Mike is Medical Director of the British Medical Acupuncture Society (BMAS). This is a full time post that involves running the BMAS London Teaching Clinic (LTC), co-ordinating and lecturing on BMAS courses in Western medical acupuncture, acting as an associate editor for the Medline-listed journal Acupuncture in Medicine, and representing the BMAS at various academic and political meetings. Mike is an Honorary Clinical Specialist at the Royal London Hospital for Integrated Medicine, which is part of the University College London Hospitals NHS Foundation Trust, where he supports acupuncture services.

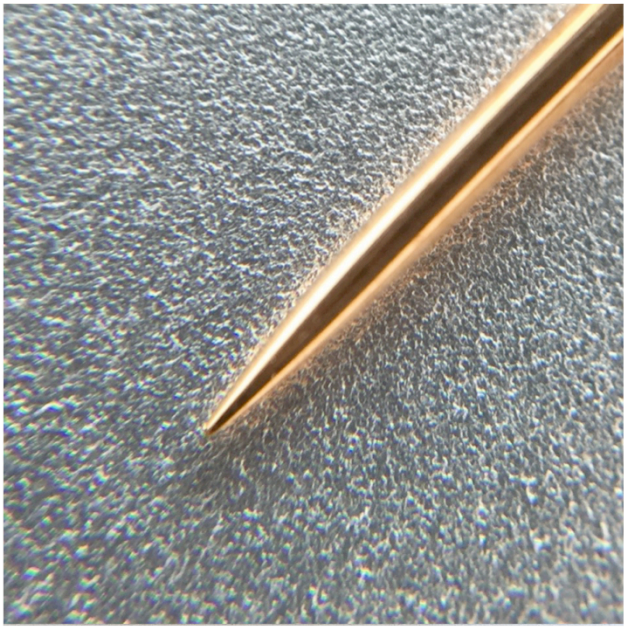
His principal academic and clinical interest is musculoskeletal pain, and in particular, needling therapies in the treatment of myofascial pain syndromes.

After completing his medical degree at Leeds, and several hospital jobs in the north of England, Mike joined the Royal Air Force for a six and a half year short service commission. A substantial portion of the workload for a general duties medical officer (GDMO) in the RAF is musculoskeletal medicine. Mike came across acupuncture by accident whilst working as a GDMO. He followed his interest in musculoskeletal medicine and acupuncture on retiring from military service, and finally found himself occupied full time in the field of acupuncture (see start of the piece).

Read Mike's profile in the Leeds University Medical School Alumni magazine from 2003.

Read a description of how Mike unexpectedly got into acupuncture in Toby Murcott's book - The Whole Story from 2005.

Acupuncture in Chronic Pain



Interpreting the evidence
Perspectives on the biggest data sets

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Medical Acupuncturist

Medical Director BMAS
Director of Education BMAS
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Declaration of interests

I am the salaried medical director of the British Medical Acupuncture Society (BMAS), a membership organisation and charity established to stimulate and promote the use and scientific understanding of acupuncture as part of the practice of medicine for the public benefit.

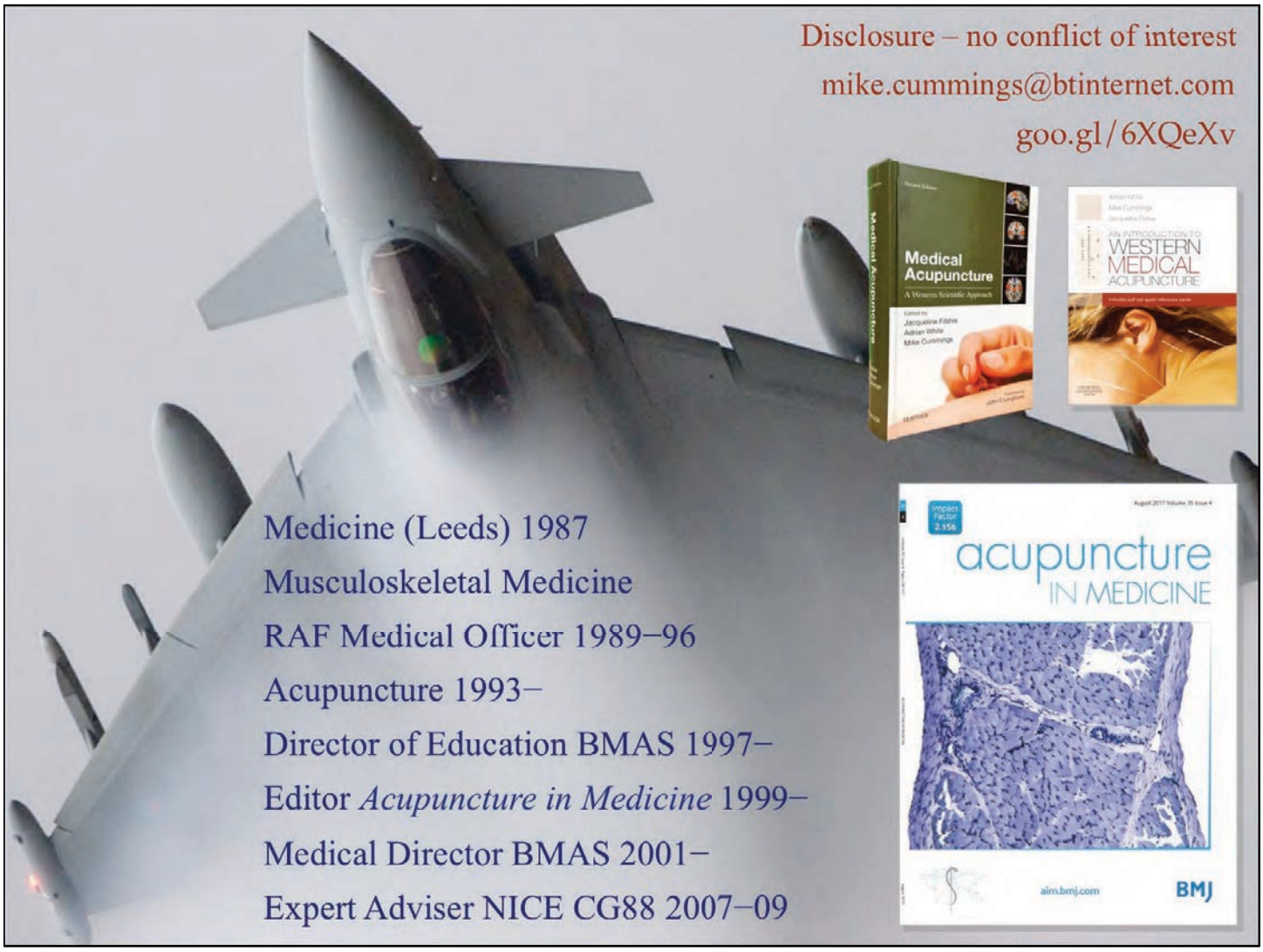
I am an associate editor for *Acupuncture in Medicine*.

I have a very modest private income from lecturing outside the UK, royalties from textbooks and a partnership teaching veterinary surgeons in Western veterinary acupuncture. I have no private income from clinical practice in acupuncture. My income is not directly affected by whether or not I recommend the intervention to patients or colleagues, or by whether or not it is recommended in national guidelines.

I have not chaired any NICE guideline development group with undeclared private income directly associated with the interventions under discussion. I have participated in a NICE GDG as an expert advisor discussing acupuncture.

I have used Western medical acupuncture in clinical practice following a chance observation as a medical officer in the Royal Air Force in 1989. My opinions are formed by data that spans the range of quality and reliability, much of which is in the public domain.

I have a logical mistrust of the motives of anyone who advertises an interest or hobby in being a 'Skeptic', as opposed to using appropriate scepticism within their primary profession, or indeed organisations that claim to promote generic 'science' as opposed to actually engaging in it.

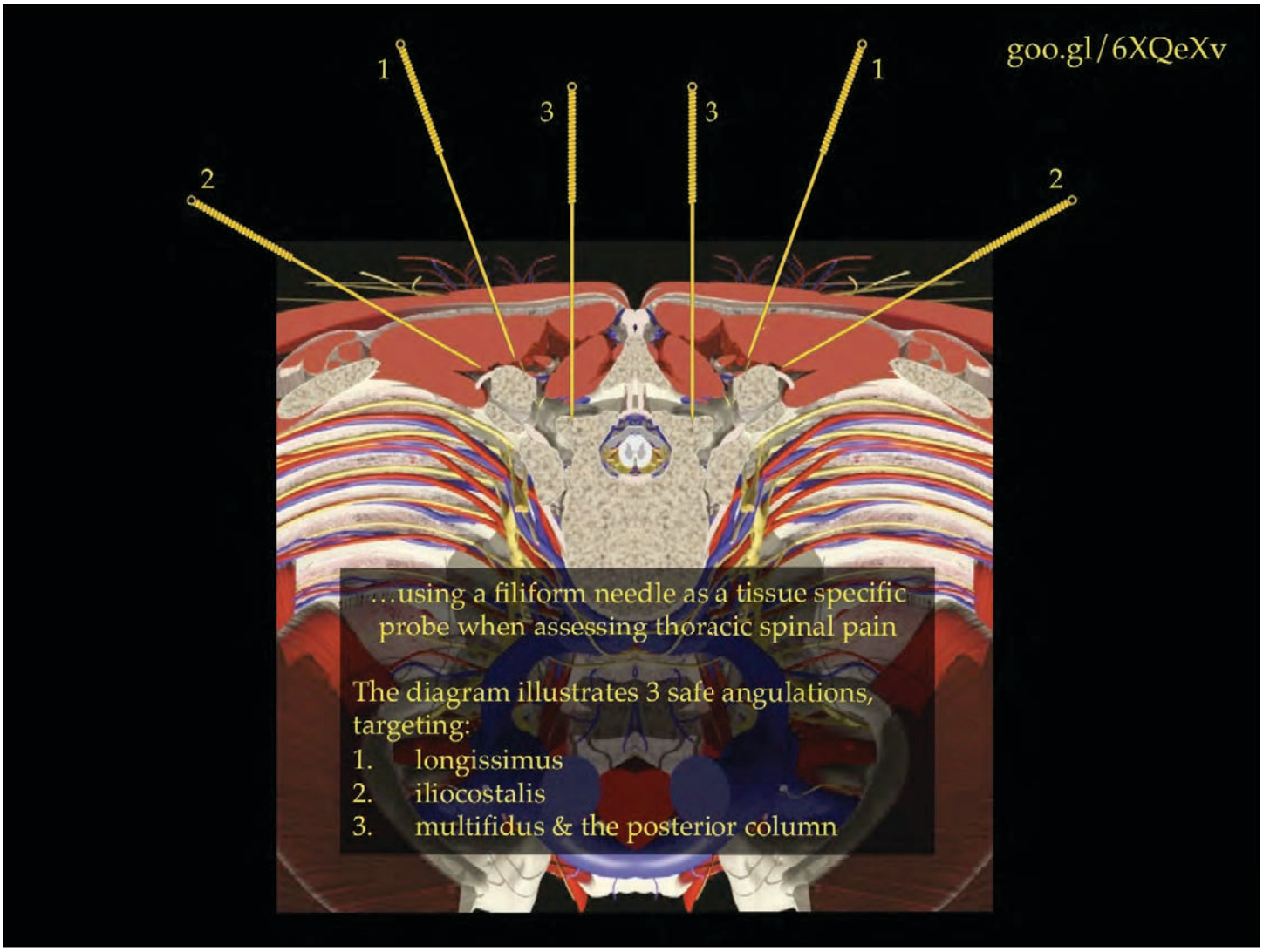


From an early age I was interested in somatic anatomy and of musculoskeletal physiology. I continued that interest through medical school and beyond. Acupuncture was a chance discovery whilst serving as a medical officer in the British military. After retiring from the Royal Air Force, my career took a path that was guided by my interest in musculoskeletal pain and strongly influenced by taking over an acupuncture practice that was formerly run by Dr Adrian White. At the time Adrian was the president of the British Medical Acupuncture Society (BMAS), and when I took over his practice, he went into research at Exeter University. I continued my interest in clinical medicine, but at the same time was inducted into the world of systematic reviews and publishing. I kept a foot in both camps, and this has served me well in my position as medical director of the BMAS.

Fritillaria imperialis is a species of flowering plant in the lily family, native to a wide stretch from Kurdistan across the plateau of Turkey, Iraq and Iran to Afghanistan, Pakistan and the Himalayan foothills.
It grows to about 1m in height, and bears lance-shaped, glossy leaves at intervals along the stem. It bears a prominent whorl of downward facing flowers at the top of the stem, topped by a 'crown' of small leaves, hence the name. While the wild form is usually orange-red, various colours are found in cultivation, ranging from nearly a true scarlet through oranges to yellow. The pendulous flowers make a bold statement in the late spring garden; in the northern hemisphere, flowering takes place in late spring, accompanied by a distinctly foxy odour that repels mice, moles and other small animals.
Due to the way that the bulb is formed, with the stem emerging from a depression, it is best to plant it on its side, to prevent water causing rot at the top of the bulb.

