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Biofeedback therapeutic effects on blood pressure levels in hypertensive individuals: A systematic review and meta-analysis

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ABSTRACT

Introduction: Systemic arterial hypertension (SAH) is considered a multifactorial disease characterized by a persistent increase in blood pressure levels. Currently, the efficient control of blood pressure is achieved by both the use of pharmacological therapy and the control of risk factors. In addition, the use of biofeedback (BFB) as a non-pharmacological strategy represents a promising therapy.
Objective: This study aims to evaluate the effects of BFB on systolic and diastolic blood pressure levels, as well as on environmental and psychosocial factors in patients with essential SAH.
Methods: A systematic review (SR) of the literature was carried out in English and Portuguese using the following databases: SCIELO, LILACS, CINAHL, Cochrane, and PubMed. The search strategy included a mix of terms for the key concepts Biofeedback, Heart Rate Variability, Psychophysiological Feedback, and Heart Biofeedback. Studies were analyzed independently.
Results: The included studies evaluated a total of 462 subjects of both sexes. The meta-analysis revealed that BFB significantly elicited greater blood pressure control, mainly improving DBP levels ($Z = 2.15$; $P = 0.03$).
Discussion: Besides improvement in DBP readings post-intervention, BFB also resulted in better disease-related environmental and psychosocial factors, such as reduced stress levels. The magnitude of effect did not appear to depend on the type of BFB applied.
Conclusion: This SR demonstrated that BFB with visual and/or auditory information is a complementary option to pharmacological treatment in the management of individuals with systolic and diastolic arterial hypertension. Moreover, the use of this adjuvant therapy seems to facilitate better DPB control.

1. Introduction

Systemic arterial hypertension (SAH) is considered a multifactorial disease characterized by a persistent elevation of blood pressure (BP) levels which can be aggravated by risk factors, such as obesity and dyslipidemia. SAH has a high mortality rate and is related to conditions such as stroke and heart attack. Currently, it affects around 36 million Brazilian adults of whom 60% are elderly [1], about 60 million people in the US, and 1 billion people worldwide [32]. According to the recommendations of the American Heart Association, stage 1 SAH is defined by systolic blood pressure (SBP) of 130–139 and/or diastolic blood pressure (DBP) of 80–89 mmHg [2].

Greater BP control can be achieved by using medication and controlling risk factors. The six main classes of drugs used for that purpose

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are thiazide diuretics, beta-blockers, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, calcium channel blockers, and alpha-blockers [3]. However, treatment adherence is one of the greatest challenges regarding the control of SAH since the prolonged use of medication may often lead to treatment withdrawal [4]. Among the risk factors associated with SAH, the influence of stress and unhealthy lifestyle habits (e.g., physical inactivity and poor diet) can be highlighted. Studies indicate that the control of BP and its risk factors are crucial to the success of these patients' therapy [4–6].

In addition, alternative strategies to pharmacological therapy can contribute to control SBP and reduce health costs [4]. Among the existing non-pharmacological therapies, the use of biofeedback devices (BFB) appears to be a promising therapeutic strategy, which are composed of precise instruments that allow the individual to modulate their physiological activity (e.g., brain waves, cardiac function, breathing, muscle activity, and skin temperature) in real-time, thus positively impacting their health and performance. Together with changes in thoughts, emotions, and behavior, they support the desired physiological adaptations, and over the time these changes can be maintained without the continuous use of a BFB instrument [7].

Given that SAH is linked to autonomic nervous system instability, BFB can be used to improve BP control since it has the ability to develop autonomic self-regulation [8,9]. BFB has been studied in several clinical situations and has shown benefits in controlling both BP and stress levels [4]. Yucha, Tsai, Calderon, Tian [10] demonstrated that BFB was an effective complementary option to antihypertensive drugs, concluding that BFB could be an important adjuvant therapy in the management of SAH since a significant reduction in BP was observed post-BFB training in their sample of hypertensive individuals.

The effects of BFB in patients with hypertension have been studied and reported in the literature, under the hypothesis that its application as an adjuvant therapy would contribute to the treatment of SAH. Given the difficulty observed in patients with hypertension to maintain treatment adherence to traditionally used therapies, an alternative strategy that is easy to apply and effective in the short- and long-terms represent a promising and practical therapeutic approach. Therefore, this review aims to evaluate the effects of BFB on SBP and DBP levels, as well as on environmental and psychosocial factors in patients with essential SAH. This study also aimed at identifying whether differences in treatment effect exist across BFB types.

2. Methods

This meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).

2.1. Search strategy

A comprehensive literature search was carried out in English and Portuguese using the following databases: PubMed, Scientific Electronic Library Online (SCIELO), Latin American and Caribbean Literature in Health Sciences (LILACS), Cochrane Central, and Cumulative Index to Nursing and Allied Health Literature (CINAHL). The search strategy included a mix of terms for the key concepts: Biofeedback, heart rate variability biofeedback, psychophysiological feedback, heart biofeedback, biofeedback therapeutic, biofeedback cardiac, cardiac reflex, essential hypertension, high blood pressure, primary hypertension, arterial hypertension, anxiety, depression, and stress. Searches were carried out on September 16, 2020 with no publishing date restriction. All synonyms of the descriptors were associated using Boolean operators adapted according to each database. The actual search strategy was provided as supplementary material. .

