The impact of music guided deep breathing exercise on blood pressure control - A participant blinded randomised controlled study

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ABSTRACT

Introduction: As pharmacological treatment of hypertension has become a burden worldwide, the study looked into non-pharmacological ways of reducing blood pressure. The objective was to determine if music guided, slow and deep breathing will reduce the blood pressure among patients with hypertension in eight weeks.

Methods: A participant blinded, multi-centre, randomised controlled trial was conducted in which the participants in the intervention group (IG) practiced deep breathing exercise guided by sound cues and those in the control group (CG) listened to the music. The primary end point was reduction in blood pressure at eight weeks.

Results: 87 patients, 46 males and 41 females with mean age of 61.1 years were recruited and 93.1% of them successfully completed the study. There was significant reduction in systolic and diastolic Blood Pressure from baseline by 8 weeks in both groups. The reduction in Mean systolic blood pressure (SBP) in the control arm was 10.5mmHg compared to 8.3mmHg (p<0.001) in intervention group. Diastolic blood pressure (DBP) reduction in control and intervention groups were 5.2 mmHg (p<0.001) and 5.6 mmHg (p<0.001) respectively. The absolute difference in SBP reduction from baseline in IG & CG was -2.2 (95%CI: -7.8 to 3.5) and DBP was -0.4 (95%CI: -2.9 to 3.6). However, blood pressure reduction between the two groups was not significant.

Conclusions: Both listening to music and deep breathing exercise were associated with a clinically significant reduction in SBP and DBP. However, deep breathing exercise did not augment the benefit of music in reducing BP.

KEY WORDS:
Hypertension; Music guided deep breathing; Blood Pressure

INTRODUCTION

Hypertension is an important worldwide public health problem because of its high frequency and serious complications. It is estimated that nearly one billion people are affected by hypertension worldwide and this figure is predicted to increase to 1.5 billion by 2025.[1] Hypertension is generally treated by lifestyle modifications with or without medications. The side effects and cost of antihypertensive medications have led to a search for effective non-pharmacological treatment to be tried alone or complementary to drug therapy.[2]

Non-pharmacological treatments that are effective in reducing blood pressure (BP) include lifestyle modifications like physical exercise, salt restriction and weight reduction.[2,3] Relaxation and stress-relieving techniques such as yoga, meditation and biofeedback have also been effective in lowering BP.[4-13] However, reviews of such treatments have not produced consistent results and their mechanism of action is still unclear.

Elevated sympathetic activity is often associated with desensitisation of arterial and cardiopulmonary baroreceptors, which leads to increase BP and sustained elevations in resting BP. Slow breathing, less than 10 breaths per minute, especially with prolonged exhalation, appears to reduce sympathetic nerve traffic thus causes arteriolar dilatation. The process is believed to be initiated by activated pulmonary mechanoreceptors, which respond to the increased tidal volume that accompanies slow breathing. This mechanism will act in concert with cardiac mechanoreceptors to inhibit sympathetic outflow. Therefore, the probable mechanism of action by slowing down breathing rate is that it increases baroreceptor sensitivity.[14-16]

However, it may be quite difficult to get patients to perform paced breathing sessions on their own. Apart from the training, practicing skill and motivation, effortlessly performed paced breathing involves individualised breathing patterns that typically require personal coaching. Device-guided regulation of breathing has been shown in randomised controlled trials to reduce BP.[17-18] Such devices guide the user towards slow and regular breathing by creating a musical pattern tempo related to the breathing movements monitored by a sensor. Regular use of such devices for 10 to 15 minutes per day was effective in lowering BP with no reported adverse effects.

Commercially available devices which incorporate sensors which monitor patients' breathing and automatically adjust the music rhythm to guide the patient towards the target breathing rate may be too costly for the average patient. We presumed that a simple audio compact disc (CD) can be used

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for this purpose and it will be an affordable alternative. Hence, we decided to incorporate deep, slow breathing which has been shown to be effective in reducing BP by Mori[19] in this study to determine its effectiveness in reducing the blood pressure.

