Effect of nurse-led home-based biofeedback intervention on the blood pressure levels among patients with hypertension: Pretest–posttest study

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Abstract

Aim: To investigate the effect of nurse-led home-based biofeedback intervention on the blood pressure levels among patients with hypertension. **Background:** Nurse-led interventions are emerging as cost-effective as well as clinically proven in chronic illness management. Hypertension, a leading long-term cardiovascular condition, has autonomic dysregulation and increased sympathetic tone as its pathophysiological background. Complementary interventions evidenced to interplay hypertension pathophysiology. **Design:** A pretest–posttest design. **Materials and Methods:** Uncomplicated primary hypertension outpatients were randomly assigned as study group ($n = 173$) and control group ($n = 173$) at a tertiary care hospital. Sociodemographic, clinical, and outcome variables [the baseline blood pressure and galvanic skin response (GSR)] were collected. Study group patients were given four teaching sessions of abdominal breathing-assisted relaxation facilitated by GSR biofeedback. Daily home practice was encouraged and monitored to measure the effects on blood pressure and GSR at the end of the 1st, 2nd, and 3rd month of intervention. **Results:** The study group participants showed significant decrease in mean (SD) systolic [140.77 (8.31) to 136.93 (7.96), $F = 469.08$] and diastolic blood pressure [88.24 (5.42) to 85.77 (4.66), $F = 208.21$]. In contrast, control group participants had a mild increase in the mean systolic ($F = 6.02$) and diastolic blood pressure ($F = 4.70$) values from pretest to posttests. GSR showed a significant increase from 559.63 (226.33) to 615.03 (232.24), ($F = 80.21$) from pretest to posttest III. **Conclusions:** Use of home-based biofeedback-centered behavioral interventions enabled BP reduction among hypertensive patients. Further studies should use biochemical markers of sympathetic nervous system activity to endorse this home-based chronic illness intervention.

Keywords: Biofeedback, breathing relaxation, complementary therapy, hypertension, nurse-led interventions

Introduction

Globally, around one billion people live with uncontrolled hypertension. Middle income countries report a prevalence rate of 40% for hypertension and despite pharmacological advances in management, it remains a common cause for premature mortality rates due to its cardio- and cerebro-vascular complications.[1,2] There is a vast body of evidence which agrees that most non-pharmacological interventions are both clinically and economically effective in hypertension management,[3-5] with less or no side effects. Systematic reviews reported

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that non-pharmacological mind–body interventions such as biofeedback, self-blood pressure monitoring, mindfulness, and yoga focused on neuro-psychological and behavioral components to reduce blood pressure and slow down the progress of hypertension.[6-8]

Biofeedback is a self-regulation-based complementary therapy which helps patients acquire mental and emotional control over body processes.[9] This is achieved through feeding back individuals with information on his/her own unconscious body functions and helping them to voluntarily control these functions[10] and to decrease the activation of the autonomic nervous system.[11] Biofeedback is also proved to have long-term useful effects in different ways for an array of diseases like Type 2 Diabetes mellitus,[12] constipation, migraine headache, and chronic pain.[13-15]

Evidence also suggests that breathing exercises are helpful in hypertension management when combined with biofeedback.[15,16] Breathing relaxation stimulates parasympathetic nervous system activity via diaphragmatic stretch and consequent vagal stimulation,[17] causing a fall in sympathetic parameters including heart rate, respiratory rate, and blood pressure[18,19] and a rise in Galvanic Skin Response.[20] Thus, galvanic skin response (GSR), a sensitive indicator of sympathetic nervous system activity,[20,21] was selected for biofeedback.

Home-based interventions were proven to be successful in both cost terms and clinical effectiveness in many long-term

conditions,[22,23] especially in the context of resource constrained countries. Patient empowerment models are suggested for effective Control of hypertension in such countries.[24] This study aimed to measure the effectiveness of nurse-led, home-based biofeedback-assisted breathing relaxation therapy on blood pressure levels among patients with primary hypertension.

