

# Friends of Science in Medicine

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# Is there any place for acupuncture in 21st century medical practice?

#### Introduction

Acupuncture is an integral part of traditional Chinese medicine (TCM). Over the past few decades, acupuncture has become popular in a number of countries as a stand-alone intervention. As part of TCM, acupuncture needs to be considered as a pre-scientific modality, and, as such, unlikely to be accepted by global modern medical science. As a separate technique it has received much attention. However, after much promise and extensive investigation, it is now becoming clear that there is no evidence based support for its use in modern medicine. This paper examines the evidence for this conclusion. Acupuncture is examined as a part of TCM and the results of research studies asking if acupuncture has the potential for contributing to modern scientific medicine are reviewed.

#### **Traditional Chinese Medicine**

#### What is traditional Chinese medicine?

TCM, also present in Japan, where it is called *Kampo*, is, together with Indian Ayurveda and pre-Enlightenment European medicine, one of the major pre-scientific medicines. They share common roots, probably from ancient Indian philosophies, according to which the equilibrium of the healthy human body is believed to be the result of a balance of a number of elements. Diseases are thought to be due to their imbalance.

In TCM, these elements are wood, water, fire, earth and metal, a belief similar to that of ancient Indian Unani medicine, with its four humours (*akhlaat*) – air, earth, fire and water, and Indian Ayurveda medicine's air, water and fire. Pre-scientific European (from Greco-Roman) medicine proposed four humours, each associated with the four natural universal elements (blood – air; phlegm – water; yellow bile – fire; black bile – earth). Although these theoretical constructs represented an initial attempt to unify knowledge about the world and ourselves, none has any scientific foundation.

#### The history of traditional Chinese medicine

TCM involves imaginary structures and undemonstrable 'vitalistic' forces. An undetectable, immaterial life force, qi, is said to flow through channels ('meridians') in the body. Circulating within these channels is the hypothetical qi, which regulates bodily function, modulated by 12 bilaterally distributed channels (six Yin and six Yang channels), supplemented by two midline channels (one in the front, and the other in the back, of the body). Disease is said to occur when the flow of qi becomes blocked. TCM uses several approaches to correct such blockage, including acupuncture, moxibustion and multiple herbal and animal extracts.

## The politics of traditional Chinese medicine

TCM, as is true for many other traditional medicines, plays important cultural and political roles in modern geopolitics.

In the 19th century, China started to accept the emerging scientific bases of medicine. In 1822, Emperor Dao Guang issued an imperial edict, stating that acupuncture and moxibustion should be banned forever from the Imperial Medical Academy. Indeed, the teaching of acupuncture was banned by the Imperial Medical Academy in 1882 and its use banned in 1929. In parallel, modern medicine had developed rapidly. The four humours theory had long been discredited by evidence-based developments and TCM was being superseded. Acupuncture continued as a minor activity in China till the Chinese Civil War finally ended in 1950. Not surprisingly, the Chinese Communist Party, based on the materialist philosophy of Marxism, rejected TCM, including acupuncture, as superstitious.

However, Chairman Mao Zedong revived TCM as part of the Great Proletarian Cultural Revolution of 1966, giving medical authority to peasant doctors still using TCM and establishing 'barefoot doctors' with a comprehensive manual. The revival was a useful way to increase Mao's authority amongst peasants and has since become part of Chinese nationalism.

Despite the overwhelming importance of modern medicine in modern China, supported by the vast majority of health workers, the emergence of China as a political and economic giant has given the traditionalists a further impetus, by supporting TCM with cultural pride, to expand China's influence in the world.

The Chinese government has started to promote TCM heavily, both in China and abroad. The WHO in 2008 endorsed an international agreement drawn up in Beijing to support the safe and effective use of traditional medicine within the modern healthcare system of member states. In 2011, China signed 91 TMC partnership agreements with more than 70 countries with the aim of promoting greater recognition of TCM around the world. Recently the trade agreement with China and Australia (2015) included a special agreement to enable TCM professionals to practice, and TCM methods to be fostered in Australia.

This process of globalising aspects of TCM is also finding it way into the most important scientific journals such as *Nature*, which sponsored an entire section on <u>'Traditional Asian Medicine'</u>. Interestingly, in China, a bachelor of medicine is only conferred currently on students of modern scientific medicine. Today, Western medicine is highly respected in China, while TCM (including acupuncture and herbs) is mainly used by those with lower socio-economic status. Since the early 20<sup>th</sup> century, the number of TCM practitioners in China has dropped from 800,000 to 270,000, and the <u>number of Western-trained physicians has risen from 87,000 to about 1.75 million</u>. In China, 'medicine' always implies 'modern medicine', not TCM.

