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Recommended, not recommended, strongly recommended

Reviews of the research evidence for the effectiveness/efficacy of acupuncture for chronic low back pain have led different reviewers to reach very different conclusions despite reviewing essentially the same body of evidence. Nowhere is this contrast clearer than in the difference between the findings of the NICE review of 2016 (1), which recommended against acupuncture, compared to the NICE review of 2009 which recommended acupuncture and the American College of Physicians review in 2017(2), which gave acupuncture a strong recommendation.

The main difference in the methodologies of these three reviews appears to have been the interpretation of the significance of comparisons between real and sham acupuncture, as opposed to comparators such as usual care, wait list and no treatment. It is clear that the effect sizes estimated by comparing verum acupuncture with sham acupuncture are consistently much smaller than when acupuncture is compared to usual care, wait list or no treatment (3-5). The Society for Acupuncture Research has dubbed this phenomenon "The paradox of acupuncture research"(3). **How this paradox is interpreted is pivotal to clinical decision-making in developing clinical practice guidelines.**

The Paradox of Acupuncture Research

There are three possible explanations for this paradox. Firstly, it has been suggested that acupuncture may be nothing more than a "theatrical placebo" (6). Secondly, if the sham acupuncture was not inert, it would lead to an underestimation of the true effect size of the verum acupuncture (7). Thirdly, if the verum acupuncture was suboptimal (not designed to achieve maximum therapeutic benefit) then the effect size would again be underestimated.

Five main types of placebo/sham controls have been used to date in acupuncture research, all of which have been demonstrated to be physiologically active (4, 7-10). Not only have sham acupuncture controls been shown to produce changes in the brain, but some of these effects are not produced by real acupuncture (11-14). Consequently, the effect size of real acupuncture is highly likely to be underestimated compared to sham acupuncture controls (7). For a more detailed discussion of the paradox in acupuncture research see McDonald, 2019 (15).

Problems with sham controls in acupuncture, surgery and psychotherapy research

Complex skill-based interventions including acupuncture, surgery and psychotherapy share a common challenge in designing sham-controlled studies, namely creating an inert but credible sham intervention to allowing subject blinding/masking. It is noteworthy that in trials of surgery and psychotherapy where sham controls have been attempted, that a similar picture emerges to the paradox of acupuncture research (16, 17). There is consistently a much smaller difference between

real and sham interventions than when other comparators such as usual care, waitlist or no treatment are used (16, 17). This has not prevented various surgical procedures and psychotherapy

being recommended in numerous clinical practice guidelines, or indeed, led to such interventions being recommended against on the grounds that they may merely be placebo.

Harms vs benefits

The question of whether or not the effects of acupuncture on chronic low back pain include placebo effects, and, if so, how large these placebo effects might be, is very difficult to answer using sham-controlled acupuncture trials. However, in developing clinical practice guidelines, the issue of harms to benefits ratio is surely more relevant. Acupuncture has been shown to be effective in numerous trials, superior to sham acupuncture when high quality trials with large sample sizes are used, has a very low adverse events profile, is relatively cost-effective compared to other available therapies, and has been given a strong recommendation (based on moderate evidence) from the American College of Physicians. **On this basis, we respectfully submit that acupuncture should be recommended for the management of chronic low back pain.**

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The Acupuncture Evidence Project: A Comparative Literature Review

In 2016, The Australian Acupuncture and Chinese Medicine Association Ltd (AACMA) commissioned Dr John McDonald, PhD and Stephen Janz to prepare a comparative literature review of acupuncture systematic reviews to provide a snapshot of current evidence from acupuncture clinical research. This process was intended to update two previous reviews conducted by the Australian Government Department of Veterans Affairs in 2010, and the US Department of Veterans Affairs in 2014. A similar methodology was used as was used in the previous two reviews, however, although three professors of acupuncture research provided written pre-publication feedback and advice, the review was not formally peer-reviewed. The methods and outcomes summary section (on low back pain) of the Acupuncture Evidence Project are reproduced below. The full text of The Acupuncture Evidence Project is available as a free download from the website of the Australian Acupuncture and Chinese Medicine Association Ltd: https://www.acupuncture.org.au/wp-content/uploads/2017/11/28-NOV-The-Acupuncture-Evidence-Project_Mcdonald-and-Janz_-REISSUED_28_Nov.pdf

