Acupuncture and Electroacupuncture:

Evidence-Based Treatment Guidelines

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These guidelines have been adopted or endorsed by:

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Acupuncture and Oriental Medicine National Coalition
American Academy of Medical Acupuncturists
California Society of Physical Medicine and Rehabilitation
California State Oriental Medicine Association
Council of Acupuncture and Oriental Medicine Associations
Foundation for Acupuncture Research
National Oriental Medicine Accreditation Agency
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1. Introduction

The scientific investigation of complementary medicines and the demand for more natural and less invasive forms of medical interventions has resulted in an increased review of all medical interventions. This has resulted in a desire to develop universal, evidence-based, "best practice" medicine. Only by comparing all available options can the most effective and efficient treatment protocols for each and every condition of ill health and disease be identified.

Operating under the microscope of modern medicine, practitioners of traditional Chinese and Oriental medicine have been upgrading their own knowledge, skills and protocols. The principles and knowledge of traditional Chinese and Oriental medicines are consistent with modern science and can be applied in a systematic manner, as demonstrated by the successful use of acupuncture throughout the world to treat a wide variety of health conditions.

The expanding coverage of acupuncture treatment by third party payer systems has resulted in a need for a more routine and standardized practice. Without ready access to professional standards of practice, many managed care organizations have been forced to rely upon staff to conduct medical literature reviews – which have often been poorly designed or inconclusive – and to develop in-house utilization standards that are based upon faulty science.

In recent years, medical researchers have come under increased scrutiny themselves, as statistical evidence demonstrates that the source of funding can skew results in favor of the interests of the sponsors. Therefore, medical research and statistical analysis have become more detailed in their own standardization, which has resulted in new studies on acupuncture and electroacupuncture that are more reliable and of better quality.

With increased demands by organized medicine, and with practitioners who are better adapted to the practice of integrated medicine, it has become incumbent upon the acupuncture and Oriental medicine professional community to develop evidence-based acupuncture and electroacupuncture practice guidelines that can be utilized by practitioners, patients, regulators, and third-party payers.

2. Statement of Purpose

Given the broad variations in the individual application of acupuncture and electroacupuncture, and given the availability of experts who believe that there is a scientific approach to the application of all forms of medical treatment, the Council of Acupuncture and Oriental Medicine Associations, a nationally-based organization, and the Foundation for Acupuncture Research, assigned respective committees to work jointly with the following directive:

To establish evidence-based best practice guidelines for acupuncture and electroacupuncture that can be utilized by practitioners, patients, regulators, and third-party payors to make health-related decisions that result in medically sound treatment approaches and that lead to effective and reproducible outcomes in the clinical setting.

3. Guideline Development

A. Background

Oriental medicine is a primary health care system recognized by the National Institutes of Health and the World Health Organization and legally viewed as a distinct branch of contemporary health care delivery throughout the world. Presently, about one-quarter of the world's population uses Oriental medicine. In various forms, Oriental medicine has spread to Japan, Korea, Southeast Asia, Europe, and the Americas. In the United States, some twelve million people currently go to Oriental medical practitioners. Out of the estimated $14 billion a year that Americans spend on alternative medicine, Oriental medicine accounts for $1 billion, 75 percent of which goes for acupuncture.[1] Nearly one in ten adults (approximately 20 million people) in this country has received acupuncture. While the total number of acupuncturists in each state varies widely, the number of practitioners nationwide is on the rise. According to the most recent survey of state acupuncturist licensing agencies, there were 20,750 active acupuncturist licenses in thirty-nine states in 2003, with California accounting for 38% of the total. [2] The integration of traditional and modern Oriental medicine techniques and modalities into contemporary health care renders it subject to commonly accepted criteria for evaluation of effectiveness, safety, and appropriateness of care.

B. Objective of These Guidelines

The intent of this document is to delineate guidelines that may be used to assist practitioners of acupuncture and electroacupuncture. It may also help third party payors and evaluators, health care administrators, judges and attorneys in resolving issues that relate to standards of care for acupuncture and electroacupuncture. It is intended that these guidelines lead to a more standardized approach to the application of acupuncture and electroacupuncture to various conditions of injury and ill health, in order to promote the appropriate utilization of these therapeutic interventions, and to ensure safe, effective, reliable, and cost effective care for the consumer. These guidelines serve an important role in ensuring the most adequate and appropriate health care to patients and injured workers, and provide the most cost effective health care for third party insurance payors in order to restore function and enable injured workers to return to work as quickly as possible. Acupuncture can be utilized in a variety of medical conditions and at different stages of disease processes, i.e. acute, sub-acute and chronic conditions. These conditions include pre and post surgical conditions, cases where patients have adverse reactions to medications, patients that are inappropriate candidates for surgical intervention or conventional care, failed surgeries, management of flare ups to chronic conditions, and to allow the patient to continue working at full capacity.

When the patient is an injured worker, it is the intention of these guidelines throughout to return the injured worker back to work and functional restoration as quickly and efficiently as possible. There is sufficient evidence available to show that injured workers recover faster when they are allowed to re-enter the workforce and work at capacities that are appropriate for their medical conditions. It is our opinion that the goal in any workers compensation system should always be to get the injured worker the treatment they need for recovery in the most

timely manner in order to allow for the return of that injured worker back to the workforce as quickly as possible.

C. Clinical Applications of These Guidelines

These guidelines are a set of recommendations on the use of acupuncture and electro-acupuncture (percutaneous electrical nerve stimulation or PENS) for neuromusculoskeletal conditions affecting all regions of the body. There is a growing body of evidence establishing the efficacy of acupuncture in treating neuromusculoskeletal conditions. While research supports the efficacy of acupuncture for many other conditions such as asthma, dental pain, nausea and vomiting, and other internal conditions, gynecological and psychiatric conditions, these guidelines make recommendations for conditions affecting the neuromusculoskeletal systems. Such conditions include, but are not limited to industrial or occupational injuries, sports injuries, auto injuries, personal injuries and other non–work-related injuries. These guidelines address frequency, intensity, and duration of treatment but do not make specific recommendations on styles of acupuncture, diagnostic methods, and point selection involved in the acupuncture treatments. The reason for this is due to the variety of effective acupuncture techniques currently being used in this country, and the fact that a particular patient may respond to one technique more readily than another. It is the responsibility of the practitioner to adopt the most effective technique and point selection for each patient's needs.

D. Scope of Acupuncture and Oriental Medicine

While acupuncture and electroacupuncture are used by a variety of medical professionals in various states in accordance with their laws, it is most commonly practiced by licensed acupuncturists. Acupuncturists' scope of practice varies from state to state and is regulated by the licensing bodies in each state. In states such as California, Florida, and New Mexico, it has been legislated that acupuncturists are primary care providers required to diagnose and treat medical conditions.

The scope of acupuncture and Oriental medicine commonly practiced in both Asia and the United States includes the treatment of numerous structural and organic dysfunctions with acupuncture (needling therapy, trigger point) and electroacupuncture (percutaneous electronerual stimulation, percutaneous neuromodulation therapy,, etc), as well as a wide variety of additional treatment modalities and procedures. These modalities and procedures include transcutaneous electroneural stimulation, therapeutic exercise and manipulation (Qigong, Taiji Quan, strength and aerobic training, neuromuscular re-education, myofascial release, trigger point therapy, joint mobilization, tui na, etc), injection of analgesics and sterile solutions, moxibustion and cupping, gua sha, cold and heat therapy (ultrasound, diathermy, infrared heat lamps, low-level infrared laser devices, hot packs), Chinese herbal medicine, diet, and nutritional prescriptions. It has been recommended that these guidelines be expanded in the future to include recommendations of some of these other therapies and procedures, and the treatment of a wider variety of health conditions.

E. Patients Views and Preferences

The critical importance of including patient views and preferences in the development of clinical practice guidelines is powerfully stated in a recent editorial in the Journal of Informed Pharmacotherapy:

"Evidence-based medicine (EBM) has been defined as "the integration of best research evidence with clinical expertise and patient values." Patient values are defined as "the unique preferences, concerns and expectations each patient brings to a clinical encounter and which must be integrated into clinical decisions if they are to serve the patient". (1) The integration of these three critical elements ensures that clinicians and patients can form a diagnostic and therapeutic alliance that will optimize clinical outcomes and quality of life. [3]

In 1999, the National Health and Medical Research Council of Australia produced a document entitled "A guide to the development, implementation and evaluation of clinical practice guidelines". [4](2) In this extensive publication, the authors state that one of the key principles for developing guidelines is that "guidelines should make provision for accommodating the different values and preferences of patients" and that guidelines should be developed using a "multidisciplinary approach that includes consumers..."

