

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

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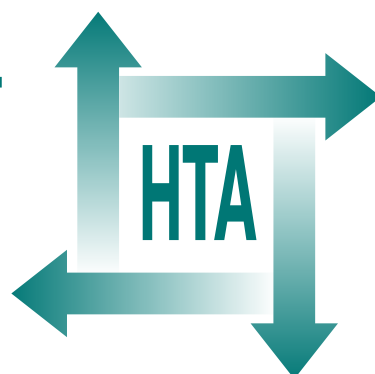
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Executive summary

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Executive summary

Background

Hypertension is defined as persistently high blood pressure, with currently accepted thresholds in the UK at 140/90 mmHg. It is one of the most prevalent and powerful risk factors contributing to the development of cardiovascular disease (CVD) and one of the most important preventable causes of premature morbidity and mortality in developed and developing countries. The estimated lifetime risk of middle-aged men and women developing hypertension is 80–90%. The most common type of hypertension is essential hypertension, which has no known cause. Its estimated prevalence is 30.6%. Current treatment options include lifestyle changes and pharmacological agents.

Biofeedback is defined as a group of non-pharmacological therapeutic procedures that use electronic instruments to measure, process and provide information (feedback) to patients regarding their neuromuscular and autonomic nervous system activity. Patients have been taught these procedures in an attempt to control their blood pressure. If shown to be effective they could be used in the treatment of essential hypertension.

Objectives

The primary objective of this report was to assess the evidence for the long-term effectiveness of biofeedback procedures in treating adults with essential hypertension. Other objectives were to model any clinical benefits of biofeedback for the treatment of essential hypertension, provide an overview of currently used biofeedback equipment and offer recommendations for future research.

Methods

Two recent systematic reviews with meta-analyses were critically appraised and used as a basis for this updated systematic review, which compares biofeedback procedures with placebo (sham biofeedback treatment), no intervention or other behavioural treatments, as well as with antihypertensive medication.

The assessment of clinical effectiveness evidence was conducted according to accepted procedures for conducting and reporting systematic reviews. This included a comprehensive search (for the period to May 2007) of bibliographic databases [including the Cochrane Library, EMBASE, MEDLINE, ISI Web of Knowledge/Web of Science, ISI Web of Knowledge/ISI Proceedings, the Cochrane Library 2007, CINAHL (Cumulative Index to Nursing and Allied Health Literature), AMED (Allied and Complementary Medicine) and PsycINFO], as well as hand-searching activities. Unpublished evidence (such as conference abstracts) was considered for inclusion in the assessment. Information regarding biofeedback equipment was sought from a range of sources: the British Hypertension Society (BHS); the American Society for Hypertension (ASH); the American Association for Applied Physiology and Biofeedback (AAPB); the National Centre for Complementary and Alternative Medicine (NCCAM); the Biofeedback Foundation of Europe (BFE); and the European Society for Hypertension (ESH). Equipment used in randomised controlled trials (RCTs) was also noted. Additionally, a panel of clinical advisers was asked to comment on equipment.

Results

The two existing systematic reviews were judged to be of high quality although there is a question regarding the appropriateness of the pooling of data. Neither review considered any evidence for biofeedback treatment versus antihypertensive medication. The authors of the first review concluded that biofeedback was more effective than no intervention, but was only superior to sham or non-specific interventions when combined with a relaxation technique. The second systematic review indicated that both biofeedback and active control treatments (relaxation training, cognitive therapy and home monitoring) reduced systolic blood pressure (SBP) and diastolic blood pressure (DBP), but only biofeedback significantly reduced SBP and DBP when compared with inactive control treatments (waiting list, blood pressure measured in a clinic, placebo biofeedback controls).

The systematic review presented here compared biofeedback treatment with antihypertensive medication, placebo (sham biofeedback treatment), no intervention or another behavioural therapy (including biofeedback) and the primary outcome was effect on blood pressure. The patient population was limited to adults with essential hypertension (taking or not taking antihypertensive medication) as defined above.

A total of 927 non-duplicate references were identified by the search strategy and subsequently screened for inclusion in the review. From these, 41 publications (including three abstracts) reporting 36 RCTs with a total population of 1660 treated patients met the inclusion criteria of the review. In total, 21 trials employed biofeedback treatment with no adjunctive therapy and 15 used biofeedback treatment alongside another treatment. The majority of trials were small and had either no post-treatment follow-up or follow-up of less than 6 months.

No statistical meta-analysis was carried out as the general quality of reporting of trials was poor and there was a large degree of heterogeneity in terms of treatments and comparators. Outcome measures were inconsistently reported. A narrative summary of the data is presented. Data were grouped first by treatment type and then by comparator. In addition, the type of biofeedback was used to further delineate trials. Author conclusions regarding the efficacy or otherwise of biofeedback treatment versus the comparator were summarised and used as the basis of the analysis.

Trial results were variable and conflicting, demonstrating no evidence of short- or long-term benefits of biofeedback in relation to moderation of hypertension. The trials comparing biofeedback with antihypertensive treatment were small and dated and showed no clear evidence for the efficacy of biofeedback treatment. The evidence

was equivocal for the effectiveness of biofeedback treatment compared with either no intervention or placebo (sham biofeedback treatment). There was also no clear evidence for the superiority of biofeedback over other behavioural treatments. When benefits were shown they were within the standard error of reproducibility of blood pressure measurement and may therefore have arisen by chance. No trials reporting long-term outcomes were identified for inclusion in the review.

The information obtained concerning biofeedback equipment is summarised. Front-runner technologies could not be identified within this review as the treatment protocols were diverse. There was no consistent evidence of a treatment effect and therefore we were unable to model any benefits.

Conclusions

The quality of research in this area is poor. There is currently no evidence that consistently demonstrates the effectiveness of the use of any particular biofeedback treatment in the control of essential hypertension when compared with pharmacotherapy, placebo (sham biofeedback treatment), no intervention or other behavioural therapies. The lack of evidence of clinical effectiveness negated the need to conduct an economic analysis. Given the current standards for the treatment of hypertension, further research is likely to be considered only as an adjunct to pharmacological interventions.

Publication

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NIHR Health Technology Assessment programme

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