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ARTICLE

Benefits of mindfulness meditation in reducing blood pressure and stress in patients with arterial hypertension

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Abstract

The objective of this randomized controlled trial is to evaluate the benefits of mindfulness meditation in controlling ambulatory blood pressure (BP) and the impact of the intervention on anxiety, stress and depression levels in a Mediterranean population. Twenty-four and 18 patients [$n = 42$; mean age 56.5 (7.7) years; similar men and women proportions] with high-normal BP or grade I hypertension were enrolled to an intervention and a control group, respectively. For 2 h/week over 8 weeks, the intervention group received mindfulness training and the control group attended health education talks. The patients attended pre-intervention, week 4, week 8 and week 20 follow-up visits. 61.9% of the patients had anxiety, 21.4% depression, 19.0% were smokers and 14.2% were diabetic (no significant differences between the 2 groups). At baseline, the intervention group had non-significant higher clinically measured BP values, whereas both groups had similar ambulatory BP monitoring (ABPM) values. At week 8, the intervention group had statistically significant lower ABPM scores than the control group (124/77 mmHg vs 126/80 mmHg ($p < 0.05$) and 108/65 mmHg vs 114/69 mmHg ($p < 0.05$) for 24-h and night-time systolic BP (SBP), respectively) and also had lower clinically measured SBP values (130 mmHg vs 133 mmHg; $p = 0.02$). At week 20 (follow-up), means were lower in the intervention group (although not statistically significant). Improvements were observed in the intervention group in terms of being less judgemental, more accepting and less depressed. In conclusion, by week 8 the mindfulness group had lower clinically measured SBP, 24-h SBP, at-rest SBP and diastolic BP values.

Introduction

Hypertension is considered to be a major cardiovascular risk factor worldwide, with some 35% of the adult population estimated to be affected [1]. It has also been estimated that, of the European population aged over 50 years, 45.7% have had at least one psychiatric episode in their life, 17.4% currently have a mental disorder, and anxiety prevalence is 29.4% [2]. Recent data for Spain report anxiety prevalence of 14.3% [3].

The main cardiovascular effect of stress and depression is acute and chronic activation of the sympathetic nervous system, which may lead, in predisposed individuals, to the

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development of hypertension or to a worsening of blood pressure (BP) levels in patients who are already hypertensive. An accessible, cost-effective and reproducible therapeutic technique like mindfulness could considerably reduce this pathology and subsequent organic damage.

A high proportion of patients with hypertension take several pharmacological agents to treat their BP, yet usually fail to achieve BP control [4]. Stress reduction through meditation is a potentially important non-pharmacological treatment that could both reduce polypharmacy and improve BP control [5]. In current guidelines for cardiovascular risk prevention and hypertension treatment, the level of evidence for meditation is IIaB. It would be useful to assess psychosocial factors through interviews or standardized questionnaires, as this would enhance individualized clinical management aimed at improving the quality of life and prognosis of patients [1]. However, despite the evidence, most patients do not receive adjuvant treatment for stress and depression symptoms.

The benefits of mindfulness have not only been demonstrated for BP, but also for other conditions associated with vascular risk, such as glycaemia control in diabetes mellitus [6], cardiovascular risk reduction, improvements in memory and even as adjuvant therapy for pain control in cancer patients [2].

There is growing evidence of the positive effect of meditation on BP. A meta-analysis published in 2007 by Rainforth et al. [7] concluded meditation to be the only psychological intervention for stress that obtained significant BP benefits for patients diagnosed with pre-hypertension or arterial hypertension (AHT). The same meta-analysis reported that less beneficial results were obtained for other techniques such as muscle relaxation, biofeedback and stress management—all techniques mentioned in the recommendations of the American Heart Association (AHA) published in 2013 [8] and 2015 [9]. Many studies evaluating meditation [4] have included young populations or African American subjects and, less frequently, Anglo-Saxon populations.

A recent meta-analysis published by Park [10] demonstrates that relaxation techniques are effective and safe alternatives to pharmacotherapy, although the benefits vary according to population, age and the meditation technique used. In another review by Shi et al. [11] age was an independent predictor of reduced systolic BP (SBP) and diastolic BP (DBP) values, irrespective of the technique and of the BP measurement method used. Shi et al. [11] comments that older people (aged 54–56 years) may benefit more from meditation in terms of BP reduction, as they may be more motivated to adhere to behavioural interventions in a desire to reduce pharmacological dependence.

As pointed out by Goldstein [4] and Blom [12], however, methodological differences in studies published to date make it impossible to extrapolate the benefits of meditation to different populations and, in particular, to middle-aged Mediterranean populations. No comparable studies have been published for Spain, and neither has data been obtained that compare physiological and psychological variables.

Few studies have evaluated BP response using 24-h ambulatory BP monitoring (ABPM), a technique that rules out any potential placebo (white-coat) effect associated with psychological techniques and that also allows smaller samples to be studied. The limited use of ABPM, combined with methodological diversity and the absence of control groups, has led to criticisms of a number of studies, as documented in reviews published by Scheider [13] in 2005 and Rainforth [7] in 2007.

Studies of meditation and ABPM, such as those by Barnes [14] and Manikonda [15], demonstrate the superiority of meditation over other techniques in reducing BP in intervention groups compared to control groups. In contrast, in the study by Blom [12], no significant reduction in BP was observed for meditation for ABPM in patients with untreated grade 1 AHT. The review by Shi et al. [11] highlighted the beneficial effects of meditation but also reported erratic differences in BP reductions: values of −2.4 mmHg for SBP and −4.26 mmHg for DBP for ABPM and of −5.5 mmHg for SBP and −2.8 mmHg for DBP for clinically measured BP. These contradictory results and the lack of a suitable number of studies points to the need for more data, and especially for ABPM.