### The history of acupuncture

#### "An ancient Chinese method"?

Acupuncture is said to be 3,000 years old, but the earliest Chinese medical texts don't mention it. The earliest reference to 'needling' is from 90 BC and apparently refers to lancing abscesses with large needles or lancets made of stone and bone; early diagrams of lines on the body corresponded to visible veins, not 'meridians,' and were probably guides for bloodletting.

The total number of 'acupoints' changes over time. It was only 160 in *The Inner Classic of the Yellow* under Emperor Huangdi Neijing (between 200 and 100 BC - "The inner classic of the yellow emperor – plain questions"). After its report in the Yellow Emperor's *Manual of Corporeal Medicine* (Huang Di Nei Jing, also known as *Inner Canon*) in the 2nd century BC, acupuncture became widely used (J.L. Needham Science and civilization in China).

In addition, there seems to be little agreement about acupuncture. There <u>is disagreement about the location and number of meridians</u>: different texts mention 9, 11, or 12, or even as many as 36 meridians along with sub meridians. Some systems of acupuncture disregard meridians entirely and only use points on the tongue, scalp, ear or hand. There is <u>disagreement about the location and number of acupoints</u>. Originally there were 365, symbolically corresponding to the number of days in a year (<u>acupuncture's origins are tied to astrology</u>). Now over 2,000 have been described. In Korean acupuncture, there are 300 acupoints, but these are all on the hand. In auricular acupuncture, there were originally 30 acupoints, but now there are more than 120, all on the ear. If you add up all the <u>acupoints described in all the different systems of acupuncture</u>, it's hard to find an area on the skin that has *not* been designated as an acupoint.

Furthermore, historians have suggested that the ideas behind the use of acupuncture might have <u>originated in ancient Greece</u> and travelled to China via trade routes. The first European accounts of Chinese medicine in the 13th century didn't mention acupuncture. Before the 20th century, needles were commonly inserted directly into the site of pain rather than into acupoints. One popular version of acupuncture, ear acupuncture, was invented by a Frenchman, Nogier, as recently as 1957.

#### The place of acupuncture in traditional Chinese medicine

Acupuncture within TCM is believed to balance the energy flows of Yin and Yang, the two major 'negative' and 'positive' forces governing the body. By inserting a needle followed by its appropriate manipulation, it is believed that one can unblock the channel, thereby re-establishing the free flow of *qi*, relieving the pain and correcting imbalances and thus removing illness (e.g. D. Ehling Oriental medicine: an introduction, Eastern concepts of acupuncture (Veterinary Acupuncture (2nd ed.)), and Traditional and evidence-based acupuncture: history, mechanisms, and present status.

#### Why acupuncture has become popular in the rest of the world

As globalisation began to meld international relations, so interest in other cultural enclaves grew. During Nixon's visit to China in 1972, an accompanying reporter commented on symptomatic relief by acupuncture of pain after an appendicectomy operation. This event triggered interest in possible drug-free-induced anesthesia. The National Institutes of Health (NIH) gave the first grant to study acupuncture in 1972. Despite the significant interest in potential useful applications of ancient traditional medicines, the American Medical Association Council in 1981 (Reports of the Council on Scientific Affairs of the American Medical Association, and in 1991, the National Council Against Health Fraud: Acupuncture Position Paper, concluded that acupuncture has no scientific basis. But the attraction to 'miracle cures' of diseases was too strong, and the interest in acupuncture did not abate.

In Taiwan, only 6% of the population has used acupuncture (compared to 6.5% in the US). One could argue that acupuncture might just as well be called 'Californian' as 'Chinese.' And ear acupuncture, the kind being taught to American military doctors as 'battlefield acupuncture' is more 'modern French' than 'ancient Chinese'.

### What could be the mechanisms by which acupuncture might work?

The proponents of acupuncture have postulated possible mechanisms involving neurovascular bundles, trigger points, connective tissue fascial planes, electrical impedance, migration of nuclear tracers, and other factors. These studies are flawed, inconclusive, contradict one another, and have not been replicated.