METHODS

We conducted a participant blind; two arms, parallel group, multicentre randomised controlled study to compare the effectiveness of music guided, slow and deep breathing with listening to similar music CD without any prompt for deep breathing in reducing the diastolic, systolic and mean arterial blood pressures among hypertensive patients over a period of eight weeks. The study was approved by an independent ethics committee (NMRR -11-661-10072) and was conducted in compliance with Good Clinical Practice principles. The study was registered in ClinicalTrials.gov and the registration number is NCT01285193. Informed consent was obtained from all patients.

Study participants were adult patients with stage 1 essential hypertension (BP of 140-159/90-99mmHg)[20] diagnosed at least six months prior to study entry with or without antihypertensive medications. For those on treatment, they should be stable on anti-hypertensive treatment for a minimum of two months prior to the study and no change in medications during participation in the trial. Excluded from the study were patients with impaired hearing, ischaemic heart disease, congestive heart failure, renal impairment (serum creatinine>120µmol/L), diabetes mellitus of suboptimal control (HbA1C>7mmol/l), stroke within the previous two years, major organ failure, respiratory diseases resulting in dyspnoea at rest and those who were unable to operate a CD player or did not have access to a CD player. Patients were withdrawn from the study during their participation if the systolic BP or diastolic BP was greater than 160mmHg and 100mmHg respectively and if there was a change in the medical condition that did not allow the patient to continue participation according to the protocol.

The three participating centres were the outpatient department of Penang hospital, Butterworth health clinic and health clinic Bandar Baru, Air Itam, Penang. Patients were recruited over a period of four months starting from April to August 2011. Eligible patients were randomised in a 1:1 ratio to either the intervention or control group. Randomisation sequence generation and implementation is explained in detail under statistical considerations

The device was a CD with background music without any identifiable rhythm which might interfere with patients' breathing pattern. Both groups were taught how to use the music CD by trained therapists. Patients were masked by being informed that they would be taught a relaxation technique by using a music CD without mention of the breathing exercise. The intervention consisted of listening to the music CD with sound cues incorporated to guide the patient into a regular breathing pattern with a breath rate of five breaths per minute. The duration of breathing was four seconds for inspiration and eight seconds for expiration.

They were trained on deep breathing technique and use of an audio CD to reduce breathing rate to five breaths per minute. The training sessions were conducted by occupational therapists. Patients were asked to be in sitting position and taught to take a deep breath for four seconds and slowly breathe out for eight seconds mentally counting eight. Then the occupational therapist plays the CD which has the birds chirping sound to prompt them to breathe in and the stream flowing sound prompting them to breathe out. They breathe deeply in while birds chirping and breathe out slowly when the stream is flowing. The therapists trained them until they could do it well. The patients were asked to document the starting and ending time of the breathing sessions in their diary every day.

The control group who were supposed to be listening to the music CD were taught how to use the music CD. They were masked by being informed that they would be taught a relaxation technique by using a music CD without mention of the breathing exercise.

The patients were given instructions to sit comfortably in a quiet room and avoid any disturbances such as use of telephone, television or engaging in any form of conversation. Both groups listened to the music CDs at home for at least 15 minutes per day and the intervention group performed the CD-guided breathing exercise while listening to the music. Patients recorded each session in a log sheet. The duration of the study was eight weeks.

Patients were assessed by the study staff in the clinic at four, six and eight weeks respectively and the assessment staffs were blinded to treatment allocation. Assessment consisted of blood pressure measurement and enquiry into adverse effects, lifestyle modifications, change of hypertensive medication and concomitant medication. A personal diary that was given to each patient for recording of the number of sessions and duration of each session was checked to ensure compliance.

BP was measured with a validated automated device by a trained research assistant. For each visit, at least three BP readings were measured, at least one minute apart, stopping when two consecutive readings (both systolic and diastolic) did not differ by more than 5mmHg. BP measurement for the visit was calculated by averaging the data of the last two consecutive readings. All subjects had their blood pressure measured at the same time of the day (either morning or afternoon) throughout the study visits.

Baseline BP was defined as average of the last two readings, measured a few days apart before enrolment. The primary study outcomes for an individual patient were changes in the systolic BP, diastolic BP and mean arterial pressure (MAP) from baseline to 'end value', where the latter is the value measured during the last visit. MAP is calculated using the formula: MAP = diastolic BP + 1/3(systolic BP – diastolic BP).

