The effect of biofeedback in hypertension
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Authors' objectives
To determine the effectiveness of biofeedback in the treatment of stage 1 and 2 essential hypertension.

Searching
CINAHL, MEDLINE, EMBASE, Evidence Based Medicine, Dissertation Abstracts, PsycINFO and AMED were searched from their inception to the end of 1996. The terms used included 'hypertension', 'meditation', 'relaxation', 'psychotherapy', 'yoga', 'patient education', 'educational program', 'massage', 'therapeutic touch', 'biofeedback' and 'guided imagery'. The search was limited to clinical trials conducted in humans and reported in the English language. In addition, relevant papers were checked for additional references. The resulting references were further reduced by limiting the search solely to 'biofeedback'.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials lasting over 4 weeks were sought.

Specific interventions included in the review
Biofeedback, defined as a group of non-pharmacological therapeutic procedures that use electronic instruments to measure, process and provide information to patients regarding their neuromuscular and autonomic nervous system activity. It includes an element of cognitive therapy and relaxation training. In the included studies, the methods of biofeedback were thermal biofeedback, electromyography, electrodermal activity, blood-pressure (BP) measures, pulse wave velocity, respiratory sinus arrhythmia and heart rate. Groups receiving combined therapy (i.e. also including cognitive therapy or relaxation therapy) were included in the biofeedback group. Comparison was with two control groups; an active control group, including those treatments known to reduce BP (relaxation training, cognitive therapy, home BP monitoring, [discussion and self-relaxation, meditation]); and an inactive control group, including those treatments not known to reduce BP (placement on a waiting list, BP measured in clinic, sham biofeedback, [self-relaxation, support group, stress education]). [Length of treatment ranged from 6 to 20 weeks and sessions were either weekly or biweekly]. Drug treatment studies and those with interventions labelled dietary, exercise or alcohol reduction were excluded.

Participants included in the review
The inclusion criteria stated the participants had to be adults with essential hypertension (stages 1 and 2). Those with secondary hypertension or hypertension in pregnancy were excluded. One study with only 'elderly' participants and a further study on in-patients were excluded. [Ages of participants ranged from 21 to 75 years. Both male and female participants were included.] No other details of the included participants were provided.

Outcomes assessed in the review
Differences in BP levels were assessed. Studies that did not include this as an outcome were excluded. The results reported were for the mean differences in systolic and diastolic BP (SBP and DBP, respectively).

How were decisions on the relevance of primary studies made?
At least two of the authors reviewed each article for inclusion. The reviewers were blinded to both the author and journal of publication. Articles were only rejected if both reviewers agreed they did not meet the inclusion criteria.

Assessment of study quality
An existing quality assessment instrument (see Other Publications of Related Interest no.1) was adapted by removing categories that were considered either irrelevant or inappropriate. The adapted instrument consisted of 17 items leading to a quality score; further details were provided in the paper. Articles were discarded if they were deficient in at least
12 of the 17 criteria. Two authors reviewed each article and consensus had to be reached before scoring each item. The reviewers were blinded to both the author and journal of publication.

**Data extraction**
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data extraction.

The extracted data included the raw mean difference in BP calculated from the studies (see Other Publications of Related Interest no.2) and the type of biofeedback. If standard deviations (SDs) for the mean differences were not reported, they were calculated.

[A:Data extracted also included number of participants, age, race, sex, treatment length, treatments.]

**Methods of synthesis**
How were the studies combined?
The studies were combined using a random-effects analysis (see Other Publications of Related Interest nos.3-4). The results were presented as the mean differences in SBP and DBP, together with 95% confidence intervals (CIs). Studies reporting the SD of the difference were given more weight in the analysis than those for which the SD had been estimated.

How were differences between studies investigated?
The authors performed a subgroup analysis based on the type of biofeedback used.

**Results of the review**
Twenty studies were included. [A:1,110 participants]

Biofeedback showed a non statistically-significant benefit over active control (6 studies): the mean difference was -2.1 mmHg (95% CI: -7.0, 2.9, p>0.05) in SBP and -3.4 mmHg (95% CI: -7.4, 0.6 p>0.05) in DBP.

Biofeedback showed a statistically-significant benefit over inactive control: the mean difference was -6.7 mmHg (95% CI: -10.2, -3.2) in SBP and -4.8 mmHg (95% CI: -7.2, -2.3) in DBP, (p<0.05).

Subgroup analysis.

Thermal biofeedback showed a statistically-significant benefit compared with inactive control (5 studies): the mean differences in SBP and DBP were -5.0 mmHg (95% CI: -9.1, -0.9, p less than or equal to 0.05) and -6.3 mmHg (95% CI: -9.9, -2.7, p less than or equal to 0.05), respectively. When compared with active control, DBP was significantly lowered in the biofeedback group (4 studies): the mean difference in DBP was -4.4 mmHg (95% CI: -8.5, -0.3, p less than or equal to 0.05), whereas there was no statistical difference in SBP (-0.6 mmHg, 95% CI: -6.5, 5.3). For electrodermal activity compared with inactive control (3 studies), the mean difference was -7.1 mmHg (95% CI: -14.3, 0.2) in SBP and -3.8 mmHg (95% CI: -7.0, -0.6, p less than or equal to 0.05) in DBP. For electromyography and BP monitoring compared with inactive control (2 studies), the mean differences in SBP and DBP were 0.2 mmHg (95% CI: -5.6, 6.1) and 1.3 mmHg (95% CI: -1.6, 4.3), respectively.

**Authors’ conclusions**
Both biofeedback and active control treatments resulted in a reduction in SBP and DBP. Only biofeedback (with related cognitive therapy and relaxation training) showed a significantly greater reduction in both the SBP and DBP in comparison with inactive control.

**CRD commentary**
This was a clearly written paper with clearly stated aims. The initial search appeared satisfactory; however, this was
limited initially to 'clinical trials', and later, by searching solely on 'biofeedback'. In addition, non-English language papers and reports in other types of literature (e.g. letters, reviews, commentaries) were excluded. It is therefore possible that papers were missed.

The methods of the review process were stated clearly. There was little information on the participants in the included studies, which means that it is difficult to generalise from the results. The numbers of participants were not reported, and there was very little description of the interventions used and the length of the intervention or follow-up in the individual studies. In addition, references to the included studies were not provided. The authors have since supplied details of the numbers of participants, age ranges and treatment length.

No test for heterogeneity was reported. Some studies seem to have been included more than once in the meta-analysis, as they compared three or more intervention groups. It is unclear how the control groups were dealt with in these cases. Use of the same control group more than once in the meta-analysis may produce misleading results. This lack of information means that it is difficult to comment upon the extent of the validity of the conclusions. In addition, although the authors concluded that 'only biofeedback showed significantly greater reduction in BP', they have not compared 'active control' with 'inactive control'. Thus, it may be difficult to deduce from these results what effect the different components of the 'biofeedback' treatment had, i.e. was it the cognitive therapy/relaxation or the biofeedback itself that resulted in changes in BP. The mean SBP and DBP for each group, rather than the mean difference between the groups, could have allowed an approximation of the relative contributions.

Implications of the review for practice and research
Practice: The authors state that practice nurses who prescribe medication should consider the role of biofeedback as a treatment for stage 1 or 2 hypertension in healthy adults before pharmacological treatments. In addition, biofeedback should be considered as an adjunct to standard pharmacological therapy.

Research: The authors state that there is a need for a large, well-conducted multicentre study on the use of biofeedback for hypertension. In addition, nurses should conduct small-scale, research utilisation trials.

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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.