



## Scientific Facts on Evaluating effectiveness and safety of acupuncture

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### Level 2 - Details on Evaluating effectiveness and safety of acupuncture

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This is a faithful summary of the leading report  
produced in 2014 by French National Institute of Health and Medical Research (INSERM):  
*"Review of the scientific literature conducted by INSERM - Unit 669 - 2014"*

The full Digest is available at: <https://www.greenfacts.org/en/acupuncture/>



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- Each question is answered in Level 1 with a short summary.
- These answers are developed in more detail in Level 2.
- Level 3 consists of the Source document, the internationally recognised scientific consensus report which is faithfully summarised in Level 2 and further in Level 1.

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## 1. What is the context of this report?

Evaluation of so-called 'non-conventionnal' therapies is generally difficult or even impossible due to a lack of objective data. Even if it's not the case for acupuncture, for which thousands of publications and more than 400 systematic reviews are available, results are however far from consistent.

Conclusions of these evaluations lack consistency in large part because of problems with the methodology of the trials conducted as well as because of a potential bias in the interpretation of results.

Validity of some estimates of level of proof were questioned because they have been published either by acupuncturists or by detractors of non-conventional medicine.

The report published by the Institut National de la Santé et de la Recherche Médicale (INSERM, France) aims to first select the most reliable data published by national and international sources that are recognized by the scientific and medical community (for about 250 cited publications) and to present a synthesis that was then analysed and reviewed by experts in the evaluation of therapies.

## 2. What is acupuncture?

Acupuncture is a widely used therapeutic approach.

In France, there are currently training available for people in the medical field.

This training is offered in medical faculties as an interuniversity diploma.

Reasons for consulting an acupuncturist are most commonly pain-related, such as joint pains and headaches, and are also often linked to stress, fatigue and sleep disorders.

Even if many neurobiological pathways have been suggested to explain the way that acupuncture could have analgesic clinical effects or could help the action of conventional painkillers, the biological mechanisms are not really known.

Non-specific effects are often considered to originate from the psychobiological processes triggered by the overall therapeutic context, the patient-therapist relation, expectations and beliefs of the patient, etc..., a group of elements that are part of the « placebo effect ».

Acupuncture is a discipline that stems from traditional Chinese medicine, consisting of the stimulation of « acupuncture points » with a therapeutic aim. Stimulation techniques are punctual (limited in area and centered around an acupuncture point), and done in a variety of ways, either physical (mechanical, electrical, magnetic, thermal, light) or physico-chemical.

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Reasons for consulting an acupuncturist are most commonly pain-related, such as joint pains and headaches, and are also often linked to stress, fatigue and sleep disorders. The exact biological mechanism of acupuncture is not really known, especially since it is difficult to define and distinguish between specific and non-specific effects. Many neurobiological

pathways have been suggested to explain the way that acupuncture could have analgesic clinical effects. It has also been suggested that some of those mechanisms could help the action of conventional painkillers.

Non-specific effects are often considered to originate from the psychobiological processes triggered by the overall therapeutic context, the patient-therapist relation, expectations and beliefs of the patient, etc..., a group of elements that are part of the « placebo effect ».

### 3. What are the applications where acupuncture seems to have an effect, according to the report?

Many good quality systematic reviews provide convincing data that acupuncture might have some benefits in alleviating or treating some forms of pain, like headaches, migraines or pain linked to arthritis as well as a better satisfaction by the patient concerning how pain is addressed and a reduction in drug intake.

Even if more trials are needed to confirm this conclusion, data suggests that acupuncture could also help in relieving back pain, labor pain or menstrual cramps.

Some forms of acupuncture also seem to be beneficial for patients suffering from nausea and vomiting after chemotherapy of surgery, with minimal side effects. However these recommendations are systematically moderated by concerns on the quality of studies.

For the vast majority of other afflictions and conditions that acupuncture claims to address, like smoking cessation or epilepsy, the available data is not sufficient to be able to assess the effectiveness of the treatment. There is a large contrast between the number of clinical trials available and the small number of studies where a level of proof could be obtained and used to make recommendations. Out of the 42 publications evaluated by the Cochrane Collaboration statistical reviews, 33 were considered to have insufficient data to be able to draw a conclusion on the therapeutic effect of the treatment. Out of those for which there seems to have an effect (level of proof moderate to high), the treatment of pain is the most common.

Evidence is considered coherent and sufficient to conclude that acupuncture could be a useful non pharmaceutical tool for patients with occasional or frequent headaches. Some studies suggest that acupuncture could be at least as effective in the preventive treatment of migraines than drugs, and have less side effects. These studies conclude that acupuncture should be considered as a treatment option for patients who wish to use it.

Effects of acupuncture on arthritis compared to an absence of treatment were considered to be clinically relevant, even if authors suggest that the measured effects could be due to the placebo effect.

**With a limited level of proof** that requires more and better quality trials, it was also suggested that acupuncture could :

- be a useful complement to other therapies for the treatment of back pains.
- play a role in the management of pain during labor and delivery, and in the patient satisfaction with the way that pain is managed as well as in reducing the use of drugs.
- reduce pain associated with menstruation
- be more effective than an absence of treatment to alleviate neck pain.