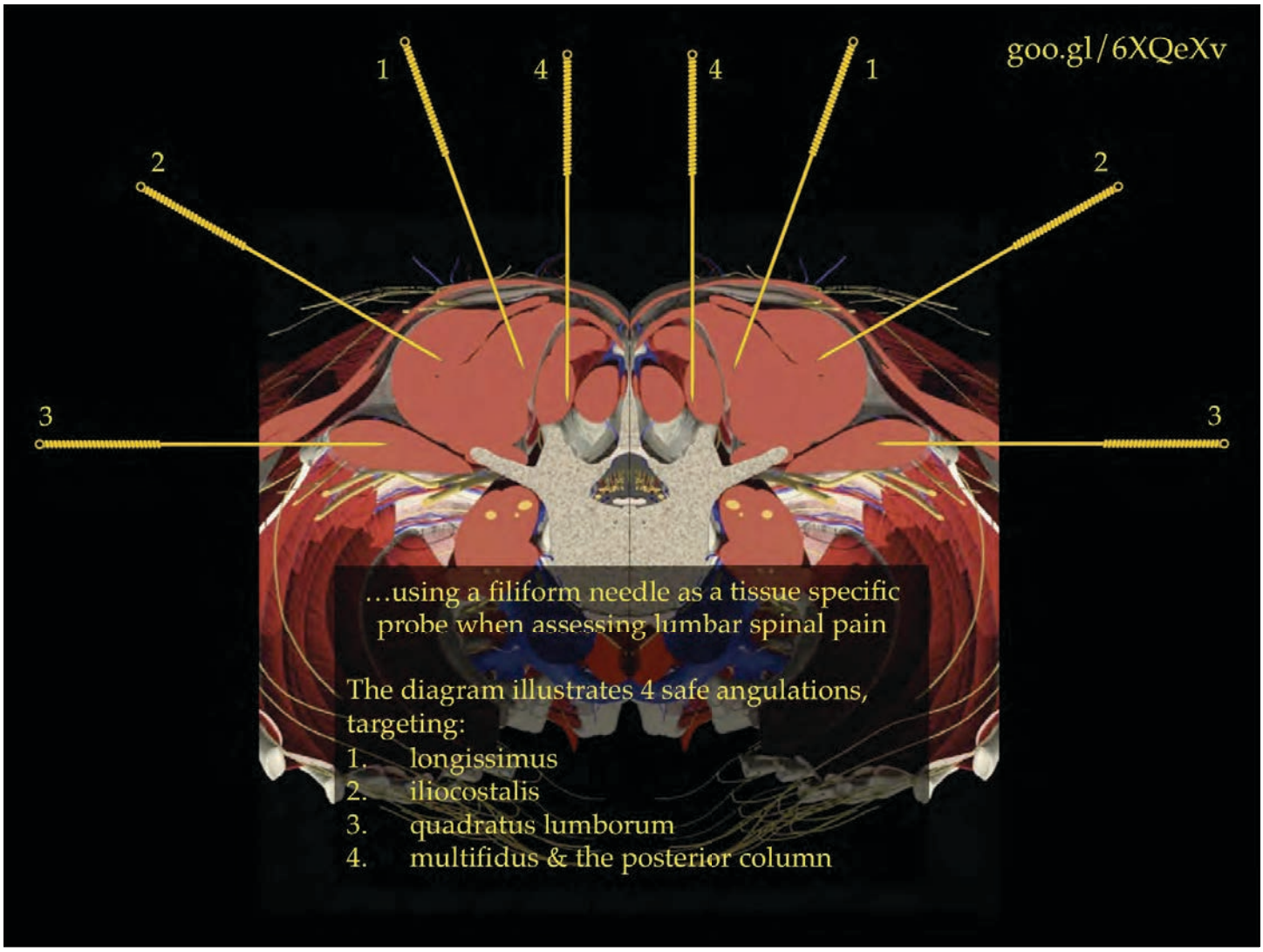
This photo was taken at the Royal Botanical Gardens in Kew on 14 April 2018.
I placed the camera on the grass as an experiment to avoid including the crowds of admiring visitors.

Canon EOS 5D Mark III
Canon EF24-70mm f/2.8L II USM
Taken at f/8.0 24mm 1/250 iso100



This slide demonstrates safe angulations when needling different muscle groups in the dorsal spine for assessment of pain in the dorsal back or chest. Typically each muscle group will be needled individually and the patient questioned about provocation of recognised pain. Pain referral to the anterior chest is generally only seen with 3: multifidus and the deep posterior spinal elements – pars, lamina and facet joints.

In order to safely place a needle in position 2 avoiding the lung, the practitioner must make firm contact with the angles of the ribs and transverse processes. Position 1 targets longissimus, which is the most superficial muscle band and easily palpated.



This slides demonstrates the safe approaches to the main muscle compartments in the lumbar spine.

Typically 50mm needles are used at 0.30mm gauge. Bony contact with posterior spinal elements is usually only made in position 4, and the depth can vary from around 45mm to 55mm. It is useful to be aware for orientation when needling that the mamillary processes may be 7mm closer than the lamina.

Note that all needle directions are towards the ipsilateral posterior articular column, not the midline.

It is important to maintain firm pressure on the soft tissues anterior to quadratus lumborum to avoid inadvertent puncture of viscera.

This image attempts to illustrate the difference in the distribution of pressure applied with a fingertip and a filiform needle. The needle concentrates high mechanical loading around the tip, whereas the finger applies pressure through multiple layers at the same time. In terms of mechanical loading for pain provocation tests, the needle is likely to be much more tissue specific in terms of loading.

At the same time as loading tissues we typically ask: "Is this reproducing a pain you recognise?"

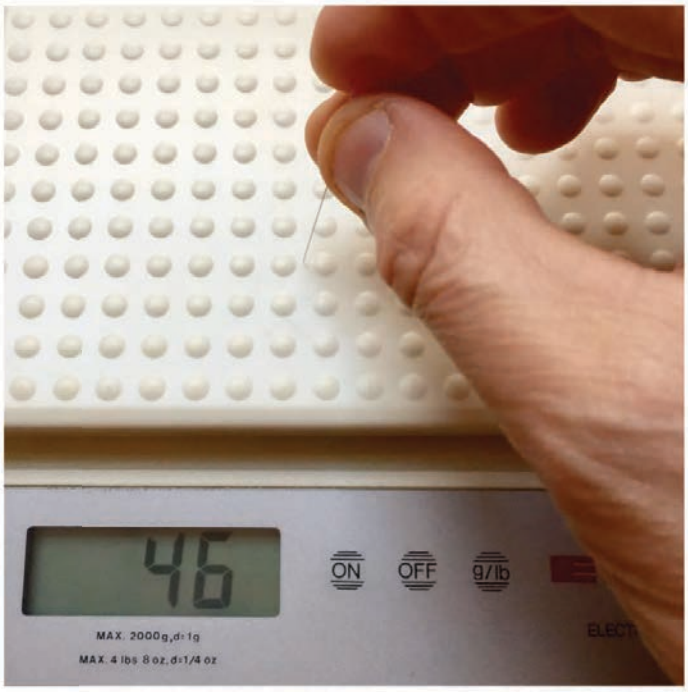
Where there is doubt, it is useful to give the patient the option of having another pain in the same area as their pain:
"Is this reproducing your pain, or giving you a different pain in the same area?"
This is particularly important when needling a patient who has not experience needling of this sort before.

If the patient answers that it is a different pain, then ask:
"Is this sensation more towards the surface, or the right depth?"

You can also ask about precise positioning. If the patient can guide you to this level of accuracy it automatically implies there must be a peripheral source nearby, since the tissues do not have such a level of discrimination.

How much pressure do we apply

…with our fingers versus a needle



Typically the maximum loading applied by a finger is around 5kg, although normal palpation would be 1-2kg, and a standard filiform needle is around 50g before it bends. This is roughly 100 times less absolute loading at the needle tip.

The acupuncture needle…

Average pressures compared…

low diffuse pressure
not tissue specific

Digit	Dimensions	Weight applied	Average pressure
Middle fingertip (gentle)	100mm²	150g	0.15kg/cm²
Middle fingertip (firm)	100mm²	1-2kg	1-2kg/cm²
Thumb pad (maximum)	200mm²	5-10kg	2-5kg/cm²

Needle	Dimensions	Surface area of cone tip	Weight before bending	Average pressure at tip
Lilac	0.25x30mm	0.2mm²	30-50g	15-25kg/cm²

Needle	Dimensions	Surface area of flat tip	Weight before bending	Average pressure at tip
Lilac	0.25x30mm	0.05mm²	25-50g	50-100kg/cm²
		1/500 to 1/4000	1/50 to 1/400	10x to 100x

high localised pressure
tissue specific

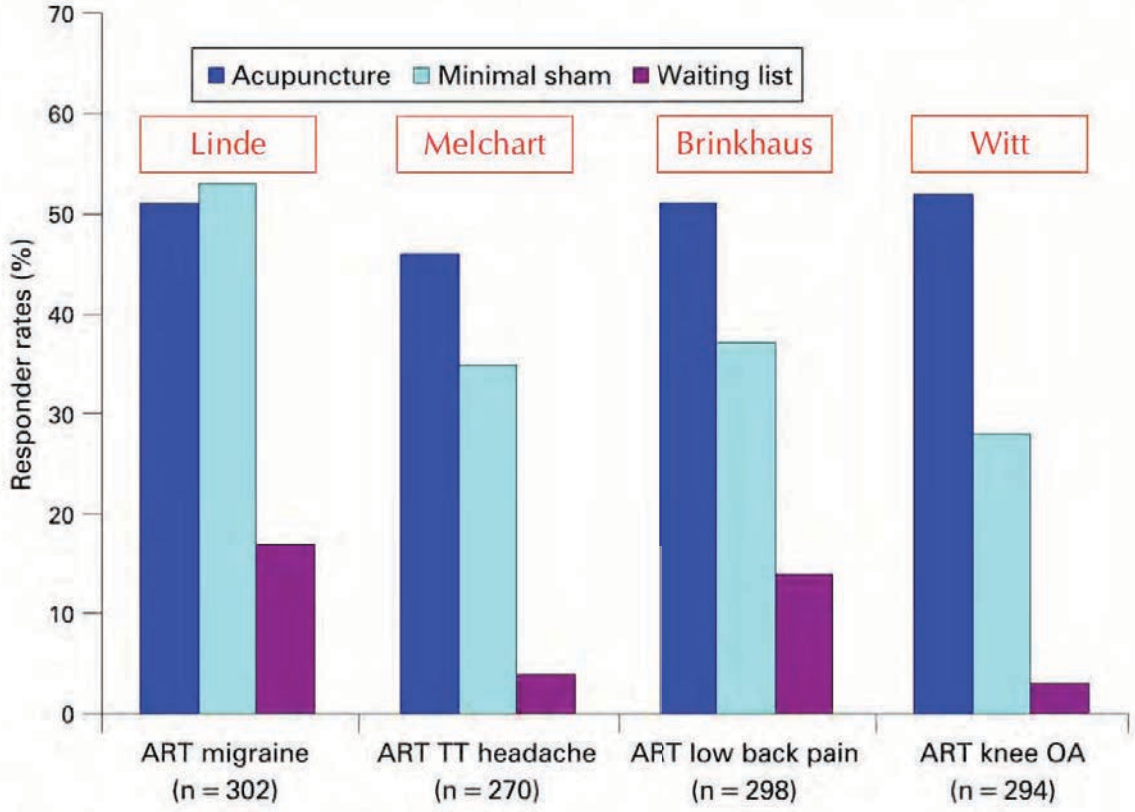
When we estimate the average pressure at the tip of the needle we see an opposite trend because whilst the load applied with fine needle may be 100 times less than a finger, the load is distributed over an area around 1000 times less. So we see much higher pressures at the needle tip that are targeted much more precisely in the tissue layers.

Three large research programmes investigating the efficacy, effectiveness, cost effectiveness and safety of acupuncture treatment for certain chronic conditions ('*Modellvorhaben Akupunktur*') have been conducted in Germany since October 2000. These programmes were initiated after the German Federal Committee of Physicians and Health Insurers determined, in October 2000, that the scientific evidence supporting the use of acupuncture was not sufficient to justify routine reimbursement within the German healthcare system. Formerly, some of the cost of acupuncture treatment was covered by the German statutory health insurance funds, provided that the acupuncture was performed by physicians with at least 140 hours of acupuncture training.

Following the decision of the German Federal Committee of Physicians and Health Insurers in October 2000, reimbursement for acupuncture treatment was only possible for patients suffering from certain chronic conditions (knee osteoarthritis, low back pain, migraine, tension-type headache), and only if the physician performing the acupuncture participated in one of the three research programmes. The results discussed in this paper are from the controlled trials that made up the core of these research programmes: the Acupuncture Randomised Trials (ART), the Acupuncture in Routine Care studies (ARC), one comparative trial (COMP), and the German Acupuncture trials (GERAC).

These *Modellvorhaben* (trial phases) were funded by a number of the German statutory health insurance funds, and they were organised by groups of researchers and physicians based at three large German universities: the Charité University, Berlin (ART and ARC); the Technical University, Munich (ART and COMP); and the University of Bochum (GERAC).

Figure 1 Responder rates in the Acupuncture Randomised Trials (ART) trials after 8 weeks from baseline (9-12 weeks in ART migraine and tension-type (TT) headache); responder rates were defined (post hoc) as a 50% or greater reduction in the primary outcome measure. Acupuncture and minimal acupuncture were significantly superior to waiting list in all trials. Acupuncture was superior to minimal acupuncture only in ART knee osteoarthritis (OA).



Cummings, M. Acupunct Med 2009;27:26-30

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ART

These were four RCTs with roughly 300 subjects in each. They were performed principally as efficacy trials in four conditions: migraine; tension-type headache; chronic low back pain; and osteoarthritis of the knee. Each of the trials followed the same design: three parallel arms with a 2:1:1 distribution of subjects, so that there were approximately 150 subjects in the real (verum) acupuncture arm, and 75 in the others – the minimal acupuncture and waiting list arms. The acupuncture involved deep needling to classical acupuncture points with manipulation of the needles to produce de qi – a characteristic needling sensation. Twelve treatments were given over eight weeks. Minimal acupuncture involved superficial needling to standardised sites that were not near to any recognised acupuncture points. The waiting list group received acupuncture 2 or 3 months after randomisation ie after the data were collected for the primary outcome.