Statistical Methods

The primary outcome for sample size calculation was change in diastolic BP from baseline to "end-value". Based on the study by Schein,[17] the difference in means between the intervention and control group was 4.4 with a pooled

standard deviation of 6.36. By using the Power and Sample Size Program,[21] Version 2.1 for T Test with 80% power and 5% level of significance, the sample size required was 34 patients per arm. With a consideration of 20% drop out rate, a total of 84 patients were required in this study.

Randomisation and treatment allocation: Random permuted block randomisation stratified by centre was used to generate the randomisation sequence separately for each centre. In block randomisation the potential patients are divided into block sizes of 2, 4 and 6 and then the blocks are chosen randomly. This method of permuted block randomisation with varying block sizes besides ensuring equal treatment allocation within each block it also enhances the randomness of allocation. Each centre had its own randomisation sequence generated by the statistician.

Subjects were then randomly allocated to either music alone (Control group) or music and breathing exercise (Intervention group) in a 1:1 ratio using interactive voice response system (IVRS) provided by Penang hospital Clinical Research Centre (CRC). The participating centre calls CRC for randomisation. CRC after confirming the eligibility of the subject gets the subject's initials and study registration number and provides the randomisation code from the sequence generated for the centre. CRC also enters the subject registration number and randomisation code provided for each subject in the randomisation log of that centre.

Statistical analysis: Baseline characteristics between groups were analysed using independent t-test or Mann-Whitney two-sample test (following the normality assumptions) for continuous variables and chi-square test or Fischer's exact test (following the assumptions) for categorical variables.

The changes in measurements from baseline for each group were analysed using paired t-test if the assumption of normality is assumed. Otherwise, Wilcoxon matched-pairs signed-ranks test was performed.

The mean arterial pressures (MAP), systolic and diastolic BPs were measured at baseline and at the end of the study. The comparison of these measurements between the groups was analysed using independent t-test. Repeated measure analysis with ANOVA was used to determine if there were significant changes in primary and secondary outcomes after adjusting baseline values and other numerical covariates. Correlation was used to analyse relationship between BP change and total duration of practice with the music CD.

RESULTS

Of the 117 patients screened in three participating centres, 87 were found to be eligible. Forty-two subjects were randomised to the intervention arm (music and breathing) and 45 were allocated to the control group (music only). In the intervention group, three subjects withdrew before the first efficacy assessment at Visit-3 without reasons while one subject from the control group was withdrawn before visit-3. Hence number of patients who received at least one session of study intervention and had at least one efficacy assessment (ITT population for efficacy analysis) was 39 in the breathing group and in the music group were 44. Eighty subjects completed the study per protocol as three more patients in music group withdrew during the course of the study. The study profile is shown in Figure 1.

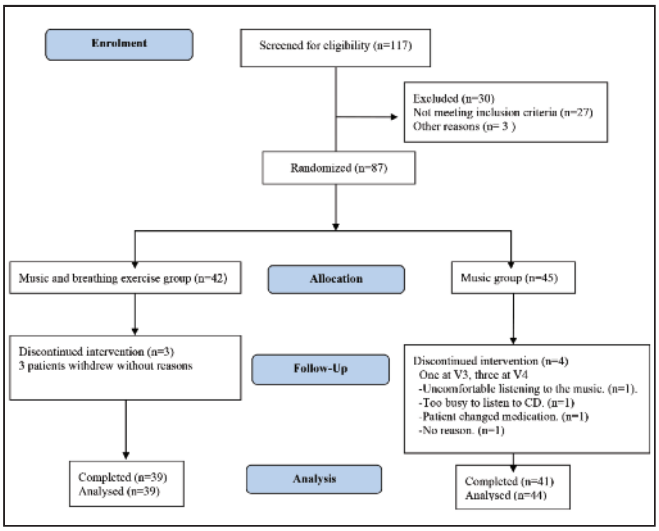

Fig. 1: Study Profile.

The demographics and baseline characteristics of the patients are given in Table I.

