# Effects of the DASH Diet and Walking on Blood Pressure in Patients With Type 2 Diabetes and Uncontrolled Hypertension: A Randomized Controlled Trial

Tatiana P. Paula, PhD RD; Luciana V. Viana, PhD MD; Alessandra T. Z. Neto, MSc; Cristiane B. Leitão, PhD MD; Jorge L. Gross, PhD MD; Mirela J. Azevedo, PhD, MD

From the Endocrine Division, Hospital de Clínicas de Porto Alegre, Federal University of Rio Grande do Sul, Porto Alegre, Brazil

Data on the potential beneficial effects of combining diet and exercise on blood pressure (BP) are still scarce. A 4week randomized controlled clinical trial was undertaken in 40 hypertensive patients with type 2 diabetes with uncontrolled blood pressure (BP) in office and daytime ambulatory BP monitoring (ABPM). Patients were assigned to follow a Dietary Approaches to Stop Hypertension (DASH) diet associated with advice to increase walking using a pedometer (intervention group) or a diet based on the American Diabetes Association recommendations (control group). The lifestyle intervention caused a greater ABPM

Hypertension is a major risk factor for the development and progression of chronic diabetic complications.<sup>1</sup> A seminal clinical trial demonstrated that lowering blood pressure (BP) reduces ischemic cardiac events, stroke, and nephropathy in patients with type 2 diabetes.<sup>2</sup> However, the BP control must be lifelong in order to maintain the reduction of risk for diabetic complications.<sup>3</sup> Generally, hypertensive diabetic patients take three or more antihypertensive drugs and most do not attain the BP goals.<sup>4</sup> In this sense, lifestyle modifications such as diet and physical activity, besides their beneficial influence on glucose control,<sup>5</sup> are key factors in the management of BP in patients with diabetes.<sup>6</sup>

Dietary recommendations for patients with hypertension include reduction of sodium intake, moderation of alcohol consumption, and the adoption of the Dietary Approaches to Stop Hypertension (DASH) diet eating plan.<sup>6–10</sup> Most of these dietary guidelines<sup>7–10</sup> were based on studies conducted in nondiabetic patients<sup>11,12</sup> and data on the effects of the DASH diet on BP in diabetic patients are scarce. BP reduction was observed in a trial conducted in Iranian patients with type 2 diabetes following a DASH diet.<sup>13</sup> Previously, in a cross-sectional study, we also described the beneficial effect of the DASH diet component on BP in patients with type 2 diabetes.<sup>14</sup> In those studies, BP was measured in the office. It is well-known that ambulatory BP monitoring (ABPM) provides the most

Address for correspondence: Tatiana P. de Paula, Hospital de Clínicas de Porto Alegre. Rua Ramiro Barcelos, 2350, Prédio 12, 4° andar. 90035-003 Porto Alegre, RS, Brazil E-mail: tatiana.ppaula@gmail.com

Manuscript received: March 18, 2015; revised: April 13, 2015; accepted: April 15, 2015 DOI: 10.1111/jch.12597 (mm Hg) reduction in systolic 24-hour, diastolic 24-hour, nighttime systolic, daytime systolic, and daytime diastolic measurements than observed in the control group. In the intervention group there was a decrease in urinary sodium and an increase in urinary potassium, plasma aldosterone, and the number of steps per day (P<.05). The DASH diet and increased walking were associated with clinically significant reductions in ABPM values in hypertensive patients with type 2 diabetes. *J Clin Hypertens* (*Greenwich*). 2015;17:895–901. © 2015 Wiley Periodicals, Inc.

accurate data on BP homeostasis.<sup>15</sup> However, we identified only one study conducted in nondiabetic patients that demonstrated an inverse association of the adherence to the DASH diet with BP as measured by ABPM.<sup>16</sup>

The long-term BP beneficial health effect of walking has already been demonstrated in patients with type 2 diabetes<sup>17</sup> and over 10,000 steps per day have been recommended for these patients.<sup>18</sup> A cross-sectional study conducted in patients with type 2 diabetes demonstrated that each increment of 1000 steps per day was associated with a small decrease in systolic and diastolic office BP in women.<sup>19</sup>

Therefore, the aim of the present study was to evaluate the effect of the DASH diet associated with increased walking on ABPM in patients with type 2 diabetes and uncontrolled hypertension.

