3: 82 and 87.8%, for visit 4: 84.4 and 85.4%, and for visit 5: 89.3 and 88.8%, respectively.

Primary outcomes

Table 2 summarizes the primary outcomes after 6 months of follow-up according to the study groups. SBP decreased in both groups (Supplementary Material Table S4, http://links.lww.com/HJH/C423); however, after adjusting for baseline values, no significant difference was found between them [intervention-control difference: -0.03 (-3.01; 2.94); $P = 0.98$]. These results remained the same after adjusting for sex and socioeconomic status as well (data not shown). The proportion of individuals who achieved BP control was also not different between the groups at the end of the study [68.3 and 62.4% in the NUPRESS and control groups, respectively; intervention-control difference: 1.27 (0.82; 1.97); $P = 0.28$].

Secondary outcomes

Regarding cardiometabolic secondary outcomes, serum creatinine and albuminuria were lower in the NUPRESS group than in the control group after 6 months [intervention-control differences: -0.06 (95% CI -0.1; -0.01); $P = 0.01$ and -4.29 (95% CI -8.44; -0.15); $P = 0.04$, respectively], and no significant differences were found regarding the other biochemical data including urinary sodium (a nutrition biomarker of sodium intake). In addition, no differences were observed in BMI and waist circumference according to the groups (Table 2).

The results of mAHEI, quality of life, and self-care are described in Tables 3–5, respectively. Both groups improved the overall mAHEI score at the end of the study (Supplementary Material S5, http://links.lww.com/HJH/C423); however, no difference was observed between them after 6 months [intervention-control difference: 0.17 (95% CI -1.58; 1.92); $P = 0.85$]; there was also no difference between the groups regarding the individual components of the mAHEI (Table 3). Table 4 shows the quality of life identified by MINICHAL at baseline and after 6 months. No difference was found between the groups in the general score and individual domains (mental status and somatic manifestations) at baseline and neither after follow-up. Regarding self-care, after 6 months, the intervention group had a higher score in the "self-care management" domain of the EAC-HI scale than the control group [intervention-control difference: 1.73 (95% CI 0.85; 2.6); $P < 0.01$] (Table 5). Although in an intragroup analysis, we identified a significant improvement in both groups regarding overall EAC-HI score [control

