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ORIGINAL ARTICLE

Breathing-control lowers blood pressure

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We hypothesise that routinely applied short sessions of slow and regular breathing can lower blood pressure (BP). Using a new technology BIM (Breathe with Interactive Music), hypertensive patients were guided towards slow and regular breathing. The present study evaluates the efficacy of the BIM in lowering BP. We studied 33 patients (23M/10F), aged 25–75 years, with uncontrolled BP. Patients were randomised into either active treatment with the BIM (n = 18) or a control treatment with a Walkman (n = 15). Treatment at home included either musically-guided breathing exercises with the BIM or listening to quiet music played by a Walkman for 10 min daily for 8 weeks. BP and heart rate were measured both at the clinic and at home with an Omron IC BP monitor. Clinic BP levels were measured at baseline, and after 4 and 8 weeks of treatment. Home BP measurements were taken daily, morning and evening, throughout the study. The two groups were matched by initial BP, age, gender, body mass index and medication status. The BP change at the clinic was −7.5/−4.0 mm Hg in the active treatment group, *vs* −2.9/−1.5 mm Hg in the control group (P = 0.001 for systolic BP). Analysis of home-measured data showed an average BP change of −5.0/−2.7 mm Hg in the active treatment group and −1.2/+0.9 mm Hg in the control group. Ten out of 18 (56%) were defined as responders in the active treatment group but only two out of 14 (14%) in the control group (P = 0.02). Thus, breathing exercise guided by the BIM device for 10 min daily is an effective non-pharmacological modality to reduce BP.
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Introduction

Hypertension has been well documented as a major risk factor for cardiovascular morbidity and mortality and lowering blood pressure (BP) with antihypertensive drugs can reduce this risk.[1] The side effects and cost of antihypertensive drugs have stimulated the search for a non-pharmacological approach to control BP either as a first line or adjunctive treatment. Several studies have demonstrated that lifestyle modifications such as physical exercise, salt restriction and weight reduction can lower BP.[1,2] Relaxation and stress-relieving techniques such as yoga, meditation and biofeedback have also been shown capable of lowering BP.[3–12] However, the results of these behavioural-based treatments have not been uniform and the mechanisms by which they lower BP are not clear.

Accumulating evidence shows that slow and regular breathing elicits acutely a number of beneficial effects via the cardiovascular reflex control system,[13,14] including increased heart rate variability and baroreflex sensitivity, BP reduction[15,16] and an increase of oxygen saturation in chronic heart failure.[17,18]

The apparent role of slow and regular breathing as an active component in relaxation exercises, raises the hypothesis that routinely performed sessions of breathing exercises, as the sole intervention, may lead to a sustained reduction in BP. No attempt has been made in the past to test this hypothesis. Recently, a double-blind randomised study was conducted to evaluate the effect of breathing modulation on BP, using a new device called BIM (Breathe with Interactive Music, developed by InterCure Ltd, Israel).[19] The BIM guides the user towards slow and regular breathing[20] by creating a musical pattern temporally-related to the breathing movements monitored by a sensor. It has been shown that daily use of the BIM is able to change respiration pattern.[20] Results showed that 10 min of daily use of the BIM over an 8-week period elicited a clinically significant reduction in the BP level, as checked weekly at the clinic.

The objective of the present study was to re-evaluate the effect of this treatment on BP by self BP measurements taken at home, using a data logging digital BP monitor, and in parallel, to check BP at the clinic using the same BP monitor.