Objectives

1. To evaluate the effect of nurse-led home-based biofeedback intervention on blood pressure, GSR and dosage of antihypertensive medications among primary hypertensives
2. To assess the compliance of breathing relaxation at home among the study group participants.

Materials and Methods

A randomized controlled study with pre- and posttest design was conducted among patients with primary (essential) hypertension in a tertiary university teaching hospital. Institutional Ethics Committee (IEC) and local department approvals were obtained before starting the data collection.

Setting and sample

A total of 666 patients with diagnoses of stage I uncomplicated primary hypertension in the age range 35–75 years attending the cardiology outpatient department of the selected setting were approached. Patients who were on the same antihypertensive regimen for at least 3 months at the point of selection were
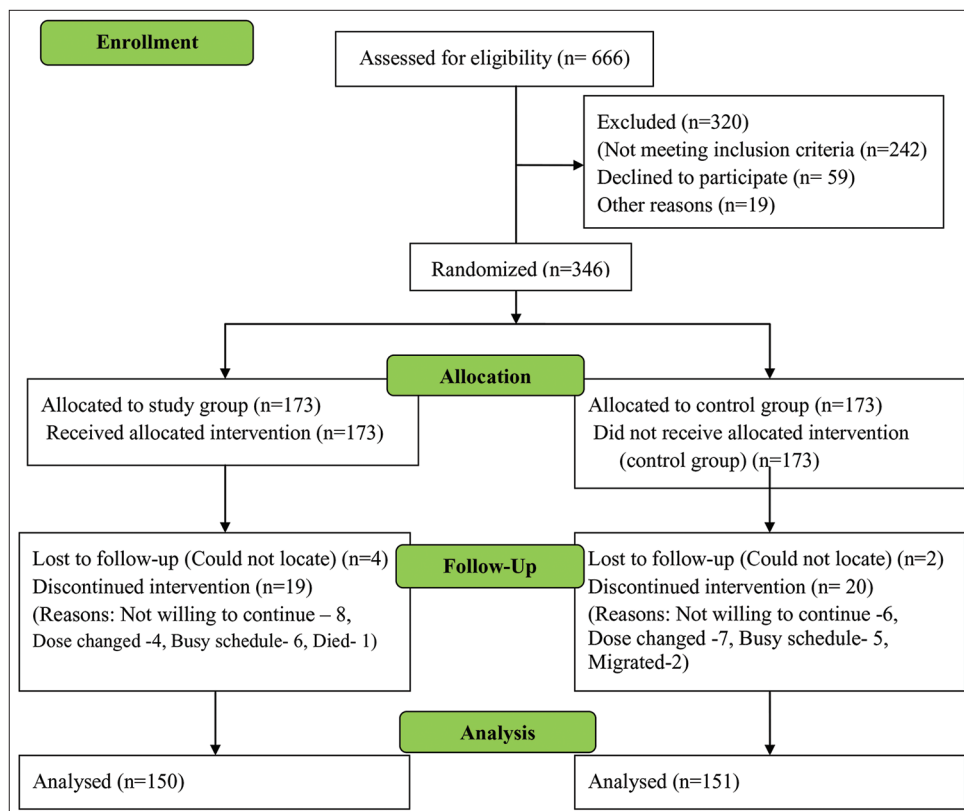

Figure 1: CONSORT diagram of recruitment

considered for inclusion. Those who were practicing any form of structured relaxation program or had serious visual disability were excluded. Also, those patients whose type of antihypertensive medications was changed during the study period for any reason were excluded from analysis. As the researcher simultaneously explored the level of anxiety among the same cohort in a different study, those on beta-blockers were excluded. A total of 346 patients who met the inclusion criteria were enrolled. This sample size was fixed to substantiate findings by applying $\alpha = 5\%$ and power $(1-\beta) = 80\%$, and 15% expected attrition.