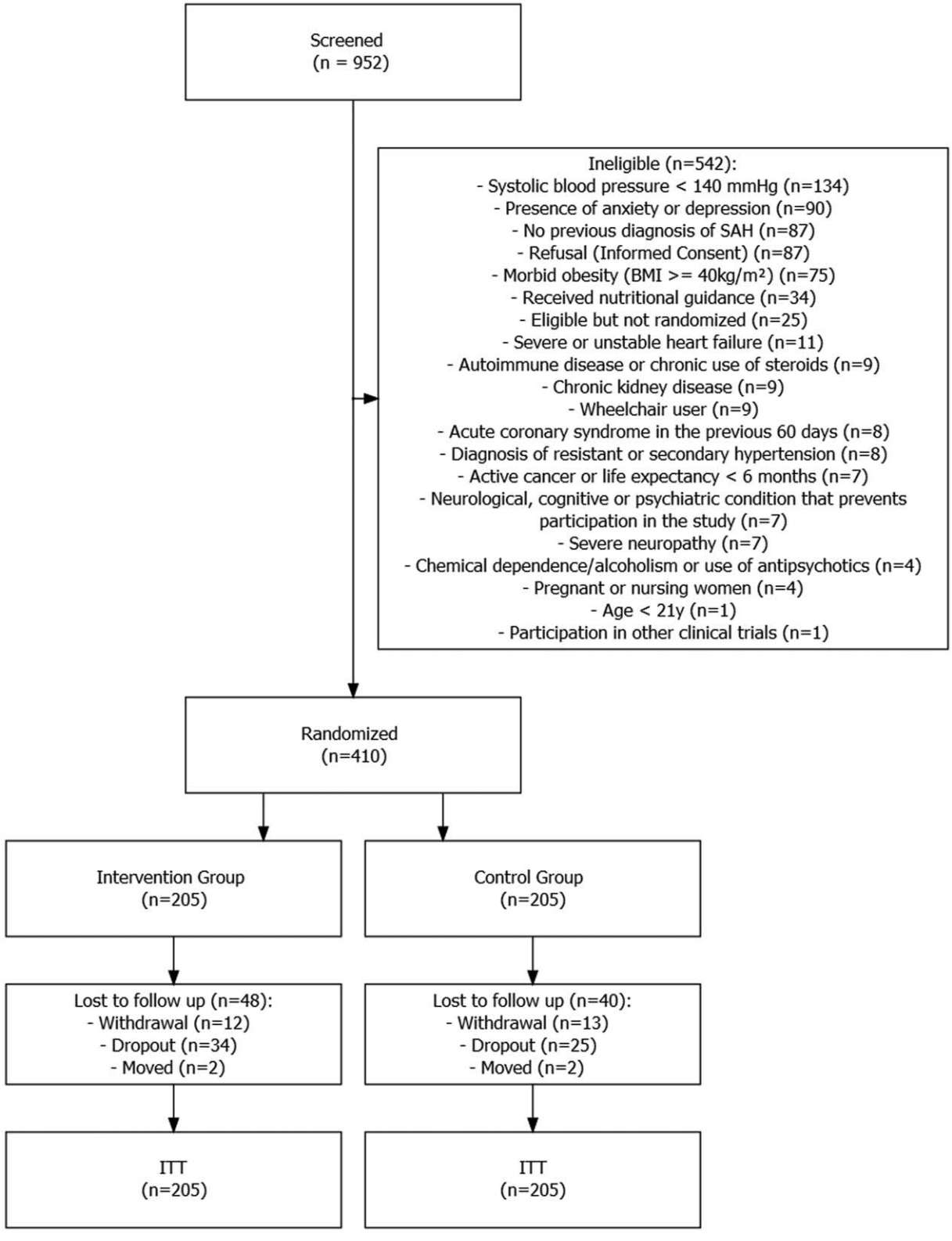

FIGURE 1 NUPRESS study flowchart. ITT, intention to treat; SAH, systemic arterial hypertension.

group: 2.42 (95% CI 0.66; 4.18); $P = 0.007$; NUPRESS group: 4.63 (95% CI 2.66; 6.60); $P < 0.001$], no difference was found between the groups in the overall score of the scale and in the proportion of individuals considered to have adequate self-care ($\geq$ 70 points) (Table 5).

Prespecified tertiary outcomes

No difference was observed between the groups about the antihypertensive drugs in use after 6 months (Supplementary Material Table S6, http://links.lww.com/HJH/C423). A slight improvement in the prevalence of individuals who