However, interest in acupuncture, particularly for analgesia, has been related to the 'gate control' theory (R. Melzack and P.D. Wall, "Pain mechanisms: a new theory"). According to this theory, the activation of large sensory fibres (touch pressure and vibration) inhibits transmission of nociceptive (pain recognising) pathways carried by small unmyelinated nerve fibres. This was postulated to occur in the spinal cord and might explain the effect of 'rubbing' the skin to reduce acute pain, the use of 'counter irritants', defined by the USA FDA as "externally applied substances that cause irritation or mild inflammation of the skin for the purpose of relieving pain in muscles, joints and viscera distal to the site of application". It has been suggested that acupuncture could act as a counter irritant.

Interest grew, in the 1970s, with the discovery of brain endogenous opioid peptides, which mimic the actions of morphine on pain. These discoveries triggered extensive research, both in China and around the world, on the involvement of endogenous opioid peptides and a plethora of many neuropeptides and purines in acupuncture-induced analgesia (H.M. Langevin et al., "Mechanical signaling through connective tissue: A mechanism for the therapeutic effect of acupuncture," N. Goldman et al., "Adenosine A1 receptors mediate local anti-nociceptive effects of acupuncture," Z.Q. Zhao "Neural mechanism underlying acupuncture analgesia".) The discovery of novel neurotransmitters capable of affecting nociception gave extra impetus to explain some analgesic responses to sensory stimulation (e.g. mini-review on "Acupuncture and endorphins" in Neuroscience Letters).

However while the concept that sensory stimulation affects pain sensation is well established, efforts to date have not established that this phenomenon is responsible for acupuncture induced analysesia.

Although acupuncture is supposed to be a very specific intervention involving skin penetration with needles and manipulation (twirling), <u>many studies include a plethora of other interventions</u>, assumed to be, to a lesser or greater degree, equivalent. These include acupressure, electro-acupuncture, transcutaneous nerve electrical stimulation (TENS), laser acupuncture, tiny gold beads implanted under the skin, and injection of homeopathic

remedies into acupoints. Electro-acupuncture, manipulated by passing electric currents through implanted needles, is widely used and allows a more objective control over stimulating parameters. Electro-acupuncture appears to be able to activate or deactivate a variety of brain regions and promote the release of endogenous opioid peptides, which are responsible for mediating its analgesic effects.

Other non-penetrating methods include stimulation with sound, pressure, heat (moxibustion, sometimes with deliberate burn injury), electromagnetic frequencies (laser stimulation, capsicum plaster, an acu-stimulation device such as Electro-acupuncture of Voll [EAV]), chemical (capsicum plaster and Sweet Bee Venom Pharmaco-puncture), vacuum (cupping), color, waving hands over acupoints, and striking the appropriate meridian on an acupuncture doll with a metal hammer (Tong Ren). Even some forms of bloodletting are thought to involve activation of acupuncture points.

Because of the aforementioned scientific studies on the neuroscience of nociception, acupuncture seemed to gain somewhat more plausibility than other forms of alternative medicine. Acupuncture has even been said to have positive effects on animals' cognitive functions.

### Acupuncture and the proven principles of Brain Science

Any hypothesis on the mechanism of action of acupuncture and equivalent interventions needs to be placed within the well established, proven principles of the brain sciences. Brain activity is due to the activity of billions of nerve cells, each generating small electrical currents which carry signals from one end to the other of each nerve cell; and, due to communication through the release of small amounts of chemicals, called neurotransmitters, with other nerve cells and with muscle and glands. These electrical and chemical aspects of the nervous system represent the most important foundations of modern brain science.

This principle of organisation and function of the nervous system became well-established by the middle of the 20th Century, thanks to the research of the Australian neuroscientist, Sir John Eccles, Nobel prize-winner in Medicine because of this discovery. Since then, a plethora of neurotransmitter substances have been identified in the brain and in peripheral organs. Amongst these are endogenous opioids, as mentioned above, and other neuropeptides; these are recognised as important potential modulators of brain function. Not surprisingly, the idea that activating sensory inputs might affect central neural circuits and that, in particular, acupuncture might well work for analgesia, has triggered extensive research.