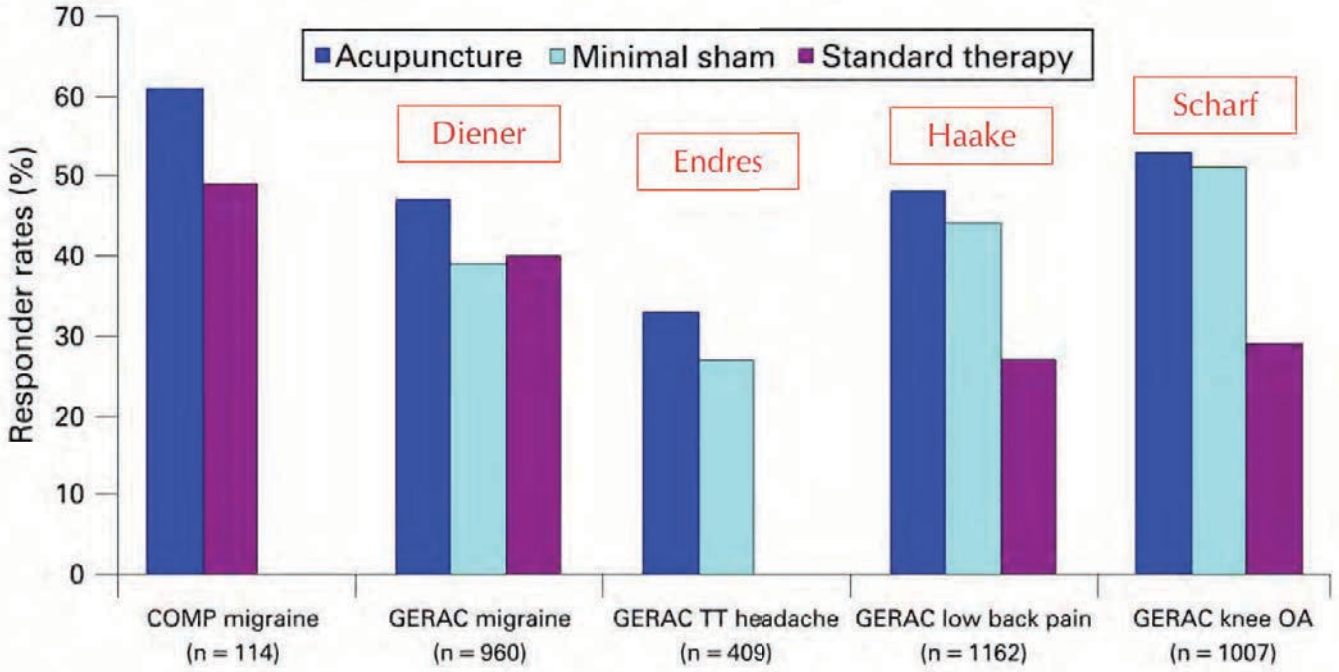
The primary outcomes were short term, just after the interventions at around 8 weeks, although outcomes were also assessed at 26 and 52 weeks from baseline.

The primary outcome for ART migraine was the difference in number of days with headache of moderate or severe intensity between the four weeks before randomisation (baseline phase) and weeks 9 to 12 after randomisation. Responders were defined (post hoc) as those with a 50% reduction or greater in days with moderate or severe pain (headache). The primary outcome and responder rates for ART tension-type headache were the same, with an additional comment that patients with missing data were automatically counted as non-responders.

The primary outcome in ART low back pain was the change in low back pain intensity from baseline to the end of week eight after randomisation, as measured by a visual analogue scale (range, 0-100 mm), and responders were defined (post hoc) by at least 50% reduction in pain intensity. Finally, the primary outcome measure in ART knee osteoarthritis was the change in the Western Ontario and McMasters Universities Osteoarthritis Index (WOMAC) between baseline and week eight after randomisation, and responders were defined (post hoc) by a decrease of at least 50% in their WOMAC index score.

The ART programme trials were performed across between 18 and 30 outpatient centres across Germany: ART migraine 18; ART tension-type headache 28; ART low back pain 30; ART knee osteoarthritis 28.

Figure 2 Responder rates in the comparative trial (COMP) at 9-12 weeks from baseline, and the German Acupuncture trials (GERAC) at 6 months from baseline; responder rates were defined as: >=50% reduction in migraine days (COMP and GERAC migraine); >50% reduction in headache days (GERAC tension-type (TT) headache); >=33% improvement on Chronic Pain Grade Scale questionnaire (CPGS) or >=12% improvement on the Hanover Functional Ability Questionnaire (GERAC low back pain); and >=36% improvement in Western Ontario and McMasters Universities Osteoarthritis Index (GERAC knee osteoarthritis (OA)). Acupuncture and sham acupuncture were both significantly superior to standard therapy in GERAC low back pain and GERAC knee OA. There were no other statistically significant differences between groups.



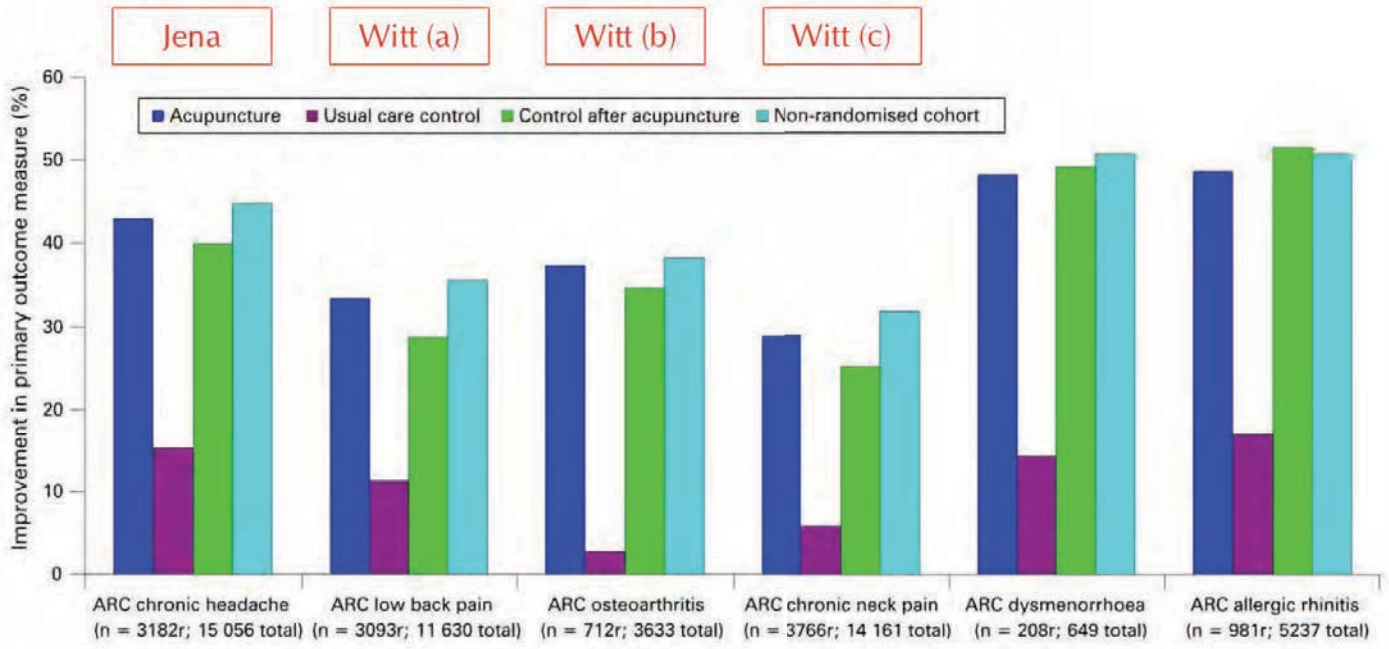
GERAC

There were four GERAC trials with up to 1000 subjects in each. They were designed as comparative trials with three equal parallel arms: acupuncture vs sham acupuncture vs standard care (note that the terminology: 'sham' is used rather than 'minimal'). They were performed in migraine, tension-type headache, chronic low back pain, and knee osteoarthritis. Rather like the ART trials, the real acupuncture involved deep needling to classical acupuncture points with manipulation of the needles to produce de qi. Ten treatments were given over six weeks, with the option to extend treatment by a further five sessions for partial response. Sham acupuncture involved superficial needling to standardised sites that were not near to any recognised acupuncture points. The standard care arms used best conventional care based on guidelines where available: GERAC migraine – beta blockers first choice, flunarizine second, valproic acid third; GERAC tension-type headache – the intention was to use amitriptyline; GERAC chronic low back pain – multimodal treatment programme including physiotherapy, exercise and NSAIDs; GERAC knee osteoarthritis – physiotherapy, physician visits, NSAIDs (in this trial all groups had six sessions of physiotherapy, and acupuncture groups were allowed limited NSAIDs as rescue medication).

The primary outcomes were measured around six months from baseline, although secondary outcomes were measured at six weeks and three months as well. The primary outcome in GERAC migraine was the difference in migraine days between four weeks before randomisation and weeks 23–26 after randomisation, and response was defined as a reduction in the number of migraine days by 50% or more. GERAC tension-type headache was somewhat different in that the response (defined as >50% reduction in number of headache days per four weeks from baseline to six months) was the primary outcome, and all minor variations from protocol resulted in patients being classified as non-responders. In GERAC low back pain the primary outcome was response after six months, defined as 33% improvement or better on three pain related items on the Von Korff Chronic Pain Grade Scale questionnaire (CPGS) or 12% improvement or better on the back specific Hanover Functional Ability Questionnaire (HFAQ). Patients who were unblinded or who used (disallowed) co-interventions during follow up were classified as non-responders regardless of symptom improvement. In GERAC knee osteoarthritis the effect on pain and function was measured with the WOMAC score (total score and the subscales were standardised to 0 to 10). 'Success' rates were calculated according to a change of at least 36% from baseline WOMAC scores at 13 and 26 weeks after the start of treatment. Patients with missing data were considered to have had treatment failure.

The GERAC trials were performed across between 122 and 340 practices across Germany: GERAC migraine 149; GERAC tension-type headache 122; GERAC chronic low back pain 340; GERAC knee osteoarthritis 315.

Figure 3 Percentage improvement in the primary outcome measure at 3 months from baseline in the Acupuncture in Routine Care (ARC) trials ("control after acupuncture" is 6 months from baseline -- 3 months usual care followed by 3 months acupuncture treatment). Numbers in brackets are those randomised (r) followed by the total sample including the non-randomised cohort. In all six trials there was a very highly significant difference between acupuncture and usual care alone at 3 months (p<0.001).



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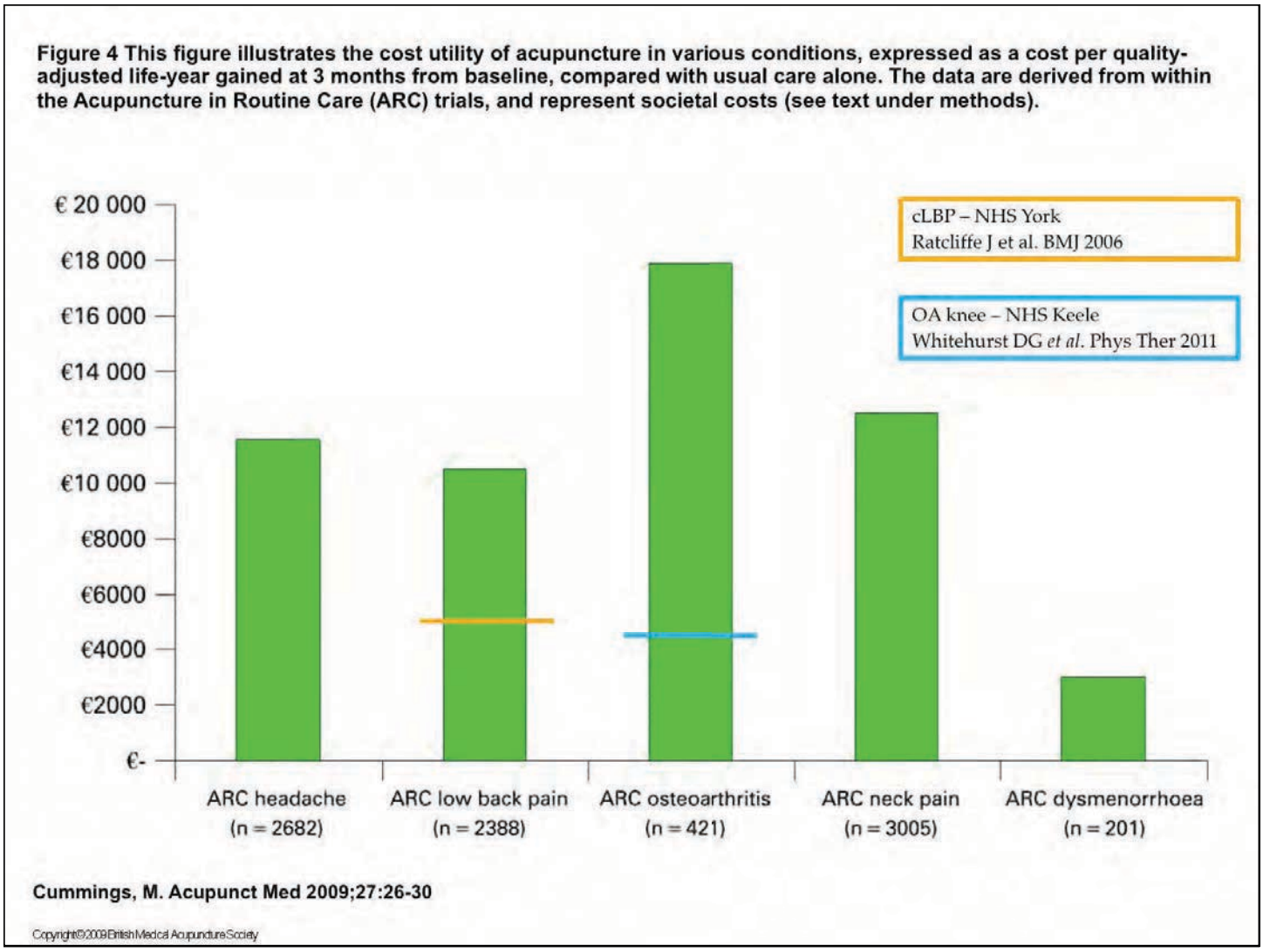
ARC

The ARC studies were a series of large to very large pragmatic RCTs, with associated non-randomised cohorts. They used a standard design and included detailed economic analysis from a societal perspective. Subjects insured by one of the participating social health insurance funds were recruited by general practitioners across Germany for acupuncture treatment of either: osteoarthritis of the hip or knee; chronic neck pain; chronic low back pain; chronic headache; dysmenorrhoea; allergic rhinitis; or asthma (awaiting publication). If they agreed to be randomised, they either received 15 sessions of manual acupuncture over three months, or they waited three months for acupuncture treatment. If they expressed a strong preference for acupuncture and declined to be randomised, they received acupuncture treatment immediately. There was no standardisation of treatment, but only manual acupuncture was allowed.