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Subjects and methods

Subjects

Thirty-three patients, 23 males and 10 females, aged 25 to 75 years, recruited from an out-patient clinic, participated in the study. All participants had essential hypertension and were either without drug therapy ($n = 15$), treated with one medication ($n = 10$) or two or more medications ($n = 8$) for at least 2 months prior to and throughout the study. For those patients who were medicated, the regimen was unchanged throughout the study. Patients were included only if their BP was uncontrolled. Criteria for uncontrolled BP were systolic BP $\geqslant$140 mm Hg and/or diastolic BP $\geqslant$90 mm Hg on two consecutive out-patient visits at least 2 weeks apart, and home BP $>$135/85 mm Hg, calculated from averaging 2 weeks of patient self-measurements at home twice daily (morning and evening). Excluded from the study were patients with ischaemic heart disease, congestive heart failure, chronic atrial fibrillation, renal failure, diabetes mellitus, previous stroke, major organ failure, respiratory diseases or psychiatric disorders. Also excluded were patients with severe obesity (BMI $>$35 kg/m^2), patients with hearing impairment, or patients who were unable to operate a portable tape. The protocol of the study was approved by the research ethics committee of the Hadassah University Hospital, and each patient gave written informed consent.

Study design

During the study each patient visited the clinic four times. The first two visits, 2 weeks apart, were devoted to baseline measurements and enrolment. During this period the patients measured their BP prior to enrolment. After enrolment, patients were randomised into either an active treatment group ($n = 18$) or a control treatment group ($n = 15$). Randomisation involved random assignment into the two groups while matching of baseline characteristics with the preferences for mean BP $>$ age $>$ gender $>$ medication status. Double blinding was achieved by using the services of a third party for delivering the treatment and control devices and providing the necessary training at the patient's home as well as maintaining the devices. This assured that the doctors were masked. Patients were masked since they consented to 'a treatment by a musical device', without being aware of the type of device or about breathing exercises.

Patients were invited for BP measurement at the clinic after 4 and 8 treatment weeks. The study was terminated on the last visit, after 8 weeks of treatment.

Treatment

Treatment in both groups consisted of listening at home to music produced by one of two devices for 10 min in the evening, each day during an 8-week period, either passively (with Walkman) or actively by performing breathing exercises (with BIM).

The BIM device consists of a belt-type respiration sensor, a computerised control unit and headphones. Based on the analysed monitored breathing pattern, the device composes in real-time sound patterns with temporal structure similar to the actual breathing pattern but with prolonged 'expiration' (in the sound pattern). The breathing pattern modification occurs as the user voluntarily follows the sound pattern with his/her breathing movements.[20] This process continues until it reaches a steady state at the lowest breathing rate convenient to the user. The device also has a data logger that stores and displays data including date, time and duration of use, and breathing rate at a number of time points during its use.

A Walkman was used as an active control, playing a 10-min recorded cassette of quiet synthesised music similar to that of the BIM, but with a non-identifiable rhythm. The patients' compliance with treatment was checked by the personal diary they signed each day.

BP measurements

Blood pressure was measured at the clinic and at home with the Omron IC—a digital BP monitor that stores all data including BP, heart rate, date and hour, up to 350 measurements. Patients could observe BP levels and heart rate from the display during the measurements. The devices were checked for accuracy against a mercury sphygmomanometer. BP determination at the clinic involved a series of consecutive measurements, about 1 min apart, until the last two measurements did not differ by more than 10% in both systolic and diastolic BP values. The average of these last measurements was taken as the BP level. The patient examined home measurements daily in the morning and the evening. However, to control for the fact that treatment was carried out in the evening, only morning BP and heart rate values were analysed for the evaluation of BP changes. Blood pressure and heart rate data were downloaded at each visit and at the end of the study. The patient's compliance with home BP examination was confirmed by the number of measurements stored. Patients who had less than 30 days of measurements, or did not measure BP during the last 3 weeks of treatment were considered as non-compliant (one patient).

Data analysis and statistics

The selected group size was large enough for a significance level of $P < 0.05$ with 80% power of test, taking clinical BP changes, as the study outcome. Values are presented as mean $\pm$ s.d. Mean arterial pressure (MAP) was calculated as the diastolic pressure plus one-third of the pulse pressure.

Clinic BP analysis: The effect of treatment on BP and heart rate was assessed by calculating the average of individual BP changes from baseline (average of BP values obtained in visits 1 and 2) to values obtained at 4 and 8 weeks of treatment. The treatment groups were then compared.

