Thermal biofeedback for primary Raynaud's phenomenon: a review of the literature

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CRD summary

This review assessed thermal biofeedback in the treatment of Raynaud's phenomenon. Based on evidence from three randomised controlled trials, it concluded that thermal biofeedback is efficacious for treating this condition. The limited evidence available and lack of clarity about individual study results do not support this conclusion.

Authors' objectives

To review the evidence for the efficacy of thermal biofeedback treatment in Raynaud's phenomenon.

Searching

MEDLINE and PsycINFO were searched for articles published in English between 1975 and 2005. Search terms were reported.

Study selection

Randomised controlled trials (RCTs), non-randomised controlled clinical trials (CCTs) and follow-up studies investigating thermal biofeedback were eligible for inclusion. Studies where participants were diagnosed with primary Raynaud's phenomenon were eligible. The outcomes of interest were symptom frequency, symptom intensity and temperature response to cold. Included studies had to report at least one of these outcomes to be included.

Most participants in the included studies were female (ranging from 75 to 100%) and ages ranged from 14 to 65 years. There was a wide range of intervention and comparator treatments studied including: thermal biofeedback alone and with autogenic training; autogenic training alone; thermal biofeedback under cold stress compared with waiting list or no controls; progressive relaxation; classical conditioning; electromyography; drug treatment. Treatment schedules varied between studies with total hours ranging between two and 24 hours between three and 20 weeks.

The authors did not state how papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality

The authors stated that papers were rated for quality and they discussed details of intention to treat analyses (ITT) for the RCTs, whether seasonal effects were controlled for in analyses, adequacy of training and use of suitable control groups. No further details were reported.

Data were extracted by two reviewers independently, with disagreements resolved by a third reviewer.

Data extraction

Data on outcomes, as they were reported by the individual studies, were extracted by two reviewers independently, with disagreements resolved by a third reviewer.

Methods of synthesis

Results were presented narratively, grouped by study design. As there were different outcomes and treatment comparisons, a meta-analysis was not appropriate. Differences between the studies were described in the review.

Results of the review

Ten studies were included: seven RCTs (n=465, range 21 to 313); one CCT (n=15); and two follow-up trials (n=19, n=32). All studies had some methodological flaws including; not accounting for seasonal temperature effects (three studies); mostly female participants; inconsistent reporting; outdoor temperature considered as a confounding factor; ineffective training methods for biofeedback; and a lack of comparison of thermal biofeedback with a control group.

Six studies showed that thermal biofeedback did not provide better outcomes to other types of relaxation, classical

conditioning, non-thermal biofeedback or a calcium channel blocker. Two studies reported problems in teaching hand warming skills and neither found any benefit of thermal biofeedback compared with a no treatment or placebo control.

Two small RCTs found that thermal biofeedback provided greater reductions in symptom frequency compared with either autogenic training or electromyography. Both these studies were considered to be the highest quality and showed statistically significant differences favouring thermal biofeedback for hand warming and reductions in attacks. The largest RCT showed no evidence of a reduction in attacks compared with control biofeedback and an increase in attacks compared with a calcium channel blocker.

Authors' conclusions

The procedures for training thermal biofeedback varied between studies but, based on evidence from three RCTs, thermal biofeedback is efficacious for treating Raynaud's phenomenon.

CRD commentary

This review had a clear aim and specified study inclusion criteria for participants, interventions, outcomes and study design. The literature search was limited to only published studies and those written in English, so relevant evidence could have been excluded. Some discussion of study quality was provided in the text but full details of a quality assessment of each study were not presented. Data extraction was performed in duplicate, which reduced the risk of error. It was unclear if studies were selected in the same way. Some details of results were reported but a clear narrative presentation of all studies, and all between group comparisons, was lacking. The limited evidence presented and unclear reporting of the individual studies does not appear to support the authors' conclusions that thermal biofeedback is efficacious.

Implications of the review for practice and research

Practice: The authors presented a number of treatment guidelines for clinical practice. Subjects should be trained to predetermined criteria (raising temperature to 93 degrees Fahrenheit for at least 15 minutes). Cold stress conditions should be included in training. A no feedback session should be included. Home practice and applied practice in the natural environment should be included. A multiple treatment approach should be considered. Research should address anxiety and comorbid emotional disorders which may complicate treatment.

Research: The authors made a number of recommendations for future research. Disease duration, gender, age, medication status of participants should be better specified. More consistent criteria for study outcomes should be used. More details of the thermal biofeedback treatment protocol should be provided. A placebo or no treatment control group should be used. Learning criteria for thermal biofeedback training should be included. Positive relationships with the therapists should evaluated, with treatment pacing similar to that used in clinical practice.

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