# MATERIALS AND METHODS

The primary outcome was BP values as evaluated by ABPM and office BP measurements.

#### Patients

Outpatients with type 2 diabetes and hypertension were recruited to attend the study at the Endocrine Division of the Hospital de Clínicas in Porto Alegre, Brazil. Patients were selected if they had uncontrolled BP, defined as office BP  $\geq$ 140/90 mm Hg<sup>7</sup> and daytime ABPM  $\geq$ 135/85 mm Hg<sup>20</sup>, body mass index (BMI)  $\leq$ 40 kg/m<sup>2</sup>, and serum creatinine <176 mmol/L. Exclusion criteria were night shift work, physical disability that prevents patients from walking, presence of secondary causes of hypertension, or severe elevations in BP (>180/120 mm Hg). A total of 51 patients were initially screened and eight patients were excluded because of normal ABPM (white-coat hypertension), two refused to participate, and one presented a serious medical problem before the beginning of the protocol. Thus, 40 patients were included in the study.

The present study was conducted according to the Declaration of Helsinki<sup>21</sup> and was approved by the research ethics committee of the Hospital de Clínicas de Porto Alegre. Written informed consent was obtained from all patients. The present trial was registered at clinicaltrials.gov as NCT 01461330.

### Study Protocol

In this controlled randomized trial, patients were randomly assigned to the intervention group or the control group according to a computer-generated allocation system. At baseline, patients underwent 24-hour ABPM and their usual walking habits were assessed by daily step count using a pedometer during 1 week. Clinical, nutritional, and physical activity were assessed and laboratory evaluations were performed. This run-in period involved two office visits. The duration of the trial was 4 weeks and at the end of the study, ABPM and anthropometric and laboratory measurements were performed. Patients were advised not to change any usual medication during the study.

Intervention Group. This group was assigned to follow the DASH diet and to increase physical activity during the study. The DASH diet eating plan<sup>11,12</sup> was adapted to local dietary habits and was individually prescribed: total energy 25 kcal to 30 kcal of body weight, 55% of energy as carbohydrates, 18% as proteins, and 27% as total fat. The consumption of fruits, vegetables, low-fat dairy foods, whole grains, lean meat, nuts, seeds, and beans was encouraged. The intake of salt, fats, and sweets was discouraged. Whole bread and soya oil were provided during the study. An example of a dietary prescription is described in Appendix S1. Patients were asked to increase physical activity by walking at least 15 to 20 minutes per day, 5 days per week, in addition to their baseline activities. A pedometer was provided to be used during the 4-week intervention period. During the study, twice a week, text messages (SMS) were sent or phone calls were made to stimulate compliance with the general protocol. Patient counseling on diet was performed by the research dietitian (TPP) and on physical activity by the physical educator (AZN).

**Control Group.** Patients received dietary recommendations according to American Diabetes Association guidelines<sup>6</sup> and were instructed to maintain their usual physical activity during the study. The diet was individually prescribed: total daily energy, 25 kcal to 30 kcal of body weight, 50% to 60% of energy as carbohydrates, 10% to 20% as proteins, and 25% to 30% as total fat. Patients were advised to consume their usual type of bread, and soya oil was provided. An example of a dietary prescription for a patient in the control group is described in Appendix S1. A pedometer was provided to be used every day exclusively in the first and last week of the study to record usual physical activity.