Over the past twenty-five years the acceptance of acupuncture, by both scientists and patients alike, has grown exponentially in the United States and other Western countries. In 1991, Congress mandated the National Institutes of Health to set up the Office of Alternative Medicine. It has been estimated that by 1993 over 15 million Americans had experienced acupuncture treatment, performed by over 8,000 practitioners. [5]***)*** A 1993 article in ***JAMA*** by Eisenberg revealed that one to two-thirds of American patients used Complementary and Alternative Medicine (CAM) and spent $13 billion annually. In 1997, it was estimated that this figure had doubled to $27 billion, comparable to out-of-pocket expenses for mainstream physicians. In 1999, the World Health Organization published a paper titled: Acupuncture: A Review and Analysis of Controlled Clinical Trials, in which over 230 controlled trials on common health conditions were assessed and conclusions made on the efficacy of acupuncture, including a list of diseases, symptoms or conditions for which acupuncture has been proved—through controlled trials—to be an effective treatment. (Appendix C)

In 1997, the NIH issued a statement based on the consensus of a group of experts in the medical field who considered over 2300 trials on acupuncture. The Consensus statement recognized acupuncture as a useful therapeutic intervention for a wide range of conditions. In 2002, Americans made more visits to CAM providers (some 600 million a year) than they did to medical doctors and spent more money out-of pocket on CAM providers than for conventional doctors - about $30 billion a year by recent estimates. [6] Acupuncture is one of the most commonly sought after treatments among CAM therapies and is gaining more and more acceptance as a useful therapeutic intervention for a wide range of disorders. Currently, nearly one in ten adults (approximately 20 million people) in this country have received acupuncture, and 60 percent say they would readily consider acupuncture as a treatment option, according to the findings of a national survey by the National Certification Commission for Acupuncture and Oriental Medicine. Nearly half (48 percent) of the individuals surveyed who had received

acupuncture reported that they were extremely satisfied or very satisfied with their treatment. Disorders of the bones, muscles, joints or nervous system (e.g. arthritis, headaches, or low back, neck or shoulder pain) were selected as the top reasons (58 percent) for seeking treatment. [7]

It is also important to note that there is a large Asian population, especially in certain regions of the U.S, such as California and New York, who regularly patronize Oriental medical practitioners. A recent survey of Chinese Americans revealed that first- and second-generation Chinese immigrants tend to use Chinese therapies at a rate of 44 and 42 percent respectively. In New York's Chinatown, rheumatism is the complaint for which Chinese Americans most frequently seek Oriental treatment. Chinese Americans in San Francisco's Chinatown most often use Oriental medicine for the treatment of rheumatism, bruises, and sprains. [8]

F. Cost Efficacy of Acupuncture

Although cost efficacy studies are relatively few, there are a number of studies suggesting the potential for vast savings to our healthcare system by avoiding surgeries, reducing expensive medical treatments and returning injured workers to work earlier has been well documented.

For example, in a study of 56 male patients who were being rehabilitated at a workers' compensation clinic for chronic low back pain (average duration 28.6 weeks), and who had already failed standard therapy, were randomly assigned to either continue standard therapy or receive standard therapy plus acupuncture. Standard therapy consisted of physical therapy, remedial exercises, and occupational therapy. Acupuncture, with electrical stimulation of the needles, was administered at variable sites depending on the location of the pain, for variable numbers of treatment sessions up to a maximum of 15, (mean 7/9), depending on response to treatment. Of the 29 patients that received acupuncture, 18 returned to their original or equivalent jobs; an additional 10 returned to lighter employment. Of the 27 who received only standard therapy, 4 returned to their original or equivalent jobs and 14 to lighter employment. The significance of this study is that this study showed that a relatively simple course of acupuncture added into a standard rehabilitation program for patients with chronic back pain was found to significantly improve the treatment outcome when compared to effects of the rehabilitation program administered alone. Many more of those who received acupuncture as supplemental care were able to return to their previous type of employment. [9]

In another study, 65 patients with pain, mainly of musculoskeletal origin, were offered treatment by an acupuncturist as an alternative to hospital outpatient referral. The cost of acupuncture treatment was compared to that of the referral that would have been made if acupuncture had not been offered. The acupuncture was found to have cost $21, 886.00 (London Exchange) U.S. dollars against the cost for hospital referrals of $53, 566.00. A minimum total saving for all patients was $27,832.00 giving an average saving per patient of $464.00. Additional hidden savings through avoiding further hospital procedures and expenditure on medication were not taken into account. The study concluded that "acupuncture in selected patients and when used by an appropriately qualified practitioner appears to be a cost effective therapy for use in general practice, reducing the need for more expensive hospital referrals." [10]

In another study 29 patients with severe osteoarthritis of the knee (42 knees), each of whom was awaiting arthroplasty surgery, were randomized to receive a course of acupuncture treatment or be placed on a wait list and receive a course of acupuncture treatments starting 9 weeks later. At the end of the study, 7 patients were able to avoid surgery, at a savings of $9,000 per operation. [11]

G. Historic Use of Acupuncture Guidelines in Managed Care

Acupuncture has been widely accepted by managed care organizations and workers' compensation systems across the U.S. for over two decades. Each individual third-party payer or managed care company has had their own internal guidelines for the use of acupuncture; however, in general, the recommendations on acupuncture treatment are fairly consistent from state to state. Our current guidelines are consistent with the guidelines being used today in managed care systems already in place in California including various managed care companies [12],[13] and the California Worker's Compensation system. [14],[15],[16],[17] It is significant to note that the Huang Di Nei Jing, an ancient classical Chinese text written over 2,000 years ago, makes specific recommendations on the frequency and duration of treatment that are consistent with the recommendations contained in these guidelines.

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[10] Lindall, Steven, Is Acupuncture for Pain Relief in General Practice Cost-Effective?**,** ***Acupuncture in Medicine*** December 1999 Vol. 17 (2)

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[12] American Specialty Health Plans of California. Clinical Guidelines. Acupuncture Provider Operations Manual July 2004 (4.1):30-50.

[13] HealthNet. Acupuncture for Pain Management, Policy Number 03-10-77. HealthNet National Medical Policy, October 2003.

[14] State of California Industrial Medical Council. Treatment Guidelines. Department of Industrial Relations, 1997.

[15] Aetna. Clinical Policy Bulletin 0135 , Acupuncture, 2004.

[16] Commonwealth of Massachusetts, Department of Industrial Accidents. Treatment Guidelines. 2004.

[17] State of Colorado, Department of Labor and Employment, Division of Workers Compensation. Medical Treatment Guidelines, 2003.

H. Systematic Review of Published Research

1. Methods

Interest in acupuncture research in the U.S. is relatively recent considering the thousands of years this procedure has been in use in China and Southeast Asia. Although there is an extensive amount of research in Asian language journals establishing the efficacy of acupuncture, most of these studies are not available in English. There are also issues of methodology and quality which complicate drawing on those studies for evidence. Therefore the decision was made to limit the search for evidence to papers written in English. The current literature on the efficacy of acupuncture available in English comes largely from research done in the U.S. and Europe in the past 30 years.

Methods used to search for evidence supporting or refuting the use of acupuncture and electroacupuncture for the neuromusculoskeletal conditions considered in these guidelines: Two different searches were done on MEDLINE/PubMed to identify two categories of studies. The first was done to identify the largest, most comprehensive or systematic reviews available on acupuncture using the following search terms: "acupuncture", limiting the search to reviews in English, on human subjects, covering all dates from 1998 (post-NIH) up to July, 2004. This search identified 375 reviews. The second search was done to locate high-quality positive outcome trials on acupuncture using the following search terms: "acupuncture or electroacupuncture", limiting the search to randomized controlled trials, in English, on human subjects, covering all dates up to July, 2004. This search identified 486 randomized controlled trials. The selection of reviews and randomized controlled trials to be included in the evidence for acupuncture to be considered in our recommendations was carried out using the selection criteria below. The full articles were located and the references and bibliographies of these articles were searched for other potential comprehensive reviews and randomized controlled trials that may have been missed in the original MEDLINE searches. These potentially useful reviews and randomized controlled trials were then screened and selected using the same selection criteria as applied previously.