Recruitment

Potential patients were screened for eligibility based on the inclusion criteria by verbal questions and perusing the clinical chart. The study protocol was explained to the eligible participants. Informed consent was sought from willing patients. 346 eligible outpatients who consented to participate were randomized using a random allocation sequence prepared by the statistician into study ($n = 173$) and control ($n = 173$) groups. Separate randomization sequence was followed for men and women to include them approximately equally in each arm. Allocation were and enrollment was carried out by the principal investigator. Recruitment followed CONSORT (Consolidated Standards of Reporting Trials 2010) guidelines [See Figure 1].

Data collection

To measure the effectiveness of the intervention, we used a demographic and clinical variables data sheet (gender, age, antihypertensive medications and dosage, height, weight, duration of the hypertension, dietary pattern, menopausal status of women, smoking and alcoholism habits, fasting blood sugar and serum cholesterol). In this study, blood pressure and GSR were collected as dependent variables.

Blood pressure readings were measured as per American Heart Association guidelines[25] using a calibrated sphygmomanometer and graded according to the seventh report of the Joint National Commission on prevention, detection, and treatment of hypertension guidelines[26] [Table 1]. The baseline GSR was gauged using a 250 mV impedance meter integrated biofeedback machine, which measured the skin resistance in kiloohms. The instrument was validated by the biomedical engineering department of the hospital. The intra-rater correlation coefficient of blood pressure measurements was high (.83). The number of practice days of relaxation at home was counted with the help of participants' self-markings in a simple home practice calendar

Table 1: Classification of blood pressure according to JNC-7 (2003)

Stage	Systolic BP (mm of Hg)		Diastolic BP (mm of Hg)
Normal	<120	and	<80
Pre-hypertension	120-139	Or	80-89
Stage I	140-159	Or	90-99
Stage II	>159	Or	>99

issued to them. The dosage changes of antihypertensives were verified from the records.

Biofeedback-assisted home-based breathing relaxation intervention (BAHRI)

The BAHR intervention is a complementary therapy that included a simple abdominal breathing exercise practiced by patients at home following four teaching sessions of 30 min duration given 1 week apart at the hospital. The relaxation was facilitated by the GSR biofeedback machine. The intervention was given in a private room at a set temperature by a psychologist, assisted by the investigator. Participants were encouraged to deepen the relaxation consciously by using visual feedback. Relaxation became a learned response for each participant by the end of the teaching period. The relaxation was practiced at home for 20 min a day for 12 weeks and reinforcement was given at the end of each month. Posttest measurements of BP and GSR readings at the beginning of the reinforcement sessions were considered to appreciate the sustenance effect. All blood pressure readings were obtained between 11 am and 1 pm. The standard care, including nursing assessment, lab tests, physician consultation, follow-up advice, and medications were continued by both study and control group patients as before. Posttest measurements were carried out by a trained health professional who was blinded towards the random allotment. The number of home practice days and dosage changes were verified during every posttest session. Random telephonic reinforcement was employed to ensure compliance, with their consent.

Ethical considerations

Approval from the Institutional Ethics Committee (IEC –NI/10/AUG/18/27) was obtained. We maintained confidentiality of the data. All data were stored in a password-protected computer in a locked cupboard and the access to the data was limited to principal investigator and co-investigators.

Statistical analysis

The data were analyzed using SPSS version 17. Descriptive methods were used to summarize the characteristics of the participants and to describe the changes in the outcome parameters from the beginning to the end of the study. Since data followed a normal distribution, parametric analysis methods were selected. All significance was assessed at a level of $P < 0.05$. Chi-squared test was used to assess the baseline differences between the groups. Paired "*t*" tests analyzed differences within the groups for the consecutive measurements and for first–last measurements. Independent "*t*" tests were used to know the difference between the groups for any two measurements. Repeated measures ANOVA was employed to identify the intervention effect on blood pressure and GSR across the three posttests. Bonferroni correction was employed.