Proportion of patients who were on one antihypertensive agent or more than one drug in both groups is given in the table above. However, none of them altered the dose of their antihypertensive during the study

Mean Blood pressure and heart rate measurements and their standard deviations at every study visit are given in Table II.

There is a progressive reduction in both systolic and diastolic blood pressure in both groups from screening visit, baseline visit final study visit at 8-week.

The quantum of reduction in blood pressure and heart rate at every visit after the intervention is given in Table III.

Comparison of change in blood pressure and heart rate between the two groups for "Intention to Treat Population" (ITT population = those patients who had at least one efficacy end point measured) is given in Table IV.

In both ITT population and per protocol population there is a significant reduction in systolic and diastolic blood pressure and the heart rate. Mean systolic BP reduction in the control arm was 10.5mmHg compared to 8.3mmHg ($p<0.001$) in intervention group. There was reduction in mean diastolic BP of 5.2mmHg ($p<0.001$) and 5.6mmHg ($p<0.001$) in control and intervention groups respectively. The absolute difference in systolic blood pressure reduction from baseline in intervention group and control group was -2.2 (95%CI: -7.8 to 3.5) and diastolic blood pressure was -0.4 (95%CI: -2.9 to 3.6). There was no significant difference between the intervention and control groups.

Table I: Patient Demographics and Baseline Characteristics

	Music (N=44)	Music and Breathing (N=39)
Gender: No (%)		
Male, Female	22(48.9), 23 (51.1)	24 (57.1), 18(42.9)
Ethnic group:		
Malay, Chinese, Indians, Others	3(6.7), 40 (88.9) 1(2.2), 1(2.2)	2(4.8), 36(85.7), 3(7.1),1(2.4)
Education level:		
Primary, Secondary, Tertiary, Nil	6(13.3), 29(64.4), 7(15.6), 3(6.7)	8(19), 22(52.4), 9(21.4), 3(7.1)
Age (years)Mean (SD)	59.7 (9.6)	62.6 (9.6)
Weight (kg) Mean (SD)	67.1(12.0)	66.9(12.8)
Height (m) Mean (SD)	1.6(0.1)	1.6(0.1)
BMI Mean (SD)	25.7(3.5)	25.5(3.5)
Arm circumference (cm)	30.2(3.3)	30.3(2.7)
Mean Systolic BP (mm Hg) Mean (SD)	145.7(8.3)	150.6(7.1)
Mean Diastolic BP (mm Hg) Mean (SD)	90.1(4.5)	88.7(7.3)
Mean heart rate (beats/min) Mean (SD)	66.8(13.4)	61.7(13.1)
Mean arterial pressure, Mean (SD)	108.6 (4.3)	109.3(5.9)
Total QOL score, Mean (SD)	36.3(5.9)	36.2(6.6)
No. of anti-hypertensive medications		
Patients on one drug: No (%)	19 (42.2%)	17 (40.5%)
Patients on > one drug	23 (51.1%)	24 (57.1%)

Table II: BP and Heart Rate at each study visit from baseline

Visits	Music (Control Group)					Music & Breathing (Intervention Group)				
	N1	SBP	DBP	MAP	HR	N2	SBP	DBP	MAP	HR
		Mean (SD)					Mean (SD)			
Screening	45	145.7 (8.3)	90.1 (4.5)	108.6 (4.3)	66.8 (13.4)	42	150.6 (7.1)	88.7 (7.3)	109.3 (5.9)	61.7 (13.1)
Baseline	45	142.6 (8.3)	86.9 (6.5)	105.5 (6.0)	66.5 (14.2)	42	143.2 (10.2)	84.1 (7.6)	103.8 (6.9)	62.2 (11.8)
4 weeks	44	133.3 (13.3)	83.2 (8.7)	99.9 (9.4)	66.2 (13.6)	39	136.1 (11.5)	81.5 (7.0)	99.7 (7.4)	61.6 (12.5)
6 weeks	41	130.3 (13.9)	81.4 (9.4)	97.7 (10.3)	66.0 (12.6)	39	137.1 (12.4)	80.4 (7.6)	99.3 (8.7)	61.6 (10.8)
8 weeks	41	132.0 (13.4)	81.4 (8.9)	98.3 (9.7)	65.7 (13.3)	39	135.0 (13.3)	78.9 (10.0)	97.6 (10.3)	62.5 (11.8)