2.2. Eligibility criteria and data extraction

Eligibility criteria comprised randomized controlled trials assessing SBP and DBP before and after BFB in male and/or female patients diagnosed with essential SAH (at any stage), aging $\geq$ 18 years, and who were undergoing BFB treatment as the main intervention in the experimental group. No date limiters were set to ensure inclusion of all published research to September 2020. For articles that were not fully available, e-mails were sent to contact the authors. Studies with incomplete data before and after the intervention and those whose authors did not return the e-mails were excluded. In addition, systematic reviews, book chapters, theses, dissertations, and conference abstracts were not included in this study.

No ongoing study with the same theme was found and, therefore, were not included in our review.

2.3. Selection of studies

Initially, studies were selected and transferred to the Mendeley Reference Manager software. After removing duplicates, the title and abstracts of the remaining studies were evaluated by two independent authors (J.E.C.V and A.M.N) who applied the eligibility criteria. Divergences between evaluators were solved by a third evaluator (A.T.N.S.). Then, a full-text assessment of the potentially eligible studies was carried out by two independent authors (J.E.C.V and A.M.N) and divergences between evaluators were resolved by a third evaluator (A.T.N.S.). Finally, data were independently coded and transferred to Excel using a standardized form containing the following variables: author, publication year, gender, age of study participants, as well as mean and standard deviation of BP levels pre- and post-intervention in mmHg. Inter-rater reliability of the coding by the two authors was calculated for all variables. Cohen's Kappa determined that the coders were in complete agreement ($k = 1$). Pearson correlation analysis also demonstrated complete consistency among raters ($r = 1$).

2.4. Methodological quality assessment

Methodological quality of the included studies was assessed by two independent authors (J.E.C.V e A.M.N) using the PEDro scale. In case of divergence between the evaluations, a third evaluator (A.T.N.S.) was in charge of the final decision. The PEDro scale consists of 11 items related to eligibility criteria, random allocation, concealed allocation, baseline similarity, blinding of subjects, blinding of therapists and assessors, adequate follow-up, intention-to-treat analysis, group comparisons, and point and variability measures. The maximum score is 10 because the first item (eligibility criteria) is related to external validity only and, therefore, excluded from the total score [11].

A study is considered of high quality if the score on the PEDro scale is 6–10; moderate quality if 5-4, and low quality if the score is less than or equal to 3 [11].

2.5. Statistical analysis

The descriptive characteristics of participants and their studies' respective interventions were summarized and narratively presented in tables. When post-intervention measures of DBP and SBP were available, a meta-analysis was performed using the Review Manager 5.3 software (Copenhagen, The Nordic Cochrane Center, The Cochrane Collaboration) to compare SBP and DBP levels before and after the BFB. The results were analyzed as continuous variables, and a random-effect model with a 95% confidence interval (CI) was used. The mean difference was chosen as a measure of size effect (Z) because all included studies used the same measure to assess the main outcomes (SBP and DBP in mmHg). The effect size (Z) was considered statistically significant if the P-value was $\leq$0.05. Heterogeneity was investigated using the I-square test (I^2) and qui-squared test (Chi^2), where a $P \leq 0.10$ indicated statistical significance. I^2 values were interpreted as low (25%), moderate (50%), and high (75%) variability across studies [12]. Subgroup analysis was performed to investigate the differences in treatment effect between BFB

types in the included studies. Risk of publication bias could not be assessed because of the low number of included studies. As a rule of thumb, publication bias assessment can only be performed when there are at least 10 studies entered in the meta-analysis.

3. Results

3.1. Studies selection and assessment of methodological quality

The search resulted in 2.967 articles. After title and abstract assessment, only 16 studies were deemed potentially eligible, of which nine studies met the inclusion criteria after full-text assessment and were considered eligible.

A flow diagram of the studies retrieved for the meta-analysis is presented in Fig. 1, as per PRISMA reporting guidelines. The main reasons for exclusion were related to the lack of specific BFB therapy in patients with SAH and secondary hypertension.

Table 1 shows the methodological quality of the included studies using the PEDro scale. The study that obtained the highest score (10 points) was conducted by Schein, Gavish, Herz, Kahana, Neveh, Knishkowy et al. [13]. The other studies scored between 5 and 8 points, which characterize moderate to high methodological quality.

3.2. Characteristics of participants

Overall characteristics of participants per study are shown in Table 2. The included studies evaluated a total sample of 462 participants, of whom 212 (45.9%) were males and 250 (54.1%) were females. The mean age was 47.22 ± 3.8 years, while mean SBP and DBP were 133.61 ± 38.08 mmHg and 83.38 ± 24.70 mmHg, respectively. All included studies were of randomized design with both experimental and control groups.