Table 2: Demographic and clinical characteristics of study participants

Characteristics	Study group No. (%)	Control group No. (%)
Gender		
Male	100 (57.8)	94 (54.4)
Female	73 (42.2)	79 (45.6)
Age (in years)		
36-45	17 (10.0)	31 (17.9)
46-55	19 (10.7)	17 (09.9)
56-65	54 (31.3)	45 (25.8)
66-75	83 (48.0)	80 (46.4)
Physical activity/lifestyle		
Mild	99 (57.3)	93 (53.8)
Moderate	70 (40.7)	70 (40.6)
Heavy	04 (02.0)	10 (06.0)
Habits		
Alcoholism	40 (23.2)	25 (14.4)
Current smoking status (including passive)	29 (16.6)	28 (16.0)
Dietary pattern		
Vegetarian	24 (14.0)	23 (13.2)
Mixed diet	149 (86.0)	150 (86.8)
Menopause (women)		
Attained	38 (43.8)	42 (49.3)
Duration of hypertension		
<1 year	11 (06.6)	23 (13.2)
1-5 years	64 (37.2)	68 (39.0)
5-10 years	49 (28.0)	42 (24.6)
>10 years	49 (28.0)	40 (23.2)
BMI (kg/m²)		
<18	06 (03.4)	05 (02.6)
18-22.99	47 (28.0)	36 (21.2)
23-30	102 (59.8)	101 (58.4)
>30	18 (10.6)	31 (18.0)
FBS (mg/dl)		
<100	61 (35.3)	64 (37.1)
101-130	66 (38.0)	40 (23.2)
130	46 (26.7)	69 (39.7)
Hypercholesterolemia		
Yes	51 (29.3)	60 (34.4)
Antihypertensive medications		
1 (Diuretics)		
1+ 2	55 (32.0)	52 (29.8)
1+ 3 (Angiotensin receptor blockers-ARB)	22 (12.7)	23 (13.2)
2 (Angiotensin converting enzyme inhibitors- ACEI)	14 (08.0)	11 (6.6)
	50 (28.7)	50 (28.7)
4 (Calciun channel blockers - CCB)	14 (08.0)	14 (7.3)

Results

A total of 666 outpatients were screened for eligibility. Of these, 346 were eligible and were assigned into either study or control groups (*n* = 173 each). The overall attrition was 13% (*n* = 45). Posttest analysis was done for 150 patients in the study group and 151 patients in the control group. The groups did not differ in their baseline characteristics [Table 2]. Reasons for sample loss included not willing to continue, busy domestic schedule, death (non-cardiac related), could not be located by the investigator, or migrated to a distant location. The type of antihypertensive medications was

changed by the physician for 11 patients during the period of the study and were excluded from analysis.

Result 1: Effectiveness of biofeedback-assisted breathing relaxation intervention on overall blood pressure between study and control group

To measure the effectiveness of biofeedback-assisted breathing relaxation techniques, the number of patients who moved across the categories of blood pressure according to JNC-7 (2003)[26] between the study and control group was analyzed [Table 3].

During the pretest, all patients in both study and control groups belonged to the stage I category of blood pressure. During post-test III, the number of patients who moved from stage I to the pre-hypertension stage was 21 (14%) in the study group and five (3.3%) in the control group. Five (3.3%) in the control group got their blood pressure level accelerated to stage II. This category change was significant with a Chi-squared value of 20.06 at *P* < 0.001.

Result 2: Effectiveness of biofeedback-assisted breathing relaxation intervention on blood pressure among patients with different antihypertensive medications

We measured the effect of BAHRI on blood pressure with various antihypertensive medications. Participants who were taking a combination of diuretics and ACEI showed significant difference in mean systolic blood pressure between the study and control groups during posttest III with "*t*" values of -3.92 (*P* < 0.001). This was in contrast to participants who took diuretics, who showed maximum benefits of intervention on diastolic blood pressure only along with medications with "*t*" values of -3.71 (*P* < 0.001) [Table 4].