TABLE 1. Baseline characteristics of study participants

	NUPRESS Group ($n = 205$)	Control Group ($n = 205$)
Female sex - no./total no. (%)	144/205 (70.2)	111/205 (54.1)
Age, in years, mean (SD)	52.1 (11.5)	52.4 (11.8)
Race - no./total no. (%)		
White	97/205 (47.3)	102/205 (49.8)
Black	32/205 (15.6)	33/205 (16.1)
Multiracial	71/205 (34.6)	66/205 (32.2)
Other race	5/205 (2.4)	4/205 (2)
Family status - no./total no. (%)		
Married	107/205 (52.2)	127/205 (62)
Other	98/205 (47.8)	78/205 (38)
Years of study - no./total no. (%)		
< 5 years	16/203 (7.9)	23/202 (11.4)
5 to < 8 years	28/203 (13.8)	20/202 (9.9)
8 to < 11 years	25/203 (12.3)	20/202 (9.9)
11 to < 15 years	79/203 (38.9)	77/202 (38.1)
≥ 15 years	55/203 (27.1)	62/202 (30.7)
Average monthly family income - no./total no. (%)[a]		
US$ 4405.00	8/203 (3.9)	12/202 (5.9)
US$ 1,960.00	10/203 (4.9)	15/202 (7.4)
US$ 1012.00	46/203 (22.7)	50/202 (24.8)
US$ 560.00	53/203 (26.1)	60/202 (29.7)
US$ 371.00	58/203 (28.6)	42/202 (20.8)
US$ 134.00	28/203 (13.8)	23/202 (11.4)
Current smokers - no./total no. (%)	22/203 (10.8)	14/202 (6.9)
Alcohol abuse - no./total no. (%)	19/203 (9.4)	23/202 (11.4)
Physical activity - no./total no. (%)		
Low levels	113/203 (55.7)	137/202 (67.8)
Moderate/high levels	54/203 (26.6)	40/202 (19.8)
Time of diagnosis of hypertension, in years, mean (SD)	11.3 (9.9)	9.5 (8.9)
Drugs in use - no./total no. (%)		
Blood pressure lowering agents	193/203 (95.1)	191/202 (94.6)
Lipid-lowering agents	53/203 (26.1)	57/202 (28.2)
Glucose-lowering agents	36/203 (17.7)	34/202 (16.8)
Antiplatelet therapy	34/203 (16.7)	31/202 (15.3)
Number of antihypertensive drugs in use - no./total no. (%)		
0	10/203 (4.9)	11/202 (5.4)
1	60/203 (29.6)	69/202 (34.2)
2	86/203 (42.4)	81/202 (40.1)
≥ 3	47/203 (23.2)	41/202 (20.3)
Use of dietary supplements - no./total no. (%)[b]	58/203 (28.6)	37/202 (18.3)
Previous medical diagnosis - no./total no. (%)		
Dyslipidemia	64/203 (31.5)	78/202 (38.6)
Type-2 diabetes mellitus	35/203 (17.2)	37/202 (18.3)
Angina	8/203 (3.9)	13/202 (6.4)
Stroke	6/203 (3)	9/202 (4.5)
Myocardial infarction	11/203 (5.4)	7/202 (3.5)
Heart failure	7/203 (3.4)	4/202 (2)
Retinopathy	0/203 (0)	5/202 (2.5)

SD, standard deviation.
[a]1 US$ = 5.30 Brazilian Reais.
[b]Omega 3, phytosterol, hypercaloric supplement, hyperproteic supplement, multivitamin, calcium, iron, vitamin D, probiotic, prebiotic, and symbiotic.

reached the target's therapeutic goals at the end of the study in comparison to baseline was found in both groups. However, no difference was observed between them at 6 months (Supplementary Material Table S7, http://links.lww.com/HJH/C423).

Adverse events

Table S8 (Supplementary Material, http://links.lww.com/HJH/C423) describes the main adverse events identified during the study, according to the groups. Approximately 37% of the participants had at least one adverse event, with peak high BP (systolic and/or diastolic) being the most frequent (control group: 16.1%; intervention group: 17.1%; $P = 0.89$).

Sensitivity analysis

Sensitivity analyses, including only participants who completed the protocol, showed the same results for BP, biochemical data, therapeutic targets, and drugs in use (Supplementary Material Tables S9–S11, http://links.lww.com/HJH/C423).

DISCUSSION

In this study, compared to the control group, we observed no significant differences in SBP values or BP control between patients with hypertension who underwent a diet strategy based on nutritional advice added to other

TABLE 2. Primary and secondary biochemical outcomes according to study groups.