Home BP analysis: Home BP data analysis requires data filtration to eliminate spurious readings. We have used a simple algorithm for eliminating spurious readings. The algorithm is based on our previous observation that systolic BP is linearly related to the diastolic BP when repeated measurements are used in the same person. Spurious data were identified by their deviation from the linear regression line. Quantitatively, we excluded data that deviated by more than 2 s.d. from this regression line either along the systolic axis or along the diastolic axis. Typically, 4% of the data was excluded as a result of this filtration process.

Baseline values were calculated by averaging all day BP and heart rate data during the baseline period. The multiplicity of repeated home BP measurements enables quantitative expression of BP change, BP trend, and response to treatment. A typical daily home BP measurements collected during a 14-week period in one patient is presented in Figure 1, BP change was defined as the difference between the BP level at a time point representing the baseline, taken 1 week prior to enrolment, and at another time point corresponding to end of treatment (8th treatment week). Levels of BP and heart rate were derived from the average of data corresponding to the time points. BP trend was determined by the slope of the regression line. A negative slope means a trend of BP reduction. Standard regression analysis also provides the statistical significance (*P*-value) of a non-zero slope. A patient whose home BP data displayed a negative slope with a statistical significance of $P < 0.05$ was defined as a responder to treatment.

Groups comparison: For comparison of baseline characteristics, as well as the percentage of responders between the treatment groups *t*-test was used for continuous variables and Fischer's exact test for categorical variables. Linear regression models were used for comparing treatment effect on BP change. Covariates included baseline BP value, age, gender, medication status, and the interaction of these covariates with the type of treatment, which adjusts for the effect of difference in baseline characteristics between groups. All tests were two-tailed and a P value <0.05 considered significant.

Results

Patient characteristics

As shown in Table 1, the active and control treatment groups were comparable. Eight of the 18 patients in the active treatment group and seven of the 15 patients in the control group were not on drug therapy. Four patients in each treatment group used two or more drugs before and for the duration of the study. Home BP and heart rate levels were lower than clinic levels ($P = 0.01$ for systolic BP, and $P < 0.001$ for heart rate). Baseline BP level was slightly higher, although not statistically significant in the active treatment group than in the control group. This was mainly contributed by one patient assigned to the active treatment group who had extremely high BP levels despite maximal drug therapy. Using covariate analysis controlled the possible