Another topic of debate has been the duration of the meditation programme and the follow-up period necessary to measure benefits. A meta-analysis by Schneider [13] regarding the long-term effects of stress reduction on mortality reported, after a mean follow-up of 8 years, a drop in total and cardiovascular mortality of 23% and 30%, respectively, in the intervention compared to the control groups. Another study with a similar methodology showed that the benefits for BP were already evident and consistent from the 3rd month of follow-up [16].

According to a review by Brook [9], there is a need for more evidences to demonstrate not only the usefulness of meditation, but also to identify suitable candidate populations and the variables that could predict a good response.

The primary objective of our study was to evaluate, after 8 weeks of intervention and 3 months of follow-up, the benefits of mindfulness meditation in controlling BP measured by ABPM in a Mediterranean population with high-normal BP or grade I AHT. A secondary objective was, for the same patients, to evaluate the effects of the intervention on variables reflecting emotions and moods, with a view to evaluating how a psychological variable (stress) modulated the relationship between mindfulness meditation and BP levels.

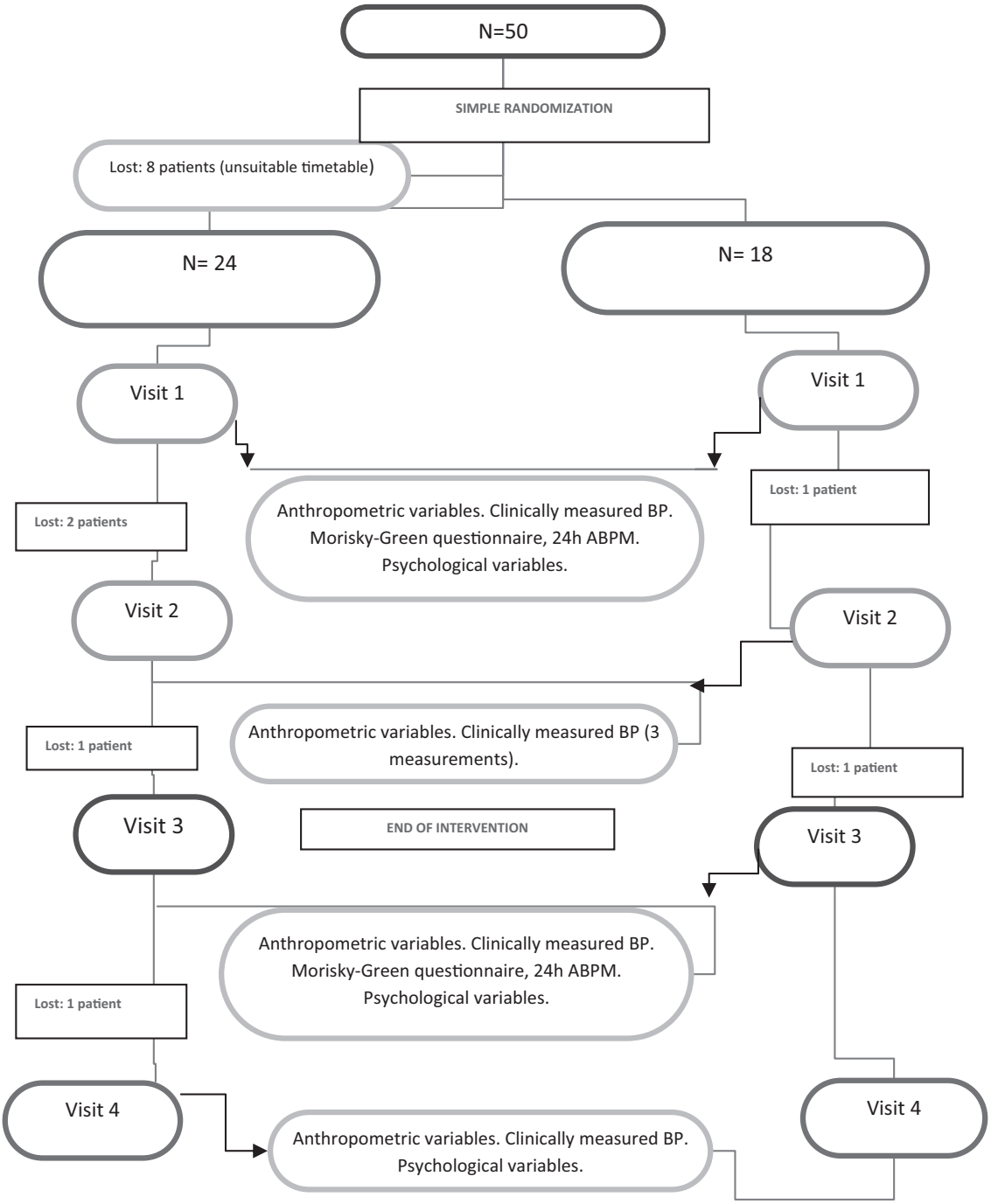

Fig. 1 Subject inclusion and visits flowchart

Methods

This prospective randomized open-label blinded-endpoint (PROBE) study included a total of 42 patients (18 men and 24 women) aged between 18 and 70 years (mean age 56.5 (7.77) years); they were recruited between July 2014 and March 2015 from among hospital employees and patients from our hypertension unit with high-normal BP or grade 1 hypertension. Once the subjects were confirmed to fulfil the inclusion criteria and had given their written consent, they were randomly allocated, 24 to the meditation (intervention) group and 18 to the health education (control) group (Fig. 1).