Outcome	Baseline CG ($n = 205$)	Baseline NG ($n = 205$)	6 months CG ($n = 205$)	6 months NG ($n = 205$)	Between-group mean difference (95% CI)[a]
Primary outcomes					
SBP (mmHg)	139.12 (136.41; 141.83)	137.85 (135.27; 140.43)	134.98 (132.73; 137.23)	134.95 (133; 136.9)	−0.03 (−3.01; 2.94)
Blood pressure control			62.4 (55.8; 69.1)	68.3 (61.9; 74.7)	1.27 (0.82; 1.97)[b]
Secondary outcomes					
DBP (mmHg)	89.79 (88.04; 91.54)	89.76 (88.01; 91.51)	88.27 (86.52; 90.03)	88.24 (86.6; 89.87)	−0.04 (−2.44; 2.36)
Fasting glucose (mg/dl)	106.31 (100.38; 112.23)	105.32 (100.37; 110.27)	101.31 (97.71; 104.9)	102.7 (98.55; 106.85)	1.39 (−4.1; 6.89)
Glycated hemoglobin, %	5.91 (5.74; 6.09)	5.96 (5.78; 6.15)	5.83 (5.69; 5.97)	5.84 (5.71; 5.97)	0.01 (−0.17; 0.2)
Total cholesterol (mg/dl)	200.87 (194.94; 206.8)	202.56 (196.52; 208.59)	199.62 (193.69; 205.56)	202.34 (196.83; 207.85)	2.72 (−5.38; 10.82)
LDL-cholesterol (mg/dl)	116.39 (111.08; 121.7)	121.28 (116; 126.56)	114.88 (109.64; 120.11)	118.22 (113.44; 123.01)	3.35 (−3.75; 10.45)
HDL-cholesterol (mg/dl)	51.74 (49.88; 53.6)	51.01 (49.41; 52.6)	52.57 (50.86; 54.29)	52.32 (50.49; 54.16)	−0.25 (−2.76; 2.26)
VLDL-cholesterol (mg/dl)	32.96 (29.44; 36.49)	30.54 (28.36; 32.72)	31.62 (29.22; 34.02)	32.64 (29.61; 35.66)	1.02 (−2.84; 4.88)
Non-HDL cholesterol (mg/dl)	149.13 (143.29; 154.96)	151.55 (145.72; 157.38)	147.05 (141.14; 152.96)	150.6 (145.07; 156.12)	3.54 (−4.55; 11.63)
Castelli I index	4.1 (3.93; 4.28)	4.13 (3.97; 4.3)	3.99 (3.82; 4.15)	4.07 (3.9; 4.24)	0.08 (−0.15; 0.32)
Castelli II index	2.49 (2.35; 2.62)	2.56 (2.43; 2.7)	2.42 (2.28; 2.55)	2.48 (2.36; 2.61)	0.06 (−0.12; 0.25)
Triglycerides (mg/dl)	164.82 (147.18; 182.45)	152.71 (141.81; 163.61)	158.08 (146.08; 170.08)	163.18 (148.06; 178.31)	5.11 (−14.2; 24.41)
Body weight (kg)	83.95 (81.66; 86.23)	83.23 (81.02; 85.44)	83.18 (80.9; 85.45)	82.69 (80.46; 84.91)	−0.49 (−3.67; 2.69)
BMI (kg/m^2)	30.95 (30.3; 31.6)	31.44 (30.81; 32.07)	30.67 (30.02; 31.31)	31.22 (30.59; 31.85)	0.55 (−0.35; 1.45)
Waist circumference (cm)	101.09 (99.54; 102.65)	100.84 (99.23; 102.45)	99.7 (98.39; 101)	99.94 (98.54; 101.33)	0.24 (−1.67; 2.15)
Creatinine (mg/dl)	0.96 (0.93; 1)	0.9 (0.87; 0.92)	0.98 (0.94; 1.01)	0.92 (0.89; 0.95)	−0.06 (−0.1; −0.01)*
Glomerular filtration rate (ml/min/1.73 m^2)	77.71 (75.05; 80.38)	78.27 (75.88; 80.66)	75.88 (73.2; 78.55)	76.1 (73.8; 78.41)	0.23 (−3.31; 3.76)
Serum sodium (mEq/l)	140.41 (140.04; 140.77)	140.38 (140.04; 140.73)	139.63 (139.15; 140.12)	139.62 (139.07; 140.18)	−0.01 (−0.75; 0.73)
Urinary sodium (mEq/l)	113.46 (106.62; 120.3)	111.65 (105.11; 118.19)	112.94 (106.7; 119.17)	111.08 (104.88; 117.27)	−1.86 (−10.65; 6.93)
Serum potassium (mEq/l)	4.22 (4.16; 4.28)	4.28 (4.21; 4.35)	4.19 (4.13; 4.24)	4.17 (4.11; 4.22)	−0.02 (−0.1; 0.05)
Urinary potassium (mEq/l)	61.83 (57.78; 65.88)	59.51 (55.64; 63.39)	59.89 (56.09; 63.69)	62.65 (58.52; 66.77)	2.75 (−2.86; 8.36)
Albuminuria (mg/g)	16.29 (10.72; 21.86)	12.22 (9.78; 14.66)	14.12 (10.35; 17.89)	9.83 (8.11; 11.55)	−4.29 (−8.44; −0.15)**