3.3. Intervention characteristics

Treatment protocols and intervention characteristics are shown in Table 3. The study by Mcgrady, Yonker, Tan, Fine, Woerner [14] used Biofeedback Surface Electromyography (EMG) and relaxation techniques, while [17] used HR biofeedback via an instrument which provided continuous feedback and digit transcription of ear lobe capillary pulsations, while [18,20] utilized heart rate variability (HRV) feedback, using two different approaches: feedback involving a smooth, sine wave-like heart rate variability pattern (i.e. heart coherence) and treatment guided by a biofeedback display of the RR interval power spectrum, respectively."The studies by Refs. [15,16,21]; and [13] used Biofeedback GSR (Galvanic Skin Response) combined with relaxation exercises; Thermal biofeedback combined with relaxation exercises (1987); DBP biofeedback with tracking cuff; and Biofeedback using a

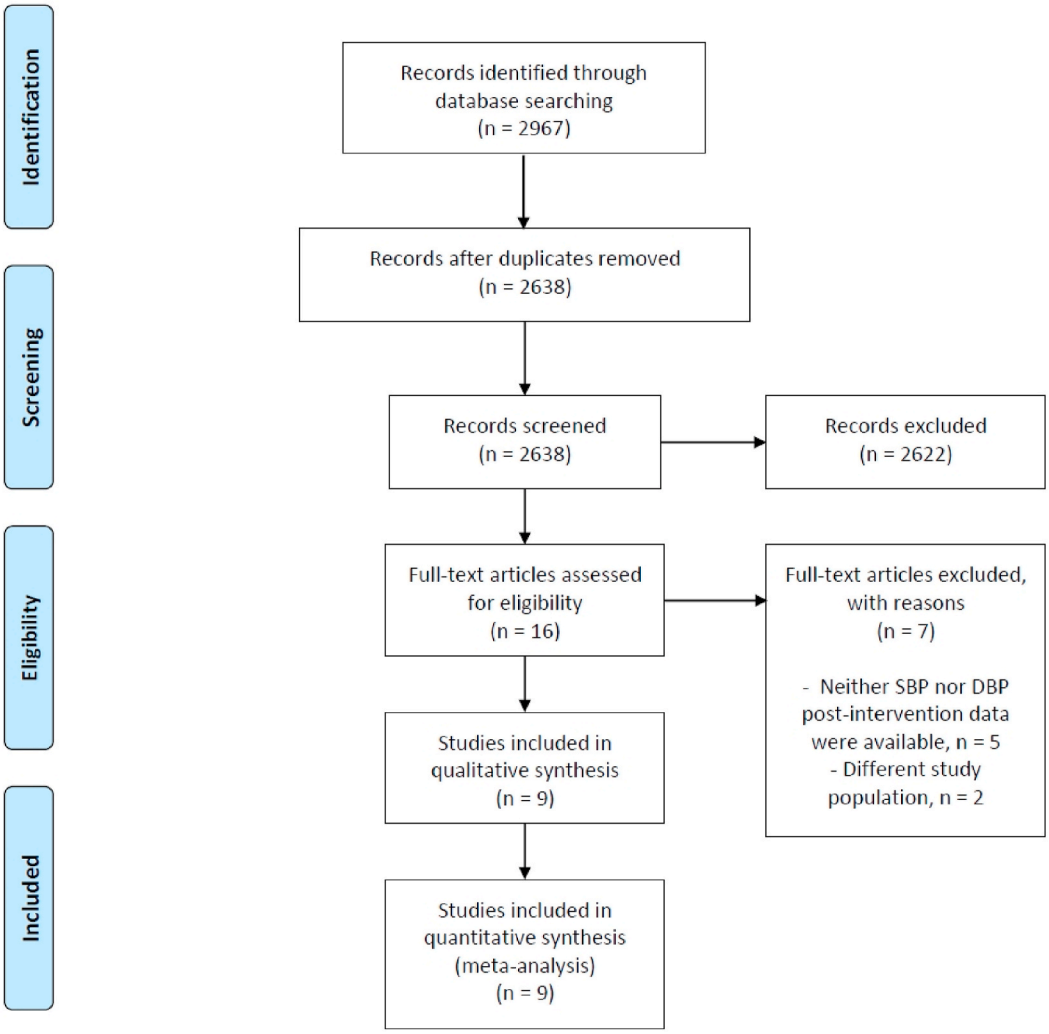

Fig. 1. Flow diagram of study selection.

Table 1
Methodological quality of the included studies assessed with the PEDro scale.

Author, year 0/10	PEDro score											
	1	2	3	4	5	6	7	8	9	10	11	TOTAL
[14]	YES	1	1	1	0	0	0	0	0	1	1	5/10
[15]	YES	1	0	1	0	0	1	1	1	1	1	7/10
[16]	YES	1	0	1	0	0	0	1	0	1	1	5/10
[17]	YES	1	1	1	1	0	0	1	1	1	1	8/10
[18]	YES	1	0	1	0	0	0	1	1	1	1	6/10
[13]	YES	1	1	1	1	1	1	1	1	1	1	10/10
[19]	YES	1	1	1	0	0	1	1	1	1	1	8/10
[33]	YES	1	1	1	0	0	1	1	1	1	1	8/10
[20]	YES	1	1	1	0	0	0	1	1	1	1	7/10

1 = Eligibility criteria; 2 = Random allocation; 3 = Concealed allocation; 4 = Baseline similarity; 5 = Blinding of subjects; 6 = Blinding of therapists; 7 = Blinding of assesssors; 8 = Adequate follow-up; 9 = Intention-to-treat analysis; 10 = Group comparisons; 11 = Point and variability measures.

BIM-prototype device that guided slow and regular breathing, respectively.

Visual BFB was used in seven studies [14,15,17–21] while auditory BFB was utilized in two studies [13,16].