Result 3: Effectiveness of biofeedback-assisted breathing relaxation intervention on mean blood pressure from pretest to posttest III

As we compared the mean blood pressure values from pretest to posttests III among participants, there was a highly significant reduction in the systolic BP at *P* < 0.001 (*F* = 469.68) in the study group, whereas in the control group, there was a significant raise from pretest to posttest III at *P* = 0.003 (*F* = 6.20). A similar pattern was observed for diastolic BP with a significant fall from pretest to posttest III among the study group with *F* = 208.21 (*P* < 0.001) and a significant rise for diastolic BP towards the end of the study with *F* = 4.70 (*P* = 0.008) [Table 5].

Result 4: Effectiveness of biofeedback-assisted breathing relaxation intervention on mean blood pressure, dosage reductions and GSR

Mean blood pressure
During the pretest, there was no significant difference in the level of mean systolic blood pressure between the study and control

Parameter	Category	Pretest		Intergroup Interaction t (*P*)	Posttest		Intergroup Interaction
		Study No. (%)	Control No. (%)		Study No. (%)	Control No. (%)	
Systolic BP	<120	0	0	0.36	05 (04)	0	t (*P*)
	120-139	41 (27.3)	46 (30.5)	0.549	87 (52)	49 (32.4)	29.32
	1402159	109 (72.7)	105 (69.5)		58 (44)	99 (65.5)	0.001
	>159	0	-		0	03 (1.9)	
Diastolic BP	<80	6 (4.0)	01 (0.7)	4.26	08 (5.3)	0	t (*P*)
	80-89	44 (29.3)	51 (34.4)	0.119	115 (76.7)	52 (34.4)	73.09
	90-99	100 (66.7)	99 (65.9)		27 (28)	97 (64.4)	0.0001
	>99	0	0		0	02 (1.2)	
Overall BP	Pre HT	0	0	-	21 (14)	5 (3.3)	χ^2
	Stage I	150	151		129 (86)	141 (93.4)	20.06
	Stage II	0	0		0	5 (3.3)	0.001

Table 3: Effect of biofeedback assisted relaxation on category-wise distribution of participants

Table 4: Comparison of effect of various antihypertensive medications on BP among the patients with stage I hypertension between study and control groups before and after intervention

Antihypertensive medications	Duration	Study Group (*n*=150)		Control Group (*n*=151)		t &*P*	Study Group (*n*=150)		Control Group (*n*=151)		t & *P*
		Systolic BP					Diastolic BP				
		Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Diuretics	Pretest	140.73	8.3	137.37	9.88	1.641, .105	88.27	4.85	89.31	4.06	−1.02, 0.312
(SG *n*=44) (CG *n*=35)	Posttest III	136.95	7.58	138.11	9.04	−.621, .537	85.95	4.03	89.20	3.64	−3.71, 0.0001
ACE I	Pretest	139.84	8.072	140.61	9.182	−.383, .703,	87.37	6.03	87.44	6.10	−0.05, 0.957
(SG *n*=27) (CG *n*=18)	Posttest III	136	7.669	141.56	9.085	−2.85, .006	85.05	5.05	88.17	5.06	−2.52, 0.014
Diuretics+ ACEI	Pretest	137.56	8.102	143.33	8.00-	−2.355, .023	88.59	4.89	87.89	6.15	0.43, 0.672
(SG *n*=44) (CG *n*=35)	Posttest III	133.85	7.294	142.89	7.977	−3.922, .0001	85.93	4.45	89.56	6.64	−2.20, 0.033
CCB	Pretest	138.17	7.506	145.05	13.44	−1.616, .117	86.33	8.69	89.58	3.24	−1.49, 0.148
(SG *n*=12) (CG *n*=19)	Posttest III	133.83	8.156	145.47	12.13	−2.925, .007	84.17	7.41	90.11	3.49	−3.02, 0.005