Excluded were patients with a medical history of symptomatic heart failure (New York Heart Association (NYHA) class II–IV) or left ventricular ejection fraction (LVEF) < 60%; patients with coronary heart disease,

Table 1 Intervention (meditation) and control (education) group programmes

Meditation programme (intervention group)	Education programme (control group)
Week 1: Body scanning/routine activity	Week 1: General aspects of high BP: what it is, how it is measured, how it is diagnosed. Causes and related factors
Week 2: Body scanning/2 routine activities/breathing	Week 2: Impact of high BP on the body
Week 3: Conscious yoga/breathing, breathing + body	Week 3: Cardiovascular risk factors. Diabetes and dyslipidaemia
Week 4: Conscious yoga/breathing, breathing + body	Week 4: Pharmacological and hygiene-dietary treatment: weight control, balanced diet, low-sodium diet, diet and cholesterol, smoking
Week 5: Breathing, breathing + body	Week 5: High BP and exercise. High BP and alcohol. Other control measures: relaxation
Week 6: Breathing, sounds and thoughts	Week 6: Periodic checks. Goals. FAQs on high BP. Types of high BP. Can high BP be cured? Are there symptoms?
Week 7: Choose and combine: body scanning/ breathing/yoga	Week 7: BP self-measurement (ABPM)
Week 8: Guidelines for future mindfulness practice	Week 8: Discussion, conclusions and feedback

BP blood pressure, *ABPM* ambulatory BP monitoring

cerebrovascular disease or any other condition that might result in death before study completion; patients concomitantly using BP-modifying drugs (cyclosporine, non-steroidal anti-inflammatory drugs (NSAIDs), steroids, vasoconstrictors, etc.); pregnant women; patients participating in another clinical trial; and patients with previous experience of mindfulness, meditation, yoga, tai chi, chi kung or similar techniques.

In weekly 2-h sessions over 8 weeks, the intervention group received group-based stress-reduction therapy based on mindfulness skills—taught by a psychiatrist trained in this technique—drawn from a range of formal and informal mindfulness-based cognitive therapy practices [17] that included mindfulness of breath, thoughts, bodily sensations, sounds and everyday activities. Intervention group patients were also encouraged to practice meditation at home for 45 min a day. The control group received weekly health education over the same period. Table 1 summarizes the content of the meditation and health education classes.

For both groups, therapeutic regimens and pharmacological doses were maintained unchanged until follow-up was concluded. Four visits were made as follows (W = week): W0, baseline (pre-intervention) visit; W4, mid-point visit; W8, post-intervention visit; and W20, follow-up visit. Psychological variables were evaluated at the pre-post intervention level (see Fig. 1). The study was evaluated and approved by an independent review board according to international standards and was conducted according to Good Clinical Practice (GCP) guidelines and protocols and in compliance with the principles of the Declaration of Helsinki.

Definition of variables

Clinically measured BP (W0, W4, W8 and W20). BP was measured (after 5 min of rest) three times at intervals of 1 min using an OMRON M6. The clinical BP values used in the analysis were the averages for the three measurements.

ABPM (W0 and W8). BP was measured at 15-min intervals by day (7:00 to 23:00) and at 30-min intervals by night (23:00 to 7:00) using a Spacelabs Model 90207 device. Results were adjusted to reflect waking and sleeping times for each patient.

SBP and DBP loads (W0 and W8). Load was calculated as the percentage of higher than normal readings, with normal readings for the 24-h period, activity period and rest period defined as 130/80, 135/85 and 120/70 mmHg, respectively.

Psychological variables (W0, W8 and W20). These were measured as follows:

- *Five-Facet Mindfulness Questionnaire (FFMQ)*, as reviewed by Baer et al. [18]. This questionnaire evaluates five mindfulness factors consisting of 39 items scored on a Likert scale ranging from 1 (never or almost never true) to 5 (very often or almost always true), with the highest scores indicating good self-reported mindfulness skills. The five factors are as follows: observing (noting or paying attention to internal or external experiences such as feelings, thoughts and emotions); describing (labelling internal experiences using words); acting with awareness (consciously focusing attention on the activities of the moment rather than acting mechanically); not judging inner feelings (taking a position of not evaluating thoughts and feelings); and finally, not reacting to inner feelings (allowing thoughts to come and go without clinging to them). We used the validated Spanish version of the FFMQ, reviewed by Cebolla et al. [19], which shows good psychometric properties and has Cronbach alpha values between 0.8 and 0.91.

- *Depression, Anxiety and Stress Scales (DASS-21)*, as reviewed by Henry et al. [20]. In this questionnaire, which aims to clearly differentiate between anxiety and depression, patients evaluate the frequency or severity—on a scale from 0 to 3—of 21 negative emotions experienced in the previous week. The questionnaire is composed of three subscales with seven items each: depression, anxiety and stress. We used the Spanish version of this questionnaire, as validated by Bados et al. [15], with Cronbach alpha values between 0.7 and 0.84.
- *Profile of Mood States (POMS)*. This scale evaluates six affective moods—tension, depression, anger, vigour, fatigue and confusion—via 65 items evaluated on a five-point scale ranging from 0 (not at all) to 4 (extremely). The total mood disturbance score is obtained from the scores for the six subscales [21], with Cronbach alpha values between 0.63 and 0.96.
- *Perceived Stress Scale (PSS-10)*, as reviewed by Cohen et al. [22]. This ten-item Likert-scale—scored 0 (never) to 4 (very often)—evaluates perceived levels of stress by participants in the month prior to a study. It has good internal consistency, as demonstrated by Remor [23], with a Cronbach alpha value of 0.82.