The following interventions were used in the control groups: antihypertensive medication [15,18,21]; muscle relaxation [16,20]; weekly BP checks [14]; educational lectures [17]; audio-guided relaxation [13]; and simulated BFB [19].

The number of BFB sessions across the studies varied from 1 to 56, and the duration of sessions varied from 10 min to 8 h long, with training frequency ranging from 1 to 5 times per week. BFB training study protocols ranged from 2 to 16 weeks total.

3.4. Systolic and diastolic blood pressure

All 9 studies showed a significant reduction in SBP after BFB (mean of 102.54 ± 4.9 mmHg) compared with baseline values (143.76 ± 5.5 mmHg). A significant decrease in DBP post-BFB training was also observed in 8 studies (62.28 ± 4.1 mmHg) compared with baseline (90.17 ± 4.3 mmHg) [13–17,20,21], while no significant difference in DBP was observed in one study [18].

3.5. Environmental and psychosocial factors

As to other factors associated with SBP, only one study [13] did not evaluate other outcomes besides SBP and DBP levels after BFB therapy. In addition, the study by McGrady, Yonker, Tan, Fine, Woerner [14] evaluated biochemical parameters and BP levels.

The study by Achmon, Granek, Golomb e Hart [17] evaluated "general anger" using the Multidimensional Anger Inventory. The results showed that BFB therapy decreased "general anger", probably due to a better HR control during therapy [15]. and Tsai et al., 2007 used tests to check cardiovascular reactivity under stressful situations. In the former study, the authors observed a significant decrease in DBP levels post-BFB treatment compared with pre-treatment. In the latter, stress levels were statistically different (P = 0.01) in the group that underwent BFB. The study by McCraty, Atkinson e Tomasino [18] assessed emotional health and psychological stress using questionnaires and observed a significant reduction in the symptoms of stress, depression, and anxiety after BFB was implemented. Quality of life was also assessed after BFB using questionnaires [21]. The authors observed an improvement in the mental health domains of the experimental group (mean of 4.9 points) compared with controls (mean of 0.8 points).

3.6. Synthesized findings

This meta-analysis on the effects of BFB on blood pressure levels showed that BFB significantly reduced DPB levels (Z = 2.15; P = 0.03; CI [-6.20,0.19]) more evidently than SBP levels. Although a clear trend favoring BFB existed and reduced SBP was also observed after training in the included studies, differences between the groups were not statistically significant (Z = 1.75, P = 0.08; CI [-7.54,0.42]). Figs. 2 and 3 show forest plots for the performed analyses. Heterogeneity assessed using the I^2 test was 48% (i.e. low) for the effect of BFB on DBP levels (Tau^2 = 5.31; Chi^2 = 13.52; P = 0.06), and 65% (i.e. moderate) regarding SBP levels (Tau^2 = 19.21; Chi^2 = 22.8; P = 0.004). The above heterogeneity can be explained by the fact that the studies presented differences beyond those expected by chance given that they showed a statistical heterogeneity, but not a methodological heterogeneity. It can also be related to aspects inherent to the studies, such as sample size, instruments used, and characteristics of the interventions.

Subgroup analyses yielded no significant differences in treatment effect across BFB types. Moderate I^2 values were observed among the studies performing visual BFB for both SBP (I^2 = 74%; Chi^2 = 22.81; Tau^2 = 24.69; P = 0.0009) and DBP (I^2 = 61%; Chi^2 = 12.78; Tau^2 = 8.23; P = 0.03); while there was no heterogeneity between the studies which implemented auditory BFB when analyzing both SBP and DBP (I^2 = 0%). The study by Tsai and collaborators did not provide post-intervention DBP data and, therefore, was not included in the analysis of the effects of BFB for this specific outcome.

4. Discussion

The overall findings from this systematic review with meta-analysis revealed that BFB significantly elicited greater BP control, mainly when it comes to DBP levels. Also, it was observed that BFB could reduce stress levels and facilitate control of other cardiovascular risk factors. The therapeutic approaches that resulted in the greatest BP reductions were those in which BFB therapy was associated with relaxing music, control of breathing, and muscle relaxation techniques.

The articles included in this review showed moderate to high methodological quality. The systematic review conducted by Greenhalgh, Dickson, Dundar [22] evaluated the quality of the studies using the Center for Reviews and Dissemination tool, which are similar to those of the PEDro scale. However, the included studies on their review showed poor methodological quality. Although the studies included in this review were classified as moderate to high quality, it is important to note that the items with the lowest scores were related to the blindness of the study subjects and therapists. These items reduce the possibility of bias in clinical trials, improving the quality of the evidence.

A significant effect of BFB in reducing SBP was observed in a systematic review conducted by Nagele, Jeitler, Horvath, Semlitsch, Posh, Herrman et al. [23]. However, although there was a trend towards decreased SBP in treatment groups, no statistical significance favoring the effect of BFB on this measure was found in the present meta-analysis. The possible reduction in SBP following BFB may be related to the action of baroreceptors. BFB training can cause the neuroplasticity of the baroreflex in hypertensive individuals, thus reducing and controlling BP behavior [24].

As to DBP levels, a statistically significant reduction was identified in

Table 2
- Overall characteristics of participants per study.