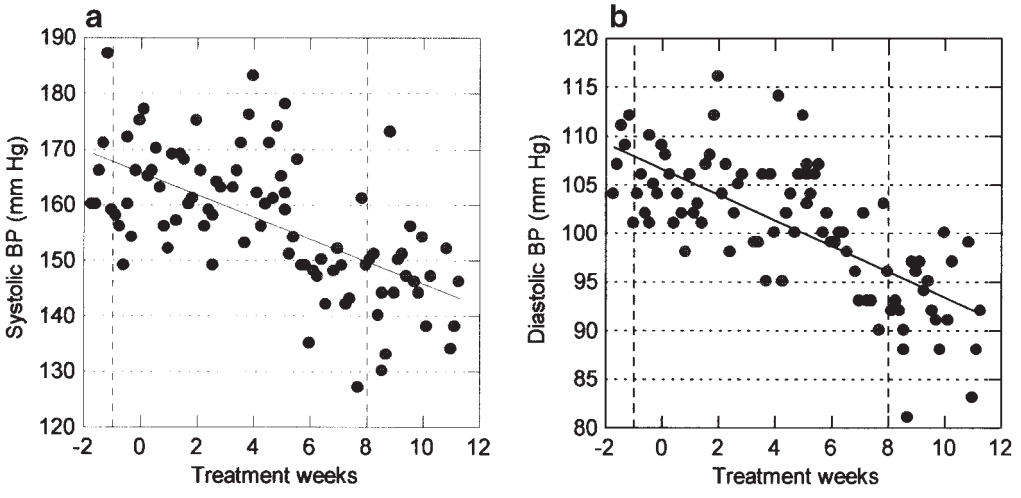

Figure 1 Time course blood pressure in patient no. 3 (active treatment group). Each point represents one morning BP measurement (**a**) systolic BP, (**b**) diastolic BP. The time is measured by weeks starting from the start of treatment. Thus negative values correspond to baseline. The regression line is marked and the vertical lines mark the middle of baseline (left) and the end of the 8th treatment week. The difference between the Y values of the regression line evaluates the BP reduction and the significance of the slope (if negative) determines if the patient is a 'responder'. As can be seen, the patient continued the treatment after the study ended and BP continued to decrease.

Table 1 Baseline patient characteristics by treatment group (mean ± s.d.)[a]

	Group		P-value
	Active treatment (n = 18)	*Control treatment (n = 15)*	
Age (year)	52 ± 12	50 ± 4	0.54
Gender (M/F)	13/5	10/5	1.00
Height (cm)	172 ± 10	174 ± 10	0.95
Weight (kg)	78 ± 13	81 ± 12	0.55
BMI (kg/m^2)	26.2 ± 3.2	26.8 ± 3.0	0.56
Patients on no treatment	8	7	1.00
Patients on one drug	6	4	0.72
Patients on ⩾2 drugs	4	4	1.00
Clinic measurements			
Systolic BP (mm Hg)	160 ± 18	155 ± 11	0.41
Diastolic BP (mm Hg)	95 ± 7	94 ± 6	0.47
MAP (mm Hg)	117 ± 9	114 ± 7	0.34
Heart rate (beats/min)	77 ± 9	81 ± 18	0.49
Home measurements			
Systolic BP (mm Hg)	157 ± 13	151 ± 13	0.21
Diastolic BP (mm Hg)	94 ± 7	90 ± 9	0.14
MAP (mm Hg)	115 ± 7	110 ± 9	0.12
Heart rate (beats/min)	71 ± 7	70 ± 12	0.80

[a]BMI, body mass index; BP, blood pressure; MAP, mean arterial pressure.

effect of such differences on the study outcome. The uneven number of the patients assigned to the studied groups was due to an administrative mistake done by the device provider, who supplied a BIM to a patient assigned to the control group.

Clinical effects of treatment

All patients complied with the treatment and tolerated it well. No side effects were observed during the study. Two patients from the control group started lifestyle modification programmes after enrolment without notifying the investigator. One patient started a low caloric diet and lost 8 kg in weight during the study, while the other started intensive physical activity and lost 3 kg. Due to the blinding of the study, we became aware of these lifestyle modifications only at the end of study. The data were therefore analysed including and excluding these two patients. One patient from the control group did not perform home measurements during the last month of treatment, preventing the evaluation of outcome at home.

Response to treatment based on clinic measurements

At the end of the study period the average BP change was −7.5 ± 12.0/−4.0 ± 7.7 mm Hg in the active treatment group (n = 18) *vs* −2.9 ± 12.1/−1.5 ± 9.1 mm Hg in the control group (n = 15) (Table 2). The average BP change in the control group was similar (−3.0 ± 12.9/0.0 ± 8.9 mm Hg) after excluding the data of the two patients, who started lifestyle modification. The BP changes were found to depend on baseline BP in a group-specific fashion, but were independent of age, gender and medication status. For the subgroup of patients with a baseline systolic BP greater than 145 mm Hg, the difference in the patient's response to treatment *vs* control was more pronounced: the change in BP was −10.1 ± 12.9/−5.2 ± 7.0 mm Hg in the active treatment group (n = 13) *vs* −0.5 ± 13.4/+2.6 ± 8.1 mm Hg in the control group (n = 10) (P = 0.01/P = 0.03). Most of the treatment effect was already observed after 4 weeks (73% of systolic BP change and 64% of the diastolic BP change). Heart rate remained unchanged in both groups (Table 2).