While there is evidence for the release by various sensory stimuli, including manual acupuncture, of some endogenous opioids and other endogenous chemical mediators potentially capable of modifying pain stimuli, there is little evidence that this is a specific effect related to any anatomical organisation which could correspond to the 'meridians' of TCM. In most cases, any physical or chemical sensory stimulus is likely to result in the release of some endogenous anti-nociceptive substances. The highest quality studies have shown that it doesn't matter where you insert the needles (acupoints or non-acupoints), and that it doesn't matter whether the skin is penetrated (in one study, touching the skin with a toothpick worked just as well). The one thing that does seem to matter is whether the patient believes in acupuncture.

It is becoming increasingly clear that the brain processes underlying the physiological 'placebo effect' in reducing pain perception share similar neurochemical mechanisms with the sensory stimulation caused by acupuncture and other sensory stimulations.

Thus the placebo effect is likely to explain many of the subjective improvements of many interventions, including acupuncture. This similarity explains, in part, why it has been so difficult, in practice, to perform satisfactory clinical trials to test the effectiveness of acupuncture separate from the placebo effect.

Another myth is that acupuncture *must be effective* because it works on animals, and they wouldn't respond to a placebo. But animals can't talk to tell us to how they feel; their owners must interpret their responses by observing the animal's behaviour, and the owners *are* susceptible to suggestion. They might inadvertently influence the animal's behavior by giving it more attention or treating it differently in some way. They might be convinced that they see a change in the animal's behavior and think that it means the animal feels better.

# Using acupuncture for its placebo effect

Recently, the weight of evidence has convinced some acupuncturists that acupuncture works no better than placebo, but they still advocate using it for its placebo effect. Medical ethicists universally condemn using placebos intentionally since it amounts to lying and can destroy trust in the doctor/patient relationship. In reality, placebos don't do much; their effects tend to be small in magnitude and short in duration. Patients who use them might defer or reject necessary effective treatment. Placebos can waste time and money, and harm can result when patients are deluded into thinking they are getting better when they really are not. One study found that patients with asthma had the same positive subjective responses to placebos as to an asthma inhaler; but objectively, only the patients in the asthma inhaler group had improvements in lung function. The response to placebos was no better than that of patients in a no-treatment control group. This could have serious consequences, since difficulty in perceiving the severity of an asthma attack is a risk factor for asthma-related death.

#### Is there clinical evidence for effectiveness of acupuncture in clinical medicine?

The proponents of acupuncture, whether as part of holistic TCM or as a separate technique, advertise that acupuncture can cure a wide range of diseases. Acupuncture has been claimed to be effective for addiction (such as alcoholism), allergies, asthma, bronchitis, carpal tunnel syndrome, chemotherapy-induced nausea and vomiting, constipation, depression, diarrhoea, endometriosis, facial tics, fibromyalgia, gastro-esophageal reflux, headaches, high blood pressure, infertility, irregular menstrual cycles, kidney infections, memory problems, multiple sclerosis, pre-menstrual syndrome, polycystic ovarian syndrome, low back pain, menopausal symptoms, menstrual cramps, osteoarthritis, pain of various natures, pharyngitis, post-operative nausea and vomiting, psychological disorders such as anxiety, sciatica, sensory disturbances, sinusitis, spastic colon (often called irritable bowel syndrome), stroke rehabilitation, tendonitis, tennis elbow, tinnitus, urinary problems such as incontinence, sports injuries, sprains, strains, ulcers, and whiplash.

#### Acupuncture trials and pitfalls

Clinical research on acupuncture is inherently difficult. The practice of acupuncture is not standardised, and some studies of 'acupuncture' are actually of electro-acupuncture, ear acupuncture, or other variants. It's next to impossible to do double-blind studies, so confounding factors cannot be eliminated. The best studies use a retractable needle in a sheath, so that the patient can't tell whether the skin has been penetrated or only touched by the needle. The results are highly variable: it's easy to find studies to support a belief in acupuncture, but it's even easier to find studies showing that it doesn't work.

The rationale for acupuncture's acceptance in some aspects of clinical medicine, particularly in emergency medicine and pain clinics, has begun to crumble on closer examination of the evidence, mostly because of the excessively variable nature of the interventions involved in various studies which did not clarify the nature of the sham interventions used and any placebo effects.

Recent reviews of the effectiveness of acupuncture on pain in general are rather damning. There have, over several decades, been several thousand acupuncture studies. After all this clinical research, acupuncture has not been clearly demonstrated to be effective for any indication. In short it is more than reasonable to suggest that acupuncture doesn't work being no more than "a theatrical placebo".