Author/ Year	Sample (EG/CG)	Gender (M/F)	Age (years)	SBP (mmHg) Baseline	DBP (mmHg) Baseline
[14]	**EG:** 22 **CG:** 16	**EG:** M (7) F (15) **CG:** M (5) F (11)	**EG:** 55 **CG:** 42	**EG:** 144.41 ± 19.83 **CG:** 140.67 ± 19.36	**EG:** 90.59 ± 10.67 **CG:** 90.94 ± 11.74
[15]	**EG:** BT (9) PMRT (13) ST[i] (13) **CG:** 13	**EG:** BT: M (4), F (5) PMRT: M (7), F (6) ST: M (4), F (9) **CG:** M (6), F (7)	**EG:** BT: 51.6 PMRT: 50.2 ST: 50.4 **CG:** 52.2	**EG:** BT: 134.5 ± 12.7 PMRT: 147.6 ± 10.6 ST: 136.0 ± 10.8 **CG:** 136 ± 13.0	**EG:** BT: 86.7 ± 8.1 PMRT: 89.4 ± 7.6 ST: 87.2 ± 9.7 **CG:** 87.7 ± 4.8
[16]	**EG** = 11 **CG** = 14	**EG:** M (7) F (4) **CG:** M (10) F (4)	**EG:** (T1): 8.14 ± 0.18 (T2): 46.86 ± 10.86 **CG:** (T1):46.67 ± 12.14 (T2): 45.30 ± 12.06	**EG:** 137.89 ± 19.22 **CG:** 137.07 ± 16.22	**EG:** 85.25 ± 17.10 **CG:** 87.14 ± 16.71
[17]	**EG:** CT[l] (30) BT (27) **CG:** 20	**EG:** CT = M (17) F (13) BT = M (17) F (10) **CG:** M (15) F (5)	**EG:** CT: 41.6 ± 9 BT: 40.1 ± 8.3 **CG:** 40.0 ± 8.6	**EG:** CT: 153.98 ± 15.27 BT: 155.00 ± 13.52 **CG:** 155.42 ± 19.95	**EG:** CT: 98.71 ± 9.23 BT: 99.75 ± 7.14 **CG:** 96.12 ± 6.26
[18]	**EG:** 18 **CG:** 14	**EG:** M (13) F (5) **CG:** M (10) F (4)	**EG:** 48.2 ± 6.5 **CG:** 43.1 ± 5.6	**EG:** 130.4 ± 11.1 **CG:** 128.1 ± 8.0	**EG:** 82.9 ± 10.2 **CG:** 84.1 ± 7.6
[13]	**EG:** 32 **CG:** 33	**EG:** M (18) F (14) **CG:** M (13) F (20)	**EG:** 57.8 ± 9.4 **CG:** 56.5 ± 8.0	**EG:** 156.6 ± 14.0 **CG:** 154.7 ± 8.5	**EG:** 96.7 ± 8.9 **CG:** 93.4 ± 7.1
[19]	**EG:** 20 **CG:** 18	**EG:** M (10) F (10) **CG:** M (14) F (4)	**EG:** 46.5 ± 10.3 **CG:** 39.9 ± 10.8	**EG:** 148.4 ± 8.6 MBP: 112.6 ± 7.1 **CG:** 142.1 ± 5.9 MBP: 110.1 ± 6.2	**EG:** NR **CG:** NR
[33]	**EG:** 9 **CG:** 9	**EG:** M (3) F (6) **CG:** M (4) F (5)	**EG:** 52.5 ± 4.97 **CG:** 60.6 ± 10.22	**EG:** 154.6 ± 14.4 **CG:** 148.7 ± 9.4	**EG:** 96.6 ± 8.7 **CG:** 92.0 ± 11.9
[20]	**EG:** 35 **CG:** 30	**EG:** M (15) F (20) **CG:** M (13) F (17)	**EG:** 55.0 ± 1.2 **CG:** 55.9 ± 1.2	**EG:** diurnal SBP: 135.1 ± 1.9 Diurnal PP: 52.3 ± 1.5 SBP 24-h: 130.3 ± 2.0 PP[o] 24-h: 52.0 ± 1.4 **CG:** diurnal SBP: 135.2 ± 2.0 Diurnal PP: 49.4 ± 1.4 SBP 24-h: 130.0 ± 1.9 PP 24-h: 48.9 ± 1.5	**EG:** diurnal DBP: 82.9 ± 1.4 DBP 24-h: 78.6 ± 1.5 **CG:** diurnal DBP: 85.8 ± 1.4 DBP 24-h: 81.3 ± 1.2

EG:Experimental group; CG:Control group; M: Male; F:Female; SBP: Systolic blood pressure, DBP:Diastolic blood pressure; BT: Biofeedback therapy; PMRT: Progressive muscle relaxation training; [i]SDT: Self-directed training; T1: Therapist 1; T2 = Therapist 2; CT: Cognitive therapy; Mean blood pressure; NR: Not reported; PP: Pulse pressure.

most studies after BFB therapy [13–17,19–21]. Similar results were observed in a review by Nagele, Jeitler, Horvath, Semlitsch, Posh, Herrman et al. [23], in which most studies also observed a significant decrease in DBP.