Statistical analysis

The sample was analysed on an intention-to-treat (ITT) basis. Clinical and demographic variables were analysed descriptively using the chi-square test for categorical variables and the Student-*t* test for quantitative variables. Analysis of covariance (ANCOVA) was used to test the hypothesis that the impact was greater for the intervention group than for the control group. The analysis was adjusted to variables showing statistically significant differences in the binary study (age and time of treatment administration). A second adjusted analysis was performed with stress as a moderating variable for the association between mindfulness and BP control. The DASS-21 score (items 1, 6, 8, 11, 12, 14 and 18) was multiplied by 2 to ensure comparability with DASS-42 (original version [24, 25]). Differences were considered significant for a bilateral significance level of 0.05. The STATA v14 packages were used for the statistical analyses.

Results

Of the 42 patients included in the study (73.8% of whom were employed), 52.4% had dyslipidaemia, 14.3% had diabetes, 19% were smokers and 2.4% had chronic kidney disease. In addition, 61.9% and 21.4% had a history of anxiety or depression, respectively. In terms of baseline characteristics (Table 2), there were no significant differences (p = ns) in the baseline variables between the intervention and control groups, except for age, which was higher in the intervention group (57.1 (5.4) years vs 55.7 (10.2) years; $p < 0.05$). Most of the patients (65%) were receiving antihypertensive treatment (with no differences in terms of the number, class or pharmacological molecule administered). Differences were observed in the time of taking antihypertensive medication, with morning administration more frequent in the intervention group compared to the control group (94.1 vs 66.7%; $p = 0.05$).

Tables 3 and 4 show clinically measured BP and ABPM values, respectively, for W0, W4, W8 and W20.

At WO (baseline visit), compared to the control group, the intervention group had non-significant higher mean clinically measured SBP values (Table 3) and had non-significant higher mean ABPM values for SBP and DBP for the 24-h period and the activity period. The intervention group also had higher SBP load values for the 24-h period

Table 2 Baseline characteristics for patients in the intervention (meditation) and education (control) groups

Variables	Education ($n = 18$)	Meditation ($n = 24$)	Total	*P*
Mean (SD)				
Abdominal perimeter (cm)	90.5 (9.9)	92.9 (9.8)		0.97
Age (years)	**55.7 (10.2)**	**57.1 (5.4)**		**0.05**
Body mass index (kg/m^2)	26.8 (3.0)	28.2 (3.9)		0.48
n (%)				
Male	7 (38.9%)	11 (45.8%)	18 (42.9%)	0.65
Dyslipidaemia	9 (50%)	13 (54.2%)	22 (52.4%)	0.79
Diabetes mellitus	3 (16.7%)	3 (12.5%)	6 (14.3%)	0.70
Smoker	3 (16.7%)	5 (20.8%)	8 (19%)	0.80
Chronic kidney disease	0 (0%)	1 (4.2%)	1 (2.4%)	0.38
Atrial fibrillation	2 (11.1%)	2 (8.3%)	4 (9.5%)	0.76
Obstructive sleep apnoea	2 (11.1%)	3 (12.5%)	5 (11.9%)	0.59
Hyperuricaemia	1 (5.6%)	1 (4.2%)	2 (4.8%)	0.83
Depression	5 (27.8%)	4 (16.7%)	9 (21.4%)	0.65
Anxiety	11 (61.1%)	15 (62.5%)	26 (61.9%)	0.66
Occupationally active	16 (88.9%)	15 (62.5%)	31 (73.8%)	0.10
Family history of:				
Premature acute myocardial infarction	2 (11.1%)	3 (12.5%)	5 (11.9%)	0.99
Sudden death	1 (5.6%)	0 (0%)	1 (2.4%)	0.50
Antihypertensive treatment	12 (66.7%)	17 (70.8%)	29 (69.0%)	0.77

Statistically significant differences are highlited in bold type.

Table 3 Clinically measured blood pressure (BP) values

	GROUP	Baseline (W0)	*p*	Mid-point (W4)	*p*	Final (W8)	*p*	Follow-up (W20)	p	P[a] TOTAL
SBP[a], mmHg	Education	131.34 (3.06) [125.10–137.58]	0.74	125.11 (3.15) [118.68–131.55]	0.13	**133.21 (2.64) [127.84–138.59]**	**0.02**	129.73 (3.70) [122.19–137.28]	0.36	0.36
	Meditation	136.41 (2.80) [130.69–142.15]		124.59 (2.90) [118.68–130.49]		**130.54 (2.42) [125.30–135.48]**		123.38 (3.40) [116.45–130.31]		
DBP[a], mmHg	Education	85.09 (1.92) [81.17–89.00]	0.95	82.33 (1.77) [78.72–85.93]	0.37	87.11 (2.08) [82.87–91.34]	0.89	81.68 (3.86) [73.81–89.55]	0.97	0.66
	Meditation	87.88 (1.74) [84.34–91.42]		81.20 (1.60) [77.94–84.46]		84.25 (1.88) [80.41–880.8]		74.36 (3.49) [67.25–84.49]		

Expressed as mean (SD), CI 95%. Means adjusted to 57.64 years and daytime medication administration

SBP systolic blood pressure, *DBP* diastolic blood pressure

[a]ANOVA for clinically measured BP. The included variables were age, medication administration time and study group

[b]Mean clinically measured values

than the control group (33.89% vs 29.4%; $p = 0.05$). For the rest period, values for SBP, DBP, SBP load and DBP load were lower in the intervention group than in the control group as follows: SBP, 111.67 mmHg vs 113.06 mmHg ($p = 0.01$); DBP, 67.42 mmHg vs 68.11 mmHg ($p = 0.04$); SBS load, 26.50% vs 30.76% ($p = 0.003$); and DBS load, 41.84% vs 46.37% ($p = 0.05$) (Table 4).

