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Acupuncture for tinnitus: A series of six *n* = 1 controlled trials

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Summary
Objective: To explore patient perceived benefits of acupuncture for tinnitus.
Design: Controlled *n* = 1 trials, with two phases A and B.
Subjects: Six patients with tinnitus.
Outcome measures: Primary outcome was Daily Diary records related to four tinnitus symptoms: loudness of tinnitus; pitch of tinnitus; waking hours affected with tinnitus; quality of sleep. Secondary outcomes were the Tinnitus Handicap Inventory (THI) and Measure Your Medical Outcome Profile (MYMOP).
Methods: Patients received a course of 10 acupuncture treatments over a 2-week period. Daily Diary entries related to the four tinnitus symptoms were recorded by patients for 14 days pre-treatment (phase A) and 14 days post-treatment (phase B). A hierarchical Bayesian model was used to combine the results from the individual patients to obtain estimates of the population and individual patient treatment effects, incorporating random variations at both levels (between patients and within patient). Tinnitus Handicap Inventory (THI) and Measure Your Medical Outcome Profile (MYMOP) were recorded at assessment points pre-treatment and post-treatment.
Results: Six patients participated in the trials, each receiving 10 treatments and completing all Daily Diary entries and outcome measures. For the of symptoms of loudness and pitch, there were variable treatment effects between patients, with a trend for the median overall reduction for loudness of −2.49 (−5.04, 0.02) and for pitch −1.39 (−3.74, 0.89), 95% credibility intervals being shown in brackets. For the other two symptoms, the waking hours affected and quality of sleep, patients' responses were more consistent, with amore credible overall median reduction for affected waking hours of −2.76 (−3.94, −1.63) and for quality of sleep −2.72 (−3.45, −2.03). The THI and MYMOP measures showed a trend of improvement after treatment.

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Conclusion: The $n = 1$ trial methodology, with an AB design and Bayesian analysis, can be considered of value in exploring treatment effects for small numbers of patients receiving individualised treatments, as is common within complementary medicine. When the treatment effects from six patients were synthesized, the results of this study suggest that acupuncture may have a beneficial role in the treatment of tinnitus.
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Introduction

Tinnitus, from the Latin ''tinnere'' meaning to ring, has a reputation for being a difficult disease to treat, whether by conventional medicine or by acupuncture. For people with tinnitus, the condition can vary from a low level buzzing to a noise of such intensity it can lead to severe anxiety, despair and even suicidal tendencies.

Acupuncture has been much used for tinnitus over the years, however recent attempts to demonstrate acupuncture's effectiveness have not provided definitive evidence. A systematic review by Park et al.[1] found that the evidence from six eligible randomised controlled trials was not adequate to make a judgment as to acupuncture's effectiveness for tinnitus. Their commentary highlighted various shortcomings from these trials, including ''disappointing'' methodology. They criticised the inappropriate use of crossover designs in four of these trials, because carryover effects can be expected from acupuncture. Inadequate reporting meant that the rationale for points used was not always stated. No authors quoted the classical literature and the trials using individualized points did not report traditional diagnostic frameworks nor related procedures for point selection. One trial used only ear points.[2] Another used the same points for both the real and ''sham'' acupuncture, but with the so-called sham points being inserted subcutaneously,[3] an approach that has largely been rejected on the grounds that such sham treatments can be expected to result in acupuncture effects.[4] Extraordinarily, this trial received the highest quality rating on Park et al.'s methodology scale. Despite the problematic nature of the reviewed trials, Park et al's research has led to a questionable reinterpretation and unsubstantiated conclusion that acupuncture is ineffective for tinnitus.[5]

On the basis that there is inadequate evidence to draw conclusions to date, we have designed a simple study on a limited budget to explore patient's perceptions of outcome from acupuncture. We utilised an $n = 1$ design which can fit well with a treatment approach based on individualised acupuncture, and where point selection is usually reformulated at each ongoing session based on changes to presenting symptoms over time.[6] If the condition under investigation is chronic, then we can argue that sufficient baseline measures might demonstrate reasonable stability to the pre-treatment chronicity. If so, improvements cannot therefore so easily be dismissed as due to the natural history of the disease.

In the investigation of new drugs, the usual $n = 1$ trials are double blind, cross-over, randomised, and controlled. They are generally used for chronic, stable conditions for which the proposed treatment has a rapid onset of action and ceases to act soon after it is discontinued, that is with no carry-over effect.[7] The patient undergoes a series of pairs of treatment periods, one period of each pair with the active drug and one with matched placebo, assigned at random. Pairs of treatment periods, sometimes labelled ABAB, etc., are continued until effectiveness is proved or refuted. There are a number of problems with importing this model into complementary and alternative medicine, even though it has been argued that $n = 1$ designs are ''suitable for some research initiatives in complementary medical practice''.[8] First the treatment effects in CAM may be slow, with a number of treatments usually being required as a minimum ''dose'' for the full beneficial effects to manifest. For example the impact of acupuncture for the treatment of chronic pain seems to require a minimum of six treatments.[9] A second problem is that the ABAB designs require no carry-over effect, so that the effect of treatment in say phase B needs to be sufficiently ''washed out'' to not affect the measurements in the subsequent phase A. However, we know that CAM therapies, and acupuncture in particular,[10] can be expected to have ongoing and progressing change both during and after a course of treatment. No time period would be long enough to ''wash out'' the effect.

As a result of these concerns, we have drawn on earlier research into behavioural therapy (Barlow and Hersen, 1984), a tradition that has continued in rehabilitation research,[11] and chosen the simple AB design as our $n = 1$ framework. The unique feature of $n = 1$ controlled trials is that each trial is of a single patient who acts as his/her own control.

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