BFB types utilized across the included studies in the present work involved auditory or visual devices/techniques. Most reviewed articles used visual BFB [14,15,17–21] while only two studies used auditory BFB [13,16]. All included studies showed a trend towards reduced SBP and DBP levels after BFB, indicating that both visual and auditory BFB are effective in reducing BP levels. However, the subgroup analysis showed that techniques adopting visual BFB appeared to be more effective in controlling BP, especially DBP. Some patients may be more sensitive to certain BFB techniques [34], so distinct responses may be present when using different BFB types. Also, it has been observed that patients with higher sympathetic excitability (i.e., higher baseline BP levels, higher heart rates, cold hands, and increased electromyographic response) may present a better response to BFB interventions [34].

Although there were differences in BFB types across the studies in the present review, the overall effect we found in the analysis indicates that BFB in general seems to be a useful approach to facilitate BP control in subjects with hypertension. It is important to note, though, that there is a possibility that the choice of BFB type may perhaps influence training outcomes, considering that physiological responses may vary based on the patient and methods used for the training. Nevertheless, BFB seems to be a promising adjuvant therapy to complement patients' pharmacological management in favoring a greater control of SAH [4].

The relationship between SAH and both environmental and psychosocial factors are worth analyzing further, given that these variables are frequently investigated in individuals with SAH or other cardiovascular diseases as factors leading to disease neglect and/or exacerbation [25,26]. High stress levels are commonly found in this population. Recent data have shown that stress control can reduce cardiac events in patients with cardiovascular disease [27]. In the present review, four studies [15,17–19] either subjectively or objectively reported that participants improved their ability to handle stress or stressful situations after BFB training. Overall, the participants showed greater psychological well-being after therapy. In agreement with these findings, Goessl, Curtiss and Hofmann [28] demonstrated an association between BFB and reduced levels of self-reported stress, probably due to the intrinsic relationship between SAH and stress. The cardiovascular reactivity of hypertensive individuals in the face of stressful situations may be greater than healthy individuals. Also, repeated stress situations in people predisposed to the development of SAH triggers the artery wall thickening, which is one of the factors causing SAH [29,30].

Additionally, two other studies [15,21] evaluated outcomes other than BP and stress. The study by Olsson, Alaoui, Carlberg, Carlbring, Ghaderi [21] showed that a better overall quality of life existed after training through improvements of mental and physical aspects. Such improvements in the overall quality of life of hypertensive patients treated with non-pharmacological therapies have been investigated previously [31] and support the effectiveness of these strategies to assist the pharmacological treatment in controlling SAH, which may reduce total health costs in the long-term.

A few limitations exist in this meta-analysis and include a small number of studies examining the effects of BFB on SBP and DBP, but in a relatively large number of patients with SAH. A rather moderate to high degree of heterogeneity across studies was another important concern in the current meta-analysis, which was addressed through its incorporation into random-effects models. Finally, a major limitation was the limited data available on BFB as a sole intervention in this population.

Table 3
Summary of protocols and outcomes from the included studies.

Author/ Year	Type of Intervention	Biofeedback Device/Type	Session Characteristics	Total Treatment Time (weeks)	Secondary outcomes	SBP/DBP (mmHg) Post-intervention	P-value
[14]	**EG:** relaxation exercises assisted by BFB. **GC**: weekly blood pressure measurements.	BFB EMG (Autogeniograph 1700, from Autogen)/Visual.	16 sessions (15 min, twice per week)	8	Reduction of muscle tension and response to stress mediated by the adrenal cortex.	**EG:** SBP: 133.18 ± 16.77 DBP: 84.91 ± 10.52 **CG**: SBP 139.25 ± 14. 29 DBP: 84.91 ± 11.50	SBP (P = 0.02) DBP (P = 0.004)
[15]	**EG:** BT: training with BFB. PMRT: instructions to contract and relax the body muscles. ST[h]: verbal and written instructions for home relaxation. **GC:** Use of medication.	Diastolic blood pressure BFB with tracking cuff/ Visual.	12 session (90 min, twice per week)	6 to 12	Reduced use of antihypertensive medications.	**EG:** SBP: BT: 134.6 ± 9.2 PMRT: 129.3 ± 14.4 ST: 133.7 ± 8.5 DBP: BT: 85 ± 6.7 PMRT: 79 ± 6.0 ST: 80.0 ± 9.5 **CG**: SBP: 125.2 ± 13.2 DBP: 82.2 ± 8.1	SBP (P < 0.05) DBP (P < 0.05)
[16]	**EG:** BFB training and "mental scan" exercise para (i.e., closing the eyes and 'examining' the body) **GC:** Muscle relaxation, breathing techniques, relaxation images and diary to take notes of stressful situations.	GSR of BFB (Model GSR 5140 units)/Auditory.	8 session (60–90 min, once per week)	8	NR	**EG:** SBP: 136.27 ± 11.81 DBP: 89.36 ± 12.97 **CG:** SBP: 127.88 ± 15.11 DBP: 79.34 ± 5.78 Follow-up: **EG:** SBP: 126.81 ± 13.99 DBP 79.19 ± 8.78 **CG:** SBP: 129.07 ± 17.48 DBP: 80.30 ± 9.54	SBP (P = 0.086) DBP (P = 0.01)
[17]	**EG:** CT: Used Meichenbaum cognitive therapy. **BT**: BFB, practiced at home involving HR deceleration, twice daily through pulse counting. **CG:** Educational lectures.	BFB with HR transmission (Pulseminder, modelo 77,194 – Computer Instruments Corp., Nova Iorque, NY)/Visual.	17 sessions (90min, once per week)	16	Multidimensional Anger Inventory with decreased "general anger" domain	**EG:** CT: SBP: 136.93 ± 13.82 DBP: 87.31 ± 8.40 BT: SBP 128.44 ± 12.26 DBP: 84.31 ± 9.75 **CG:** SBP: 152.37 ± 21.73 DBP: 96.92 ± 7.1	P = 0.0005
[18]	**EG:** BFB, rational control of positive emotions and emotional restructuring techniques. **CG:** Conventional medication treatment.	BFB cardiac r rhythm monitor(Freeze-Framer®; Quantum Intech, Inc., Boulder Creek, CA)/ Visual.	1 session of 8 h and 2 sessions of 4 h (16 h total).	2	Reduced feelings of distress and improved psychological well-being.	**EG:** SBP: −10.6 ± 2.1 DBP: −6.3 ± 1.2 **CG:** SBP: 3.7 ± 2.4 DBP: −3.9 ± 1.4	SBP (P < 0.05) DBP (there was no significance).