Data expressed as means (95% CI) or proportions (95% CI).
CG, control group; HDL, high-density lipoprotein; LDL, low-density lipoprotein; NG, NUPRESS group; VLDL, very low-density lipoprotein.
[a]Mean differences between groups (intervention − control) at 6 months, 95% CI, and *P* values were obtained using the Generalized Estimating Equation with gamma distribution.
[b]Odds ratio, 95% CI, and *P* values were obtained using GEE with a binomial distribution.
*$P = 0.01$.
**$P = 0.04$.

TABLE 3. mAHEI components scores and total mAHEI score at baseline and after 6 months of follow-up according to study groups

	Baseline CG ($n = 205$)	Baseline NG ($n = 205$)	6 months CG ($n = 205$)	6 months NG ($n = 205$)	Between-group mean difference (95% CI)[a]
Fruits	3.92 (3.43; 4.42)	4 (3.49; 4.52)	4.23 (3.79; 4.67)	4.38 (3.95; 4.82)	0.15 (−0.46; 0.77)
Vegetables	2.81 (2.42; 3.19)	2.77 (2.38; 3.16)	3.37 (3.04; 3.7)	3.6 (3.23; 3.96)	0.23 (−0.27; 0.72)
Nuts and soy protein	5.39 (4.77; 6.01)	5.58 (4.97; 6.18)	5.68 (5.13; 6.23)	5.54 (5.03; 6.05)	−0.14 (−0.89; 0.61)
Ratio of fish/(meat + eggs)	0.28 (0.07; 0.49)	0.25 (0.05; 0.45)	0.6 (0.32; 0.88)	0.4 (0.19; 0.6)	−0.2 (−0.55; 0.14)
Whole grains	2.43 (1.92; 2.93)	2.39 (1.9; 2.88)	3.54 (3.04; 4.04)	3.36 (2.92; 3.81)	−0.18 (−0.85; 0.49)
Fried foods	7.4 (6.86; 7.94)	8.16 (7.71; 8.61)	8.36 (7.97; 8.74)	8.76 (8.43; 9.09)	0.41 (−0.1; 0.91)
Alcohol intake	0.63 (0.33; 0.92)	0.18 (0.02; 0.34)	0.64 (0.37; 0.91)	0.55 (0.28; 0.82)	−0.09 (−0.48; 0.29)
Total mAHEI score	22.86 (21.53; 24.19)	23.33 (22.1; 24.55)	26.41 (25.21; 27.62)	26.59 (25.32; 27.85)	0.17 (−1.58; 1.92)

Data expressed as means (95%CI). All *P* values > 0.05.
CG, control group; mAHEI, modified Alternative Healthy Eating Index; NG, NUPRESS group.
[a]Mean differences between groups (intervention − control) at 6 months, 95% CI, and *P* values were obtained using the Generalized Estimating Equation with a Gaussian distribution.

TABLE 4. MINICHAL domains scores and total MINICHAL score at baseline and after 6 months of follow-up according to study groups.

	Baseline CG ($n = 205$)	Baseline NG ($n = 205$)	6 months CG ($n = 205$)	6 months NG ($n = 205$)	95% CI[a]
Mental status domain	6 [3; 9]	7 [4; 10]	−1 [−4; 3]	−1 [−4; 2]	0 (−1; 1)
Somatic manifestations domain	3 [1; 5]	4 [2; 6]	−1 [−3; 0]	−1 [−3; 0]	0 (0; 1)
Total MINICHAL score	10 [6; 15]	12 [7; 17]	−2 [−6; 1]	−2 [−6; 1]	0 (−1; 1)

Data expressed as median (interquartile range). All *P* values > 0.05.
CG, control group; MINICHAL, Mini Cuestionario de Calidad de Vida en Hipertensión Arterial; NG, NUPRESS group.
[a]Differences between groups considering the difference between 6 months and baseline, 95% CI, and *P* values were obtained using the Mann–Whitney test.