Outcomes were measured at three and six months. After three months the group randomised to usual care alone were given acupuncture treatment. The primary outcomes were all set at three months. ARC chronic headache used the reduction in days with headache per month. ARC low back pain measured back function assessed by the HFAQ. ARC osteoarthritis used the change in WOMAC score, and ARC chronic neck pain used a validated neck pain and disability scale (NPAD). In ARC dysmenorrhoea the main outcome was the average pain intensity during the last menstruation before assessment measured on a numeric rating scale. ARC allergic rhinitis used the Rhinitis Quality of Life Questionnaire (RQLQ).



ARC

As part of the ARC programme of studies, additional measurements were performed to assess quality of life (QoL), costs and the cost effectiveness relationship of routine care plus acupuncture compared with routine care alone. QoL was assessed with the Short Form (SF)-36 questionnaire, using the subscales and the components scales. The SF-36 also served as the basic benefit estimator for the cost effectiveness analyses. At baseline and at three months the patients completed questionnaires which assessed the quality of life over the previous seven days. The costs considered were measured in societal perspective and included the direct healthcare related costs of acupuncture (cost of each acupuncture session was €35), physician visits and hospital stays, and any drugs prescribed. In addition to health insurance costs, the indirect costs caused by lost workdays were also taken into account. These were estimated to be approximately €78 per lost workday. Additional analyses were performed to estimate cost utility in the case of higher costs and better medical outcome. QoL measures using SF-36 were converted to quality adjusted life years (QALY), and the excess cost in the acupuncture group in each study was divided by the increment in QALYs gained in the acupuncture group compared with the usual care group. This gave an incremental cost effectiveness ratio (ICER) expressed as a cost per additional QALY.

The additional information here is from two trials carried out in the UK. These calculated direct costs to the NHS only, whereas the ARC trials reported societal costs, which included costs related to working days lost.

The Acupuncture Trialists' Collaboration performed the first individual patient data meta-analysis (IDPM) of chronic pain trials, which was finally published in 2012 after being rejected by 4 or 5 general journals without significant negative peer review. This meta-analysis included individual data on 17 922 patients, from 29 trials, and clearly demonstrated efficacy of acupuncture over sham in chronic pain, and effectiveness over non-acupuncture controls.

A further analysis of this data with meta-regression attempted to define the characteristics of treatment associated with better or worse outcomes. Better outcomes were observed when more needles were used when acupuncture was compared with non-acupuncture controls. A sensitivity analysis (excluding three outlying RCTs with very much larger effect sizes than the others) showed that trials allowing electrical stimulation had a significantly stronger effect of acupuncture compared with sham and those with a longer average treatment session duration had a smaller effect compared to sham.

The patient level analysis showed a small but highly significant association between better outcomes and a higher number of treatment sessions.

ONLINE FIRST

Acupuncture for Chronic Pain

Individual Patient Data Meta-analysis

Andrew J. Vickers, DPhil; Angel M. Cronin, MS; Alexandra C. Maschino, BS; George Lewith, MD; Hugh MacPherson, PhD; Nadine E. Foster, DPhil; Karen J. Sherman, PhD; Claudia M. Witt, MD; Klaus Linde, MD; for the Acupuncture Trialists' Collaboration

Background: Although acupuncture is widely used for chronic pain, there remains considerable controversy as to its value. We aimed to determine the effect size of acupuncture for 4 chronic pain conditions: back and neck pain, osteoarthritis, chronic headache, and shoulder pain.

Methods: We conducted a systematic review to identify randomized controlled trials (RCTs) of acupuncture for chronic pain in which allocation concealment was determined unambiguously to be adequate. Individual patient data meta-analyses were conducted using data from 29 of 31 eligible RCTs, with a total of 17 922 patients analyzed.

Results: In the primary analysis, including all eligible RCTs, acupuncture was superior to both sham and no-acupuncture control for each pain condition ($P < .001$ for all comparisons). After exclusion of an outlying set of RCTs that strongly favored acupuncture, the effect sizes were similar across pain conditions. Patients receiving acupuncture had less pain, with scores that were 0.23 (95% CI, 0.13-0.33), 0.16 (95% CI, 0.07-0.25), and 0.15 (95% CI, 0.07-0.24) SDs lower than sham controls for back and neck pain, osteoarthritis, and chronic headache, respectively; the effect sizes in comparison to no-acupuncture controls were 0.55 (95% CI, 0.51-0.58), 0.57 (95% CI, 0.50-0.64), and 0.42 (95% CI, 0.37-0.46) SDs. These results were robust to a variety of sensitivity analyses, including those related to publication bias.

Conclusions: Acupuncture is effective for the treatment of chronic pain and is therefore a reasonable referral option. Significant differences between true and sham acupuncture indicate that acupuncture is more than a placebo. However, these differences are relatively modest, suggesting that factors in addition to the specific effects of needling are important contributors to the therapeutic effects of acupuncture.

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ONLINE FIRST
Acupuncture for Chronic Pain
Individual Patient Data Meta-analysis
Arch Int Med 2012;172:1444–53.
Andrew J. Vickers, DPhil; Angel M. Cronin, MS; Alexandra C. Maschino, BS; George Lewith, MD; Hugh MacPherson, PhD; Nadine E. Foster, DPhil; Karen J. Sherman, PhD; Claudia M. Witt, MD; Klaus Linde, MD; for the Acupuncture Trialists' Collaboration

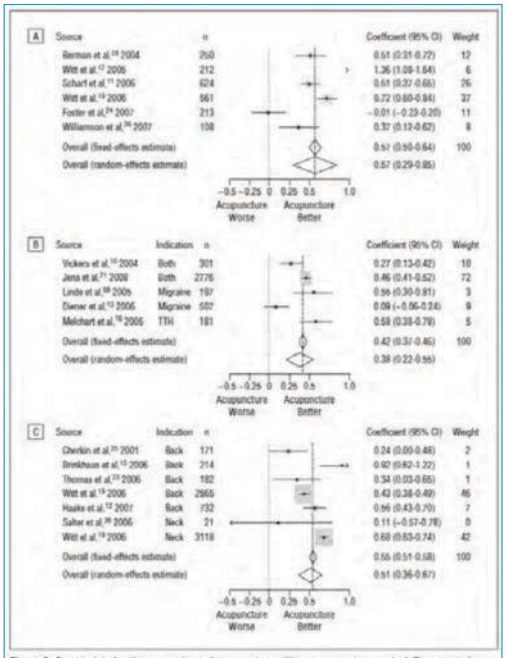

Figure 2. Forest plots for the comparison of acupuncture with no-acupuncture control. There were fewer than 3 trials for shoulder pain, so no meta-analyses were performed. A, Osteoarthritis; B, chronic headache; C, musculoskeletal pain.

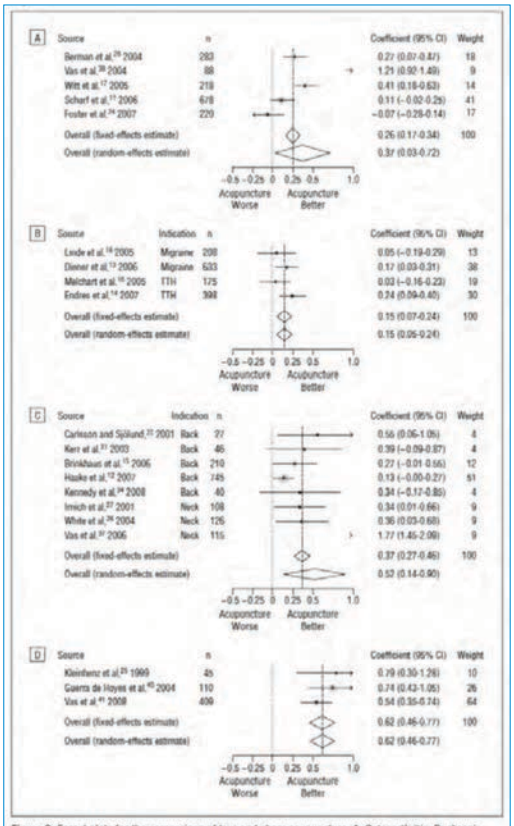

Figure 3. Forest plots for the comparison of true and sham acupuncture. A, Osteoarthritis; B, chronic headache; C, musculoskeletal pain; D, shoulder pain.

Education and practice

Responses to the Acupuncture Trialists' Collaboration individual patient data meta-analysis

Andrew J Vickers,[1] Alexandra C Maschino,[1] George Lewith,[2] Hugh MacPherson,[3] Karen J Sherman,[4] Claudia M Witt,[5] on behalf of the Acupuncture Trialists' Collaboration

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ABSTRACT

In September 2012 the Acupuncture Trialists' Collaboration published the results of an individual patient data meta-analysis of almost 18 000 patients in high quality randomised trials. The results favoured acupuncture. Although there was little argument about the findings in the scientific press, a controversy played out in blog posts and the lay press. This controversy was characterised by ad hominem remarks, anonymous criticism, phony expertise and the use of opinion to contradict data, predominantly by self-proclaimed sceptics. There was a near complete absence of substantive scientific critique. The lack of any reasoned debate about the main findings of the Acupuncture Trialists' Collaboration paper underlines the fact that mainstream science has moved on from the intellectual sterility and ad hominem attacks that characterise the sceptics' movement.

INTRODUCTION

In September 2012 the Acupuncture Trialists' Collaboration published the results of an individual patient data meta-analysis of almost 18 000 patients in high quality randomised trials. The results favoured acupuncture, with statistically significant differences from both no acupuncture and sham acupuncture controls.[1] Acupuncture has long been controversial and therefore, as might be imagined, the findings of the Acupuncture Trialists' Collaboration generated a fair degree of controversy.

What is remarkable is that this controversy played out predominantly in blog posts and the lay press. There has been little argument about the findings in the usual scientific channels. Three letters to the editor were submitted, but they dealt with peripheral issues such as whether acupuncturists might miss diagnoses in routine clinical practice. Only one substantive critique of the paper has appeared in a scientific forum.[2]

STYLE OF CRITICISM

In addition to appearing outside of traditional scientific forums, criticisms of the Acupuncture Trialists' Collaboration meta-analysis have been characterised by one or more of the following.

Ad hominem remarks

In a typical blog post, the study authors were accused of displaying 'considerable pro-acupuncture bias',[3] a comment on another blog described senior author Klaus Linde as a 'homeopath',[4] One poster, who claims that the study shows that the 'desperation of NCCAM' and the 'gullibility' of the media, opined that 'Dr Vickers … needs to go back and take an introductory course on statistics' and warned 'like loaded guns, some people shouldn't be left alone with a statistical software program'.[5] A somewhat bizarre accusation levelled at two authors was that they may have 'read only the abstract of the paper'.[2] One post made a direct accusation of statistical misconduct: 'The whole thing looks like a number the authors pulled out of their nether regions and then plugged into their meta-analysis software in order to see if it would affect anything.'[4]

Anonymity

The individual who advised Dr Vickers to take a statistics course signed off as 'A. Skeptic'.[5] The blog post about the Collaboration's nether regions was posted by 'Orac'.[4]

To cite: Vickers AJ, Maschino AC, Lewith G, et al. Acupunct Med 2013;31:98–100.

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Knowledge is better than ignorance — Enrico Fermi

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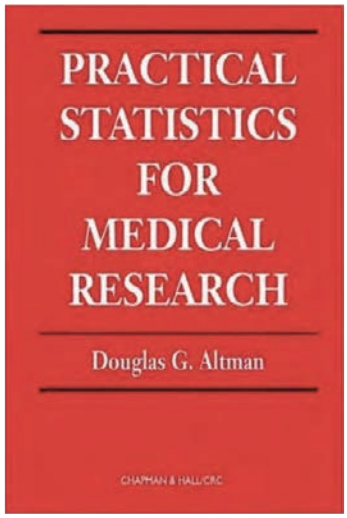
Acupuncture study reveals new desperation on the part of NCCAM

September 17, 2012 in Health & Medicine by Askeptic | No comments

Dr. Vickers… clearly, needs to go back and take an introductory course on statistics.

Like loaded guns, some people shouldn't be left alone with a statistical software program.