Table 5: Repeated measures ANOVA of systolic and diastolic BP among patients with stage I hypertension in the study and the control groups before and after intervention

Duration	Study group	Control group	Study group	Control group
	Systolic BP		Diastolic BP	
Pretest	140.77	140.59	88.24	88.28
Posttest I	139.43	140.61	87.67	88.44
Posttest II	138.15	141.03	86.79	88.64
Posttest III	136.93	141.06	85.77	88.70
F & *P*	469.08 .0001	6.02 .003	208.21 .0001	4.70 .008

groups. The 't' value was 0.17 (*P* = 0.866). During posttest I, the mean blood pressure values among the study and control groups did not show a significant difference. However, during posttest III, there were significant differences between the study and control group mean systolic blood pressure values, indicated by the "*t*" value of 4.13 (*P* < 0.001) [Table 6]. Similarly, during

pretest, the mean diastolic blood pressure did not differ between the study and control groups, with "*t*" value of 0.95 (*P* = 0.066). However, there were significant differences between the study and control groups indicated by the "*t*" (*P*) value of 5.50 (0.001) during posttest III [Table 6].

Dosage reductions
We analyzed the effect of BAHRI on dosage reduction of antihypertensive medications among the study and control groups. At the end of the study, the total number of dosage reduction events was 19 (12.6%) among the study group participants. Six (3.9%) dosage reductions were reported in the control group. The difference in the number of dosage reductions of anti-hypertensive medications between the study and control group patients was significant at *P* < 0.05 with a Chi-squared value of 7.47 [Table 6].

GSR
The results indicated the effectiveness of biofeedback-assisted breathing relaxation technique on GSR over time. The difference in GSR in the study group participants between the pre and

Variable	Pre-intervention			Post Int I	Post int II	Post intervention III			Intra-group interaction F (P)
	SG	CG	Intergroup interaction t (P)	SG	SG	SG	CG	Intergroup interaction t (P)	
SBP Mean (SD)	140.6 8.2	140.73 10.23	.169, .866			136.81 8.45	141.18 8.72	4.134 .0001	-
DBP Mean (SD)	88.24 5.88	88. 04 5.14	.948, .066			85.8 5.52	88.70 5.32	5.496 .0001	-
GSR Mean (SD)	559. 63 (226.33)	-	-	578. 29 (225.98)	600. 79 (225.28)	615.03 (232.24)	-	-	80.209 .0001
Home practice Mean (SD)	-	-	-	25.73 (1.68)	25.62 (1.789)	25.80 (1.70)	-	-	.950 .022
Dosage reduction no. (%)	- -	- -	-	-	-	19 (12.7)	6 (4.00)	7.47.005	-

Table 6: Effect of biofeedback assisted relaxation on outcome measures

posttests was significant with an *F* value of 80.21 at level *P* < 0.001 [Table 6].

Result 5: Compliance of home relaxation practice among study group participants

Home practice

The total number of days of home relaxation practice was 84 in the study group. On an average, the participants performed breathing relaxation on 91.7% of the days during intervention period. The mean (SD) monthly scores of study group accounted for an F *(P)* value of 0.950 (0.022), which was uniform between the intervention intervals [Table 6].

Discussion

We conducted a larger RCT to investigate the effectiveness of BAHRI on blood pressure among a population with stage I primary hypertension in a middle income country. Following a 3 month intervention, the study group participants were found to have statistically significant reductions in their blood pressure and dosage of antihypertensive medications. GSR increased from baseline values in the intervention group patients, signifying a fall in the sympathetic nervous system activity.