### **Clinical Evaluation**

Office BP was measured twice after 10 minutes by a standard digital sphygmomanometer (Omron HEM-705CP, Omron Healthcare, Inc, Lake Forest, IL) with patients in a sitting position after a 5-minute rest. The mean of two measurements was used for analysis. Office hypertension was defined as BP  $\geq$ 140/90 mm Hg, measured on two occasions, and/or the use of antihypertensive drugs.<sup>7</sup> ABPM was evaluated by oscillometry using a Spacelabs device (90207; Spacelabs Healthcare, Snoqualmie, WA) with a validated certificate<sup>22</sup> at 15-minute intervals during the day and 20-minute intervals overnight, on an ordinary working day, starting around 8 AM. Sleep time was recorded as the period between the time when the patient went to bed and the time when the patient working.

Positive alcohol intake was considered in patients who mentioned the current intake of any amount of alcoholic beverage. Patients were classified as current smokers or not and were self-identified as white or nonwhite. Twenty-four-hour urinary albumin excretion (UAE) was classified as normal (<30 mg) or increased (>30 mg).<sup>6,23</sup> Increased UAE was always confirmed. Glomerular filtration rate (GFR) was estimated by GFR-EPIC<sup>24</sup> equation. Fundus examination was performed and diabetic retinopathy was graded as present or absent.

### **Physical Activity Assessment**

Physical activity was assessed by a standardized questionnaire<sup>25</sup> adapted to local habits and graded from a sedentary lifestyle to high physical activity and by a pedometer (Digi-Walker CW200, Yamax, Tokyo, Japan). While using a pedometer, patients also recorded their daily physical activity.

#### Nutritional Assessment

The body weight and height of patients were obtained using an anthropometric scale with measurements recorded to the nearest 100 g for weight and to the nearest 0.1 cm for height. Waist circumference was measured midway between the lowest rib margin and the iliac crest, near the umbilicus, using flexible nonstretch fiberglass tape. The percentage of fat was calculated by bioimpedance (InBody 230, Seoul, South Korea).

Dietary intake was evaluated by 24-hour dietary records, and nutrients were analyzed using Nutribase Clinical Nutritional software version 9 (CyberSoft Inc, Harris County, TX).

#### Laboratory Measurements

Blood samples were obtained after a 12-hour fast. Plasma glucose was determined by a glucose oxidase method, creatinine by Jaffe's reaction, glycated hemoglobin by ion-exchange high-performance liquid chromatography (reference range, 4.8%–6.0%), total cholesterol and triglycerides by enzymatic colorimetric methods, and high-density lipoprotein by a homogeneous direct

method. Low-density lipoprotein cholesterol was calculated using Friedewald's formula.<sup>26</sup> UAE was measured by immunoturbidimetry (Ames-Bayer, Tarrytown, NY). Serum brain natriuretic peptide (BNP) was measured in batches using a chemiluminescence technique (Centaur XP, Siemens, Munich, Germany). Plasma renin activity (PRA) and plasma aldosterone were determined by radioimmunoassay (Genesys LTi 1001, GMI, Ramsey, MN), potassium by colorimetric method, calcium by O-Cresolphtalein colorimetric technique, and sodium by selective ion

electrode.

#### Statistics and Data Analyses

Sample size was calculated based on a reduction of 22 mm Hg in office systolic BP after a 7-day dietary salt restriction (50 mmol of sodium) in patients with resistant hypertension.<sup>27</sup> Twenty participants would be required in each group to achieve a power of 80% and an  $\alpha$  of 0.05.

Student *t* test, Mann–Whitney *U* test, and Pearson chi-square were used as appropriate. Changes in variables during the study were analyzed by the general linear model (GLM) for repeated measures. Results were expressed as mean ( $\pm$ standard deviation), median ( $P^{25}-P^{75}$ ), or number of patients with the characteristic (percentage). Variables with non-Gaussian distribution

were log transformed before analyses; covariates were selected based on univariate analysis results and biological plausibility. *P* values <.05 were considered statistically significant. SPSS 18.0 statistical software (SPSS, Chicago, IL) was used for analysis.