PRACTICAL STATISTICS FOR MEDICAL RESEARCH

Douglas G. Altman

CHAPMAN & HALL/CRC

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Knowledge is better than ignorance — Enrico Fermi

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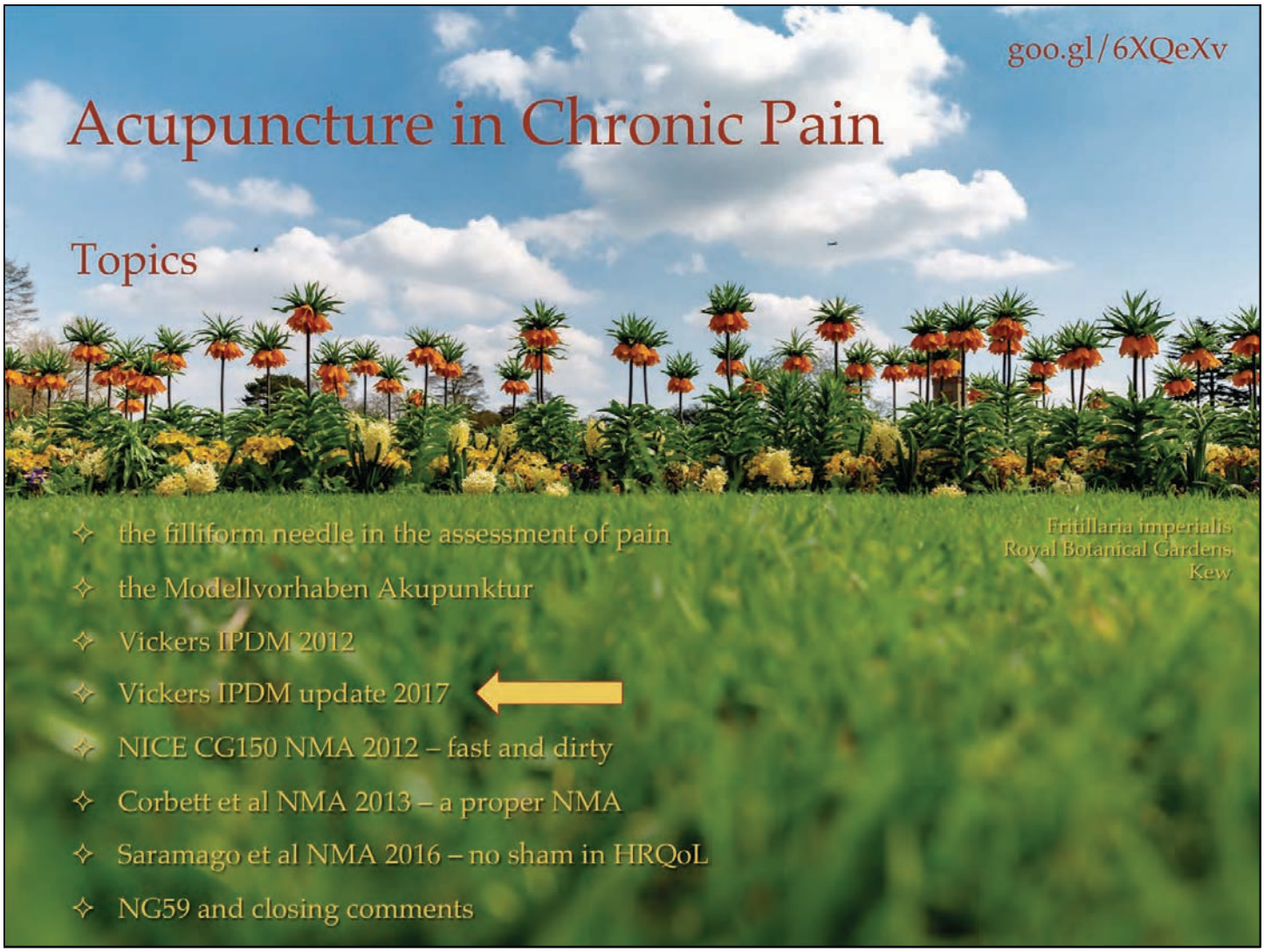
Acupuncture study reveals new desperation on the part of NCCAM

September 17, 2012 in Health & Medicine by Askeptic | No comments

Dr. Vickers… clearly, needs to go back and take an introductory course on statistics.

Like loaded guns, some people shouldn't be left alone with a statistical software program.

1: **Vickers AJ**, **Altman DG**. Statistics notes: Analysing controlled trials with baseline and follow up measurements. ***BMJ*** 2001.
2: Hrynaszkiewicz I, Norton ML, **Vickers AJ**, **Altman DG**. Preparing raw clinical data for publication: guidance for journal editors, authors, and peer reviewers. ***BMJ*** 2010.
3: **Vickers AJ**, **Altman DG**. Statistics notes: missing outcomes in randomised trials. ***BMJ*** 2013.



The latest version of the Acupuncture Trialists' Collaboration IPDM reports data on 20 827 patients from 39 trials. Many of the results in terms of effect size are similar to the original IPDM and a clear dose effect is seen when comparing acupuncture to no acupuncture controls in terms of the number of sessions.

This update also has sufficient data to demonstrate a significant difference in the effect size of acupuncture over sham acupuncture when penetrating as opposed to non-penetrating sham is used as a control. As might be expected the effect of acupuncture appears larger when compared with controls that do not pierce the skin.

A word of caution here though. It appears that the use of sham devices may reduce the effect of both acupuncture and sham acupuncture, even though the difference between them may be larger than that between acupuncture and penetrating shams. So there may be a nocebo element from the use of these rather artificial devices used to support non-penetrating needles.

Vickers AJ *et al*. Acupuncture for Chronic Pain: Update of an Individual Patient Data Meta-Analysis. *J Pain* Published Online First: 2017. doi:10.1016/j.jpain.2017.11.005

Table 2
Primary Analyses (N = 44 Trials)

Analysis	Indication	Sham				No Acupuncture Control			
		Studies, n	FE (95% CI)	Heterogeneity *P*	RE (95% CI)	Studies, n	FE (95% CI)	Heterogeneity *P*	RE (95% CI)
Main analysis	Nonspecific musculoskeletal pain	10	.30 (.21–.38)	< .001	.49 (.16–.81)	12	.54 (.50–.57)	< .001	.50 (.38–.63)
	Osteoarthritis	9	.24 (.17–.31)	< .001	.45 (.15–.75)	10	.63 (.56–.69)	< .001	.74 (.46–1.01)
	Chronic headache	5	.16 (.08–.25)	.4	.16 (.08–.25)	7	.44 (.39–.48)	< .001	.56 (.35–.76)
	Shoulder	4	.57 (.44–.69)	.4	.57 (.44–.69)	0	No trials		

Table 3
Sensitivity Analyses Including Only Pain End Points Measured Between 2 and 3 Months After Randomization

Analysis	Indication	Sham				No Acupuncture Control			
		Studies, n	FE (95% CI)	Heterogeneity *P*	RE (95% CI)	Studies, n	FE (95% CI)	Heterogeneity *P*	RE (95% CI)
Main analysis	Nonspecific musculoskeletal pain	5	.13 (.01–.25)	.005	.23 (–.03 to .49)	9	.60 (.56–.64)	< .0001	.47 (.34–.61)
	Osteoarthritis	7	.31 (.23–.39)	< .0001	.69 (.24–1.14)	9	.73 (.66–.80)	< .0001	.88 (.61–1.15)
	Chronic headache	5	.14 (.06–.22)	.4	.14 (.06–.22)	7	.43 (.38–.47)	< .0001	.45 (.27–.63)
	Shoulder	2	No meta-analysis						

Abbreviations: FE, fixed effects estimate; RE, random effects estimate.

In summary, the effect of acupuncture over sham acupuncture in chronic pain is about 0.2 SMD (standardised mean difference: mean difference divided by standard deviation – referred to here as effect size), and the effect of acupuncture over no acupuncture controls is about 0.5 SMD. An effect size of 0.2 is small, but 0.5 is moderately large an very likely to be of clinical relevance. There is no practical point in assessing clinical relevance over a sham intervention, since the latter is not an option in practice; however, unfortunately the main guideline producer in the UK (NICE) insists on measuring the clinical relevance of acupuncture compared with sham acupuncture and not usual care (no acupuncture) controls.

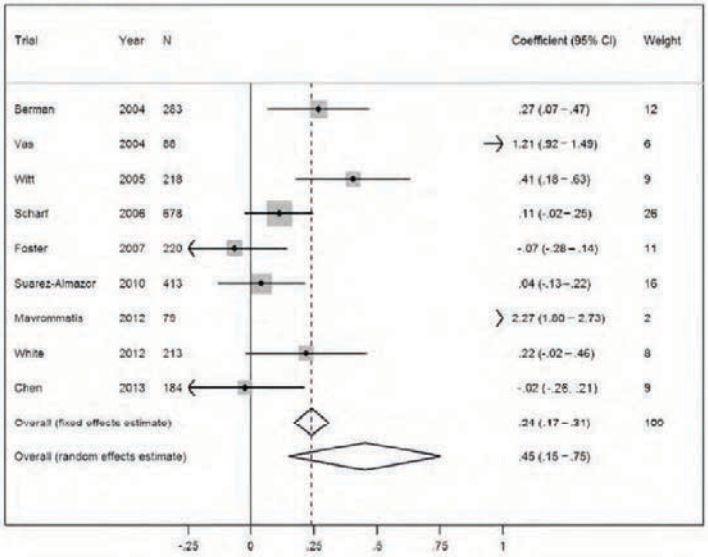
There are often arguments over whether fixed effects or random effects should be used. These are two methods of pooling data – similar methods with different assumptions. The fixed effect method assumes that the test intervention is better than control, and the random effects method does not make this assumption. I prefer fixed effects for acupuncture versus sham but I am not so clear that this is better when comparing acupuncture with no acupuncture controls, some of which may include best conventional care. Note that the Cis (confidence intervals) are generally much wider with the random effects method.

Heterogeneity (variability) of the results is high in most of the analyses – reflected in the very low p values. This does not concern me when pooling acupuncture data. Normally it would reduce the level of certainty in a result, but in the case of acupuncture trials we know that there is considerable clinical heterogeneity in the way acupuncture and sham acupuncture is applied, so statistical heterogeneity is not a surprise.

Vickers AJ *et al*. Acupuncture for Chronic Pain: Update of an Individual Patient Data Meta-Analysis. *J Pain* Published Online First: 2017. doi:10.1016/j.jpain.2017.11.005

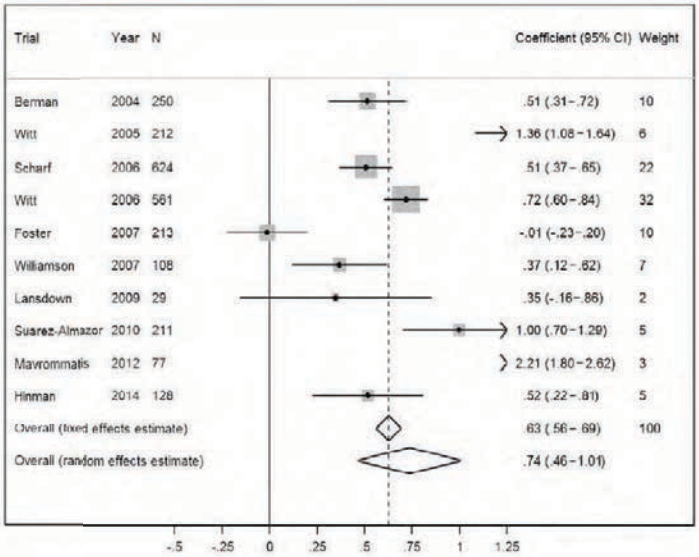
acupuncture vs sham

Osteoarthritis



acupuncture vs no acupuncture

Osteoarthritis



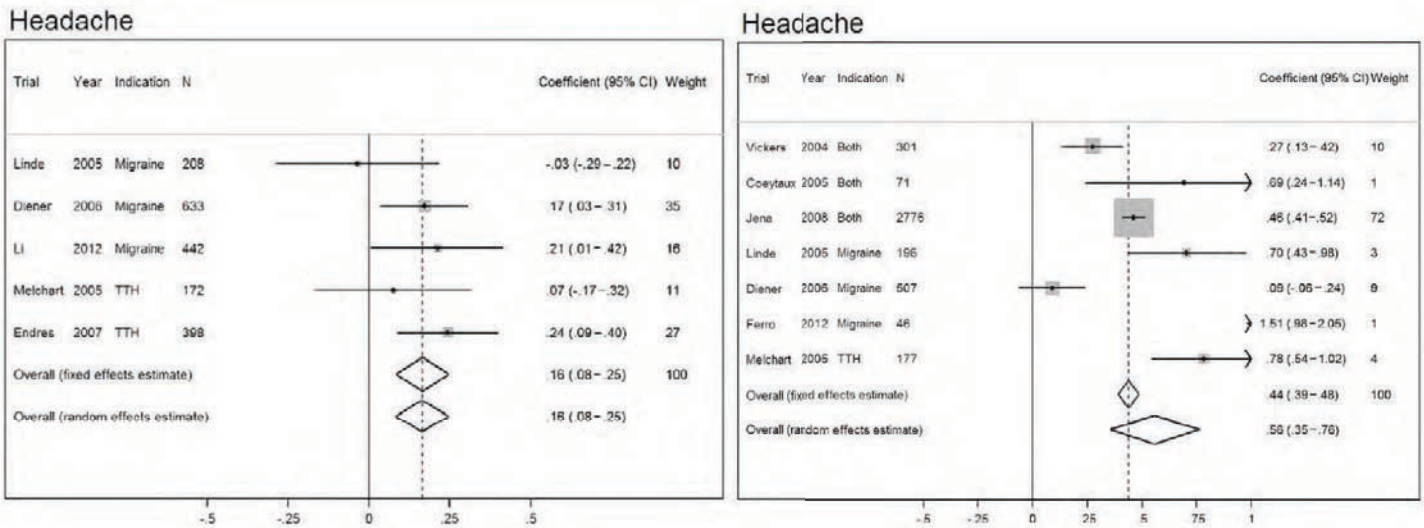
The forest plot on the left shows a small but highly significant effect of acupuncture over sham. The analysis is dominated by Scharf 2006 – one of the three arm comparative GERAC trials. Directly above it in the plot is the ART trial (Witt 2005). Go back to the slides summarising the ART and GERAC trials and compare the results in the acupuncture and sham acupuncture groups. You will see that the responder rate for acupuncture is similar, but there is a very big difference in the result of the sham group. Why such a difference? Well the ART studies were more tightly controlled and involved fewer centres (28 versus 315 in GERAC). All the practitioners in the ART studies met and were instructed on correct application of the sham technique. In the GERAC trial the practitioners received written instructions only.