Traditional Chinese acupuncture is no better for treating menopausal symptoms than a 'sham' version using blunt needles, according to a University of Melbourne study, published in the *Annals of Internal Medicine*, involving 327 Australian women over 40 who had at least seven moderately hot flushes daily. Half were given ten sessions of standard Chinese medicine acupuncture, where thin needles were inserted into the body at specific points. The others had their skin stimulated with blunt-tipped needles, which had a milder effect without penetrating the skin. After eight weeks of treatment, both had led to a 40% improvement in the severity and frequency of hot flushes; this was sustained six months later. However, there was no statistical difference between the two therapies. The authors said that both groups might have improved as a result of the placebo effect or because attending a clinic to talk about symptoms helped.

The authors also noted that hot flushes tended to improve spontaneously with time adding "This was a large and rigorous study, and we are confident there is no additional benefit from inserting needles compared with stimulation from pressuring the blunt needles without skin penetration for hot flushes."

The most positive results from acupuncture have been for pain and <u>post-operative nausea and vomiting</u> (PONV). But even for those, the evidence is unconvincing. For PONV, the <u>most recent meta-analysis</u> indicated a small effect of P6 acupoint stimulation, but it mixed studies of acupuncture with electro-acupuncture, transcutaneous nerve stimulation, laser stimulation, capsicum plaster, an acu-stimulation device, and acupressure. There were questionable randomisation procedures, incomplete data, and the conclusion of the reviewers (that P6 acupoint stimulation "prevented PONV") was not justified by the data. There is a lot of 'noise' in the data from these studies, but there doesn't appear to be any 'signal' mixed with the 'noise'.

It has been shown that the analgesic benefits of acupuncture are partially mediated through placebo effects related to the acupuncturist's behavior. It is becoming increasingly clear that any reported benefits of acupuncture are largely due to the surrounding ritual, the beliefs of patient and practitioner, and the other non-specific effects of treatment, not to the needles themselves.

The team studying PONV also examined 'Acupuncture for pelvic and back pain in pregnancy: a systematic review'. They concluded "limited evidence supports acupuncture use in treating pregnancy-related pelvic and

back pain. Additional high-quality trials are needed to test the existing promising evidence for this relatively safe and popular complementary therapy".

A systematic review of <u>acupuncture for various pain conditions</u> found a mix of negative, positive and inconclusive results. Out of 57 systematic reviews, there were only 4 pain conditions for which more than one systematic review reached the same conclusion: in 3 cases, they agreed that it was ineffective, and in only one (neck pain) was it agreed that it was effective.

That finding is suspect, because it doesn't make sense that a treatment could relieve pain only in one part of the body but not elsewhere.

Over the past 10-15 years the **Cochrane collaboration** has addressed the efficacy of acupuncture for many of these indications. When clinical trials have been performed properly, **lack or insufficient evidence of effectiveness for acupuncture** was demonstrated in most cases. The following is a list, not exhaustive, of such trials.

- In thirty trials for depression, with 2,812 participants, manual and electro acupuncture were compared with medication; they found no difference between the two groups.
- A review by the Cochrane Collaboration on the question 'Do acupuncture and related therapies help smokers who are trying to quit' "did not find consistent evidence that active acupuncture or related techniques increased the number of people who could successfully quit smoking".
- A study by RMIT researchers in 2016 showed that acupuncture <u>is no better than placebo</u> for menopausal symptoms such as hot flashes.
- A Cochrane Collaboration study (2014) demonstrated no effects on <u>functional dyspepsia</u>. A similar lack of effect on rheumatoid arthritis was demonstrated in 2005.
- Even proponents of acupuncture from the team at the RMIT in Melbourne, in their attempt to prove that acupuncture is effective in a "range of health conditions", admitted, "No solid conclusion of which design is the most appropriate sham control of Ear-acupuncture/ear-acupressure could be drawn in this review".
- Very clear experimental work performed by a University of Melbourne team on one of the projects funded by the NH&MRC on laser acupuncture, "Acupuncture for Chronic Knee Pain published A Randomized Clinical Trial on chronic knee pain", showed that neither needle nor laser acupuncture significantly improved pain and concluded that their findings did not support acupuncture for these patients.
- A paper in *Obstetrics & Gynecology* in 2008 "<u>Acupuncture to Induce Labor: A Randomized Controlled Trial</u>" concluded "Two sessions of manual acupuncture, using local and distal acupuncture points, administered 2 days before a scheduled induction of labor did not reduce the need for induction methods or the duration of labor for women with a post-term pregnancy".