# RESULTS

#### **Baseline Characteristics**

The baseline features of patients with type 2 diabetes are shown in Table I. There were no differences between the intervention and control groups regarding demographic features, anthropometric indices, lifestyle characteristics, office BP and ABPM values, and proportion of patients with diabetic retinopathy and increased UAE. In addition, GFR was not different between groups. The proportion of patients using angiotensin receptor blockers was higher in the control group than in the intervention group.

#### BP Measurements During the Study

Table II describes the changes in BP during the study. ABPM reduction in 24-hour and daytime, both systolic and diastolic, as well as systolic at nighttime, were greater in the intervention group than in the control group. There was no difference in the reduction of nighttime diastolic ABPM measurements between

<b>TABLE I.</b> Baseline Characteristics of Patients With Type 2 Diabetes						
	Control Group	Intervention Group	P Value			
Male/female, No.	6/14	12/8	.057 <sup>a</sup>			
Age, y	62.5±8.8	61.8±8.1	.810 <sup>b</sup>			
White ethnicity, No. (%)	18.0 (90.0)	16.0 (80.0)	.376 <sup>a</sup>			
Diabetes duration, y	16.1±7.4	16.9±7.9	.778 <sup>b</sup>			
Hypertension duration, y	18.4±7.8	16.7±9.5	.531 <sup>b</sup>			
Body mass index, kg/m <sup>2</sup>	30.2±3.5	28.6±2.5	.069 <sup>b</sup>			
Waist circumference, cm	103.7±11.6	99.4±9.6	.215 <sup>b</sup>			
Fat mass, %	<b>34.9</b> ±7.8	31.5±5.9	.120 <sup>a</sup>			
Sedentary, No. (%)	15 (75)	15 (75)	1.000 <sup>a</sup>			
Current alcohol intake, No. (%)	9 (45)	9 (45)	1.000 <sup>a</sup>			
Current smoking, No. (%)	1 (5)	3 (15)	.292 <sup>a</sup>			
Office systolic BP, mm Hg	163.6±19.0	166.9±16.2	.260 <sup>b</sup>			
Office diastolic ABPM, mm Hg	86.3±9.0	85.3±12.0	.206 <sup>b</sup>			
24-h systolic ABPM, mm Hg	147.4±15.4	148.1±12.2	.887 <sup>b</sup>			
24-h diastolic ABPM, mm Hg	82.2±8.9	82.4±8.4	.948 <sup>b</sup>			
Use of ACE inhibitors, No. (%)	11 (55)	16 (80)	.091 <sup>a</sup>			
Use of diuretics, No. (%)	15 (75)	15 (75)	1.000 <sup>a</sup>			
Use of ARB, No. (%)	9 (45)	2 (10)	.013 <sup>a</sup>			
Use of β-blockers, No. (%)	8 (40)	10 (50)	.525 <sup>a</sup>			
Use of aspirin, No. (%)	11 (55)	11 (55)	1.000 <sup>a</sup>			
Diabetic retinopathy, No. (%)	4 (22.2)	4 (22.2)	.704 <sup>a</sup>			
UAE >30 mg/24 h, No. (%)	12 (60)	12 (60)	<b>1.000</b> <sup>a</sup>			
eGFR, mL/min/1.73 m <sup>b</sup>	80.3±14.4	84.6±19.3	.425 <sup>b</sup>			

Abbreviations: ABPM, ambulatory blood pressure monitoring; ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blocker; BP, blood pressure; eGFR, estimated glomerular filtration rate; UAE, urinary albumin excretion. Data are expressed as mean (standard deviation), median ( $P^{25}-P^{75}$ ), number of patients with the characteristic (percentage).

<sup>a</sup>Pearson's chi-square.

<sup>b</sup>t test.