The forest plot on the right shows a moderately large and highly significant effect of acupuncture over no acupuncture controls. The biggest influence this time is from the ARC trial (Witt 2006 – note this is not the same as the ART trial: Witt 2005). This trial compared acupuncture with a waiting list made up of patients who agreed to defer the start of their treatment by 3 months. It probably gives the most useful measure of the effect of acupuncture in practice. The comparison above this is from the GERAC trial (Scharf 2006), and the results are quite similar, but in this case both groups received physical therapy sessions, and the no acupuncture group received normal doses of NSAIDs.

Vickers AJ *et al*. Acupuncture for Chronic Pain: Update of an Individual Patient Data Meta-Analysis. *J Pain* Published Online First: 2017. doi:10.1016/j.jpain.2017.11.005

acupuncture vs sham

acupuncture vs no acupuncture



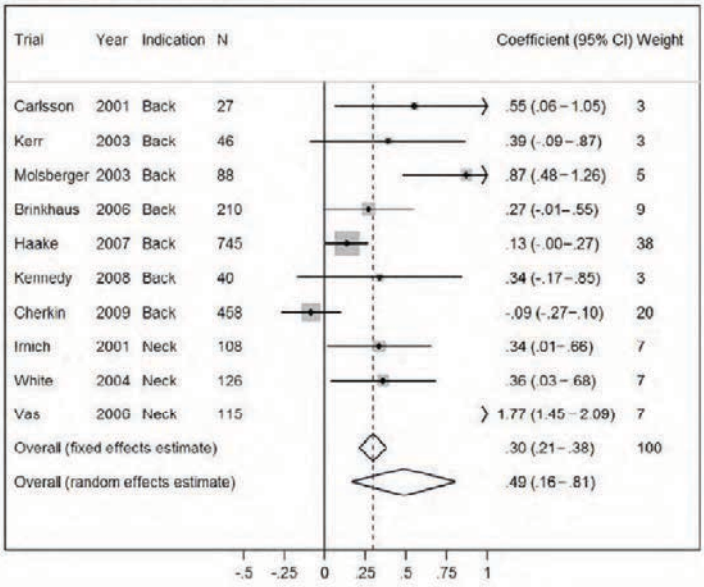
The forest plot on the left shows a very small but significant effect of acupuncture over sham. The first trial listed in this analysis is the ART migraine trial (Linde 2005). As you can see the point estimate is left of the line of no effect. This means that the sham group did marginally (not significantly) better than the true acupuncture group. If you look back to the ART summary slide you will see that the responder rate in the sham group was over 50% - probably the biggest surprise of the ART studies.

The forest plot on the right shows a moderately large and highly significant effect of acupuncture over no acupuncture controls. This plot is dominated by the ARC trial (Jena 2008) – it is given a 72% weighting in the analysis (this is based on size and narrow confidence intervals).

Vickers AJ *et al*. Acupuncture for Chronic Pain: Update of an Individual Patient Data Meta-Analysis. *J Pain* Published Online First: 2017. doi:10.1016/j.jpain.2017.11.005

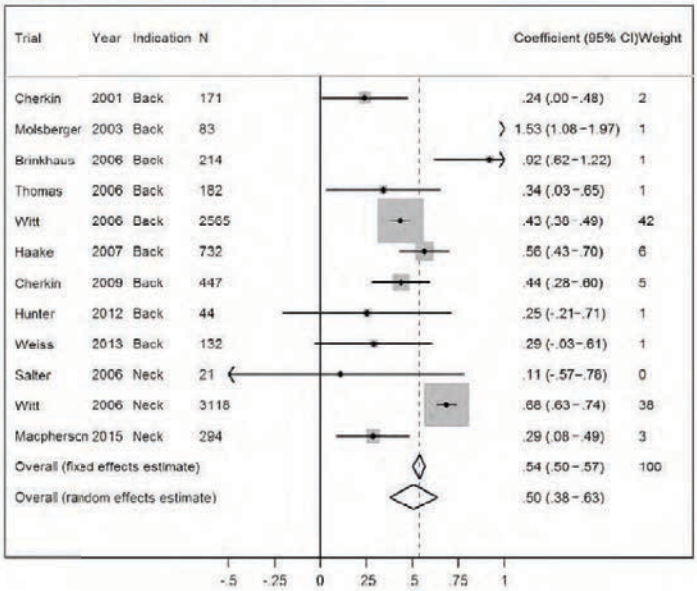
acupuncture vs sham

Musculoskeletal Pain



acupuncture vs no acupuncture

Musculoskeletal Pain



The forest plot on the left shows a small but significant effect of acupuncture over sham in back and neck pain. This analysis is dominated by Haake 2007 (GERAC low back pain) and Cherkin 2009 (a 4-arm trial from the US in which all three acupuncture groups, including a cocktail stick sham, were twice as good as conventional care). If you look at the same two trials in the forest plot on the right, you will see moderately large effects over guideline-based conventional care, with results similar to the very large ARC trial (Witt (a) 2006). The difference reflects the moderately large effect of sham acupuncture in these trials. Data from the forest plot on the left has been used to create summary data that estimates the effect of acupuncture in back pain at 0.2 and the effect in neck pain at 0.8. This grossly exaggerates the real difference in effect, and the difference is dominated by different effects in the sham groups rather than the real acupuncture groups (see below). Note the very large effect measured in Vas 2006 in neck pain. The sham used in this trial was mock TENS. Note also a comment in the IPDM paper that the effect of acupuncture in neck pain appears to disappear faster than for other types of pain. This is entirely due to the change (gradual improvement) over time in the mock TENS group of Vas 2006. The effect of acupuncture in neck pain appears stable and similar to other forms of chronic pain assessed. This example illustrates the risk of only looking at intergroup differences in meta-analysis, and using small heterogeneous data sets.

The forest plot on the right shows a moderately large and highly significant effect of acupuncture over no acupuncture controls in back and neck pain. This analysis is dominated by the ARC trials (Witt (a) 2006 and Witt (b) 2006), and these give a more accurate, real world, picture of the difference in the effect of acupuncture in back pain and neck pain. There does appear to be a difference, with neck pain showing a slightly larger effect. Returning to the summary slide of the ARC trial results will reveal a larger percentage change in the primary outcome measure in back pain than neck pain in both real and control groups, but a bigger difference in neck pain. These trials used different outcome measures, so in this case it is safer to look at the difference over control.

Vickers AJ *et al*. Acupuncture for Chronic Pain: Update of an Individual Patient Data Meta-Analysis. *J Pain* Published Online First: 2017. doi:10.1016/j.jpain.2017.11.005

Table 6. Results of Univariate Metaregression Analyses for the Effect of Acupuncture Characteristics on Acupuncture Effect

	Sham Acupuncture				No Acupuncture Control			
Characteristic	Trials, n	β	95% CI	P	Trials, n	β	95% CI	P
Style of acupuncture	25				25			
Some TCM versus Western only		−.00	−.49 to .48	>.9		.10	−.55 to .74	.8
TCM only versus some Western		.02	−.38 to .42	.9		−.07	−.42 to .28	.7
Point prescription	25				25			
Fixed needle formula		Reference		.6		Reference		.075
Flexible formula		.20	−.21 to .60			.01	−.45 to .46	
Fully individualized		−.01	−.75 to .73			−.34	−.79 to .10	
Electrical stimulation allowed	25	.32	−.11 to .75	.14	25	−.12	−.50 to .26	.5
Manual stimulation allowed	25	.26	−.42 to .95	.5	25	−.38	−.99 to .23	.2
Moxibustion allowed		No trials allowed			25	−.32	−.71, .06	.10
Other adjunctive treatment allowed	25	−.04	−1.00 to .92	.9	25	−.22	−.59 to .16	.3
De qi attempted	25	.29	−.67 to 1.24	.6	21	.74	−.04 to 1.52	.063
Acupuncture-specific patient practitioner interactions allowed	25	−.03	−.50 to .44	.9	25	−.05	−.38 to .28	.8
Minimum years of experience required	25	.04	−.05 to .13	.4	25	.05	−.03 to .12	.2
Maximum number of sessions (per 5 sessions)	25	−.01	−.23 to .22	.9	25	.01	−.12 to .14	.9
Patient-level analysis	5 (1,317/1,377)	.09	−.31 to .48	.7	5 (8,036/10,157)	.10	−.01 to .21	.001
Patient-level analysis, including Hinman et al[39]	6 (1,421/1,517)	−.03	−.36 to −.30	.9				
Frequency of sessions (per week)	25	−.06	−.29 to .18	.6	25	.21	−.22 to .64	.3
Duration of sessions (per 5 minutes)	25	.06	−.13 to .25	.5	20	−.06	−.25 to .13	.5
Patient-level analysis	6 (2,863/2,969)	.01	−.08 to .09	.9				
Number of needles used (per 5 needles)	25	.05	−.17 to .27	.6	19	.16	−.05 to .38	.13
Patient-level analysis	5 (2,232/2,317)	.04	−.08 to .16	.5				
Age of practitioner (per 5 years)								
Patient-level analysis					6 (9,127/10,550)	−.01	−.04 to .02	.5
Male practitioner								
Patient-level analysis					6 (9,384/10,550)	−.07	−.16 to .02	.084

Abbreviation: TCM, traditional Chinese medicine.

NOTE. β is an estimate of the change in the effect of acupuncture in terms of standardized difference compared with controls for each characteristic; a positive β indicates a larger effect of acupuncture compared with controls for trials. The number of patients in the analysis and number of patients in included trials are given in parentheses where applicable.

In terms of the characteristics of acupuncture, the only factor that had a clear influence was the number of treatments, and this was only apparent in the comparison against no acupuncture. This perhaps does not come as a surprise, but it does suggest that we should be more focussed on providing enough treatment sessions and not worrying as much about other aspects of the acupuncture approach.

In this update the effect based on number of needles used was no longer significant, but a positive trend remained.

I have a particular interest in electroacupuncture (EA), so I am keen to highlight the fact that in the more mechanistic comparison of acupuncture over sham the use of EA as a treatment characteristic had the largest effect size (0.32) and the lowest p value (p=0.14) of any characteristic studied. This does not reach the commonly adopted level of statistical probability, but equates to a 6:7 chance of being a real effect.

Going back to the more pragmatic comparison of acupuncture over no acupuncture, there are a couple of interesting trends apparent. The largest was for 'de qi attempted', and this reached 0.74 with p=0.063. This might also suggest a dose effect, but strangely the characteristic 'manual stimulation allowed' actually had a moderately negative effect.

Another characteristic that approached significance in the pragmatic comparison was 'male practitioner' at a p value of p=0.084. The effect size associated with this was very small and negative at -0.07, but it is tempting to view this against a backdrop of mechanistic research on nocebo in pain, and suggest that male practitioners might think about channelling their more feminine sides during consultations.

goo.gl/6XQeXv

Acupuncture in Chronic Pain

Topics

- the filliform needle in the assessment of pain
- the Modellvorhaben Akupunktur
- Vickers IPDM 2012
- Vickers IPDM update 2017
- NICE CG150 NMA 2012 – fast and dirty
- Corbett et al NMA 2013 – a proper NMA
- Saramago et al NMA 2016 – no sham in HRQoL
- NG59 and closing comments

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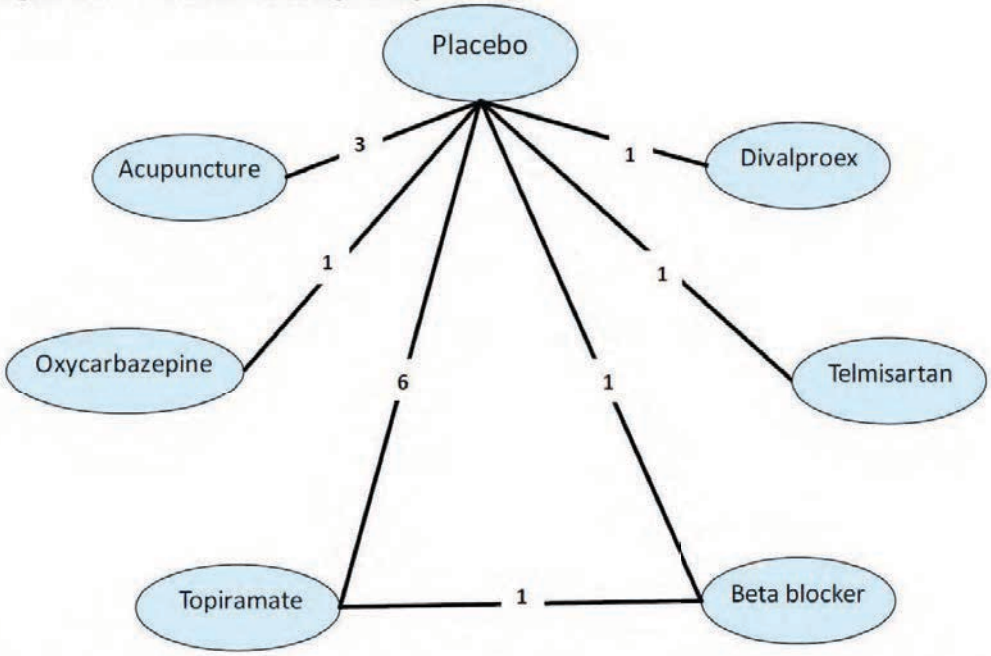
K.3 Results

A total of 12 studies from the original evidence review met the inclusion criteria for the network. Figure 282 shows the network created by eligible comparisons for the NMA, with numbers on the connecting lines indicating the number of studies for each comparison.