At W4 (midpoint visit) no statistically significant differences were observed in clinical BP measurements between the two groups (Table 3), although SBP and DBP values tended to be lower in the intervention group.

At W8 (post-intervention visit) a reduction of 3 mmHg was observed in clinically measured SBP in the intervention group compared to the control group (130.54 mmHg vs 133.21 mmHg; $p = 0.02$) (Table 3). Clinically measured differences between baseline (W0) and W8 for SBP values were also significantly improved in the intervention group compared to the control group (5.82 (2.51) mmHg vs +1.90 (2.78) mmHg respectively; $p = 0.04$). Clinically measured DBP values were also different in the intervention group compared to the control group (−3.62 (1.76) mmHg vs 2.01 (1.94) mmHg; $p = 0.45$). Regarding the 24-h ABPM measurements (Table 4), the intervention group compared to the control group had lower SBP (124.39 mmHg vs 126.30 mmHg; $p = 0.02$), DBP (77.73 mmHg vs 80.00 mmHg; $p = 0.07$) and SBP load (31.51% vs 35.96%; $p = 0.05$) values. While no significant differences were observed for the daytime values, for the night-time period, the intervention group had lower SBP, DBP, SBP load and DBP load values than the control group (SBP: 108.73 mmHg vs 114.00 mmHg; $p = 0.009$; DBP: 65.01 mmHg vs 69.05 mmHg; $p = 0.01$; SBP load: 21% vs 30.17%; $p = 0.005$; DBP load: 32.29% vs 40.43%, $p < 0.01$).

At W20 (follow-up visit), the intervention group had lower clinically measured SBP values, although the difference was not statistically significant (Table 3). Compared to baseline (W0), clinically measured SBP values were significantly lower in the intervention group vs the control group (difference in initial to follow-up SBP: −13.04 (3.3) mmHg vs −1.06 mmHg; $p = 0.02$). Clinically measured DBP in the invention compared to the control group showed a similar decrease that, likewise, was not statistically significant (−13.51 (3.87) mmHg vs −3.40 mmHg; $p = 0.09$).

The multivariate analysis adjusted for age and daytime medication pointed to lower clinically measured and ABPM mean values for SBP and DBP for the intervention group, although the differences were not statistically significant (Tables 3 and 4; Fig. 2). A second analysis adjusted for stress showed reductions in clinically measured BP for the intervention group by the end of follow-up, to −5.26 mmHg and −3.70 mmHg for SBP and DBP, respectively. For ABPM measurements, the reduction in mean DBP was −4.00 mmHg for the intervention group, mainly for the activity and rest periods. These differences were not statistically significant (Supplementary data Tables 1 to 4).

As for the psychological variables, significant post-intervention differences were observed between the two groups, specifically in terms of lower intervention group levels of anxiety ($p = 0.02$) and stress ($p = 0.05$), as measured by DASS-21, and of depression ($p = 0.02$), fatigue ($p = 0.03$) and confusion ($p = 0.02$), as measured by the POMS subscales. Overall, and consistent with the intervention received, higher levels of mindfulness were observed in the intervention group (FFMQ_observing, $p = 0.04$; FFMQ_not reacting, $p = 0.04$; FFMQ_total score, $p = 0.005$). At W20, the intervention group had even lower stress levels ($p = 0.05$), whereas levels for the other variables for the two groups were comparable (further details in Table 5)

Discussion

Our study points to the benefits of meditation for BP control. In the education (control) group, clinically measured