TABLE 5. EAC-HI domains scores and total EAC-HI score at baseline and after 6 months of follow-up according to study groups.

	Baseline CG ($n = 205$)	Baseline NG ($n = 205$)	6 months CG ($n = 205$)	6 months NG ($n = 205$)	Between-group mean difference (95% CI)[a]
Self-care maintenance domain	38.49 (37.53; 39.45)	38.92 (37.9; 39.95)	40.48 (39.55; 41.41)	41.15 (40.26; 42.04)	0.68 (−0.61; 1.96)
Self-care management domain	17.82 (17.1; 18.55)	18.45 (17.78; 19.13)	17.53 (16.89; 18.17)	19.26 (18.66; 19.86)	1.73 (0.85; 2.6)*
Self-care confidence domain	25.14 (24.49; 25.79)	24.35 (23.76; 24.95)	26.19 (25.7; 26.68)	25.67 (25.12; 26.23)	−0.52 (−1.26; 0.23)
Total EAC-HI score	81.4 (79.86; 82.94)	81.69 (80.12; 83.25)	84.08 (82.54; 85.62)	86.03 (84.48; 87.59)	1.95 (−0.24; 4.14)
$\geq$ 70 points	85.85 (81.08; 90.63)	86.34 (81.63; 91.05)	92.2 (88.52; 95.87)	92.2 (88.52; 95.87)	1 (0.95; 1.05)[b]

Data expressed as means (95% CI) or proportions (95% CI).
CG, control group; EAC-HI, Brazilian Self-care of Hypertension Inventory scale; NG, NUPRESS group.
[a]Mean differences between groups (intervention – control) at 6 months, 95% CI, and *P* values were obtained using the Generalized Estimating Equation (GEE) with gamma distribution.
[b]Odds ratio, 95% CI, and P-values were obtained using the GEE with a binomial distribution.
*$P \leq 0.01$.

components. No differences between groups were also observed regarding cardiometabolic markers, diet quality, self-care, and quality of life.

Studies that evaluated the effect of multicomponent interventions on BP/metabolic control and diet quality in individuals with high BP are scarce were conducted in different socioeconomic contexts. These presented heterogeneous designs and interventions and had controversial results. For the most part, diet is one of the components that make up the intervention; however, assessing how it is guided was not the main focus. For example, a cluster study conducted in Argentina concluded that a strategy comprising health coaching for patients and families in their homes (conducted by community workers), residential BP monitoring, medical intervention, and messaging and text was more effective in reducing SBP, DBP, and improvement in BP control than in the control group at 6 months [13]. Among African–Americans, a before-and-after study where health coaching and social support strategies performed by individuals from the community were used, self-monitoring of BP and monthly sessions of nutrition education and physical activity found a reduction in SBP and DBP at 6 months, rather than in anthropometric parameters, lipid and glycemic profile, and overall diet quality [14]. Similar results (including improved quality of life) were obtained in Latin Americans in another before-and-after study conducted for 90 days, where a similar intervention was applied [15]. In the PREMIER trial, the participants allocated to the groups that received from health professionals guidelines established for BP reduction (reduction of body mass, increase in physical activity, reduction of sodium, and alcohol consumption) plus or not the DASH diet guidance; similarly, SBP decreased. The prevalence of participants with controlled BP at the end of the study did not differ between the groups [16].

Our study was designed for a socioeconomic context representative of most of our population. Although social support and the participation of community members who translate health knowledge in an accessible manner to the population contribute to the maintenance of health-related behaviors and, consequently, to the management of BP [32], the effectiveness of this strategy has not yet been established [33]. Furthermore, we adapted our protocol based on the service structures available in the public system.