Figure 282: Network for change in migraine days



The trial data from the 12 studies included in the NMA for change in migraine days are shown in Table 24.

Network meta-analysis (NMA) is a method for combining data from multiple two-way comparisons of interventions so that both direct and indirect comparisons between interventions can be performed. For indirect comparisons there must be a common node (or intervention). In CG150 a limited network meta-analysis used placebo as a common node to compare acupuncture directly with topiramate, and concluded that topiramate was twice as good as acupuncture.

Note that there are only 12 studies included in this NMA.

Chart produced by Adrian White from data in CG150

White A, Cummings M. Inconsistent placebo effects in NICE's network analysis. *Acupunct Med* 2012;30(4):364-5.

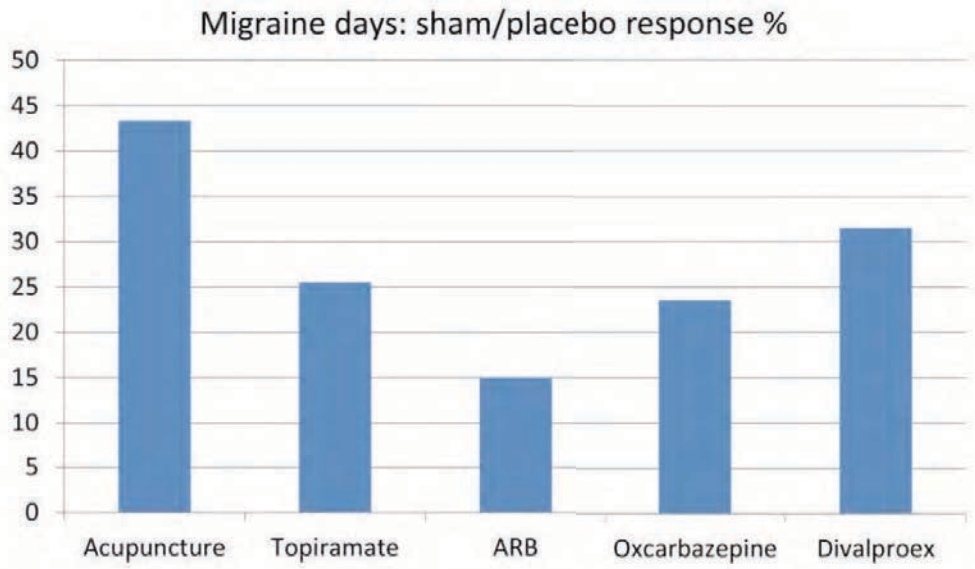


Figure 1 Migraine days: response rates of sham/placebo groups. ARB, angiotension receptor blocker.

Acupunct Med December 2012 Vol 30 No 4

For this to be a valid analysis, sham acupuncture would have had to be the same as placebo topiramate, yet the absolute data (see above) seemed to indicate that sham acupuncture was associated with a higher responder rate than any other placebo included.

Chart produced by Adrian White from data in CG150

- modified by MC to include an estimate of the efficacy of topiramate & real acupuncture

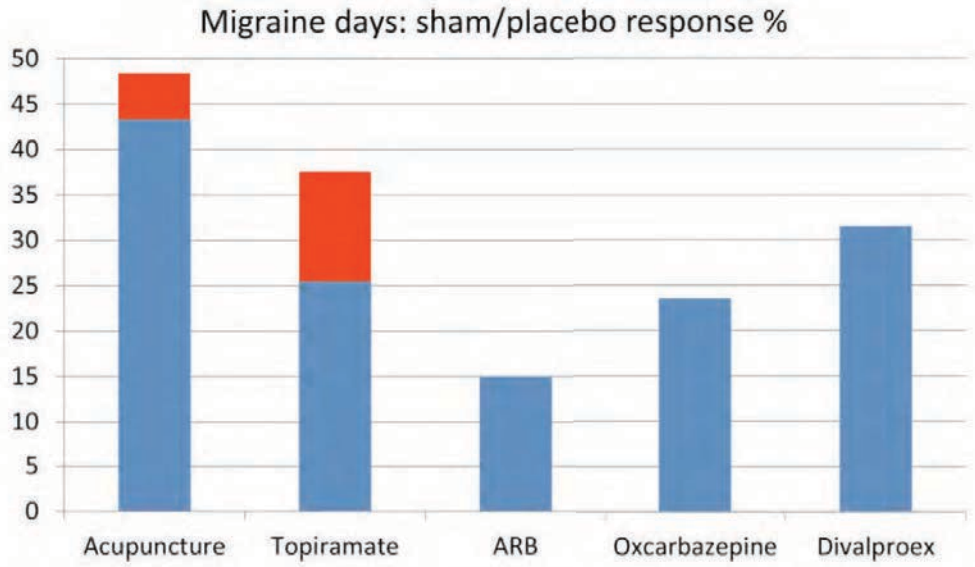


Figure 1 Migraine days: response rates of sham/placebo groups. ARB, angiotension receptor blocker.

Acupunct Med December 2012 Vol 30 No 4

In this chart, the effect of acupuncture and topiramate over their respective shams is included, and this reveals why NICE concluded that topiramate was twice a good as acupuncture (compare the height of just the red portions) whereas a different view seems to imply that sham acupuncture is superior to real topiramate.

goo.gl/6XQeXv

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Osteoarthritis and Cartilage

OARSI OSTEOARTHRITIS RESEARCH SOCIETY INTERNATIONAL

Acupuncture and other physical treatments for the relief of pain due to osteoarthritis of the knee: network meta-analysis☆

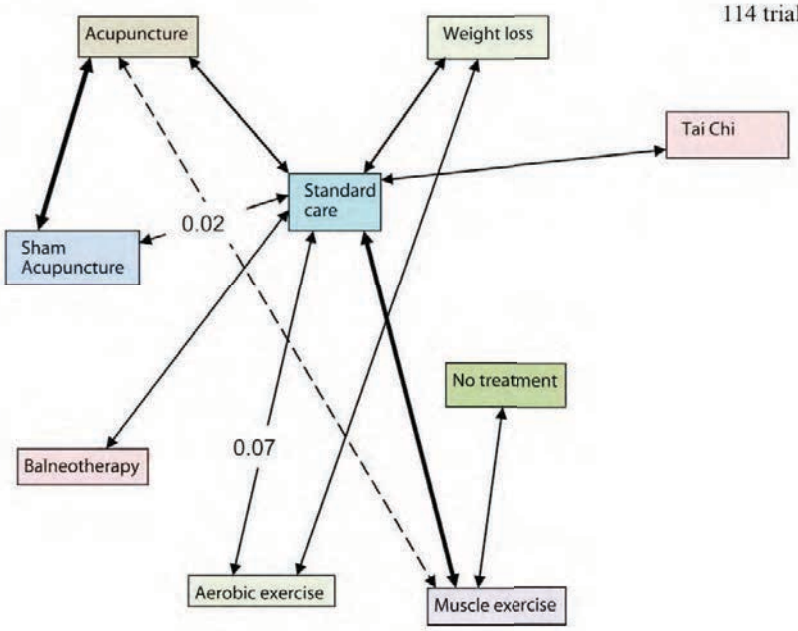
M.S. Corbett †*, S.J.C. Rice †, V. Madurasinghe †[a], R. Slack †, D.A. Fayter †, M. Harden †, A.J. Sutton ‡, H. MacPherson †, N.F. Woolacott †

† University of York, UK
‡ University of Leicester, UK

Osteoarthritis and Cartilage 21 (2013) 1290–1298

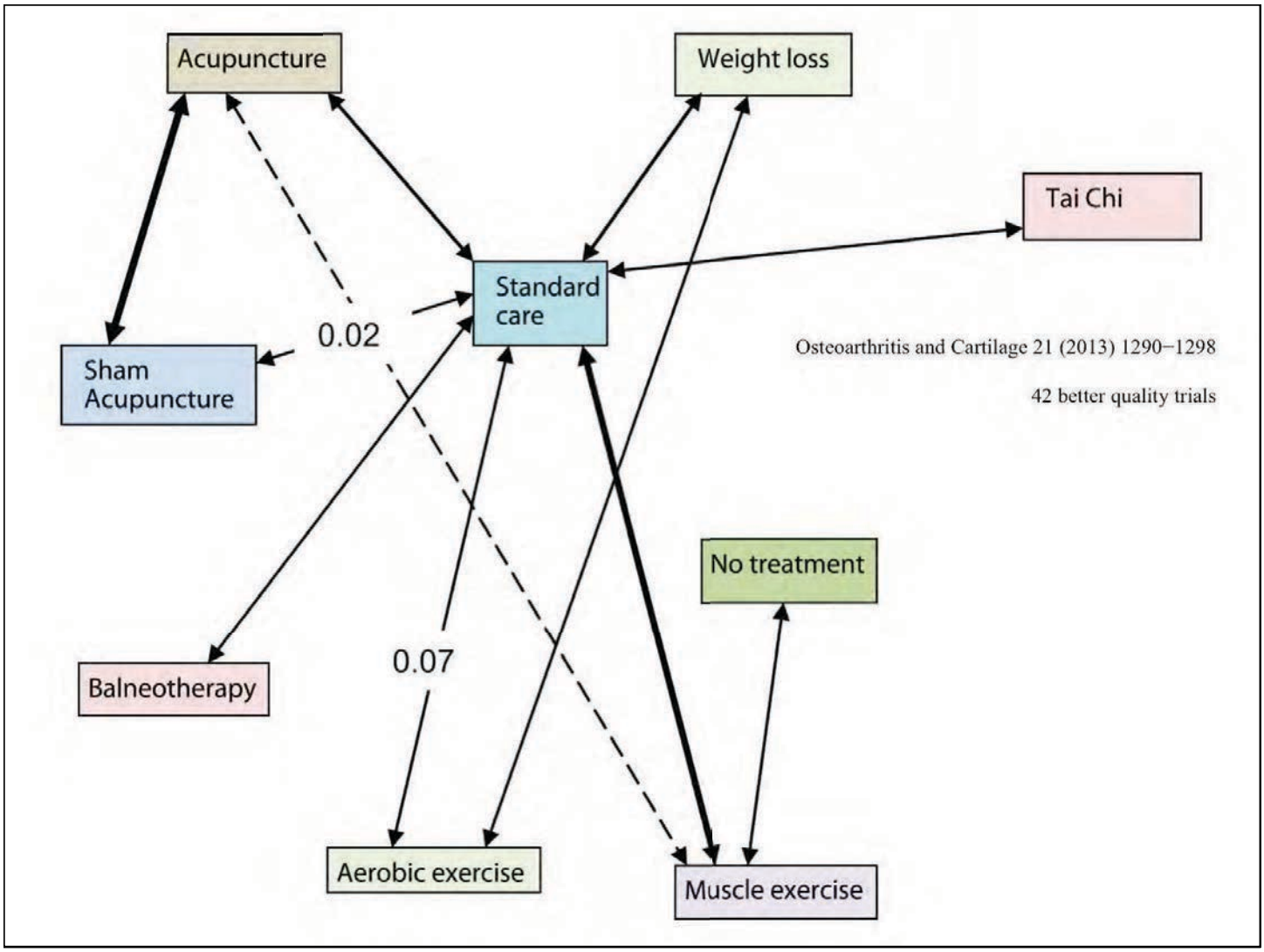
114 trials, 22 treatments, 9709 patients

42 better quality trials



This is a proper NMA, and the first performed including acupuncture. It was performed in a very well respected centre – the Centre for Reviews and Dissemination (CRD), York.

CRD is a research department that specialises in evidence synthesis, assembling and analysing data from multiple research studies to generate policy relevant research. We undertake high quality systematic reviews and associated economic evaluations, develop underpinning methods, and promote and facilitate the use of research evidence in decision-making.



Network diagram for the end of treatment analysis of better-quality trials. Each solid arrow indicates that there is a data point for that comparison entered into the analysis. The thickness reflects the number of trials. The dotted line reflects an extra comparison in a multi-arm trial. The numbers are a measure of inconsistency: 0 is no inconsistency; 1 is complete inconsistency.