Table 4 Ambulatory blood pressure monitoring (ABPM) values

	Group	Baseline (W0)	Final (W8)	DIFF	W0(p)	W8(p)	P^a Total
24 h							
SBP 24 h, mmHg	Education	123.94 (3.20) [119.94–127.91]	**126.30 (2.18) [121.86–130.74]**	+1.6	0.07	**0.02**	0.64
	Meditation	125.23(1.79) [121.61–128.86]	**124.39 (1.97) [120.37–128.40]**	−0.3			
DBP 24 h, mmHg	Education	77.57 (1.69) [74.13–81.00]	80.00 (1.73) [76.49–83.53]	+1.3	0.18	0.06	0.91
	Meditation	78.53 (1.55) [75.40–81.66]	77.73 (1.57) [74.54–80.92]	−0.3			
SBP load 24 h (%)	Education	**29.46 (4.27) [20.80–38.11]**	**35.96 (5.43) [24.91–47.01]**	+4.3	**0.05**	**0.05**	0.89
	Meditation	**33.89 (3.90) [26.00–41.79]**	**31.51 (4.91) [21.51–41.51]**	−0.12			
DBP load 24 h (%)	Education	38.52 (5.77) [26.83–50.21]	45.87 (5.44) [34.79–56.95]	+2.7	0.34	0.07	0.88
	Meditation	41.63 (5.26) [30.97–52.94]	36.49 (4.92) [26.46–46.52]	−2.9			
Activity							
SBP daytime, mmHg	Education	129.46 (2.18) [125.04–133.87]	131.68 (2.34) [126.91–136.44]	+1.2	0.11	0.13	0.73
	Meditation	130.11 (1.99) [126.09–134.14]	129.47 (2.12) [125.15–133.78]	−0.2			
DBP daytime, mmHg	Education	81.16 (1.60) [77.92–84.40]	84.49 (1.84) [80.74–88.25]	+2.1	0.40	0.42	0.47
	Meditation	82.68 (1.46) [79.72–85.63]	81.75 (1.67) [78.36–85.15]	−0.4			
SBP load daytime (%)	Education	30.04 (4.51) [20.90–39.18]	38.01 (5.90) [26.00–50.02]	+6.2	0.18	0.21	0.97
	Meditation	35.56 (4.11) [27.24–43.91]	34.20 (5.34) [23.34–45.07]	−3.4			
DBP load daytime (%)	Education	37.54 (5.72) [25.95–49.13]	47.66 (5.96) [35.52–59.80]	+5.3	0.54	0.31	0.80
	Meditation	41.12 (5.22) [30.55–51.69]	36.97 (5.40) [25.99–47.96]	−1.7			
Rest							
SBP night-time, mmHg	Education	**113.06 (2.74) [107.52–118.61]**	**114.00 (2.99) [107.92–120.08]**	+0.2	**0.01**	**0.009**	0.83
	Meditation	**111.67 (2.50) [106.61–116.73]**	**108.73 (2.70) [103.23–114.24]**	−2.6			
DBP night-time, mmHg	Education	**68.11 (2.18) [63.70–72.52]**	**69.05 (2.02) [64.94–73.16]**	−0.5	**0.04**	**0.01**	0.76
	Meditation	**67.42 (1.99) [63.40–71.44]**	**65.01 (1.83) [61.29–68.73]**	−2.1			
SBP load night-time (%)	Education	**30.76 (6.90) [16.77–44.75]**	**30.17 (6.83) [16.26–44.09]**	−4.8	**0.003**	**0.005**	0.66
	Meditation	**26.50 (6.30) [13.73–39.25]**	**21.00 (6.18) [8.41–33.59]**	−4.4			
DBP load night-time (%)	Education	**46.37 (8.31) [29.54–63.20]**	**40.43 (7.38) [25.40–55.47]**	−10.5	**0.05**	**0.01**	0.99

Table 4 (continued)

	Group	Baseline (W0)	Final (W8)	DIFF	W0(p)	W8(p)	P^a Total
	Meditation	**41.84(7.58) [26.49–57.20]**	**32.29 (6.68) [18.68–45.89]**	−9.2			

Expressed as mean (SD); CI 95%. Means adjusted to 56.50 years and daytime medication administration

SBP systolic blood pressure, *DBP* diastolic blood pressure

[a]ANOVA for 24 h ABPM. The included variables were age, medication administration time and study group

Statistically significant differences are highlited in bold type.

BP mean values increased from baseline to the final visit, by +1.61 mmHg for SBP and by +2.02 mmHg for DBP. In contrast, for the meditation (intervention) group, there was a statistically significant and clinically relevant reduction of −5.8 mmHg and −3.62 mmHg in SBP and DBP mean values, respectively. This benefit was maintained—although without statistical significance—as of the follow-up visit (4 weeks after the intervention concluded), when mean values for SBP and DBP were −13 mmHg in the meditation group.

BP values measured by ABPM confirm the findings for clinically measured BP. The most striking findings were observed for the night-time period, when patients in the meditation group experienced a reduction of up to −2.6 mmHg in SBP and −2.1 mmHg in DBP. These patients also experienced a significant reduction in 24-h SBP.

Our results are encouraging, as the average reduction in BP was similar to that achieved with standard validated non-pharmacological measures implemented in routine clinical practice, such as regular aerobic exercise, which has been shown to decrease BP at rest by −3.0 to −2.4 mmHg in the general population and by −6.9 to −4.9 mmHg in patients with AHT [26]. The impact of these results is even greater when we consider that a −3 mmHg reduction in SBP is estimated to reduce stroke mortality by 8% and cardiovascular mortality by 5% [11].

In the multivariate analysis, although reductions of up to −2 mmHg for the 24-h ABPM measurements were observed in favour of the meditation group, the differences were not statistically significant. Contrasting with our findings, the HARMONY study [12], published in 2012, found no beneficial effect on clinically measured BP. The authors of that study refer to different possible explanations, such as the existence of white-coat AHT, the contribution of behavioural factors to clinically measured BP (e.g., patterns of activity) and seasonal changes (starting a study in a summer month and drawing comparisons with data collected in winter months, as reported in the meta-analysis by Bain [27]). Seasonal factors, in fact, may have contributed in part to the lack of statistical significance in our study by the end of follow-up, since patients were recruited in early autumn (September) and the study was completed in early spring (March). Another intriguing yet real possibility—also commented by Hughes et al. [5]—is that patients are better able to apply the principles learned during the intervention when BP is measured at rest in a controlled room than in their daily lives [5]. What is well reflected in our study is that our findings are not attributable to anthropometric differences (e.g., height, weight), demographics (e.g., socioeconomic class) or occupational status.