Table 2 Response to active and control treatment based on clinic measurements

	Group		P-value*
	Active treatment (n = 18)	*Control treatment (n = 15)*	
Change in systolic BP (mm Hg)	−7.5 ± 12.0	−2.9 ± 12.1	0.001
Change in diastolic BP (mm Hg)	−4.0 ± 7.7	−1.5 ± 9.1	0.12
Change in MAP (mm Hg)	−5.1 ± 7.6	−2.0 ± 8.9	0.03
Change in heart rate (beats/min)	0.8 ± 7.8	−0.7 ± 9.6	0.5

*Covariate adjusted. BP, blood pressure; MAP, mean arterial pressure.

Table 3 Response to active and control treatment based on home measurements

	Group		P-value*
	Active treatment (n = 18)	*Control treatment[a] (n = 12)*	
Change in systolic BP (mm Hg)	−5.0 ± 9.6	−1.2 ± 7.3	0.07
Change in diastolic BP (mm Hg)	−2.7 ± 4.9	+0.9 ± 3.7	0.02
Change in MAP (mm Hg)	−3.5 ± 6.1	+0.2 + 4.0	0.03
Change in heart rate (beats/min)	−1.0 ± 5.2	−0.1 ± 5.0	0.05

[a]Excluding two patients who started lifestyle modification programme after enrolment and one who did not measure BP during the last month of treatment.
*Covariate adjusted. BP, blood pressure; MAP, mean arterial pressure.

Response to treatment based on home measurements

At the end of the study period the average BP change was −5.0 ± 9.6/−2.7 ± 4.9 mm Hg in the active

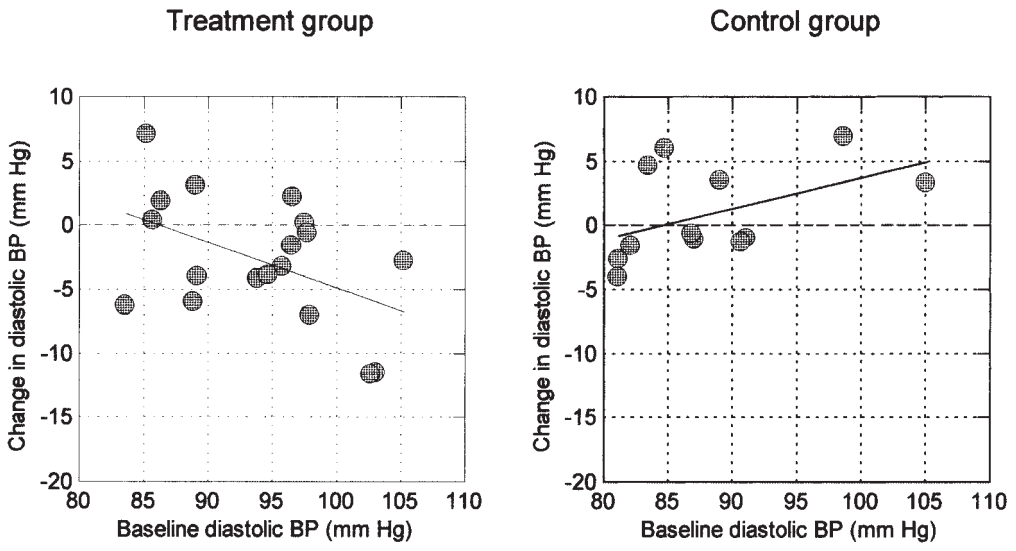

Figure 2 Dependence of home diastolic BP changes on baseline value by group. The regression line is marked.