Individuals with hypertension traditionally have low treatment adherence rates due to factors related to the patient, such as the difficulty in recognizing the severity of the disease or related to the treatment. In this sense, the greater the complexity of the guidance provided regarding modification and lifestyle and the number of prescribed drugs, the worse the adherence rates [34]. Although the NUPRESS strategy was based on elements of nutritional counseling and mindfulness (components already related to better control of body mass [35] and decrease in BP [36]), self-monitoring [37], sending simple text messages, and providing homemade recipes in an attempt to increase adherence to treatment and self-care, in the participant's perception our intervention may have added complexity to previously received guidance; however, a significant portion of our sample was on polypharmacy. Studies that evaluated the contribution of BP self-monitoring, patient engagement in their treatment, mindful-eating full protocols or mindfulness programs on BP, metabolic control, and diet quality in individuals with hypertension are inconclusive [36,38,39] and, eventually, of low methodological quality [40].

It is known that subadditivity of the effects of an intervention can occur in the presence of treatments where multiple components are implemented simultaneously; this implies that when applied together, they produce an effect at least as large as anyone individually but less than their sum [16,41,42]. Regarding lifestyle changes, adherence can influence subadditivity, considering that multiple components are frequently oriented simultaneously, and making numerous behavior changes concurrently becomes difficult.

The COVID-19 pandemic has affected food security and access to food in low-income and middle-income countries with a consequent reduction in diet quality [43–45], impacting more women and individuals with low socioeconomic status [44]. Simultaneously, there was an increase in levels of a sedentary lifestyle in the general population [45], a decrease in access to health professionals/services, and an interruption of using some medication among individuals with chronic diseases [46]. When elderly people with multiple comorbidities were asked about their interest in participating in scientific research between May and September 2020, 32% did not have it for studies that required blood collection and 27% for those whose intervention was related to behavior change [43]. Among individuals with hypertension and/or dyslipidemias interviewed in the same year, 10% reported paying less attention to their health in that period, 25% decreased adherence to treatment, and a negative association was observed between undergoing

more complex treatments and quality of life [47]. Therefore, similarly to other studies of behavioral intervention in hypertension [48], the COVID-19 pandemic may have impacted our results considering the scenario during the study, changes in the protocol necessary during the conduction of the study, and interference in data collection mainly on the primary outcome.

Although no significant differences were observed between groups, both interventions positively impacted BP, overall diet quality, and participants' self-care – despite the phenomenon of regression toward the mean might have contributed to these results. In this sense, more than one nutritional strategy could be considered in clinical practice for managing hypertension in the context of public health. Among the potential causes for the similar improvement of these parameters between the groups, we can mention the Hawthorne effect or the result of the interaction between the participants and the researchers responsible for the interventions, which was probable contamination between the groups, considering that the study was not blinded. Therefore, choosing the DASH diet as the dietary control pattern is considered the best available evidence for the dietary treatment of hypertension independently of the way of delivering (prescribed or counseled).

This study had limitations. Despite the multicentric characteristic, our sample was not representative of the population with hypertension, and it may not have been sufficient to identify any difference between the groups. We did not use ambulatory BP monitoring devices to screen for uncontrolled BP and did not consider diagnoses of masked or white-coat hypertension. Our rates of loss to follow-up were high, although similar to other clinical studies where dietary interventions were evaluated. The impact of the intervention on the primary outcome may have been diluted, considering that the NUPRESS strategy enabled adaptations in dietary counseling according to the presence of other cardiometabolic risk factors. We did not apply full protocols or mindfulness programs in the study, but only two simple strategies based on mindful eating and mindfulness. Both intensity of our intervention and the follow-up period might not have been sufficient to detect any difference between the groups. And finally, we did not evaluate the adherence of each intervention component (diet and mindfulness) isolated, as well as their impact on the outcomes when assessed in separate. Among the strengths of the study, we highlight the proximity to real life considering the scenario where the study was conducted and the accessible technologies used; standardization of equipment used by research centers to collect BP data; the changes made in the research protocol that, even limiting the collection of certain data, enabled the continuity of the study and the application of interventions; and the intensive training that both research teams and participants received regarding the management of BP.

In conclusion, this multicenter randomized clinical trial found no differences between a two-component nutritional strategy and established dietary interventions for BP control in participants with poorly controlled hypertension. However, considering the potential impacts of the COVID-19 pandemic on our study, more randomized trials are needed to confirm or not our results.

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Conflicts of interest

There are no conflicts of interest.

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