Osteoarthritis and Cartilage

OARSI OSTEOARTHRITIS RESEARCH SOCIETY INTERNATIONAL

Acupuncture and other physical treatments for the relief of pain due to osteoarthritis of the knee: network meta-analysis☆

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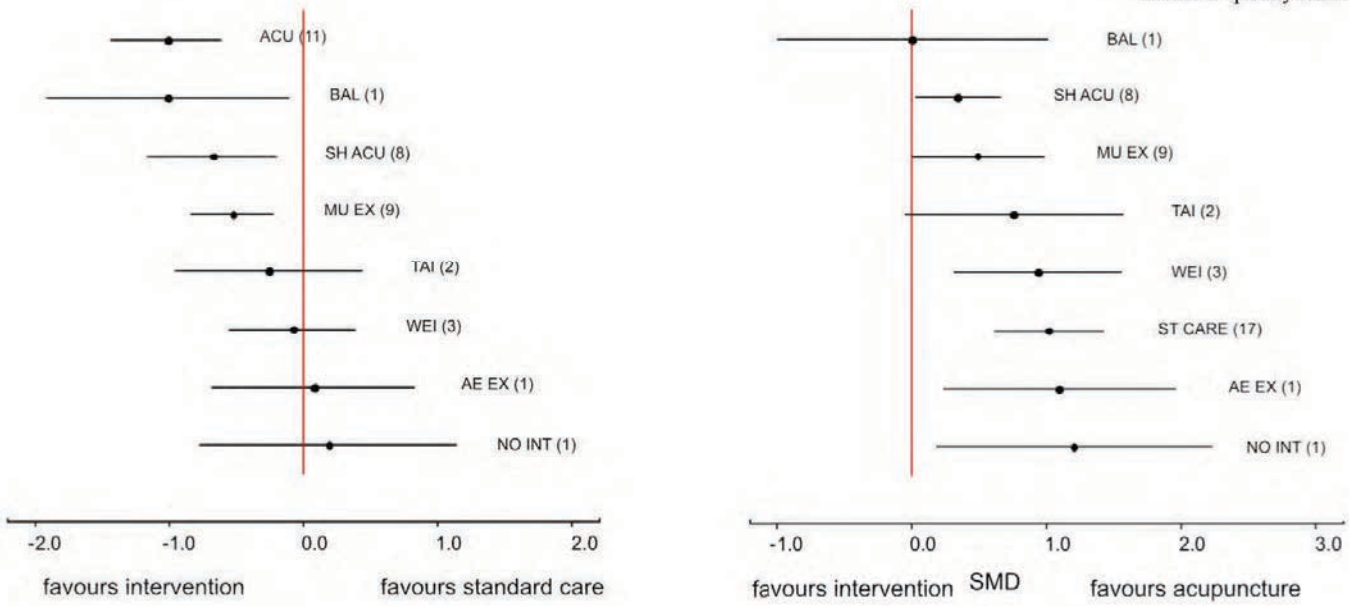

Conclusions: As a summary of the current available research, the network meta-analysis results indicate that acupuncture can be considered as one of the more effective physical treatments for alleviating osteoarthritis knee pain in the short-term. However, much of the evidence in this area of research is of poor quality, meaning there is uncertainty about the efficacy of many physical treatments.

goo.gl/6XQeXv

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Saramago *et al. BMC Medical Research Methodology* (2016) 16:131
DOI 10.1186/s12874-016-0224-1

BMC Medical Research Methodology

RESEARCH ARTICLE Open Access

Methods for network meta-analysis of continuous outcomes using individual patient data: a case study in acupuncture for chronic pain

Pedro Saramago[1*], Beth Woods[1], Helen Weatherly[1], Andrea Manca[1], Mark Sculpher[1], Kamran Khan[2], Andrew J. Vickers[3] and Hugh MacPherson[4]

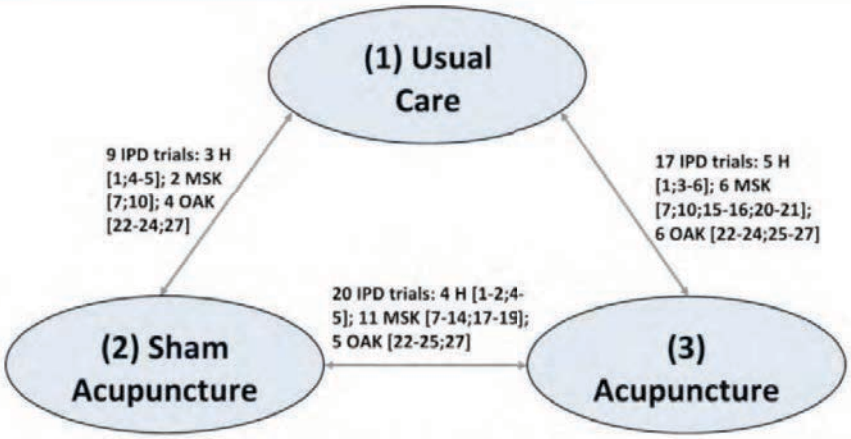


Fig. 1 Network of RCTs. Legend: In the network, a unique treatment category is indicated by a circle. Arrows between circles indicate that these treatments have been compared in a trial (trials are identified using '[]', numbered according to column 'ID' in Table 1. (Pain groups: H – Headache/migraine; MSK – Musculoskeletal; OAK – Osteoarthritis of the knee)

Data from the Acupuncture Trialists' Collaboration IPDM has been used in the first network meta-analysis using analysis of covariance in a continuous variable (VAS pain). Whilst this was not the intention of the paper, it has given us, for the first time, a large data set comparing sham acupuncture with usual care or best standard care (depending on the individual trial).

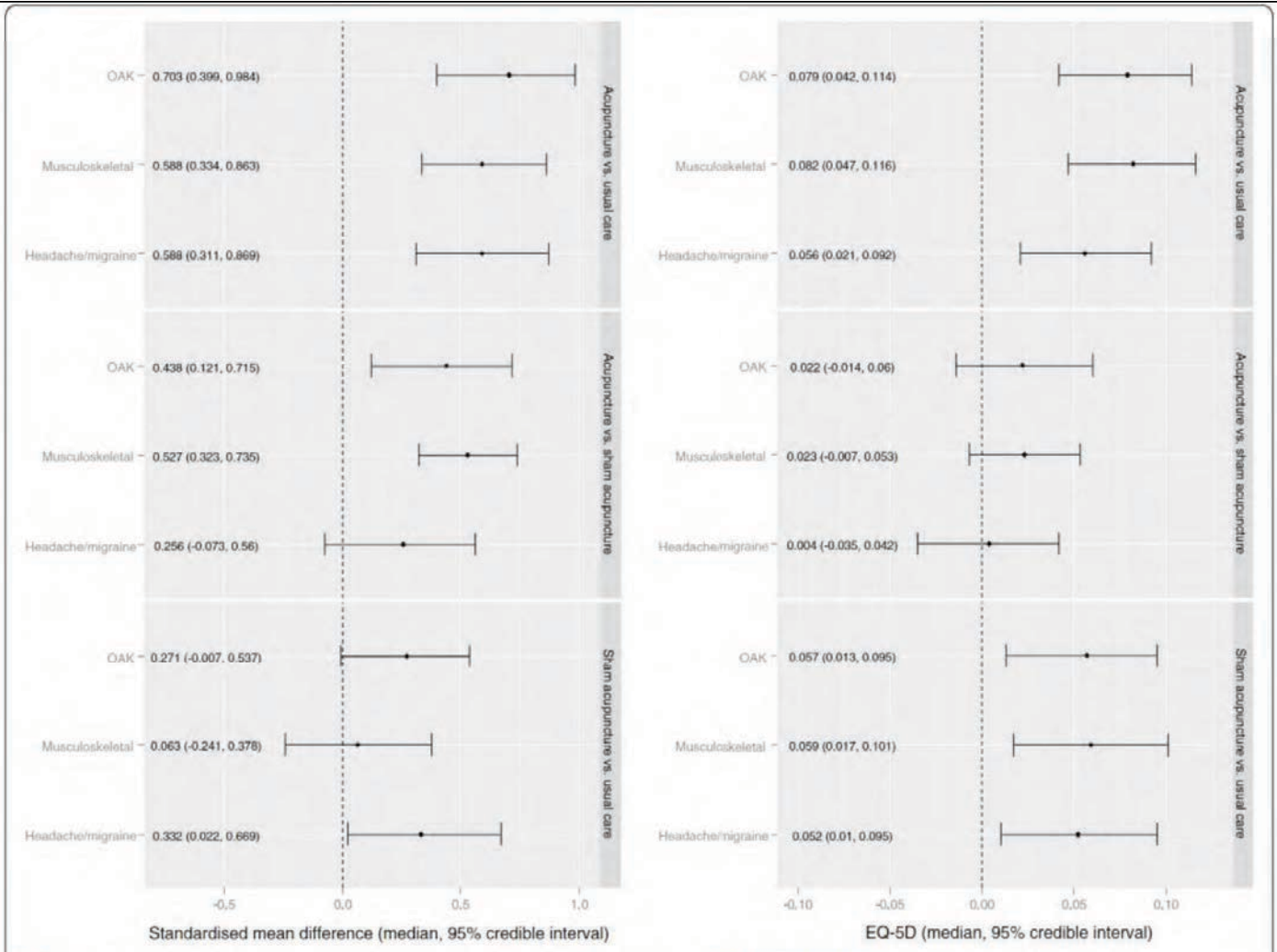


Fig. 2 Forest plot showing network meta-analysis results for standardised pain and EQ-5D outcomes

It is most interesting to note that sham is significantly superior to usual care in all conditions tested for health-related quality of life (HRQoL), and whilst acupuncture is superior to sham for pain outcomes, it is not superior in terms of HRQoL. This data must add to the weight of evidence that suggests sham acupuncture is far from being a placebo.

Note 1:
Usual care is a term used in the paper by Saramago *et al*, and it refers to the same data set labeled by Vickers *et al* as no acupuncture controls. This group includes a variety of interventions that could be described as standard or conventional care. Some involved quite intense treatment regimes, and others could be seen as more of a background usual care that might be common to all groups (ie including acupuncture and sham acupuncture groups).

Note 2:
Sham acupuncture mostly involves needling superficial tissues and has similarities with gentle forms of acupuncture. Non-penetrating sham or 'placebo' needles are blunt ended, and often cause significant discomfort and can penetrate the skin. It seems clear that sham acupuncture is not synonymous with the term 'placebo'.

goo.gl/6XQeXv

Acupuncture in Chronic Pain

Topics

- the filliform needle in the assessment of pain
- the Modellvorhaben Akupunktur
- Vickers IPDM 2012
- Vickers IPDM update 2017
- NICE CG150 NMA 2012 – fast and dirty
- Corbett et al NMA 2013 – a proper NMA
- Saramago et al NMA 2016 – no sham in HRQoL
- NG59 and closing comments

Fritillaria imperialis
Royal Botanical Gardens
Kew

Public provision or reimbursement

		UK (NHS)	Germany
2012			
Headache		yes	no
Back pain	(CG88)	yes	yes
Osteoarthritis		no	yes
2016			
Headache		yes	no
Back pain	(NG59)	no	yes
Osteoarthritis		no	yes

This slide illustrates the effect of the latest clinical guideline on back pain from NICE (NG59) on public provision of acupuncture services and compares this with reimbursement in Germany.

It is somewhat ironic to consider the other political changes underway that preceded the publication of NG59 at the end of November 2016:

23rd June 2016 – the UK votes for Brexit by a very narrow majority 17.4 million leave votes and 16.1 remain votes.

8th November 2016 – the US elects Donald Trump president.

NG59 used different levels of evidence for conventional interventions compared with those for acupuncture and did not adequately address personal financial COIs of the GDG chair (extract from: https://www.bmj.com/content/356/bmj.i6748/rr-6)

Readers of this guideline summary may not be aware of some of the factors affecting the decisions made by the GDG (guideline development group) of NG59. I would like to draw attention to two issues:

- Different levels of evidence were used for different interventions, with a perceived bias favouring conventional practice
- Personal financial conflicts of interests of interventionists on the GDG (chair SW and one other member CW) may not have been adequately addressed from the public perspective.

My own declaration of interests is below. I am openly an advocate of the appropriate evidence-based use of acupuncture techniques within conventional medicine after orthodox medical diagnosis. The evidence-based medicine (EBM) approach I take follows the broader description of Sacket *et al* in this journal 20 years ago.

So what are the different levels of evidence used in NG59? Acupuncture was required to show a clinically relevant benefit over the context of receiving acupuncture. In reality this means standard needling plus context over gentle needling plus context, not needling versus context of needling. Exercise was compared to no exercise with no context control, which is described as usual care. Exercise improved pain over usual care by 0.74 on a 0-10 VAS (visual analogue scale) of pain at 4 months or less – so it did not reach clinical relevance (1 on a 0-10 VAS), but achieved a positive recommendation. Acupuncture improved pain compared with usual care by 1.61 on the same scale at the same time point but received a negative recommendation.

Exercise was compared to sham exercise in the draft of NG59. Exercise versus the context of exercise achieved no benefit whatsoever, whereas acupuncture (standard needling plus context) achieved a very highly statistically significant benefit over sham (gentle needling plus context) that measured 0.80 on the 1-10 VAS pain. The data on exercise versus sham exercise was subsequently excluded from the analysis, leaving only the comparisons with usual care.

This page on the BMAS website includes a webcast of a presentation from the BMAS Spring meeting in 2017. The presentation describes the circumstances surrounding the change in recommendation of acupuncture for management of back pain in England.

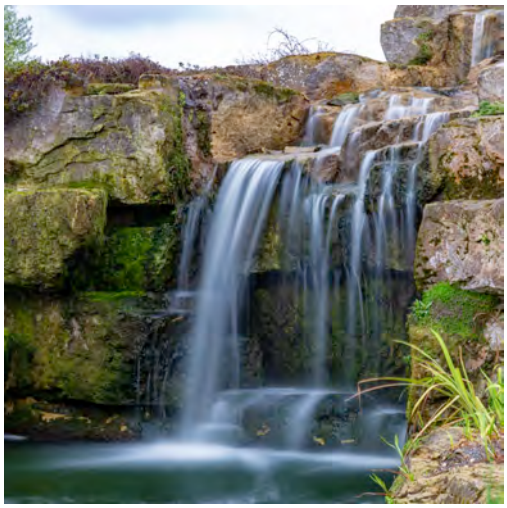
Prof Dr med Klaus Linde

Evidence of effectiveness but not efficacy – why so many complementary medicines are so hard to accept for biomedicine

Plenary session
World Congress of Medicine & Health

Acupuncture in Chronic Pain

Interpreting the evidence
Perspectives on the biggest data sets



Thank you
for listening

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