(*continued on next page*)

Table 3 (*continued*)

Author/ Year	Type of Intervention	Biofeedback Device/Type	Session Characteristics	Total Treatment Time (weeks)	Secondary outcomes	SBP/DBP (mmHg) Post-intervention	P-value
[13]	**EG**: BFB with BIM device (performance of slow regular breathing using musical sound patterns) and listening to quiet music. **CG:** Audio player with sound stimulus similar to the BIM.	The BIM device (prototypes manufactured by Inter Cure Ltd, Neve Ilan, Israel)/Auditory.	56 sessions (10min, once per day)	8	NR	**EG:** SBP: −15.2 ± 13.4 DBP: −10.0 ± 6.5 **CG:** SBP: −11.3 ± 12.8 DBP -5.6 ± 6.2	SBP (P = 0.035) DBP (P = 0.0002)
[19]	**EG:** Active BFB while watching the BP display on a monitor. **CG:** Simulated BFB.	Blood pressure BFB using the Finometer/Visual.	32 sessions (40–45 min, 4 times per week)	8	Reduction of pressure reactivity to stress.	**EG:** SBP: 135.7 ± 11.2 MBP: 104.4 ± 10.2 DBP: NR **CG:** SBP: 138.1 ± 5.5 MBP: 106.8 ± 6.3 DBP: NR	**EG:** SBP (P < 0.001) **CG:** SBP (P = 0.017)
[33]	**EG:** BFB. **CG:** Use of medication.	BFB thermal (Cstress FT 1.0.2-PBM, Stockholm, Sweden)/Visual.	5 daily sessions (7–17 min, 5 times per week)	8	SF-36 questionnaire: mental health improvement; decreased risk of coronary heart disease.	**EG:** SBP: 148.7 ± 13.0 DBP: 89.0 ± 7.5 **CG:** SBP: 147.9 ± 9.4 DBP: 89.0 ± 11.8	SBP (P = 0.27) DBP (P = 0.04)
[20]	**EG:** BNTand BFB of HR. Training to disconnect from negative or excited emotions to focus attention on BP reduction. **CG:** Autogenic relaxation with 30 min audio recording.	HRVBFB/Visual.	6 sessions (1 h duration, 4 times per week and 2 times every other week).	8	NR	**EG:** diurnal SBP: 131.8 ± 2.3 Diurnal DBP: 82.0 ± 1.6 Diurnal PP: 50.1 ± 1.8 SBP 24-h: 27.3 ± 2.3 DBP 24-h: 77.5 ± 1.7 PP 24-h: 50.0 ± 1.7 **CG:** Diurnal SBP: 135.0 ± 2.1 Diurnal DBP: 85.3 ± 1.4 Diurnal PP: 49.9 ± 1.5 SBP 24-h: 129.5 ± 2.0 DBP 24-h: 80.3 ± 1.5 PP 24-h: 49.5 ± 1.4	P = 0.02

SBP: Systolic blood pressure; DB:P Diastolic blood pressure; EG: Experimental group; CG:Control group; BFB: Biofeedback; BFBT Biofeedback therapy; PMRT:Progressive muscle relaxation training; SDT: Self-directed training; GSR: galvanic skin resistance; not rated; CT:Cognitive therapy; HR: Heart rate; BNT: Behavioral neurocardiac training; PP:Pulse pressure.

Due to the small number of studies available in the literature that examined this therapy in SAH, further investigation on the effects of either visual or auditory BFB, or even both BFB types combined is needed to determine the role BFB as a stand-alone therapy may have in the improvement of SAH.

In conclusion, this review demonstrated that BFB with visual and/or auditory information can safely and effectively be used as an adjuvant therapy to the pharmacological management of individuals with systolic and diastolic hypertension. Our findings suggest that a greater effect of BFB in reducing DBP rather than SBP appears to exist. The magnitude of effect did not seem to depend on the type of BFB applied. Besides improvement in DBP readings post-intervention, BFB also resulted in better disease-related environmental and psychosocial factors, such as reduced stress levels and greater quality of life. BFB is then a promising tool that can be used as adjuvant therapy to control SAH and factors associated with this disease.