2. Published Research Reviews

a. Selection Criteria and Results

For the first search, the most comprehensive reviews, overviews. and summaries done in English after 1997, were given priority and selected for review. It was the intention of the authors to draw upon the most comprehensive post-NIH overviews and reviews done to date as a basis for the current recommendations in order to ensure the most appropriate recommendations available and minimize the risk for biased conclusions. The inclusion criteria for the selection of these reviews and summaries were the following: 1) the review or overview was a review or a summary of other reviews (including systematic reviews) not individual trials, 2) conclusions were made on acupuncture for neuromusculoskeletal conditions, 3) the review or summary was done after 1997 (post-NIH), and 4) in the English language. The following reviews, overviews, and summaries met the inclusion criteria and were selected: Birch (2004), British Medical Association (2000), Tait (2002), Ernst (1999), and Linde et al. (2001),

Kaptchuk (2002). Linde et al. (2001) was a systematic review of the literature, Ernst (1999) was an overview of systematic reviews, and BMA (2000) was an overview of systematic reviews and meta-analyses. [18, 19,20,21,22,23]

b. Summary of Reviews on Acupuncture

The most comprehensive reviews were selected, intending to ensure that scientifically valid and commonly acceptable interpretations of research evidence would be presented. Unfortunately, the selected reviews consistently reported that their summary findings were often equivocal or inconclusive, based upon the inadequate application of basic research protocols (e.g., low sample size) in the original reviewed studies themselves. There was a notable exception and general agreement in all summaries and reviews that acupuncture is a relatively safe procedure.

The Advisory Council for these acupuncture treatment guidelines found itself in the difficult position of being unable to accept the findings of the "gold-standard" reviews at face value and would have to review and critique all of the foundation data and studies upon which the authors of the reviews had based their own unique conclusions.

The editors of these guidelines, its Advisory Council members, and the authors of the reviews themselves are unanimous in the recommendation for higher quality studies that should produce more consistent and statistically valid results. A summary of the published reviews follows.

The British Medical Association study concluded that the evidence derived from English-language published research for back pain and migraine was relatively strong, were uncertain if the positive effects for neck pain and osteoarthritis were sufficiently specific, and were uncertain on the value of acupuncture for tension headache, fibromyalgia and TMJ problems. (BMA, 2000) The Alberta study, on the other hand, concluded encouraging results for idiopathic headaches and fibromyalgia but inconclusive results for back pain and chronic pain, while being unable to establish effectiveness for neck pain. (Alberta, 2002) The Ernst study concluded there is reasonably good evidence for acupuncture to be effective in low back pain, that data are contradictory (both positive and negative) for neck pain., that evidence is negative, but not convincingly so, for osteoarthritis. (Ernst, 1999a) The Linde et al. study reported that conclusions regarding back pain were contradictory (positive and negative) while the evidence regarding neck pain was considered inconclusive. The largest review which focused on migraine and tension-type headache, drew cautionary but positive conclusions that acupuncture is effective for headaches. (Linde et al., 2002) The Kaptchuk summary of all systematic reviews to date concluded that the reviews most often report that trials of acupuncture efficacy for musculoskeletal conditions are equivocal (uncertain), or contradictory (both positive and negative) (Kaptchuk, 2002), and that it is difficult to draw conclusions from the non-specific nature of the musculoskeletal conditions being treated in many studies.

The research methodologies in the core studies that were the subject of the published reviews appeared so often flawed that they made it difficult for reviewers to reach any universal consensus, as broad variations in research methodology did not allow for equivalent comparisons, perhaps explaining the lack of published meta-analysis of the subject. The

conflicting results of the reviews left the advisory council for these guidelines to lend more weight to the NIH and WHO studies and to focus on the individual controlled clinical trials that could meet a higher level of credibility.

3. NIH and WHO Reports

Additionally, the NIH Consensus Statement (1998) and the World Health Organization's Acupuncture: Review and Analysis of Reports of Controlled Clinical Trials, (1999) were included to serve as an evidence basis due to their unique size, scope of the studies, the participation of a large number and variety of reviewers, and the sponsorship by highly credible, independent government and non-government agencies, even though these reviews did not meet the above inclusion criteria. The following represents a summary of the objectives and methods used in the development of their recommendations.

a. National Institutes of Health

The objective of the 1997 NIH Consensus Statement on Acupuncture was to inform the biomedical research and clinical practice communities of the results of the NIH Consensus Development Conference on Acupuncture. The statement provides state-of-the-art information regarding the appropriate use of acupuncture, and presents the conclusions and recommendations of the consensus panel regarding these issues. In addition, the statement identifies those areas of study that deserve further investigation.

The NIH Consensus was based on data presented to a diverse 12 member panel of experts representing various fields of medicine. Twenty-five experts from these various fields presented data on acupuncture to the panel. The literature was searched through Medline, and an extensive bibliography of over 2300 references was provided to the panel and the conference audience. Experts prepared abstracts with relevant citations from the literature. Scientific evidence was given precedence over clinical anecdotal experience. The paned developed their conclusions based on the scientific evidence presented in the open forum and the scientific literature. The panel composed a draft statement, which was read in its entirety and circulated to the experts and the audience for comment. Thereafter, the panel resolved conflicting recommendations and released a revised statement at the end of the conference. The panel finalized the revisions within a few weeks after the conference. (NIH, 1998)

The NIH Consensus statement on acupuncture was a benchmark in the assessment of acupuncture research up to 1997, and represents quite possibly the largest number of acupuncture trials in its recommendations than any other single review or consensus to date.

b. World Health Organization

The World Health Organization's Acupuncture: Review and Analysis of Reports of Controlled Clinical Trials was a review and analysis of 293 controlled clinical trials of acupuncture therapy, up until early 1999, with the following stated objective: "to provide a review and analysis of controlled clinical trials of acupuncture therapy, as reported in the current literature, with a view to strengthening and promoting the appropriate use of acupuncture in health care systems

throughout the world. Information on the therapeutic mechanisms of acupuncture has also been incorporated.

"This review is limited to controlled clinical trials that were published up to 1998 (and early 1999 for some journals), in the hope that the conclusions will prove more acceptable. Such trials have only been performed for a limited number of diseases or disorders. This should not be taken to mean, however, that acupuncture treatment of diseases or disorders not mentioned here is excluded.

"This publication is intended to facilitate research on and the evaluation and application of acupuncture. It is hoped that it will provide a useful resource for researchers, health care providers, national health authorities and the general public."

The report also notes: "It must be emphasized that the list of diseases, symptoms, or conditions covered here is based on collected reports of clinical trials, using the descriptions given in those reports. Only national health authorities can determine the diseases, symptoms, and conditions for which acupuncture treatment can be recommended." (WHO, 1999)

c. Summaries of NIH and WHO Reviews

The NIH Consensus Statement had limited conclusive findings, but noted that there are many conditions in which acupuncture might be useful as an adjunct treatment or an acceptable alternative or be included in a comprehensive management program, including HA, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, and carpal tunnel syndrome. It concluded: "The data in support of acupuncture are as strong as those for many accepted Western medical therapies…There is sufficient evidence of acupuncture's value to expand its use into conventional medicine and to encourage further studies of its physiology and clinical value (NIH, 1997)."

The WHO analysis was the most favorable on the efficacy of acupuncture in treating neuromusculoskeletal conditions. "This publication reviews selected studies on controlled clinical trials. Some of these studies have provided incontrovertible scientific evidence that acupuncture is more successful than placebo treatments in certain conditions. For example, the proportion of chronic pain relieved by acupuncture is generally in the range 55–85%, which compares favourably with that of potent drugs (morphine helps in 70% of cases) and far outweighs the placebo effect (30–35%) (***1–3***). In addition, the mechanisms of acupuncture analgesia have been studied extensively since the late 1970s, revealing the role of neural and humoral factors." The reports are first reviewed by groups of conditions for which acupuncture therapy is given (section 2). The clinical conditions covered have then been classified into four categories:

1. Diseases, symptoms, or conditions for which acupuncture has been proved—through controlled trials—to be an effective treatment.
2. Diseases, symptoms, or conditions for which the therapeutic effect of acupuncture has been shown, but for which further proof is needed.