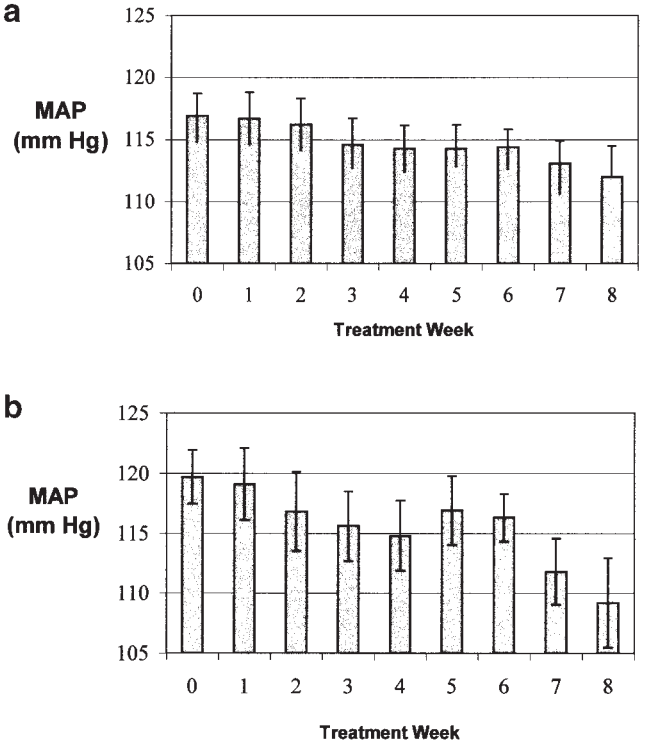

Figure 3 Variations of mean arterial pressure at home during the active treatment group ($n = 18$) (**a**) and in the subgroup of patients identified as 'responders' ($n = 10$) (**b**). The height of each bar represents the average value over 1 week (half week before and half week after the mentioned value). Standard error is marked.

treatment group and $-3.1 \pm 8.2/-1.1 \pm 6.4$ mm Hg in the control group. When the two patients from the control group who started lifestyle modification were excluded from the analysis the average BP reduction was significantly greater in the active treatment group than in the control group, which displayed BP change of $-1.2 \pm 7.3/0.9 \pm 3.7$ mm Hg (Table 3). BP changes were unrelated to age, gender and medication status. However, they were dependent on baseline BP in a group-specific way: the pattern of response in the active treatment group was entirely different from that observed in the control treatment group (Figure 2). In the active treatment group larger BP reduction was observed in those with higher initial BP levels, whereas in the control treatment group there was an opposite trend. Ten out of 18 patients (56%) in the active treatment group were responders, as against only two out of 14 (14%) in the control group ($P = 0.02$). Similar to the observation in the clinic, the treatment effect was observed after 4 weeks, but further reduction in BP was achieved after an additional 4 weeks of treatment. The trend of home BP reduction in the whole active treated group and in the subgroup of patients identified as 'responders' is shown in Figure 3. Heart rate slightly decreased in the active treated group (Table 3).

Respiration data

The performance data stored at the data logger of the BIM during the treatment showed that the average respiration rate at the end of breathing sessions during the treatment period was 7.1 (respiration period of 8.5 ± 3.4 sec).

Discussion

This study shows that breathing exercises guided by the BIM device for 10 min daily are effective in lowering BP. Unlike other clinical studies we have used, in addition to BP measurements at the clinic, daily BP recordings at home. Measurements at home were taken with a digital BP monitor that stored all data. Monitoring baseline BP at home identified patients with white coat hypertension who were excluded from the study. In fact 52 patients were screened and

only 33 patients were found to have home BP level eligible for this study. In addition, we obtained an average of 50 days of digital BP measurements for each patient enabling us to achieve significant results despite the relatively small group size. In the present study we did not evaluate the chronic changes of the breathing pattern in the active treated group, apart from at the end of exercise (see below).

The high compliance rate recorded from patients' diaries indicates that this method of non-drug therapy as well as its monitoring can be maintained for at least 2 months. As expected, BP levels at the clinic were higher, at baseline and during treatment, than BP levels at home. Patients were able to see their BP levels at home, but how it affects the response to treatment is unknown. The difference between the observed and the expected value might motivate the patient and improve his compliance.[21] On the other hand, in some patients it may induce stress by reminding them of being hypertensives.