## Trials not performed sufficiently well and therefore "need to be repeated"

Despite the several decades of significant funding for, and research on, acupuncture and, in general, on alternative medicines in Australia and around the world, far too often the conclusion from clinical trials is "more research is needed". The excuses given in the numerous reviews, mostly by the proponents, are

insufficient numbers of patients or trials or insufficient control subjects. The reality is more likely due to the reality that there is an absence of effectiveness.

For example, a review on <u>"Acupuncture to treat common reproductive health complaints: An overview of the evidence"</u> concluded "Acupuncture to treat premenstrual syndrome or polycystic ovarian syndrome and other menstrual related symptoms is under-studied, and the evidence for acupuncture to treat these conditions is frequently based on single studies. Conclusion: Further research is needed".

In a review, <u>"Pain Research in Complementary and Alternative Medicine in Australia: A Critical Review"</u>, the authors concluded that, because of the poor design and execution of research papers on pain and alternative medicines, "The quantity and the quality of CAM pain research in Australia is inconsistent with the high utilization of the relevant CAM therapies by Australians. A substantial increase in government funding is required. Collaborative research examining the multimodality or multidisciplinary approach is needed".

It has been claimed that surgery can be performed using only acupuncture anesthesia. A widely publicised picture of a patient allegedly undergoing open-heart surgery under acupuncture anesthesia appears to be a fake: it shows her with an open chest cavity that would make her lungs collapse, she is not on a respirator and a heart-bypass machine does not appear to be in use. Also, the incision is in the wrong place for the procedure being described, and the photo is curious in other respects (such as the position of the patient's head). A recent BBC video of surgery on a conscious patient anaesthetised with acupuncture was similarly misleading.

Researchers at the Centre for Complementary Medicine Research at the University of Western Sydney, commenting on studies of acupuncture for menstrual problems stated, "Five systematic reviews were included, and six RCTs. The symptoms of the menopause and of dysmenorrhea have been subject to greater clinical evaluation through RCTs, and the evidence summarised in systematic reviews, than any other reproductive health complaint. The evidence for acupuncture to treat dysmenorrhea and menopause remains unclear, due to small study populations and the presence of methodological bias.

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Many other studies by the Cochrane Collaboration concluded that there was insufficient evidence for recommending the use of acupuncture for the conditions investigated, as listed as follow: ADHD in children and adolescents (2011); autism spectrum disorders (ASD) (2011); Bell's palsy (2010); cancer-related pain (2015); glaucoma (2013); depression (2010); dysphagia in acute stroke (2008); tennis elbow (2002); 'fibromyalgia' (2013); induction of labour (2013); menopausal hot flushes (2013); mumps (2014); near-sightedness in children (2011); hypoxic ischemic encephalopathy in newborn babies (2013); pain in endometriosis (2011); period pain (2011); chronic asthma (1999); urinary incontinence (2013); stroke rehabilitation (2006); uterine fibroids (2010); labour pains (2011); vascular dementia (2007); nausea and vomiting in early pregnancy (2015); obesity (2015). Even TENS appears to give insufficient evidence for improving dementia (2003).

#### Reasonable trials with evidence for small effects.

A Cochrane study on acupuncture and dry needling for <u>low back pain</u>, based on 35 randomised clinical trials in 2005, reported a very small effect.

Another Cochrane study in 2009 suggested that acupuncture should be considered a treatment option for migraine prophylaxis, despite finding that "there was no evidence of an effect of true acupuncture over sham interventions"

A Cochrane study in 2006 found moderate evidence for a small improvement in <u>chronic neck pain</u> while a review in 2009 suggested that there was benefit from the use of acupuncture to treat <u>Tension-type headache</u>

Almost all trials of alternative medicines seem to end up with the conclusion "more research is needed". After more than 3,000 trials, we should recognise that the need for more trials is dubious.

## Acupuncture in Australia

The reader is referred to the excellent review "Acupuncture in Australia".

### Publicly funded Australian research on acupuncture

In recent years, with significant NH&MRC funding, research might have been be expected to result in some experimental evidence for acupuncture effectiveness if it existed. Starting from 2009, there were 7 NHMRC-funded CAM projects on pain. Four out of six projects were on chronic pain, one on acute pain, and the remaining one on experimental pain in rats. In all of them, acupuncture was the study intervention. All projects involved collaborative research.