<b>TABLE II.</b> Blood Pressure Measurements in Patients With Type 2 Diabetes During the Study										
	Control Group				Intervention Group			Differences Between Groups		
	P			P				Р	Р	
	Baseline	Final	Value <sup>a</sup>	Change	Baseline	Final	Value <sup>a</sup>	Change	Value <sup>b</sup>	Value <sup>c</sup>
ABPM, mm Hg										
24-h systolic	146.9±14.9	144.3±14.6	.215	-1.5 (-5.8 to 2.5)	147.9±11.8	132.6±11.3	.000	-12.5 (-18.0 to -10.3)	.000	.000
24-h diastolic	81.5±8.9	78.3±6.8	.013	-2.0 (-8.0 to 0.0)	82.7±8.0	75.2±7.0	.000	-7.0 (-11.5 to -3.5)	.018	.013
Daytime systolic	148.3±14.3	146.1±15.6	.343	-3.0 (-10.8to 4.5)	151.3±10.7	134.0±9.4	.000	-15.0 (-24,5 to -9.8)	.000	.000
Daytime diastolic	84.1±9.6	81.7±6.3	.068	-1.5 (-5.5 to 1.5)	86.0±8.3	77.7±7.1	.000	-9.0 (-11.8 to -4.3)	.001	.003
Nighttime systolic	142.6±17.7	135.9±16.0	.004	-3.5 (-10.5to -2.0)	141.7±16.0	128.5±14.3	.000	-10.5 (-18.0 to -4.0)	.047	.041
Nighttime diastolic	75.2±8.6	72.6±9.3	.048	-3.0 (-5.8 to 0.8)	76.3±7.8	70.8±7.8	.000	-6.0 (-9.8 to 0.0)	.129	.207
Office blood pressure, mm Hg										
Systolic	$158.0{\pm}21.5$	151.7±16.6	.246	-6.3 (-54.0 to 24.0)	162.7±10.8	$145.1 \pm 13.0$	.000	-17.6 (-44.0 to 14.0)	.053	.021
Diastolic	79.4±8.1	80.7±8.5	.589	-0.9 (-21.0 to 11.0)	82.8±11.5	76.8±10.3	.045	-3.9 (-14.0 to 7.0)	.060	.013
General linear model for repeated measurements: <sup>a</sup> Difference within group. <sup>b</sup> Difference between groups. All ambulatory blood pressure monitoring (ABPM) analyses were adjusted to body mass index changes (covariate) during the study. Mann–Whitney <i>U</i> test: <sup>c</sup> Difference between group changes. Data are expressed as mean (standard deviation) or median ( $P^{25}$ – $P^{75}$ ).										

groups. ABPM changes were evaluated within the groups and all ABPM reductions were significant in the intervention group. In the control group, only the 24-hour diastolic and nighttime, systolic and diastolic, ABPM reductions were significant. At the end of study, 55% of patients in the intervention group reached values of daytime BP <135/85 mm Hg as compared with 15% in the control group (*P*=.008). All ABPM analyses were adjusted to BMI changes during the study.

Values of absolute changes in ABPM during the study in the intervention and control groups are also described in Table II. ABPM reduction was greater in the intervention group than in the control group in all periods, except for diastolic ABPM at nighttime (no difference between groups). The most relevant differences between ABPM changes were observed in daytime (12.0 mm Hg) and 24-hour (11.0 mm Hg) systolic ABPM.

There was a reduction in office BP only in the intervention group and changes in BP were higher in the intervention than in the control group. However, comparison of office BP values from baseline to end of study between groups did not attain statistical significance (GLM adjusted by BMI changes).

#### Other Measurements During the Study

There were no spontaneous complaints during the study regarding any aspect of the protocol in all studied patients.

Nutritional indices, pedometer measurements, metabolic indices, and hormonal measurements are described in Table III. The comparison of all evaluated baseline variables between the intervention and control groups did not differ (P>.05) (data not shown).