In W4 (halfway through the intervention), BP was observed to be reduced in the two groups. This reduction could have several interpretations. However, we can clarify that there was no change to medication, which was recorded for all patients from baseline to the end of follow-up. The reduction may therefore be due to the change in seasons (as already mentioned, patients were recruited in early autumn and the study was completed in early spring). Another possible explanation may be observation bias; since the study was an open-label study, it is quite possible that the patients may have modified their behaviour (in terms of compliance with hygienic-dietetic measures or awareness of their disease) in a way that might have improved clinically measured BP values in the early stages of the study. However, the fact that the decrease was observed in the two groups would support the validity of the results obtained.

Other key findings of our study are the results for the psychological variables. Observed in the meditation group was a greater capacity to not issue judgements. This essential element of mindfulness is associated with a greater capacity to accept a present experience. Also observed were improved anxiety symptoms, depression symptoms and stress levels, and also less fatigue and less confusion. In our study, the effect of stress on BP was clearly reflected in the two groups but was more relevant for DBP in the intervention group. These results corroborate those obtained in other studies published in Spain, for instance, that by Delgado [28], who reported that university students who received mindfulness training improved emotional regulation after 5 consecutive weeks of two sessions of 1 h duration. The DASS-21 questionnaire and POMS also showed an improvement in symptoms. These results would reinforce the evidence for the benefits of meditation.

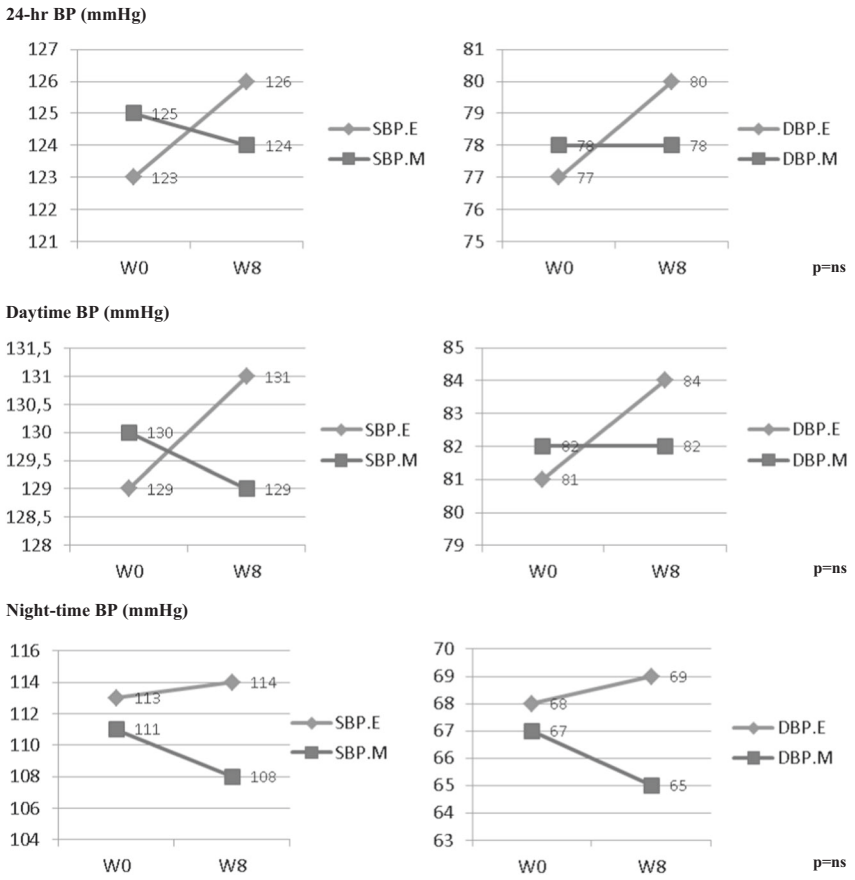

Fig. 2 Twenty-four-hour ambulatory blood pressure monitoring (ABPM) evolution from pre-intervention (W0) to final visit (W8) (left panel: SBP; right panel: DBP) 24-h BP (mmHg) $p = \text{ns}$ Daytime BP (mmHg) $p = \text{ns}$ Night-time BP (mmHg) $p = \text{ns}$ SBP.E systolic blood pressure – Education, SBP.M systolic blood pressure – Meditation, DBP.E diastolic blood pressure – Education, DBP.M diastolic blood pressure – Meditation (W8, end of intervention). 24-h BP 24-h ABPM BP mean, BP.D 24-h ABPM daytime BP mean, BP.N 24-h ABPM night-time BP mean. Means adjusted to 57.57 years and daytime medication administration

SBP.E = systolic blood pressure – Education; SBP.M = systolic blood pressure – Meditation; DBP.E = diastolic blood pressure – Education; DBP.M = diastolic blood pressure – Meditation (W8, end of intervention). 24-hr BP = 24-hour ABPM BP mean; BP.D = 24-hour ABPM daytime BP mean ; BP.N= 24-hour ABPM night-time BP mean.

Means adjusted to 57.57 years and daytime medication administration.

This randomized trial of a Mediterranean middle-aged occupationally active population, designed to evaluate the possible benefits of mindfulness meditation for patients with this profile, has several strengths. First, the veracity of the BP data is ensured by the high therapeutic adherence (assessed by the Morisky-Green test) of the study subjects, which means that changes in medication can be ruled out as a possible reason for the observed changes. Second, the use of ABPM as a standardized and objective BP measurement tool excludes the possibility of confounders, such as the white-coat effect or the effects of antihypertensive medication administered exclusively in daytime hours. Third, the study reports convincing results on the benefits of mindfulness meditation as a non-pharmacological tool for BP control, stress management, depression symptom control and mental clarity.