Among the studies from which it is « impossible to draw firm conclusions », we can cite review on smoking cessation (40 trials and 4858 patients) and on medically assisted procreation (20 trials), both of which include more than 4000 patients, as well as studies on epilepsy and insomnia.

Data suggesting that there might be a beneficial effect of acupuncture beyond the prevention and treatment of pain, in the treatment of nausea and vomiting after chemotherapy or surgery. The report also mentions a large number of interventions for which « data was insufficient to either confirm or deny an effect of acupuncture »

The report notes that the trials on acupuncture that have been conducted in East Asia, which comprise the vast majority of some of the Cochrane reviews, have been particularly questioned. The most frequent biases cited are related to the withholding some of the information, to the use of inappropriate control groups or to small number of patients, resulting in an overestimation of the effect of treatment.

#### **4. Are there unwanted side effects to acupuncture?**

For the WHO in 1999, arthritis is one of the diseases for which the effectiveness of acupuncture has been demonstrated by controlled trials and the Haute Autorité de Santé en France (2007) considers that « the effectiveness of acupuncture does not seem to have been demonstrated in the case of arthritis, when considering the available data in the literature »

In 2002, WHO, relying on an analysis of clinical trials on acupuncture, published a list of 28 symptoms or conditions for which it was considered that data was enough to conclude that acupuncture was an effective treatment. Among the evaluated actions, acupuncture got a positive evaluation as a adjunct treatment, as an acceptable alternative or as part of a comprehensive care program with recommendations for the following indications : functional urogenital diseases such as enuresis , anxiety and depression syndromes, help with neuro-motor recovery after a stroke, some facial paralysis, diseases to allergic component (asthma, rhinitis), digestive functional disorders (nausea and vomiting), addictive behaviors (smoking in early weaning), alcoholism (adjuvant) and addiction (adjuvant, excluding heroin addiction.)

For its part, the Académie nationale de médecine (France) believes that "in the present state of knowledge, acupuncture can bring benefits to patients suffering from lower back pain or chronic neck pain, migraine or tension headache, osteoarthritis of the lower limbs, epicondylitis, pregnant women experiencing lower back or pelvic pain during childbirth and to prevent nausea and vomiting induced by cancer chemotherapy. Its usefulness in fibromyalgia is uncertain. Its effect in other indications is not excluded, but is not shown."

In its 2013 report the Académie suggests that the placebo effect is the most plausible mechanism of action of acupuncture but considers that questions about the specificity of the mechanism of action "does not question the favorable effects of acupuncture as it remains, for the considered disorders, statistically better than abstention from treatment or even to an active treatment."

"Recommendations of best practice" (RBP) are also defined by the Haute Autorité de la Santé (HAS, France) as "proposals methodically developed to assist practitioner and patient in seeking the most appropriate care in a given clinical situation ". They are part of a quality improvement target and safety of care including rheumatoid arthritis, nausea in pregnant women, chronic daily headache, chronic low back pain. In other areas acupuncture is not recommended; is the case for the treatment of acute lower back pain or when the data of

the literature does not demonstrate its effectiveness as in the artificial induction of childbirth labor, the prevention and treatment of post-operative surgical pain oral or migraine.

## 5. What are the conclusions and take-away message of this report?

In trials evaluating acupuncture, blind testing effect is maintained using a control treatment that mimics an acupuncture session. This placebo intervention must by definition be credible enough that patients can not recognize the dummy acupuncture from true acupuncture, while being provided with the smallest possible physiological effects so that the difference between groups do not underestimate the specific effect of treatment.

Factors that influence the physiological effects of acupuncture with needles would essentially be the point location and stimulation of the needle through the puncture depth, manipulation of the needle and the duration of stimulation). By lying outside effective acupuncture points or by inactivating the stimulation, there are different protocols for sham acupuncture. The most commonly encountered in clinical trials are:

- "Fake acupuncture" puncture in dummy points outside of the acupuncture points and meridians
- "Nonspecific acupuncture" puncture to acupuncture points not shown for the treated pathology
- "Minimal acupuncture" superficial puncture (<4 mm penetration) and outside of acupuncture points
- Technical tools: such as placebo needles, or other technical devices which renders ineffective stimulation (non-functional laser or needles "assumed to be electrical" without current or non-magnetic "magnets" ...) and ensuring blind patient behavior and sometimes the acupuncturist.

These control techniques, however, have significant methodological limitations. So some might induce an overestimation of the specific effect of the treatment, for others, almost all of these techniques do not allow neutrality of the therapist, finally, the credibility of superficial punctures is sometimes questioned because of the lack of the "Qi" sensation which is felt as a tingling, irradiating sensation.

## 6.

Acupuncture is a therapeutic approach widely practiced in France which can provide an alternative response to frequent and debilitating health problems, and for which there are recognized training.

Overall the report emphasizes that the benefits suggested in analyzes of available studies must be interpreted with caution. The heterogeneity of the literature, because of their protocol and their methodological quality is such (more than three quarters of studies included in the Cochrane review are inconclusive), it is difficult to include them in a comparative analysis to draw firm conclusions. This report therefore describes a very temporary state of the clinical evaluation of acupuncture.