3. Diseases, symptoms, or conditions for which there are only individual controlled trials reporting some therapeutic effects, but for which acupuncture is worth trying because treatment by conventional and other therapies is difficult.
4. Diseases, symptoms, or conditions in which acupuncture may be tried provided the practitioner has special modern medical knowledge and adequate monitoring equipment.

The following represents a partial list of a variety of diseases, symptoms, or conditions for which acupuncture has been proved, through controlled trials, to be an effective treatment (neuromusculoskeletal conditions are emphasized):

- Fibromyalgia (NIH)
- Headache (NIH)
- Knee pain
- Low back pain (NIH)
- Myofascial pain (NIH only)
- Neck pain
- Periarthritis of Shoulder
- Post-operative pain
- Sciatica
- Sprain
- Stroke
- Temporo-mandibular joint dysfunction
- Tennis elbow or epicondylitis

In regards to the efficacy of acupuncture on pain, the WHO made a specific statement:
"The effectiveness of acupuncture analgesia has already been established in controlled clinical studies. As mentioned previously, acupuncture analgesia works better than a placebo for most kinds of pain, and its effective rate in the treatment of chronic pain is comparable with that of morphine. In addition, numerous laboratory studies have provided further evidence of the efficacy of acupuncture's analgesic action as well as an explanation of the mechanism involved.

In fact, the excellent analgesic effects of acupuncture have stimulated research on pain. Because of the side-effects of long-term drug therapy for pain and the risks of dependence, acupuncture analgesia can be regarded as the method of choice for treating many chronically painful conditions." (WHO, 1999)

While the research reviews had inconsistent conclusions for many of the neuromusculoskeletal conditions considered, this is not unexpected due to the large number of trials each overview represents. However, it is significant that some reviews show promising results for low back pain, headache, osteoarthritis of the knee, lateral epicondylitis and fibromyalgia. The WHO study drew the most positive conclusions on the efficacy of acupuncture in managing various types of musculoskeletal disorders, including head, neck, shoulder, low back, elbow, lower extremities (sciatica) and knee, emphasizing its remarkable effects on alleviating pain anywhere in the body. All reviews agreed, in general, the methodology involved in many acupuncture trials was inadequate , sample size low, and that higher quality of trials was needed.

4. Randomized Controlled Clinical Trials

a. Selection Criteria and Results

For the second search, 486 randomized controlled trials were found matching the above search terms. These were selected based on the following criteria: 1) trials were randomized or quasi-randomized, 2) controlled (with the control consisting of one of the following: no treatment, treatment as usual, placebo, sham acupuncture, or active control), 3) experimental treatment consisting of either acupuncture or electroacupuncture (or PENS: percutaneous electroneural stimulation, or PNT: percutaneous neuromodulation therapy), 4) the trial was on a type of neuromusculoskeletal condition, 5) there was some degree of clinical effectiveness of the experimental therapy reported and 6) available in the English language. Trials which reported sufficient sample size (over 30 in treatment group), blinding, statistical significance and other inferential statistics were preferred for selection in order to maintain high quality of studies considered. A total of 72 high quality positive randomized controlled trials of acupuncture and electroacupuncture on various neuromusculoskeletal disorders were found to fit the above criteria. (See References: Research Abstracts)

A total of 72 randomized controlled trials supporting the efficacy of acupuncture for various neuromusculoskeletal conditions were found to meet the inclusion criteria. Many of these compared real acupuncture to sham acupuncture but often had a non-treatment control. Eleven positive randomized controlled trials were found for the head, including a large trial on chronic headache of over 400 participants recently published in BMJ. The study concluded: "Acupuncture leads to persisting, clinically relevant benefits for primary care patients with chronic headache, particularly migraine."

Fourteen positive randomized controlled trials were found for the neck. One of these had a sample size of over 177 patients and concluded: "Acupuncture is an effective short term treatment in patients with chronic neck pain." Another trial on chronic neck and shoulder pain on sedentary female workers with 6 month and 3 year follow-up concluded: "Adequate acupuncture treatment may reduce chronic pain in the neck and shoulders and related headache. The effect lasted for 3 years."

Three positive studies were found on the shoulder. One of these on rotator cuff tendonitis of 52 sportsmen, using a newly developed placebo needle, reached the following conclusion: "This study showed that needling is an important part of the acupuncture effect in the treatment of chronic shoulder pain in athletes."

Four positive studies were found on the elbow. One double-blinded randomized controlled trials published in Rheumatology in 2002, on 45 participants with 2 month follow-up concluded the following: "In the treatment of chronic epicondylopathia lateralis humeri, acupuncture in which real acupuncture points were selected and stimulated was superior to non-specific acupuncture with respect to reduction in pain and improvement in the functioning of the arm."

Only one high quality study was found on the hand/wrist. This double-blinded crossover study on carpal tunnel syndrome treated with low level laser on the acupuncture points found the following: "Significant decreases in MPQ score, median nerve sensory latency, and Phalen

and Tinels signs after the real treatment series but not after the sham treatment series. Patients could perform their previous work (computer typist, handyman) and were stable for 1 to 3 years." It concluded: "This new conservative treatment was effective in treating CTS pain."

The evidence for low back pain, especially chronic LBP, appears to be well-established by a high number of high quality studies. 23 positive randomized controlled trials were found on low back pain. One double-blinded RCT published in Pain in 2002, on 174 patients and 3 month follow up, concluded: "Acupuncture can be an important supplement of conservative orthopedic treatment in the management of chronic LBP." An RCT published in Rheumatology in 2003, on chronic LBP in the elderly concluded: "Acupuncture is an effective, safe adjunctive treatment for chronic LBP in older patients." Another trial published in 2003 on 52 patients treated with 12 sessions of electroacupuncture (EA) found a significant difference between the exercise plus acupuncture treatment group and the exercise only control group. It concluded: "This study provides additional data on the potential role of EA in the treatment of LBP, and indicates that the combination between EA and back exercise might be an effective option in the treatment of pain and disability associated with chronic LBP." One blinded placebo-controlled RCT on 50 patients with long-term (6 month) follow-up found "a significant decrease in pain intensities at 1 and 3 months in the acupuncture groups compared with the placebo group. There was a significant improvement in return to work, quality of sleep , and analgesic intake in subjects treated with acupuncture." The study concluded: "The authors found a long-term pain- relieving effect of needle acupuncture compared with true placebo in some patients with chronic nociceptive back pain."

Three positive randomized controlled trials were found on osteoarthritis of the hip. One of these concluded: "This trial supports the hypothesis that acupuncture is more effective than advice and exercises in the symptomatic treatment of OA of the hip."

Seven positive randomized controlled trials were found on the knee. One crossover trial on 73 patients with osteoarthritis of the knee published in Rheumatology in 1999, found significant differences on total WOMAC Scale at 4 and 8 weeks. There appeared to be a slight decline in effect at 4 weeks after cessation of treatment (12 weeks after first treatment). The study concluded: " These data suggest that acupuncture is an effective and safe adjunctive therapy to conventional care for patients with OA of the knee."

Only one study met the inclusion criteria on ankle and foot. This trial was done on 50 patients with diabetic neuropathic pain of the foot. The study concluded: "PENS (electroacupuncture) is a useful nonpharmacological therapeutic modality for treating diabetic neuropathic pain. In addition to decreasing extremity pain, PENS therapy improved physical activity, sense of well-being, and quality of sleep while reducing the need for oral nonopioid analgesic medication."

In regards to chronic and post-op pain, three postive randomized controlled trials were found to support the efficacy of acupuncture. In a comparative study of the analgesic effect of transcutaneous nerve stimulation (TNS), electroacupuncture (EA) and meperidine in the treatment of postoperative pain, 72 patients were randomly assigned to one of the three treatment groups. The study concluded: "In all surgery types, the postoperative pain relief presented by TNS and EA groups of patients was greater than that of meperidine treated group. But, the analgesia presented by the EA treated group of patients lasted longer and increased

with the repetition of treatment. The differences of behaviour of TNS and EA analgesia suggest that their neurochemical mechanisms may not be the same."