*Nutritional Indices.* There was no difference between groups regarding total energy and the intake of protein, carbohydrates, and lipids. Total fiber intake and soluble fiber were increased only in the intervention group and insoluble fiber intake did not differ between groups. BMI was reduced during the study in the intervention group but no difference was observed when BMI changes were compared between groups. Waist circumference and fat mass changes were also not different.

Daily urinary potassium increased in the intervention group as compared with the control group. Urinary sodium decreased only in the intervention group and urinary calcium did not change in both groups.

There were no differences in UAE changes between the groups, but a reduction in UAE was observed in patients in the intervention group.

**Pedometer Measurements.** The number of daily steps increased only in the intervention group. The change (median; range) in the number of steps was 2024 steps (494–4043) in the intervention group and -31 steps (-2918 to 3178) in the control group (Mann–Whitney U test; P<.001).

*Metabolic Indices.* Glycated hemoglobin was reduced in both groups. There was a trend to improve metabolic indices in the intervention group as suggested by a

Patients With Type 2 Diabetes										
	Control Group			Intervention Group						
	Baseline	Final	P Value <sup>a</sup>	Baseline	Final	P Value <sup>a</sup>	P Value <sup>b</sup>			
Nutritional indices and UAE										
Total energy, kcal, d	1742.3±550.9	1752.2±298.5	.045	1811.2±515.2	1585.3±320.8	.009	.634			
Carbohydrate, % energy	41.3±11.1	39.3±9.9	.096	47.6±7.1	47.1±7.3	.642	.387			
Protein, % energy	20.1±5.0	23.0±3.8	.014	21.4±5.6	23.5±6.7	.068	.626			
Lipids, % energy	38.2±9.0	36.8±8.0	.449	33.3±9.3	29.4±5.8	.031	.304			
Total fiber, g/d	16.5±6.1	14.1±4.8	.007	14.8±4.1	20.1±4.3	.000	.000			
Soluble fiber, g/d	5.2±2.3	4.7±2.1	.291	4.8±1.8	6.1±2.1	.003	.005			
Insoluble fiber, g/d	10.4±5.1	11.0±5.3	.542	9.8±3.6	12.9±2.9	.007	.121			
BMI, kg/m <sup>2</sup>	30.2±3.5	30.0±3.4	.152	28.6±2.5	28.0±2.6	.011	.102			
Waist circumference, cm	103.7±11.6	102.8±10.9	.033	99.4±9.6	97.6±8.8	.003	.152			
Fat mass, %	34.9±7.8	31.5±5.8	.821	34.9±8.6	31.3±5.8	.690	.902			
Urinary sodium, mEq/24 h	186.6±77.6	174.4±71.1	.400	190.2±96.8	127.2±75.3	.000	.017			
Urinary potassium, mEq/24 h	56.6±22.5	58.4±17.6	.619	55.5±14.2	70.4±20.6	.000	.012			
Urinary calcium, mEq/24 h	92.0 (49.5–177.0)	94.0 (58.3–186.5)	.840	73.0 (48.0–97.5)	63.0 (46.5–119.8)	.464	.707			
UAE, mg/24 h	43.5 (18.5–194.4)	33.4 (11.2–119.6)	.079	41.6 (22.1–185.8)	31.8 (10.2–132.7)	.015	.602			
Pedometer measurements										
Daily steps, 3 d	5848±2827	5708±2277	.552	6294±2544	8389±2680	.000	.000			
Metabolic indices										
Glycated hemoglobin, %	8.6±1.6	8.1±1.2	.002	8.8±1.9	8.2±1.8	.001	.944			
Fasting glucose, mmol/L	9.4±3.5	8.5±3.1	.840	9.5±4.8	6.9±2.4	.012	.238			
Total cholesterol, mmol/L	4.5±0.8	4.3±0.9	.410	4.8±1.0	4.5±0.9	.107	.566			
HDL cholesterol, mmol/L	1.6±0.13	1.6±0.14	.739	1.6±0.14	1.6±0.12	.831	.910			
Triglycerides, mmol/L	1.81 (1.2–2.5)	1.7 (1.2–2.4)	.950	1.8 (1.1–2.6)	1.5 (1.0–1.9)	.013	.081			
LDL cholesterol, mmol/L	2.4±0.6	2.4±0.6	.746	2.9±0.9	2.6±0.8	.020	.144			
Hormone plasma measurements	;									
BNP, pg/mL	15.8 (12.6–18.5)	19.6 (13.9–35.5)	.100	24.2 (14.2–58.2)	12.6 (7.6–21.3)	.001	.001			
PRA, ng/mL/h	3.8 (0.6–6.0)	3.3 (0.3–5.4)	.737	4.9 (2.7-8.2)	4.4 (0.9–10.0)	.214	.517			
Aldosterone, ng/dL	7.0 (3.2–9.7)	5.9 (2.8–8.9)	.535	5.7 (4.0–7.5)	9.4 (6.8–14.7)	.010	.024			
Abbreviations: BMI, body mass index: HDL, high-density lipoprotein: LDL, low-density lipoprotein. General linear model for repeated measurements:										
Abileviations: Divit, body mass index, mbc, ingredensity inpoprotein, Ebc, fow density inpoprotein. deneral interal model for repeated measurements.										