* N1 & N2 = Total population * SBP = Systolic Blood Pressure
* DBP = Diastolic Blood Pressure * MAP = Mean Arterial Pressure * HR = Heart Rate

Table III: Change in BP and heart rate at each study visit from baseline

Visit	Music					Music & Breathing Exercise				
	N	SBP	DBP	MAP	HR	N	SBP	DBP	MAP	HR
Week 4	44	-9.2 (11.7)	-3.5 (6.6)	-5.4 (8.0)	-0.5 (8.4)	39	-7.3 (10.0)	-2.9 (6.7)	-4.4 (7.0)	-0.6 (8.4)
Week 6	41	-12.2 (12.9)	-5.3 (8.7)	-7.6 (9.8)	-0.3 (7.5)	39	-6.3 (10.4)	-4.1 (7.6)	-4.8 (7.7)	-0.6 (6.8)
Week 8	41	-10.5 (14.1)	-5.2 (7.7)	-7.0 (9.6)	-0.6 (6.7)	39	-8.3 (10.8)	-5.6 (6.9)	-6.5 (7.8)	0.3 (8.5)

There has been a steady reduction in blood pressure and heart rate in both groups.

Table IV: Comparison of change in blood pressure and heart rate between intervention and control groups

	Music (n=44)		Music and Breathing (n=39)		95% CI of mean difference	P value for group comparison**
	Mean Change	P-value for 'efficacy'*	Mean Change	P-value for 'efficacy'*		
Systolic BP	-10.2	<0.001	-8.3	<0.001	(-7.3,3.6)	0.5005
Diastolic BP	-5.2	<0.001	-5.6	<0.001	(-2.8,3.6)	0.7991
Mean arterial pressure	-6.8	<0.001	-6.5	<0.001	(-4.1,3.4)	0.8596
Heart rate	-1.0	0.3401	0.3	0.8223	(-4.8,2.1)	0.4343

*Paired t-test
**Independent t-test

There were not many adverse events reported. Two patients in breathing exercise group felt dizzy after treatment. One patient felt dizzy for first six days and the second patient felt for the first two days. In the music group one patient felt 'numbness in head' for five minutes and another patient complained of palpitations and irritability every time he listened to the music.

DISCUSSION

Device guided breathing is one of the recommendations by American heart association for its blood pressure lowering effects. Since the device is expensive, we experimented with a music CD with sound cues incorporated to guide the patient into a regular deep breathing pattern as a cheaper alternative. The result of this study suggests that music guided practice of regulated, slow and deep breathing exercise reduced the diastolic, systolic and mean arterial blood pressure among patients with hypertension after eight weeks of intervention. However similar beneficial effects were also noted among patients in control group who listened to music CD without any cues to regulate breathing pattern. Systolic and diastolic blood pressures at 8 weeks did not differ significantly between groups. There was no augmented reduction in blood pressure in the slow and deep breathing group.

The reduction in blood pressure in both groups could not be explained by 'regression to mean' or "Hawthorne effect". The regression to mean phenomenon is unlikely as the subjects were already on the same treatment for at least two months prior to the study and subjects with very high BP were excluded. Besides that, there was two weeks interval between screening visit and baseline visit by which time the BP would have regressed to the mean. Contamination of intervention and control groups was also unlikely as the subjects' appointment visits were scheduled at certain interval time of the day to avoid the possibility of any discussions between the subjects.

However, if we had three arms where the third arm does not have any treatment, neither music nor controlled breathing we could have checked if "Hawthorne effect" had any influence and all three arms had similar reductions. But then blinding of patients would have been difficult.