In that year, the NH&MRC awarded over \$2.5 million for seven grants for acupuncture research; one to Griffith University, four to RMIT University, one to the University of Queensland and one to the University of Melbourne. It has since been difficult to trace publications stemming from these projects. Only one paper was published from the team at the RMIT ("Acupuncture analgesia for temporal summation of experimental pain: a randomised controlled study"), but this had not been supported by the NH&MRC. Paradoxically, while electro-acupuncture was mildly effective when compared with a sham intervention, the result of traditional manual acupuncture (MA) was not different from that of the sham treatment (SA). Yet the authors dismiss this negative finding because "the lack of difference between the MA and SA groups in this study is likely a type II error due to a small sample size".

Most publications published by leading Australian workers in this field were **reviews** rather than research papers, with very few acknowledging their NH&MRC funding. Many are simply papers on developing "Study protocols" to be applied some time in the future.

In a review in 2013, supported by the NH&MRC, the authors stated "It is suggested in our theoretical model that, in adult subjects with allergic rhinitis, acupuncture may down-regulate certain pro-inflammatory neuropeptides and neurotrophins as well as Th2 cytokines and pro-inflammatory cytokines, thereby producing a shift in the Th1/Th2 balance of T helper cells towards Th1".

Following a meeting in 2015 on "Acupuncture and Immunity", a team from Melbourne RIMT published a review on "Mediators, Receptors, and Signaling Pathways in the Anti-Inflammatory and Antihyperalgesic Effects of Acupuncture" (Evidence-Based Complementary and Alternative Medicine, Volume 2015, Article ID 975632), a special issue published by the Hindawi Publishing Corporation). No experimental evidence was provided.

The authors of a review article on <u>"Factors Associated with Conflicting Findings on Acupuncture for Tension-Type Headache: Qualitative and Quantitative Analyses"</u> admitted "Acupuncture is a complex intervention. Its active ingredients are not well defined." But the work concludes that results from meta-analysis "showed no statistically significant difference between real and sham acupuncture on headache days" and attributed this to the problem that "stimulation mode, needle retention, and treatment frequency are important factors contributing to the outcome of acupuncture treatment for TTH". No funding from the NH&MRC was acknowledged.

Another review article by an RMIT team "The Anti-Inflammatory Effects of Acupuncture and Their Relevance to Allergic Rhinitis: A Narrative Review and Proposed Model" concluded "more research is needed to elucidate specifically how immune mechanisms might be modulated by acupuncture in allergic rhinitis". Another review by the main author from the RMIT team ("Pain Research in Complementary and Alternative Medicine in Australia: A Critical Review") found that half of the acupuncture studies were conducted by medical doctors or physiotherapists. Multidisciplinary collaboration was uncommon.

The issue of performing proper trials, taking into account the placebo effect by using suitable 'sham' treatments, appears insurmountable, as the very proponents of acupuncture admit in yet another review article from the team of the RMIT ("Sham Control Methods Used in Ear-Acupuncture/ Ear-Acupressure Randomized Controlled Trials: A Systematic Review"). They concluded, "No solid conclusion of which design is the most appropriate sham control of EAP could be drawn in this review".

The team funded by the NH&MRC at Griffith University also published mostly review articles ("Mediators, Receptors, and Signaling Pathways in the Anti-Inflammatory and Antihyperalgesic Effects of Acupuncture"). As with other review articles, this review conflates the complexity of the endless list of molecules known to be associated with pain and inflammation to hide the lack of sensible evidence for a clear relation between acupuncture and pain therapy.

The team funded by the NH&MRC set up collaborations with Chinese companies and universities and managed to have such collaboration included in the Memorandum of Understanding during the Australian-China free trade agreement ceremony. These companies appear to mislead the public by citing the use of TCM in western medicine to generate public trust in the effectiveness of TCM. Because the TCM market is worth close to \$170 billion, they received the backing of politicians. For China, this is excellent, because they can use Australia as a new export market for TCMs and, upon acceptance within Australia, with endless lobbying of the National Institute for Complementary Medicine (NICM), open up the more lucrative US and EU markets. These companies use the argument that China is the "biggest country in the world" and that TCM has been used for millennia, TCM will be effective and safe to use in Sydney clinics. It appears that the NICM plans to introduce TCM's via acupuncture clinics in Sydney, and they will use cancer as the disease of choice because the media would be reluctant to report negatively on cancer issues. This raises serious issues of safety, diverting unaware patients away from needed medical interventions, and shifting the public's need for healthy care away from scientific medicine.