Structured relaxation therapies have resulted in parasympathetic dominance among patients with hypertension.[27] Intervention studies[3,28,29] reported significant reductions in both the SBP and DBP following a GSR biofeedback training program. To contribute to this literature, our larger sample RCT (*N* = 346) has proved similar effectiveness among patients with hypertension when home-based BAHRI was implemented. Poor medication compliance, which was not explored in the current study, may be the reason for a statistically significant (*P* = 0.003 & 0.008) increase in mean systolic and diastolic BP among the control group (in spite of professional routine care), so we strongly recommend to include the medication compliance factor in the future studies. Furthermore, similar to existing evidence,[30] our study also evidenced that mean reduction in diastolic BP was less than that of systolic BP in the study group.

Current evidences reported less on the effectiveness of BAHRI on transferring patients from higher to lower level hypertension stages. In this study, we found that home-based BAHRI intervention resulted in a reduction from stage I to pre-hypertension. At the end of the study, 21 (14%) stage I hypertension participants had a reduced overall BP and moved to pre-hypertension. In contrast, five (3.3%) control group participants had their blood pressure level accelerated to stage II (*P* < 0.001). Further studies should explore the reasons for such transitions.

Our findings endorse that BAHRI increased GSR, which is an indicator of decreased sympathetic nervous system activity.[10] Limited interventional studies reported similar decreasing GSR with BAHRI[27] which is claimed to be induced by a reduced stress response.[29] Future studies should investigate biomarkers to support the current evidence of GSR increase.

A study by[31] using a 16-week complementary intervention including diaphragmatic breathing proved to reduce the dosage of diuretics in 70.4% of hypertensive participants in the intervention group. In our study, the lower percentage of dosage reductions (12.6%) in the study group may be attributed to the shorter follow-up period, that is, 3 months' duration. In particular, BAHRI produced significant BP reduction among patients on ACE inhibitors in the study group compared with the control group. Indeed, the ASCOT-BPLA hypertension trial[32] has already proved the extended cardiovascular benefits of ACE inhibitors other than BP reductions. Such positive results might be due to the fact that daily compliance rates of relaxation at home was maintained between 84 and 90%.

Finally, our study found that home-based relaxation practice results in significant reduction in systolic and diastolic blood pressure, hence we conclude the practice to be effective and suitable as an out-of-hospital intervention. The telephonic reminders were incorporated to monitor patient practice and involvement in the present study based on the fact that boosting the adherence to the therapeutic measures optimize BP control.[33] Significance of this part of the intervention is

endorsed by the results of a systematic review, which reported improved health outcomes among patients with heart failure following remote monitoring using tele-monitor, mobile phone, and video conference.[34] Similarly, in another experimental study, the feasibility, acceptance, and effectiveness of digital tools in improving hypertension control and lifestyle change was testified.[35] Future research should explore nurse-led community-based models to validate our findings.

Limitations

The scope of our findings was limited by the following factors: the shorter duration of the study; patients with poor medication compliance behavior influencing the study outcomes; and the affluent nature of patients from urban settings.

Conclusion

The study concludes that a home-based complementary intervention, biofeedback-based relaxation therapy, along with medications, reduces blood pressure among patients with hypertension. We also found that GSR is a useful indicator to measure the sympathetic output for behavioral intervention. Further studies should use biomarkers of sympathetic nervous system activity to endorse the use of this biofeedback-assisted relaxation.

Relevance to clinical practice and primary care

This paper proves that biofeedback combined with breathing exercise could cause a statistically significant drop in the blood pressure levels. When used among at-risk population, such home-based relaxation techniques can delay the onset of hypertension and defer the point of initiation of drug therapy. Nurse-led interventions can be successfully incorporated in to the public health care system to control chronic illnesses. Outpatient clinical management of hypertension can consider such initiatives to enhance treatment effectiveness.

Summary of the paper

Home-based non-pharmacological intervention is proven as feasible and clinically effective in reducing systolic and diastolic blood pressure among patients with primary hypertension. The current home-based breathing relaxation interventions is also proven as operational in reducing the SNS activity among patients with high blood pressure as indicated by the change in the GSR among the intervention group of patients.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Conflicts of interest

There are no conflicts of interest.

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