Biofeedback therapies incorporating slow and regular breathing have received attention as an adjunct therapy for treatment of hypertension. It is proposed that slow and deep breathing will lead to adaptation of the pulmonary stretch receptors and baroreceptor reflex, which in turn will lead to vascular and cardiac relaxation.[18] Evidences for the benefits of slow breathing as an adjunct treatment of hypertension have been inconsistent. Some studies are supportive of its beneficial effects on blood pressure reduction. A study involving 86 hypertensive subjects revealed intervention with music guided slow breathing exercises was associated with a significant reduction in 24-hour systolic ambulatory blood pressure.[22] A randomised controlled trial carried out in four urban family practice clinics that involved diabetic and hypertensive patients concluded that self-treatment with device-guided breathing at home for eight weeks was associated with a substantial reduction in office systolic BP.[23] A systematic review and meta-analysis done on "Device guided breathing exercises in the control of human blood pressure" reports that though DGB appears to reduce the BP in the short term, there was no overall significant reduction when the manufacturer sponsored trials were excluded from the analysis.[24] Five out of the eight trials included in the analysis were sponsored by or involved the manufacturer of "Resperate".

A more recent randomised double-blind trial among patients with Type 2 Diabetes Mellitus and hypertension also reports that deep breathing guided by a device did not appear to be a viable non pharmacologic option for hypertension treatment.[25] There were no significant changes in systolic and diastolic blood pressure between the intervention and control group. Three patients in the intervention group experienced adverse events which include shortness of breath, atypical chest pain and a patient with underlying heart failure died of respiratory failure. Our study did not encounter similar adverse events as subjects with any form of ischaemic heart disease, congestive heart failure or respiratory failure were excluded from participation.

In our study those who listened to music alone without incorporating any breathing exercise also had reduction in systolic and diastolic blood pressures by 10.2 and 5.2mmHg respectively. A clinically meaningful difference in blood pressure reduction, as used in many hypertension trials, is arbitrarily defined as an absolute DBP reduction of 3mmHg or more as per written request issued by FDA. Another report says SBP and DBP reductions of 2mm or more reduce the cardiovascular and cerebrovascular events significantly both in people with normal BP and hypertension and so reductions of even this small magnitude are considered clinically meaningful.[26] Music has long been accepted socially to affect mood and said to have a calming and relaxation effect. Often people seek music for psychological benefits but research has shown that certain type of music can reduce the blood pressure and help to recover faster from a cardiovascular stress and the effects are most apparent in reducing systolic blood pressure.[27-28] The results suggest that listening to a certain type of music serves to reduce high SBP and therefore music therapy may be an alternative for hypertension treatment. Music therapy has also been shown to improve quality of life and BP control in hypertensive patients. One meta-analysis on the effects of music reported that there was significant greater decrease in systolic and diastolic blood pressure as well as heart rate in subjects who received music therapy compared to those who did not.[29] A more recent systematic review and meta-analysis of music interventions in hypertension treatment concluded that a trend towards a decrease in blood pressure in hypertensive patients who received music interventions. However, the study failed to establish a cause-effect relationship between music interventions and blood pressure reduction.[30]

Both regulated deep breathing and listening to music seem to reduce both systolic and diastolic blood pressure. Available literatures also neither confirm nor refute the efficacy of either intervention in reducing the blood pressure.

LIMITATIONS

There are few limitations in the study. The study sample size was calculated based on change in diastolic blood pressure from baseline to 'end-value' as demonstrated in the study by Schein.[17] Subjects in the intervention group were taught on deep and slow breathing technique on the recruitment day. Subsequently, their breathing technique and compliance to the technique were not assessed. Since our study was a short term eight weeks study and the sustained long term effect of lowering blood pressure cannot be determined.

CONCLUSIONS

In conclusion, this study showed there was significant reduction in systolic and diastolic blood pressure and mean arterial blood pressure with slow and deep breathing exercise for a short duration of eight weeks. Similar reductions were also recorded in the control group who just listened to the music. Deep and slow breathing exercise however did not seem to augment the reduction in blood pressure achieved by music in our study.

Considering the value of low cost, safe interventions such as deep breathing and listening to music in the holistic management of hypertension, there is a need for independent, better designed, sufficiently powered trials with proper control groups to assess the efficacy such interventions in reducing the blood pressure.

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STATEMENT OF CONFLICT OF INTEREST

None of the study members have any conflict of interest to disclose.

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