1.1   Methods

*A review of alternative therapies was published by the Australian Government Department of Veterans Affairs in 2010 (18). In 2014, the US Department of Veterans Affairs published an Evidence Map of Acupuncture reviewing acupuncture research published in or before March 2013 (19). **This review focuses on new evidence between March 2013 and September 2016.** Like the two previous reviews, this review concentrates on systematic reviews and meta-analyses, using Cochrane Systematic Reviews where available. The primary focus of this review is to examine evidence supporting the effectiveness and efficacy of acupuncture (see section 1.3 Efficacy versus effectiveness). Where available, evidence on cost-effectiveness and safety has been included.*
A search was undertaken on PubMed and the Cochrane Library using the search term 'acupuncture' with limits set for dates between March 2013 and September 2016, and restricted to reviews. All languages were included. Systematic reviews, meta-analyses, network meta-analyses, overviews of systematic reviews (NHMRC level I evidence) and some narrative reviews were included, but protocols for systematic reviews were excluded. Systematic reviews of non-invasive or nonpharmacological interventions or of complementary and/or alternative medicine (CAM) interventions were included if they included acupuncture studies. One systematic review from the Australian Journal of Acupuncture and Chinese Medicine was included although this journal is not included in PubMed listings. A total of 134 systematic reviews, including 27 Cochrane systematic

reviews, were included in this review, three network meta-analyses, nine reviews of reviews and 20 other reviews. Meta-analyses were conducted for 59 of the non-Cochrane systematic reviews. This review includes pooled data from more than 1,000

randomised controlled trials. Some of the included systematic reviews included studies which were not randomised controlled trials.

2.3 Low back pain [Chronic – positive effect; acute – potential positive effect]

For low back pain, acupuncture was rated as 'effective (possibly)' in the Australian DVA review (2010) and 'unclear' in the USVA Evidence map of acupuncture (2014) (18, 19). The main reason given for the 'unclear' rating in the USVA Evidence map was that 'sham acupuncture controlled trials tended towards statistically nonsignificant results' and a Cochrane systematic review in 2005 which drew no firm conclusions on the effectiveness of acupuncture for acute low back pain (19). The problems associated with the interpretation of the effects of sham acupuncture have already been discussed. When reviews separate the evidence on chronic low back pain from acute low back pain, as was done in the recent review by the US Agency for Healthcare Research and Quality, it was found that there is moderate quality evidence for the effectiveness of acupuncture in chronic low back pain for both pain intensity and function, but only low quality evidence for pain intensity and function in acute low back pain (20).

In a systematic review of 32 randomised controlled trials for acupuncture treatment of chronic non-specific low back pain, acupuncture was superior (both statistically and clinically significant) to sham acupuncture in pain reduction and improved function immediately after treatment (21). Acupuncture was equivalent but not superior to usual care in pain and function, but acupuncture plus usual care was superior to usual care alone (21). The reviewers rated the evidence level of their review as Level of Evidence 1 (21). A systematic review of 11 randomised controlled trials on acute low back pain, acupuncture was superior to NSAIDS for improving symptoms (small effect), and superior to sham for pain but not function (22). A narrative review of non-invasive and alternative treatments for chronic low back pain rated the evidence for the effectiveness of acupuncture as high and for acupressure as moderate (23).

A review of 16 systematic reviews found that acupuncture alone, or when added to usual care, provided short-term improvement in pain and function for chronic low back pain (medium to large clinical effects) and hence 'should be advocated in routine clinical practice' (24). For acute low back pain, the reviewers could not make firm conclusions about the effectiveness of acupuncture due the inclusion of only two systematic reviews (24). Two studies found that acupuncture is likely to be cost-effective for low back pain or chronic non-specific low back pain, respectively (25, 26).

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