Blood pressure-lowering effects of biofeedback treatment in hypertension: a meta-analysis of randomized controlled trials
Nakao M, Yano E, Nomura S, Kaboki T

CRD summary
This review evaluated the blood pressure-lowering effects of biofeedback treatment in patients with essential hypertension. The authors concluded that biofeedback is more effective than no intervention, but additional techniques may be needed to achieve a greater decline in blood pressure. This was a well-conducted review and the results are likely to be reliable.

Authors' objectives
To evaluate the blood-pressure (BP)-lowering effects of biofeedback treatment in patients with essential hypertension.

Searching
MEDLINE (from 1966 to December 2001), PsycINFO, CINAHL and EMBASE were searched. The reference lists of identified articles were also checked.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) with at least 6 patients in each treatment group were eligible for inclusion. The number of participants in each arm of the trials ranged from 7 to 55. The follow-up period of the included studies ranged from 0 to 12 months. The drop-out rates ranged from 0 to 36%.

Specific interventions included in the review
Studies of direct and indirect, simple and relaxation-assisted biofeedback interventions, compared with no therapy, a waiting list, regular monitoring or placebo, were eligible for inclusion. Feedback interventions evaluated in the included studies were systolic BP, diastolic BP, electromyogram (EMG), galvanic skin resistance (GSR), heart rate and thermal, or a combination of these. The comparators included relaxation, sham feedback, clinic visits with and without diuretic therapy, BP self-monitoring, meditation, stress management and cognitive therapy. The number of sessions undertaken ranged from 4 to 20, over 4 to 17 weeks.

Participants included in the review
Studies of adults with essential hypertension, defined as a systolic BP of at least 140 mmHg and/or a diastolic BP of at least 90 mmHg, were eligible for inclusion. The mean age of the participants in the included studies ranged from 33 to 59 years, with 32 to 100% being male.

Outcomes assessed in the review
Studies reporting changes in BP post-intervention compared with baseline were eligible for inclusion. The outcome evaluated in the review was the difference in the change in BP between the intervention and control groups.

How were decisions on the relevance of primary studies made?
Two reviewers independently evaluated the relevance of primary studies.

Assessment of study quality
The criteria used to assess quality related to the basic descriptive materials, study protocol, statistical analysis and the presentation of the results. Two reviewers independently assessed quality, with any disagreements being resolved by recourse to a third reviewer.
Data extraction
Two reviewers independently extracted the data from the included studies. The difference in the decline in BP between the intervention and control groups was calculated for each study. Where the standard errors of the pre- and post-treatment BP changes were not reported, they were calculated using either the reported t-values and sample sizes, or using the pre- and post- intervention variances. Where the P-value was not reported, the standard error of the pre- and post-treatment BP changes were calculated using the assumption that the P-value was 0.5.

Methods of synthesis
How were the studies combined?
Weighted mean differences (WMDs) between the groups were pooled using a fixed-effect meta-analysis when the results were statistically homogeneous, or a random-effects model (DerSimonian and Laird) when the results were statistically heterogeneous. Publication bias was investigated using funnel plots, with plot asymmetry investigated using the method of Egger et al.

How were differences between studies investigated?
Heterogeneity was investigated statistically using the Q statistic. Multiple regression was performed to investigate the effect of pre-treatment BP and treatment type (intervention or control) in studies where the average BP was more than 140/90 mmHg, weighted on sample size. Subgroup analyses were performed on studies with a drop-out rate of less than 10%; studies where the intervention had no antihypertensive drug; studies reporting either simple, single interventions, or combination with therapy; and studies with different biofeedback signals. Treatment effects were discussed according to the comparator used, and whether biofeedback was used alone or in combination with another intervention.

Results of the review
Twenty-two RCTs (n=905: intervention groups, n=471; control groups, n=434) were included in the review.

The authors reported that there was no significant publication bias in either systolic or diastolic BP.

Overall, biofeedback mechanisms resulted in a slight improvement in systolic BP (WMD -5.5 mmHg, range: -24, 11) and diastolic BP (WMD -4.4 mmHg, range: -16, 12).

There was a statistically significant improvement in systolic BP (WMD -7.3 mmHg, 95% confidence interval, CI: -12.0, -2.6) and diastolic BP (WMD -5.8 mmHg, 95% CI: -8.6, -2.9) when biofeedback mechanisms were compared with no intervention. Both analyses showed statistically significant heterogeneity. There was a statistically significant improvement in systolic BP (WMD -9.5 mmHg, 95% CI: -17.6, -1.5) and diastolic BP (WMD -7.4 mmHg, 95% CI: -12.7, -2.1) with biofeedback mechanisms with no antihypertensive drugs when compared with no intervention. When the analysis was restricted to studies with an attrition rate of less than 10%, the improvement with biofeedback mechanisms was still evident for both systolic BP (WMD -8.2 mmHg, 95% CI: -14.3, -2.1) and diastolic BP (WMD -5.0 mmHg, 95% CI: -8.0, -2.0).

There was no statistically significant improvement in systolic or diastolic BP with biofeedback mechanisms when compared with sham or non-specific intervention controls when all studies were included, or when the analysis was restricted to studies with an attrition rate of less than 10%. There was a statistically significant improvement in diastolic BP when the analysis was restricted to interventions with no antihypertensive drugs (WMD -5.6 mmHg, 95% CI: -10.1, -1.40).

Multiple regression analysis suggested that pre-treatment BP predicted the pre-to-post decline in both systolic and diastolic BP for both no intervention and sham or non-specific behavioural control trials, and that treatment type was also predictive for systolic and diastolic BP in the no intervention trials.

Further subgroup analyses were reported.

Authors' conclusions
Biofeedback seems more effective in reducing BP than no intervention, but additional techniques may be needed to achieve greater BP decline.

**CRD commentary**
The research question and the inclusion criteria were clearly stated. Several relevant electronic databases were searched, and publication bias was investigated. The authors made efforts to reduce error and bias by performing the study selection validity assessment and data extraction processes in duplicate. Appropriate measures of effect were calculated, and heterogeneity was investigated. This was a well-conducted review and the results are likely to be reliable.

**Implications of the review for practice and research**
Practice: The authors did not state any implications for practice.

Research: The authors stated that further studies are required to investigate specific treatment mechanisms other than simple relaxation, and biofeedback research should investigate the activation status of the sympathetic nervous system and the psychological conditions affecting the prognosis of hypertension. The authors also suggested several points for future studies to address: the characteristics of the therapists, patient motivation and suggestibility should be assessed; mood states should be monitored as outcomes; observers should be blinded and independent of the study; the blinding status of the participants should be documented; and patient 'habituation' and 'regression to the mean' should be assessed and controlled.

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