### **Issues of safety**

Safety issues apply to acupuncture or similar interventions, as to any other interventions. Some people have asserted that acupuncture is perfectly safe, but there are at <u>least 95 published cases of serious adverse effects</u> including infection, pneumothorax, and five deaths. In the UK, a <u>total of 468 safety incidents</u> was reported over a 3-year period for patients treated with acupuncture in the National Health Service; 95% of these were categorised as low or no harm. And there are contraindications to acupuncture: metal allergies, bleeding disorders, anticoagulant drugs, and skin infections. It is generally safe as long as disposable needles are used, proper infection-control procedures are followed, and the practitioner has a good understanding of anatomy; but mishaps do occur. Recently, the ex-president of South Korea had to undergo major surgery <u>to remove a 6.5 cm acupuncture needle</u> from his lung; they had no idea when or how it had lodged there.

#### Is there any justification for the use of acupuncture in modern medicine?

Despite the conceptual difficulties, an enormous number of investigations have been publicly funded and performed over the past few decades. However, as discussed above, examination of the efficacy of acupuncture for any diseases such as that conducted by the Cochrane Collaboration, has fundamentally failed to give any credibility to claims that acupuncture is an effective intervention for any illness. Some studies have concluded that acupuncture is not effective or that there is only a small and temporary effect or that there is insufficient evidence that it is effective. Pseudo-philosophical arguments have been made that these findings do not mean that acupuncture is ineffective, simply that "absence of evidence of an effect does not imply that there is no effect". However, failure to reliably demonstrate any effectiveness of acupuncture in the diseases tested in trials should send signs of significant doubt, even to the most dedicated supporters of acupuncture.

The World Health Organization (WHO) endorsed acupuncture, but challenged by evidence from the Cochrane Collaborative has taken down their website on acupuncture which had suggested effectiveness in more than 100 conditions. Cochrane emphasized that where acupuncture appeared to be effective, the studies were of poor quality (often with no sham acupuncture control group), and the evidence was weak. When studies included sham acupuncture, both true acupuncture and sham acupuncture groups had similarly positive results, indicating that they were measuring simply a placebo effect. And for many of the conditions being treated, there was no relevant published research at all.

The <u>US Center for Inquiry Office of Public Policy</u> issued a position paper on acupuncture in 2010. It concluded that recent research had unraveled nearly all acupuncture claims and noted, "<u>The bulk of recent research strongly tends towards the hypothesis that acupuncture's positive effects are mainly due to a built-in expectation..."</u>

A 2006 review in *The Medical Letter* stated that "Acupuncture alone has not been shown in rigorous, duplicated studies to benefit any defined medical condition".

In their book <u>Trick or Treatment</u>, Simon Singh and Edzard Ernst concluded that there was only "tentative" evidence that acupuncture "might" be effective for some forms of pain relief and nausea, that it failed to deliver benefits for any other conditions, and that its underlying concepts were meaningless.

Authors, editors, and journalists often put a spin on the results according to their preconceived opinions. For example, the <u>CACTUS study</u> was essentially negative, but was reported as positive. <u>David Colquhoun</u> said that it was published with conclusions that directly contradicted the data and was <u>"the best evidence I've ever seen that not only are needles ineffective, but that placebo effects, if they are there at all, are trivial in size and have no useful benefit to the patient".</u>

As acupunctures loses support in Medicine, it is increasingly used as part of larger constellations of alternative treatments within private enterprises which mix together, almost randomly, any of the many pseudoscientific interventions under a generally attractive umbrella of 'wellness'. This makes acupuncture even less reliable and hides it from public scrutiny.

#### Conclusion

Acupuncture has been studied for decades and the evidence that it can provide clinical benefits continues to be weak and inconsistent. There is no longer any justification for more studies. There is already enough evidence to confidently conclude that acupuncture doesn't work. It is merely a theatrical placebo based on pre-scientific myths.

All health care providers who accept that they should base their treatments on scientific evidence whenever credible evidence is available, but who still include acupuncture as part of their health interventions, should seriously revise their practice.

There is no place for acupuncture in Medicine.

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