The effects of biofeedback for the treatment of essential hypertension: a systematic review

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CRD summary
This review concluded that there was no convincing evidence that consistently demonstrated the effectiveness of any particular biofeedback treatment in the control of essential hypertension when compared with pharmacotherapy, sham biofeedback treatment, no intervention or other behavioural treatments. These conclusions reflect the limited and poor quality evidence presented and they are likely to be reliable.

Authors' objectives
To assess the effectiveness of biofeedback for the treatment of essential hypertension in adults.

Searching
The following databases were searched for studies in English up to May 2007: MEDLINE, EMBASE, CINAHL, AMED, PsycINFO, ISI Web of Knowledge/Web of Science, ISI Web of Knowledge/ISI Proceedings and The Cochrane Library. Search strategies were presented in an appendix. Abstracts from PhD theses were included. An updated search was performed in the final month before the completion of the report. Reference lists of relevant publications were screened.

Study selection
Randomised controlled trials (RCTs) that compared biofeedback procedures (alone or in combination) with antihypertensive medication, placebo (sham biofeedback), no intervention, other behavioural treatments or other types of biofeedback treatment were eligible for inclusion. The eligible participants were adults with essential hypertension (140/90 mmHg or greater), medicated or unmediated with antihypertensive drugs. The outcome measure was change in blood pressure.

The included studies evaluated various types of biofeedback treatment. Most included studies used biofeedback treatment with no adjunctive therapy, while some studies employed biofeedback treatment in combination with another treatment in which relaxation was often involved. The number of biofeedback sessions ranged from four to 20. Most trials had a follow-up of less than six months or no post-treatment follow-up. Sixteen of the included studies had more than 60% male patients. Where reported, the patients' age in included studies ranged from 31 to 60 years. All studies were single centred and most were conducted in the USA. Around two-thirds of the studies were conducted in the 1970s and 1980s.

Two reviewers independently assessed studies for inclusion, with any disagreements resolved by discussion.

Assessment of study quality
The quality of studies was assessed using the following criteria: randomisation, baseline comparability, specification of eligibility criteria, identification of co-interventions, blinding, withdrawals and intention-to-treat analysis.

At least two reviewers independently assessed study quality, with any disagreement resolved by discussion.

Data extraction
Data were extracted on means and standard deviations (SDs) for diastolic and systolic blood pressure at baseline, as well as changes in diastolic and systolic blood pressure from baseline.

Data were extracted by two reviewers, and cross-checked by a third reviewer.

Methods of synthesis
The studies were combined in a narrative synthesis, grouped by treatment type and comparator.

Results of the review
Thirty-six RCTs (34 peer-reviewed publications and two PhD theses) were included in the review (1,660 patients
approximately; range 12 to 158). Only four trials described method of randomisation and only two of these reported allocation concealment. Only eight trials reported blinding of outcome assessors. None of the studies reported an intention-to-treat analysis. Baseline comparability was adequate or partially adequate in 25 trials. Most trials specified the details of eligibility criteria.

**Biofeedback alone**

Thee trials compared biofeedback alone with antihypertensive medication. The results of two trials favoured medication, while the other trials reported that biofeedback may be as effective as drug treatment. Three trials compared biofeedback alone with a placebo. One trial found biofeedback treatment to be superior, but the other two found no difference between the two groups. Most of the eight trials reported no significant effects of biofeedback treatment compared with no intervention, but three of the eight trials reported a significant effect of biofeedback treatment when compared with no intervention. Sixteen trials compared biofeedback alone with other behavioural interventions, but only three trials found biofeedback treatment to be superior.

**Biofeedback combinations**

No trials compared biofeedback combinations with antihypertensive medication. One trial compared biofeedback combination with placebo and showed no difference in blood pressure between the two groups. Only five out of thirteen trials showed a significant benefit for biofeedback compared with no intervention. Only one out of the eight trials found biofeedback to be superior over other behavioural treatments.

**Authors' conclusions**

There was no convincing evidence that consistently demonstrated the effectiveness of any particular biofeedback treatment in the control of essential hypertension when compared with pharmacotherapy, sham biofeedback, no intervention or other behavioural treatments.

**CRD commentary**

This review's inclusion criteria were clear. A number of relevant databases were searched. Efforts were made to find both published and unpublished studies, which minimised the potential for publication bias. Only studies in English were included in the review, which may have increased the risk of language bias. Sufficient attempts were made to minimise reviewer errors and biases in the review process. A formal quality assessment was performed. The included studies were generally of poor quality. Given the diversity of included studies in terms of biofeedback protocols and inconsistency in reporting of outcomes, a narrative synthesis was appropriately employed. The authors' conclusions reflect the limited and poor quality evidence presented and these cautious conclusions 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, given the current standards for the treatment of hypertension, further studies were likely to be considered only when biofeedback was used as an adjunct to pharmacological interventions. Any future trials need to address the major design weakness highlighted in the review.

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.