**TABLE III.** Nutritional Indices, Pedometer Measurements, Metabolic Indices, and Hormone Measurements in Patients With Type 2 Diabetes

Abbreviations: BMI, body mass index; HDL, high-density lipoprotein; LDL, low-density lipoprotein. General linear model for repeated measurements: <sup>a</sup>Difference within group. <sup>b</sup>Difference between groups. Urinary calcium, plasma aldosterone, urinary albumin excretion (UAE), plasma renin activity (PRA), brain natriuretic peptide (BNP), and triglycerides were log transformed before analyses. Data are expressed as mean (standard deviation) and median ( $P^{25}-P^{75}$ ).

significant reduction in fasting plasma glucose, triglycerides, and low-density lipoprotein cholesterol only in this group. However, these changes did not reach statistical significance.

*Hormonal Measurements.* Plasma BNP was reduced only in the intervention group. No changes in PRA occurred. Plasma aldosterone increased only in patients in the intervention group.

#### DISCUSSION

The present study demonstrated that hypertensive patients with type 2 diabetes and uncontrolled hypertension who followed a DASH diet associated with an incentive to increase daily walking during a 4week period had a major reduction in ABPM values. The greatest BP reduction was observed in 24-hour and daytime systolic BP, approximately 15 mm Hg, as compared with a reduction of 3 mm Hg in the control group.

The magnitude of observed BP reduction seems to be clinically relevant. ABPM measurements allow a full evaluation of BP homeostasis and are more predictive of cardiovascular events than office-based BP.15 Indeed, we have demonstrated in a cross-sectional study in patients with type 2 diabetes that systolic BP was the ABPM parameter mostly associated with echocardiographic left ventricular structural abnormalities and albuminuria.<sup>28</sup> Furthermore, every 10-mm Hg reduction in systolic BP was associated with a decrease of 13% in microvascular chronic diabetic complications and of 12% in fatal and nonfatal myocardial infarction.<sup>1</sup> Moreover, in our trial more than half of the patients in the intervention group reached the recommended goals for daytime ABPM.<sup>6,20,29</sup> Therefore, it should also be taken into account that lifestyle intervention was not associated with common side effects presented by antihypertensive drugs.<sup>7</sup>

The BP reduction of our patients assigned to the intervention group was comparable to office BP changes

observed in hypertensive patients included in the original DASH diet trial.<sup>11</sup> However, patients with uncontrolled hypertension were not included in that trial. A recent trial in Iranian patients with type 2 diabetes, designed to evaluate the effect of a DASH diet on cardiovascular risk factors, demonstrated a reduction of about 10 mm Hg in office BP after 8 weeks following a DASH diet.<sup>13</sup> In that study, patients had normal BP at baseline and there was no reference to the presence of hypertension or use of antihypertensive medications.