Active treatment with the BIM lowered BP significantly more than did the control intervention, based on both clinic and home measurements, without any side effects. The response rate, based on home BP measurements, was significantly higher in the active treatment group than in the control group. The definition of 'responder', as a significant trend of declining BP, appears to be valuable in quantifying the response to treatment using home BP measurements. The pattern of BP response as a function of the initial BP was different in the two treatment groups. The drop in BP was greater in those with higher initial BP levels only in the active treatment group. The present study, which is based on home and clinic measurements controls for the white coat effect.

The choice of a Walkman as an active control in our study (relaxation treatment) differed mainly in the treatment component, ie breathing exercises, and thus satisfied the criteria of a 'good control'.[22] The effect of the Walkman has potential benefits, since it has been demonstrated that quiet music can elicit a cardiovascular response in the direction opposite to that caused by mental stress.[23,24] The similarities between both devices used in the study include cognitive components related to using a hand-held musical device, listening to music, a short period of technical training and similar environmental conditions during treatment.

The data suggests that music-guided breathing exercise performed with the BIM can lower BP. This effect was observed after 4 weeks of treatment and was associated with a slight decrease in heart rate. Listening to music 10 min a day may be considered as a relaxation method and therefore, this modality slightly reduced BP. The further reduction in BP observed in the active treatment group is probably related to the breathing modulation achieved in these patients. Even though about half of the patients were treated with antihypertensive agents, the BP reduction cannot be attributed to drug treatment, since the treatment was unchanged 2 months before and during the study. Furthermore, the response to the breathing exercise was not dependent on the medication status. Thus, it seems that modulation of respiration achieved by the applied breathing exercises is the active component of the BP reduction.

The dependence of BP changes on the baseline values appears to represent a real effect and not the so-called 'regression to the mean'. The latter represents a statistical phenomenon, which may appear when the baseline value is based on a single observation, representing a low-probability and relatively high value of the patient's BP, making the subject eligible for the study.[25] In the present study, however, both baseline BP values as well as BP changes represent averages of many home-based measurements. The results of our study are supported by studies in the literature showing that an acute slow and regular breathing pattern may beneficially affect reflex control of the cardiovascular system and modulates BP, probably via stimulation of slowly adapting pulmonary stretch receptors.[13,16,26] More specifically, slowing down breathing rate increases baroreceptor sensitivity.[15] The breathing rate achieved by the patients during the active treatment is much slower than normal breathing (12–20 breaths per minute) and overlays the frequency range of large effects of breathing on acute cardiovascular response.[15,16,26] However, this mechanism cannot be extrapolated to explain sustained BP reduction following a series of repeated interventions. The slow breathing rate achieved by the patients in the treatment group at the end of the treatment sessions demonstrates a potential for eliciting an acute response to slow breathing. In the lack of data related to in-between treatment sessions, the question of how repeated short-term interventions decrease BP remains unanswered. We speculate that repeated response to acute slow and regular breathing reverses the vascular pathology associated with hypertension. This view is supported by the following evidence: The arterial compliance is partially determined by the vascular tone, which is controlled by the sympathetic activity;[27] excitatory autonomic changes produced by stress stimuli can be blunted following a 3 months routine of breathing exercises, similarly to β-adrenergic blockade;[28] home heart rate measurements were also slightly lower in the BIM treated group than in the control, suggesting suppression of the sympathetic nervous system activity; carotid wall thickness can be reduced in atherosclerotic hypertensives following a stress reduction with the transcendental meditation programme.[29]

The concept of an adaptive process, triggered by routinely applied short interventions rationalises the health-related benefits associated with physical activity, which has been shown to reduce BP[30] by an amount comparable with our results. The present

study, which is based on home and clinic measurements controls for the white coat effect.

Conclusions

The BIM device can be used as a safe and efficacious adjunctive therapy for hypertension. Significant BP reductions can be achieved within 1 to 2 months of daily self-treatment at home. Slow and regular breathing appears to play a prominent role in this treatment.

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