Two positive randomized controlled trials were found on fibromyalgia. In one trial published in BMJ on 70 patients with fibromyalgia, seven of the eight outcome parameters showed a significant improvement in the active treatment group whereas none were improved in the sham treatment group. Differences between the groups were significant for five of the eight outcome measures after treatment. The study concluded: "electroacupuncture is effective in relieving symptoms of fibromyalgia. Its potential in long term management should now be studied."

b. Summary of Controlled Clinical Trials

In summary, there has been much interest in researching certain regions of the body such as neck, low back or knee. For other regions, such as hand / wrist and foot / ankle, there is limited published available in the English language. This may be due to a number of reasons, such as lack of interest in researching these body regions or lack of funding available. However, acupuncture clinicians often do treat conditions affecting these body regions quite effectively. This is easily understood given our current understanding of the physiologic mechanisms of action involved in needling therapy (acupuncture) which are consistent in needling neurovascular nodes (acupuncture points) in all regions the body. (See Physiological Mechanisms of Action).

5. Summary of Research Evidence Used to FormulateGuidelines

Treatment recommendations for acupuncture and electroacupuncture for neuromusculoskeletal conditions were based on the conclusions of the NIH and WHO recommendations, a selection of high-quality positive outcome studies, the current understanding of the physiologic mechanisms of action involved in needling therapy which are consistent for all regions of the body, the consensus opinion of experts in the field on the efficacy of acupuncture in the treatment of various neuromusculoskeletal conditions, and the outstanding safety record of acupuncture therapy as documented in the literature.

I. Application of Research to Guidelines

1. Research Methodology Issues

As many of the overviews and summaries emphasize, there is a lack of high-quality research on the efficacy of acupuncture, often due to inadequate sample size. There are general considerations that affect the quality of all types of research. These considerations include insufficient sample size, heterogeneous study groups, high dropout rates, vague enrollment criteria, inadequate follow-up, use of inappropriate validated outcome measures, problems of matching study design to research questions and problems of inadequate treatment. However, there are many issues specific to acupuncture research that plague researchers and designers of

acupuncture studies, such as: inherent problems in the use of "sham" or "placebo"acupuncture, which is often sought in order to control for placebo and non-specific effects and the methods of selecting sham acupuncture points and using them for treatment.[24,25,26,27,28,29,30,31] There are problems in validating diagnosis and treatment for conditions treated and reporting these details.[32,33,34]

Descriptions of treatments are often inadequate, and fail to completely describe or control variables that are considered crucial in clinical acupuncture, including point selection; the gauge, type, materials and manufacturers of needles; depth, angle, and speed of insertion; type of stimulation (including amplitude, speed, direction, and repetition of needle manual manipulations, or mode and frequency of electrical stimulation); whether the ***de qi*** phenomenon is observed or required; and needle retention time. [35,36,37] There are problems in blinding practitioners and patients, especially in countries with populations who have experience in receiving acupuncture therapy.[38,39] There are problems in designing a trial which has a clear question it attempts to answer and a clear explanation of how the chosen design can answer that specific question.[40,41,42,43] There are problems of adequacy of treatment in acupuncture clinical trials.[44,45,46] All of these problems lead to difficulty in interpretation of clinical trials and systematic reviews of the acupuncture literature.[47,48,49,50,51,52]

As an example of the complexities involved in just one of these issues, we shall consider briefly some of the problems involved in comparing real acupuncture treatment with "sham" acupuncture treatment. Many of the most recent studies attempt to control the placebo effects and non-specific effects of acupuncture by using a type of "sham" acupuncture which is intended to mimic real acupuncture. The reasoning behind this is due to the documented placebo effects of acupuncture and the desire to eliminate these effects and the non-specific effects of the therapy. Trials without placebo control cannot be blinded and therefore typically score lower than on quality scales. Additionally, many of these "sham" types of needling methods involve needling the body at locations which are not classically-described acupuncture locations.

Often these 'sham' points are often only centimeters apart from the actual locations, which is inadequately distanced from the established point location. Sometimes, the exact same point location is used, with the only difference being that "shallow" needling is performed, instead of classical Chinese-style deep tissue needling. Shallow needling can also engage these same physiologic effects, and in fact, many acupuncture practitioners in this country use these same shallow needling methods that come from Japan and Korea, with very high success rates.

Furthermore, using "sham" acupuncture as a control for "real" acupuncture assumes an absence of common mechanisms and effects of needling at described acupuncture nodes vs. elsewhere on the body. However, considerable basic research suggests that needling ***anywhere*** on the body will provoke an acute local inflammatory defensive response which subsequently activates nociceptive and proprioceptive neural responses, with resulting inhibitory controls mediated through neural and vascular mechanisms (Kendall 2002).

Positive outcomes observed with "sham acupuncture" study arms should ***not*** be considered as calling into question the efficacy of acupuncture at classically described nodal locations. "Sham acupuncture" should instead be considered a study of the ***non-specific*** effects of needling

anywhere on the body. Classical Chinese medical theory and modern basic science research into acupuncture mechanisms both suggest that these non-specific effects of needling may themselves be clinically significant, although generally less potent and specific than acupuncture performed at classical locations. However, major Chinese medical texts prescribe needling at non-nodal sites for treatment of certain diseases, as well as a wide variety of needling techniques, including needling at muscle belly interfaces, local and radial puncture around disease sites, needling of tender or reactive points subjectively defined by the patient (***ah-shi*** points) and superficial subcutaneous pricking over wide areas of skin. Studies claiming to use "sham acupuncture" as a control must be reviewed with the consideration that the "sham" intervention may in fact be a classically prescribed treatment for the disease, or have predictable clinical outcomes, and sample sizes in "sham" studies must be carefully scrutinized for beta-type errors.

2. Drawing Conclusions from Acupuncture Research

In light of these problematic issues involved in acupuncture research it is very difficult to place much credibility in large reviews, such as systematic reviews or overviews of acupuncture research unless there is critical evaluation of the methodology involved in the trials considered. Most of the summaries and overviews considered in these treatment guidelines do not adequately assess the credibility of the individual trials reviewed in these reviews and systematic reviews. Therefore, the conclusions reached by these overviews is not as authoritative as it initially appears. Quality of evidence is established not by the quantity of trials or systematic reviews considered but by the credibility of the individual trials involved. It is therefore the opinions of the authors that it is of paramount importance to develop higher standards for acupuncture research and to place greater consideration to those individual trials that meet the higher standards of acupuncture research rather than to an overview or systematic review which does not make an appropriate critical evaluation of the evidence.[53,54,55,56,57,58,59,60]

3. STRICTA and Other Standards for Acupuncture Research

There has been general and broad agreement by the authors of these summaries and overviews that more important than conducting more reviews on the current available research, is the need to develop higher standards for the development and reporting of trials on acupuncture. Some recent attempts have been made to address these issues.

In 2002, the STRICTA Recommendations (Standards for Reporting Interventions in Controlled Trials of Acupuncture) were developed by researchers and evaluators of trials on acupuncture with the intention of setting a standard for the proper reporting of acupuncture trials. (STRICTA, 2002) These recommendations were published by the editors of several journals of alternative medicine as part of their Instructions to Authors. Below is a summary of their recommendations on reporting of acupuncture trials:

1. Acupuncture rationale: clear explanation of explicit rationale for chosen treatment, (diagnosis, point selection, treatment procedures, etc.)

2. Needling details: specific point locations, unilateral vs. bilateral, number of needle insertions, depth of insertion, specific responses to needling, stimulation techniques, needle retention time, types of needles used, gauge, length, material, etc. For EA or PENS, current, amplitude, frequency must be reported.
3. Treatment regimen: total number and frequency of treatment should be reported.
4. Co-interventions: use of moxibustion, cupping, Chinese herbs, etc. must be reported as well as self-help treatments and lifestyle advice.
5. Practitioner background: duration of relevant training, length of clinical experience, details of expertise in treating the specific condition being evaluated.