One of the limitations of this study is the small number of included patients and the loss of six (14.3%) participants over the course of the study. Another limitation is the lack of a longer-term follow-up that could confirm the persistence of the decrease in mean BP and its statistical significance. Therefore, we suggest the need for new studies to be designed in the future that enrol more patients, in which the intervention lasts longer than 8 weeks and in which follow-up is longer. Such studies should also include biological variables (cortisol, catecholamine and norepinephrine levels, tumour necrosis factor alpha, interferon, white blood cell count and inflammatory interleukin 1, 2 and 10 levels) to be able to corroborate effects both at the clinical and molecular levels and also to improve understanding of the biological mechanisms involved and the benefits of reduced BP levels.

As a conclusion of our study of individuals of Mediterranean origin aged 18–65 years with high-normal BP or grade I AHT who received 8 weeks of 2-h weekly sessions of mindfulness training, we suggest that mindfulness meditation is an effective tool in reducing clinical BP—mainly clinically measured SBP and 24-h and night-time SBP as measured by ABPM. No statistically significant differences were found in clinically measured BP mean values after

Table 5 Psychological variables

	Education ($N = 14$)			Meditation ($N = 16$)			p Post	p W20
	Pre	Post	W20	Pre	Post	W20		
Clinical variables								
DASS_Depression	9.67 (12.08)	8.00 (9.98)	9.33 (10.17)	5.50 (5.49)	3.37 (3.48)	4.75 (5.05)	0.19	0.27
DASS_Anxiety	6.20 (7.02)	7.00 (8.76)	6.60 (8.95)	4.27 (5.39)	2.53 (3.07)	3.20 (4.06)	**0.02**	0.25
DASS_Stress	12.33 (9.60)	11.50 (7.91)	9.67 (9.75)	10.25 (5.10)	7.35 (5.25)	9.62 (4.74)	**0.05**	0.94
PSS	14.43 (9.90)	13.79 (7.77)	15.64 (7.50)	13.18 (4.58)	11.06 (3.75)	12.12 (5.55)	0.06	**0.05**
POMS_Tension	9.36 (7.41)	6.91 (5.77)	–	8.07 (4.16)	5.00 (3.25)	–	0.38	–
POMS_Depression	5.42 (8.59)	7.92 (10.94)		5.56 (6.69)	3.72 (3.77)	–	**0.02**	–
POMS_Anger	4.00 (6.03)	4.18 (6.18)	–	5.44 (6.52)	4.06 (4.14)	–	0.63	–
POMS_Vigour	17.83 (4.88)	18.42 (4.54)	–	18.65 (5.46)	18.84 (5.16)	–	0.97	–
POMS_Fatigue	7.29 (6.50)	7.71 (6.47)	–	5.72 (3.53)	3.94 (2.82)	–	**0.03**	–
POMS_Confusion	4.67 (2.90)	5.08 (4.10)	–	4.61 (3.45)	3.00 (2.17)	–	**0.02**	–
POMS_Friendliness	19.15 (3.29)	18.46 (5.36)	–	20.39 (3.53)	20.28 (3.92)	–	0.57	–
Mindfulness								
FFMQ_Observe	23.08 (5.54)	23.08 (5.48)	23.69 (5.41)	25.00 (6.25)	28.19 (6.14)	24.14 (6.31)	**0.04**	0.30
FFMQ_Describe	25.50 (7.00)	27.64 (6.08)	26.00 (7.68)	28.71 (5.52)	29.00 (4.02)	27.94 (4.07)	0.96	0.66
FFMQ_ActAware	31.75 (5.88)	32.00 (5.67)	29.92 (4.68)	31.82 (5.20)	30.65 (6.12)	29.47 (4.09)	0.88	0.58
FFMQ_Nonjudge	29.45 (5.82)	29.00 (6.37)	26.45 (5.00)	27.08 (6.79)	29.85 (6.09)	27.85 (6.67)	0.07	0.13
FFMQ_Nonreact	20.15 (6.67)	19.08 (5.63)	21.08 (4.72)	23.44 (5.42)	22.43 (2.73)	22.43 (3.67)	**0.04**	0.88
FFMQ_Total score	25.44 (3.57)	25.18 (2.81)	24.89 (3.96)	27.98 (2.80)	28.50 (2.87)	27.17 (2.21)	**0.005**	0.62

Expressed as mean (SD)

DASS Depression Anxiety Stress Scale, *FFMQ* Five-Facet Mindfulness Scale, *POMS* Profile of Mood States, *PSS* Perceived Stress Scale

Statistically significant differences are highlited in bold type.

follow-up concluded, yet some effect was maintained. Our findings of an improved ability to avoid issuing judgments, improved depression symptoms and greater mental clarity confirm the psychological benefits of practising mindfulness already reported in several published studies. It would seem appropriate to further examine the specific moderating role of certain psychological factors on the association between mindfulness and BP levels. Although our study would suggest that the reported benefits of mindfulness meditation could be extrapolated to other health areas, further research is necessary to analyse this possibility.

Summary

What is known about this topic

- The mindfulness intervention for stress obtained significant BP benefits for patients with hypertension
- Relaxation techniques are effective and safe alternatives to pharmacotherapy
- The benefits of mindfulness vary according to population, age and the technique used

What this study adds

- The meditation group experienced a significant BP reduction of −2.1 to −2.6 mmHg in 24 h
- The Mediterranean population experienced beneficial effects in terms of BP reduction after the 8-week mindfulness intervention

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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