It is impossible to say today whether acupuncture, whatever the indication, is most effective when it is carried out "in the rules of art", or in areas of random pictures or simply by simulating the punctures.

It is thus still difficult today to have a precise opinion with respect to the effectiveness of this treatment:

- For many chronic pains or to treat nausea and vomiting, acupuncture has superior efficacy to a lack of care.
- As for the many other indications, it is difficult to be so clear.

## 7.

Side effects can potentially be serious, but their frequency is rare, at least in the Western context of a well-controlled practice, especially in comparison with the adverse effects of medicinal products commonly used to treat the same disorders.

This is mainly local pain at needle insertion or upon stimulation. Other effects have been reported: severe skin contusions at acupuncture points in a patient on anticoagulant, bleeding or bruising at stimulation points, headaches (usually slight, can sometimes be moderate), feeling tired, nausea and fainting during treatment with electro-acupuncture.

Other problems result mainly of either a hygiene problem - the hands of the practitioner and / or the use of non-sterile Needle - or a deviation from the angles and depths of puncture codified for more than two millennia.

The Collège Français d'Acupuncture et de Médecine Traditionnelle Chinoise has proposed a series of 13 recommendations for good medical practices on the risk of infection in acupuncture, available online at their website.  
(<http://www.cfa-mtc.org/stephan-recommandations-FINAL.pdf> [see <http://www.cfa-mtc.org/stephan-recommandations-FINAL.pdf>])

## 8.

It is important to consider the impact of economic issues on the methodologies currently used to evaluate care, particularly medical care for which the economic and conceptual model is radically different from that in the industrialized world of drugs.

In all studies, the addition of acupuncture to usual care was accompanied by an increase in health care costs, primarily related to professional fees for acupuncturists. A measure of quality of life after medical treatment seems to be favorable to the accompaniment acupuncture but even if this measure of quality of life had not been made in a blind, neutral way, the differences were moderate.

In all the German studies on pain, there is a sufficient difference in cost between a treatment "with" and "without" acupuncture and concluded that acupuncture seems a cost-effective treatment according to international thresholds. It is based on these studies that the German Federal Committee decided in 2006 to reimburse acupuncture treatments in case of low back pain and osteoarthritis, increased spending per patient appearing offset by lower medication costs. Consultations for other conditions such as headaches, migraines or allergies remained the responsibility of the patient.

Obviously the ability to generalize these data is very limited due to the non-standardization of the costs of acupuncture.

## 9.

As some commentators expressed in the report, in a context where the data is so abundant, acupuncture indeed calls into question the Western scientific medicine by the destabilizing nature of the theory of acupuncture. In addition, it calls for a closer look at the assumptions that currently underpin the evaluation of treatment of Western medicine.

Paradoxically, the methodology used today to assess the care is not based on physiological data but mainly on clinical and statistical studies that directly observe the effects on patients based on strict protocols where treatment is given to patients blind and compared to placebo treatment.

However it is questionable to what extent this evaluation model can be applied to a completely different therapeutic approach that is heavily customized (the practitioner adapts its care according to the patient that he has in front of him)?

- Should the effectiveness of acupuncture be assessed in comparison to no treatment or to sham acupuncture?
- Should we try to determine the specific effect of acupuncture or the overall effect of the therapy, which can include effects directly related to the patient-therapist relation?
- Should we test the efficacy of acupuncture or the relevance of the theory that underlies it?

Chinese government investment to fund clinical research on Chinese medicine and the emergence of major European research gives hope in a not too distant future of evidence that will allow a better risk-benefit analysis of acupuncture.

## 10.

The report was submitted for comments before publication and these are included in the final publication. The reality of the heterogeneity of the studies evaluated has led some reviewers to judge that the data was indeed adequate. Others highlight the limits of studies that are related to the particular character of the evaluated treatment, which is not based on traditional scientific bases, and that there is no conclusive evidence of the effectiveness of acupuncture. One of these reviews states in particular that the analysis should include all the documented information and not solely the information analyzed by statistical reviews of the Cochrane Collaboration. By limiting the evaluation of acupuncture to the conclusions of a single incomplete source, it considers that there is a high risk of bias in the interpretation of data.

In another comment, it is also noted that the Cochrane reviews uniformly conclude that the evidence for the effectiveness of acupuncture compared to placebo acupuncture is either missing or insufficient and that the acupuncturists lobby seems to have taken precedence over scientific rigor. It is therefore urgent to create a working group of acupuncturists and specialists tests for testing on the scale imposed by the scope of practice.

Another commentator believes that what should be extracted from the Cochrane Collaboration reviews is that a quarter of the studies are conclusive.

The particular nature of care was also emphasized to highlight the difficulty in applying double blind/placebo evaluation methods which are usually used in Western medicine.

Finally, for another commentator, the work done with the greatest methodological rigor by the INSERM researchers must be considered as the reference for the future of medical acupuncture in France but also in the European Union and all countries linked to it.