Control interventions: the choice of control and its intended effect should be presented and justified in relation to the research question and methodology. Care must be taken to describe what the sham acupuncture is intended to control for. Control procedures involving invasive sham needling (invasive needling near acupuncture points, or shallow needling, etc.) will evoke a neurophysiologic response. The credibility of the control needs to be tested and reported. A precise description of the control intervention itself should be reported.

Recently, a more exhaustive list of 45 criteria for reporting of acupuncture trials was recommended by Birch in order to ensure adequate research design and reporting of acupuncture trials. [61] Below is a partial list of these criteria:

1. Clear statement of study question, how chosen design can answer the question and citation of relevant literature.
2. Homogeneity / inclusion and exclusion criteria presented.
3. Randomization.
4. Blinding patients.
5. Blinding evaluator.
6. Adequate sample size.
7. Sample size calculations based on data, not estimates.
8. Adequate description of acupuncture procedure.
9. Acupuncture training stated.
10. Appropriateness of the “sham” control treatment.
11. Controlling for the non-specific effects of treatment through appropriate assessments.
12. State clearly what style of acupuncture is being tested and provide clear documentation of that style (ie: points, needling technique, etc.)
13. Follow-up of 3 months or more after treatment.
14. Endpoints described.
15. Follow-up data presented.
16. Assessment of dropout patients and assessment of data.

4. Understanding Research Design

Although these criteria are important, an understanding some basic research design theory is essential if they are to be appropriately applied. The criteria do not apply equally to all studies. The specific challenges to the validity of a study depend on the conclusions that have been reached.

With respect to acupuncture, findings may be positive (e.g., "Acupuncture is superior to treatment X on scale Y."), negative (e.g., "Treatment X is superior to acupuncture on scale Y."), or inconclusive (e.g., "No significant difference was found between acupuncture and treatment X on scale Y.").

Both positive and negative findings are susceptible to statistical Type I errors (claiming a treatment has an effect when, in fact, it does not). Inconclusive findings are susceptible to statistical Type II errors (failure to detect a real effect). Design failures that can lead to a Type I error are different from those that can lead to a Type II error. Table 1 provides a convenient summary of these issues.

Table 1. Design failures that can effect Type I and Type II errors.

Type I (Claiming an effect is real when it is not: a false positive or a false negative result)	Type II (Failing to detect a real effect: a false inconclusive result)
α level chosen	α level chosen
Non-random assignment to treatment groups	Non-random assignment to treatment groups
	Inappropriate controls
	Inadequate sample size
	Insufficient power

The α level (sometimes called the significance level) is the risk the investigator is willing to take of making an error in concluding that an effect is real. For example, the phrase "$\boldsymbol{p} < .05$" implies that the investigator has concluded that there is a treatment effect, and the probability he or she is wrong is less than .05. The phrase "$\boldsymbol{p} < .01$" implies that the investigator has concluded that there is a treatment effect, and the probability he or she is wrong is less than .01.

The α level can impact both Type I and Type II errors. An α level that is set too high (e.g. $\boldsymbol{p} < .10$) increases the likelihood of a Type I error, while an α level that is set too low (e.g., $\boldsymbol{p} < .001$) can increase the likelihood of a Type II error.

It is important that the α level not be confused with the magnitude of the effect. The α level states the probability that claiming the existence of a positive or negative effect is wrong. It is a logical consideration. Magnitude of effect refers to impact or importance of an effect.

Some reviewers believe that a more stringent significance level (e.g., $\boldsymbol{p} < .01$) implies a stronger effect than a less stringent one (e.g., $p < .05$). This is not necessarily true. It is possible to have a statistically significant, trivial effect. For example, a test of a medication to reduce blood pressure may produce $\boldsymbol{p} < .001$. However, if the magnitude of effect is a blood pressure reduction of 3mmHg/3mmHg, it can hardly be called clinically important.

In older studies, indication of the significance level was considered sufficient. There is now a growing tendency to report both significance levels and effect sizes. The addition of this information is a valuable asset in gauging the real-world importance of a finding.

Random assignment is an important consideration for both Type I and Type II errors. This issue is most frequently encountered when intact groups are selected for comparison. For example, if a sample that has had acupuncture is compared to a sample that has had medication, any characteristic that differentiates the two groups may be the cause of a positive finding. Perhaps most of the acupuncture sample consists of women while most of the medication sample consists of men. It may be that the acupuncture group had less serious problems than the medication group. Possibly, the acupuncture group was more motivated to seek relief than the medication group. In short, any plausible alternative hypothesis may account for the results as well as the hypothesis that acupuncture is responsible for the positive finding.

On the other hand, non-random assignment can obscure a positive finding and produce a Type II error. If a sample that requests acupuncture is compared to a sample that requests medication, belief in treatment effectiveness is confounded with the treatments and may be responsible for an inconclusive finding.

If subjects are not randomly assigned to treatment groups, the investigator is faced with the impossible task of demonstrating that the only difference between groups is the treatment. If assignment is random, the groups may still have differences other than the treatment, but the probability that this is true is controlled by the α level.

Inappropriate controls generally have an effect on Type II errors. Inappropriate sham controls, as described above, are relevant only if the findings are inconclusive. They have the effect of reducing the apparent difference between treatment and control groups. If the findings are positive (or negative), obviously the treatment effect is sufficient to overcome the impact of the sham control.

Statistical power is the likelihood of detecting a real effect. It involves several variables. The first is the magnitude of the effect. All other things being equal, large effects are easier to see than small effects. Thus, analyses for large effects are more powerful than small effects.

Sample size is another component of power. It is easier to detect an effect with a large sample than it is with a small sample. Because of the widespread misunderstanding of the impact of sample size, some discussion of this issue is warranted.

Consider two studies. The only difference between these studies is that one has a sample size of 10 subjects per group (Study A) while the second has a sample size of 100 subjects per group (Study B). Assume that both studies have positive findings ($\boldsymbol{p} < .01$).

It is tempting to conclude that Study B is more impressive than Study A and it should be given more weight. Technically, these studies should be given equal weight. They both produce the same conclusion, and the probability that this conclusion is wrong ($p < .01$) is identical in both studies.

In fact, a good argument can be made that Study A is more impressive than Study B. Because it is easier to detect an effect with a large sample size than with a small one, the magnitude of effect found by Study A must be larger than the magnitude of effect found by Study B.

One frequently encounters statements in reviews of the literature such as, "The results were positive, however they need to be confirmed by studies with larger sample sizes." Unfortunately, such statements are nonsense. If a study finds positive results, obviously the sample size was large enough to demonstrate the effect. While replication is always a good thing, sample size is not the issue.

These reviewers are probably confusing sample size with adequacy of sampling. If the subjects do not represent the desired population, the external validity of the study (i.e., the ability to generalize) may be called into question. The issue of sample size is related to the internal validity of the study (i.e., whether an effect has been demonstrated). Although these issues are frequently confused, they are separate considerations with different logical implications.

In sum, there are different criteria that should be applied to the evaluation of studies that yield positive or negative results on the one hand, and those that yield inclusive results on the other. Issues such as α level and non-random assignment of subjects are legitimate grounds for criticism for studies that yield positive or negative results. Issues such as power and sample size are irrelevant. These issues are of concern only when the results are inconclusive.

The other criteria described by Birch are relevant to all acupuncture studies. Two of them are of particular importance and they merit special attention.

The assessment of dropout is usually called "attrition" in the research design literature. Failure to attend to attrition in a study can lead to dramatic and, sometimes, dangerous conclusions.

Consider a randomly assigned double blind study of a treatment against a placebo control. The issue is whether the treatment is superior to the placebo with respect to pain level, measured on a scale from one to seven. Assume that the treatment has no real effect on the condition, but it has noxious side effects. Because of these side effects, half of the subjects in the treatment condition drop out. The pain level of the subjects who drop out is more severe than those who remain. They are unwilling to tolerate the side effects when they are getting no relief. There are no dropouts in the placebo condition.

Before the study, pain levels are as follows and the mean pain level is 3.5 in both groups.