CRediT authorship contribution statement

José Edimosio Costa Vital: Investigation, Methodology, writing. **Adriele de Morais Nunes:** Investigation, Methodology. **Beatriz Souza de Albuquerque Cacique New York:** Investigation, Methodology. **Barbara Dayane Araujo de Sousa:** Investigation, Methodology. **Micaele Farias Nascimento:** Investigation, Methodology. **Magno F. Formiga:** Methodology, writing. **Ana Tereza N.S.F. Fernandes:** Conceptualization, Formal analysis, writing, Supervision.

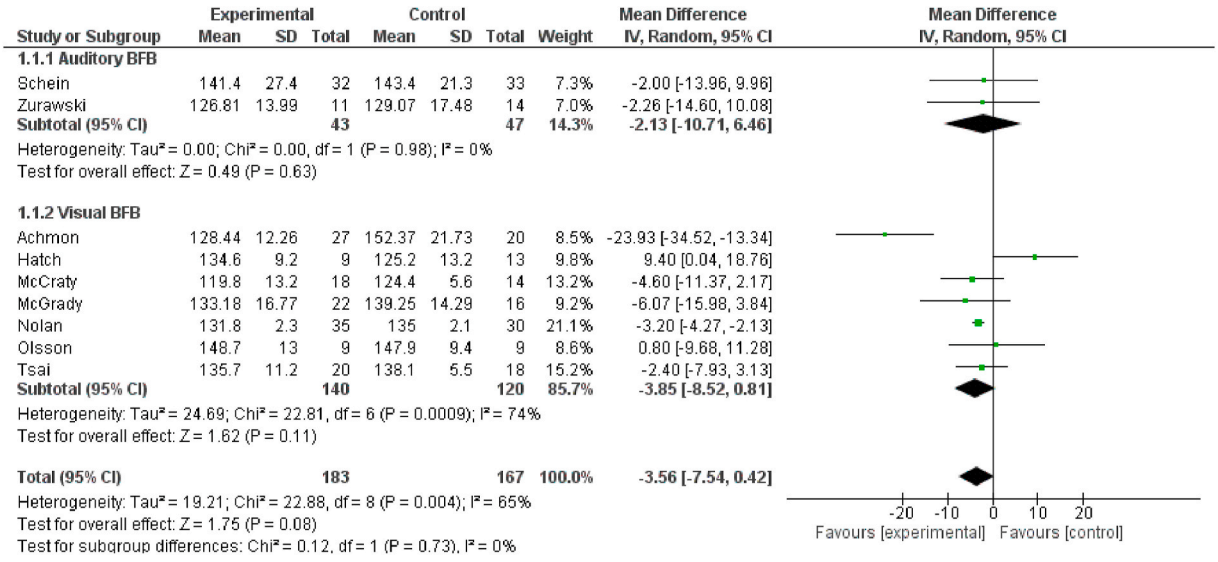

Fig. 2. Forest plot of the overall and subgroup effects of BFB on SBP levels.

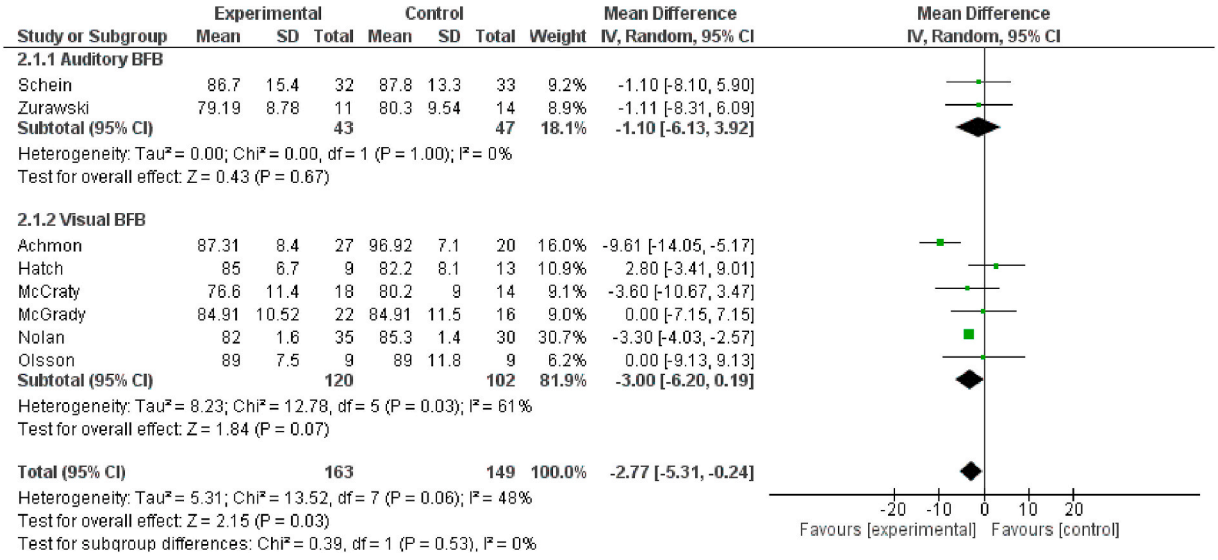

Fig. 3. Forest plot of the overall and subgroup effects of BFB on DBP levels.

Declaration of competing interest

This study has no funding source.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ctcp.2021.101420.

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