A daily increase of 33% in the number of steps (about 2000 steps) in our study confirmed the compliance with advice to increase physical activity in the intervention group. The end-of-study daily number of steps, although lower than the recommended 10,000 steps, <sup>17</sup> seemed to be important. An office BP reduction associated with a pedometer-based walking program (increment of 1562 steps per day) has already been described in patients with type 2 diabetes.<sup>30</sup> Indeed, a recent meta-analysis of randomized controlled trials demonstrated that physical activity advice reduces systolic and diastolic BP in type 2 diabetic patients.<sup>30</sup>

Our study was not designed to evaluate the independent effects of dietary and physical activity interventions on BP. However, taking into account published results of individual interventions, <sup>11–13,31</sup> we believe that both interventions have had a beneficial impact on BP in our study.

Reduction of BP in the present study has been particularly associated with the intake of some nutrients of the DASH diet. The increase in urinary potassium in the intervention group was associated with an increase in the intake of fruits and vegetables (data not shown), which are foods with a high potassium content.<sup>32,33</sup> Indeed, we previously demonstrated that fruits and vegetables were the DASH diet food groups most strongly associated with reduced BP in type 2 diabetic patients.<sup>14</sup> The beneficial effect of increased potassium consumption in reducing BP in people with hypertension was recently confirmed by a meta-analysis of randomized controlled trials and cohort studies.<sup>34,35</sup> In our study, the reduction of daily urinary sodium excretion in the intervention group indicates that these patients reduced their daily salt intake, from approximately 11.0 g to 7.0 g, which resulted in a reduction in B-type natriuretic peptide.<sup>36,37</sup> In fact, decreased urinary sodium has been connected with BP reduction in a free-living popula-tion.<sup>35,38</sup> A meta-analysis<sup>39</sup> on the health effect of lower salt intake (<5.0 g/d vs  $\geq$ 5.0 g/d) demonstrated an office BP reduction of 3.4 mm Hg in systolic BP and 1.5 mm Hg in diastolic BP in patients with and without hypertension. The simultaneous decrease in sodium excretion and increase in plasma aldosterone in the intervention group reinforces compliance with salt restricted consumption since a physiological increase in aldosterone concentrations has been associated with salt reduction.  $^{\rm 40}$ 

### STUDY LIMITATIONS

A possible limitation of the current study would be its short follow-up period. Actually, this trial represents proof of concept of combined lifestyle intervention. In addition, as far as we known, this is the first study to evaluate the BP effects of the DASH diet and increased physical activity in patients with type 2 diabetes. Another possible limitation would be related to the intrinsic characteristic of the device used to evaluate physical activity. Pedometers capture only movements of the lower body on the vertical plane. This aspect probably did not influence our results since the majority of our patients were sedentary. Another point of concern could be the small BMI reduction observed only in the intervention group, although there was no statistical difference in BMI changes between groups. Nevertheless, we included BMI changes as a covariate in the GLM analyses in order to take into account any possible influence of BMI. Finally, a loss of about 10 kg would have to occur to warrant a BP reduction as demonstrated in our study."

### CONCLUSIONS

The results of the present study demonstrated that a DASH diet combined with walking promotes a clinically relevant reduction in ABPM in patients with type 2 diabetes and hypertension. The beneficial BP effects of this lifestyle intervention should also be assessed in longterm clinical trials in order to evaluate its influence on hard cardiovascular outcomes.

Acknowledgments: CAPES—PNPD, FIPE-Hospital de Cl<sup>r</sup>nicas de Porto Alegre, and CNPq. TPP and ATZN were recipients of scholarships from CAPES.

Disclosure: None of the authors have any conflict of interest to declare.

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#### Supporting Information

Additional Supporting Information may be found in the online version of this article:

**Appendix S1.** Intervention group and control group dietary prescriptions considering a patient with type 2 diabetes and 70 kg of body weight.