Placebo Group	Treatment Group
1	1
2	2
3	3
4	4
5	5
6	6
Mean = 3.5	Mean = 3.5

When the study is complete, the results are:

Placebo Group	Treatment Group
1	1
2	2
3	3
4	Dropout
5	Dropout
6	Dropout
Mean = 3.5	**Mean = 2.0**

It appears that pain level has been reduced in the treatment group with no apparent change in the placebo group. The treatment group now shows a pain level of 2.0, while the pain level in the control group has remained at 3.5. The reason for this unfortunate result is that treatment group mean has been calculated only on those with the lowest pain levels. The placebo group mean has been calculated on all placebo subjects. In fact, the treatment has had no impact on pain.

This is one of many illustrations of this problem. The point is that any study in which dropouts occur, there must be a demonstration that the observed effects are due to the treatment and not to a dropout artifact.

The second issue is the importance of follow-up studies. The usual reason for a for a follow-up study is that an effect may be only temporary. While it may appear strong at discharge, it diminishes over time.

It is not generally recognized that the opposite may also be true. A treatment that does not appear successful at discharge may have latent effects that show up only on follow up. This was the case, for example, in Karon's work on psychotherapy in schizophrenia. Medication produced superior results to psychotherapy when measured at discharge. However, when measurements were taken at follow-up, the conclusion was reversed. Psychotherapy was shown to be superior to medication in the long run. Clearly, the inclusion of follow-up controls is important in the evaluation of any medical intervention.

It is the intention of the authors to conduct a critical evaluation of the acupuncture literature adopting higher standards such as those described above which takes into account the issues mentioned in the previous section of acupuncture methodology and to incorporate this critical evaluation into the future recommendations of evidence-based treatment guidelines.

J. Formulation of Recommendations

1. Expert Advisory Panel

Participants in the Advisory Council included members of the Foundation for Acupuncture Research, representatives from the Council of Acupuncture and Oriental Medicine Associations,

Acupuncture and Oriental Medicine National Coalition (and its Florida Chapter), California State Oriental Medicine Association, California Acupuncture Medical Association, California Alliance of Acupuncture Medicine, United California Practitioners of Chinese Medicine, Acupuncture Industrial Medicine Society, National Oriental Medicine Accreditation Agency, National Board of Acupuncture Orthopedics, the National Guild of Acupuncture and Oriental Medicine, and the Traditional Chinese Medicine Association and Alumni, Inc. Participants were primarily licensed acupuncturists, but included licensed physicians, nurses, chiropractors, physical therapists, psychologists, and massage therapists.

a. Communications and Meetings

The formulation of the treatment recommendations were made by communication through phone conferences, electronic mail, and occasional face-to-face meetings. Over thirty such meetings were conducted, during which discussion took place on various issues regarding the content of the guidelines, including the recommendations for treatment.

b. Decision-Making

Decisions were arrived at by consensus among participants following discussion of the issue in question. When there was disagreement on an issue, open discussion was encouraged, then the issue would go to the editorial committee, and then to an executive committee for final decision.

2. Selection of Health Conditions

The health conditions initially considered for review in these guidelines were selected because of their generally recognized legitimacy in the professional community, as well as among insurers and governmental agencies, and for which there was sufficient documented research to support their inclusion. Specifically, the review of neuromusculoskeletal conditions were reviewed first, as they account for the bulk of acupuncture and electroacupuncture treatments given in the United States. Other conditions for which acupuncture is known to be effective, such as for menstrual cramps, will be considered in future revisions.

3. Determining Frequency and Duration of Treatment

Acupuncture has been used for thousands of years, with consistent treatment protocols, however at this time the research literature does not address specific recommendations on frequency and duration of treatments for specific conditions. This type of research (ie: comparing different frequencies and duration of treatments or point selection for specific conditions) still needs to take place. However, there are treatment guidelines in use in various managed care organizations and insurance payor systems which are fairly consistent with the recommendations made in these guidelines. The recommendations contained in these guidelines appear to be consistent with a large number of experienced acupuncture providers, and treatment guidelines currently being utilized by health care administrators and insurance payors in the state of California and other states at the national level.*

K. Implications of Guideline Implementation

1. Organizational Considerations

There are a number of organizational barriers that will need to be overcome to implement these guidelines. These include a limited understanding and awareness of the efficacy and therapeutic benefit of acupuncture in treating neuromusculoskeletal conditions in acute, sub-acute and chronic stages, and the accompanying skepticism of the medical value of acupuncture. Consequently, most medical providers do not consider acupuncture as a primary modality for treating neuromusculoskeletal conditions. All too often acupuncture is used as a last resort for pain management when all other therapies have failed.

The delay of appropriate therapy can lead to delayed recovery, reduced quality of life, inability to work, preventable surgeries, expensive tests, chronic pain, increased risks of side effects due to pain medications or anti-depressants, long term rehabilitation, treatment that may have marginal beneficial results and perhaps irreparable complications. This in turn leads to increased costs to insurance carriers to provide long term medical treatment for chronic conditions which could otherwise be avoided. Educating decision makers of the benefits, safety and efficacy of acupuncture applied earlier in the treatment of injured patients will ensure the most appropriate and effective treatments for the patients.

2. Cost Considerations

The related cost implications are negligible. An educational program geared towards medical personnel and case managers (decision makers) already exists. These guidelines will simply supplement or replace existing printed material, web references and resources delivered on a monthly or quarterly basis. Face to face interaction between practitioners and the medical decision makers in the form of seminars and lectures will guarantee that the information will be delivered, received, understood and applied in the most appropriate manner. Members of the acupuncture profession are available to perform this task.

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4. Acupuncture

A. Introduction

The historical term for acupuncture is the Chinese term "cizhi" which translates as "needling therapy." The primary tools utilized by practitioners of Chinese or Oriental medicine is "zhenjiu" referring to both acupuncture needles and a material that used in a heating therapy known as moxibustion. Moxibustion is the burning of the herb ***Artemisia vulgaris*** (Chinese mugwort) which is used to provide localized burned on or over the skin for purposes of providing heating therapy over specific nodes or localized areas. The inclusion of moxibustion in the traditional historic definition has been codified into law in a number of states. In California, where the practice of acupuncture has been independently licensed since 1976, acupuncture is:

> ***"the insertion of needles to prevent or modify the perception of pain or to normalize physiological functions, including pain control, for the treatment of certain diseases and dysfunctions of the body and includes the techniques of electroacupuncture, cupping, and moxibustion."*** [62]

Ancient Chinese texts described the continuous circulation of blood, propelled by the heart, and containing vital air (***qi***) that had been extracted from the air by the lungs, and nutrients that had been derived from food, and were circulated through branching vascular systems to the flesh and organs. The classic textbook on Chinese Medicine, Huangdi Neijing (C. 300 BCE) detailed the total of contemporary knowledge about human physiology and anatomy at that time, based upon centuries of comparative symptomatic observation and dissections, respectively, that had been passed on and advanced from generation to generation through direct apprenticeship.

The Western interpretation of the Chinese concept of pathways in the body called channels, pathways, vessels, or conduits, through which a vital force (Qi) circulates, has been largely misunderstood as being esoteric, paranormal, and unscientific. However, further inspection has demonstrated that many of the pathways and points mapped by the early Chinese physicians actually correspond to blood and lymph vessels, central and peripheral nervous systems, myofascial distributions, neurovascular nodes, neuromuscular attachments, and motor points.

Scientific studies on acupuncture along with recent advances in neuroscience are providing a physiological basis for explaining the mechanisms involved. Acupuncture is now thought to works primarily through interaction with the spinal afferent processing system, involving somatic nociceptive (pain), proprioceptive (muscle static load, length and position), and autonomic fibers, as well as other nerves of the body that provoke local, spinal, and centrally mediated control. The principal effect of this descending control is to restore autonomic balance (homeostasis), restore blood flow, resolve spasms, and to reduce pain. [63],[64],[65]

Acupuncture needles most commonly in use are stainless steel, pre-sterilized, and pre-packaged for safety and convenient use. Acupuncture needles are very thin, typically 0.15 to 0.30 mm in

diameter (26 to 40 gauge), and generally 1 to 6 cm in length. Certain special-use needles may be longer or shorter.

Acupuncture needles are typically inserted 0.5-5 cm deep, placed perpendicular or angled to the skin. Depth and angle of insertion depend upon the thickness of the tissues, local anatomy, and target site. In addition to selecting the proper needle insertion locations, the specific technique usedto insert and stimulate the needle has an influence on the desired outcome of the treatment. There is commonly a sensation of numbness, tingling, electrical sensation, fullness, heaviness, distension, soreness, warmth, or itching that may be felt around an acupuncture needle - a sign that nerve fibers are being activated.

Various alternative methods have been tried to simulate acupuncture needles. When an electrical current was first added to the inserted needles, percutaneous electrical nerve stimulation (PENS) or electroacupuncture (EA) was created [63]. Low-level (cool) lasers have been tried to stimulate acupuncture points. Acupressure, which uses simple manual pressure or mechanical vibrating devices has been applied to simulate acupuncture, or substitute for it. Infrared heat lamps, ultrasound, electrical heating pads, diathermy, and other devices have been used as a substitute for moxibustion. Acupuncture, electroacupuncture, and moxibustion have many variations.

B. Physiological Mechanisms of Acupuncture

The mechanisms by which needling therapy works are now well understood, at least to the point where this information is applied. The physiologic effects of needling therapy direct restorative processes to any particular part or articulation in the body to address all neuromusculoskeletal and pain conditions. This approach permits application of consistent treatment protocols to obtain consistent clinical outcomes. This approach will enhance the quality of future outcome studies.

Acupuncture works by initially causing minute tissue irritation, which triggers a complex localized neurogenic inflammatory reaction through an interplay of the blood coagulation and immune response mechanisms. The reaction is further sustained by axon reflexes involving the local afferent nociceptive nerve fibers. The nociceptive and resulting proprioceptive signals (group II static load fiber) activates spinal afferent processes which direct restorative descending control signals to the area. The amount of tissue trauma induced by strength of stimulation and the retention time of needle insertion have an influence on the characteristics of the net reaction needled.

Mechanisms of needling bring about restorative effects which involves superficial tissue reactions, sensory systems, vascular system and related nerves, viscerosomatic relationships, and central nervous system. The CNS provides descending control to regions of the spinal cord that mediate inhibition of pain, relaxation of muscular tissue, normalization of vascular tone, and restoration of visceral homeostasis. Descending control processes are directed to those regions of the body activated by specific nodes.

1. Ancient Chinese Concepts

The original Chinese theories are based on anatomical physiological studies and are almost totally consistent with what is presently known by today's science (Kendall 2002). The ancient Chinese identified all the major blood vessels in the body, discovered blood circulation, and separated the outflowing arteries from the return flowing veins. They also identified all the major internal organs, but failed to identify the endocrine glands. These ancients also correctly noted the function of the internal organs; except for the spleen which they assigned an immune and metabolic role. They noted that the human body is longitudinally organized with most peripheral and deep vessels, and related nerves, traversing up and down the body. In addition it was noted the muscular system is likewise organized in similar longitudinal pathways. They identified which muscles were related to specific distributions by observing needling stimulated propagated sensation pathways.

2. Search for Physiological Basis

The first serious investigations into the physiological basis of needling therapy began shortly after liberation of China in 1948. It was soon discovered that peripheral stimulation produced powerful analgesic effects by production central nervous system neurochemicals. Some of the early work was performed by Jisheng Han who published some 145 papers on this subject with 75 of these published in Western peer review journals (Han 1998). Early ideas on an overall physiological basis of acupuncture starting being formulated by the late 1980s (Pomeranz and Stux 1989). Additional research identified likely ascending afferent neural pathways involving activation of both nociceptive (Ad fibers) and proprioceptive (group II static load fibers). Afferent signals generated by needling stimulation involve a complex neurogenic controlled inflammatory process as result of micro tissue damage by the inserted needle. The net result is to amplify the needling response even though a patient may not be aware of these signals coursing through the body.

The afferent signals stimulate several areas of the brain and activate descending control restorative processes that are directed to the same level of the spinal cord that provided the original afferent signal (Kendall 2002; Bowsher 1998). Restorative processes results in inhibition of pain signals, reducing spasms, restoring autonomic balance, normalizing blood, and promoting tissue healing. The mechanisms provide a means where certain neurovascular nodes (acupoints) can be selected to treat any body part or articulation by using local and adjacent nodes where the problem exists and then judiciously selected proximal and distal nodes can be used to provide an efficient coverage of the problem area.

3. Segmental and Non-segmental Relationships

It is clear that needling therapy cannot be produced if the peripheral nerves and not intact and therapeutic indications for nodes show a clear involvement of common integration sites between somatic and visceral afferents at the same segmental levels (Kendall 2002; Gunn 1998). There are clear segmental and non-segmental effects (Bekkering and van Bussel 1998; MacDonald 1998). These differences may be related to the fact that the propriospinal system in involved in sending signals up and down the spinal cord and may be responsible for directing the non-segmental effects, usually involving distal effects (Kendall 2002).

4. Rationale for Acupuncture Point Selection

A physiological understanding of needling therapy allows a rational treatment strategy for any particular area of the body or articulation for the treatment pain and neuromusculoskeletal disorders. Segmental relationships are usually considered in selection of local and adjacent needling sites (neurovascular nodes) and also proximal locations. The non-segmental relationships are important in considering selection of distal nodes. In addition, in the treatment of neuromusculoskeletal problems the Chinese view of longitudinal distributions is always important to consider in selecting nodes, especially those used for the proximal and distal locations (Kendall 2002).

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C. The Safety of Acupuncture

There are numerous studies which identify acupuncture treatment as a relatively low risk medical procedure.

The 1997 NIH report states that: “One of the advantages of acupuncture is that the incidence of adverse effects is substantially lower than that of many drugs or other accepted medical procedures used for the same conditions. As an example, musculoskeletal conditions, such as fibromyalgia, myofascial pain, and tennis elbow, or epicondylitis, are conditions for which acupuncture may be beneficial. These painful conditions are often treated with, among other things, anti-inflammatory medications (aspirin, ibuprofen, etc.) or with steroid injections. Both medical interventions have a potential for deleterious side effects but are still widely used and are considered acceptable treatments. The evidence supporting these therapies is no better than that for acupuncture. In addition, ample clinical experience, supported by some research data,

suggests that acupuncture may be a reasonable option for a number of clinical conditions. Examples are postoperative pain and myofascial and low back pain. Examples of disorders for which the research evidence is less convincing but for which there are some positive clinical trials include addiction, stroke rehabilitation, carpal tunnel syndrome, osteoarthritis, and headache. Acupuncture treatment for many conditions such as asthma or addiction should be part of a comprehensive management program." [66]

The World Health Organization has stated in regards to acupuncture:

> ***"Unlike many drugs, it is non-toxic, and adverse reactions are minimal. This is probably one of the chief reasons why acupuncture is so popular in the treatment of chronic pain in many countries… Even if the effect of acupuncture therapy is less potent than that of conventional treatments, acupuncture may still be worth considering because of the toxicity or adverse effects of conventional treatments."*** [67]

Two reports published on acupuncture safety in the British Medical Journal in 2001, give details of 43 minor adverse events associated with 34,407 acupuncture treatments and 91 minor events in 31,822 acupuncture treatments. If the resuls of these studies are combined with the study above, the total is 121,520 treatments with 198 minor adverse events (0.16% incidence), with no pneumothoraxes (in the conclusion they are considered to be "extremely rare.") [68]

Another study on the frequency and types of adverse events in 55,291 acupuncture treatments reported: 64 minor adverse events. 99.8% of these acupuncture treatments were performed without even minor adverse events; "During these 5 years, a total of 76 acupuncturists (13 preceptors and 63 interns) participated in the study, and the total number of acupuncture treatments was 55,291… The most frequent adverse event was failure to remove needles after treatment; no sequelae occurred after removal of the needles. The second most common adverse event was dizziness, discomfort, or perspiration probably due to transient hypotension associated with the acupuncture treatment." The most serious adverse events during acupuncture are pneumothorax and septicemia. "Instruction is given by both lectures and practical training and includes information about anatomically risky depth of insertion and use of aseptic procedure for puncturing… Most important, no serious events such as pneumothorax, spinal lesion, or infection were reported… We may, therefore, reasonably conclude that serious adverse events in acupuncture treatment are uncommon in the practice of adequately trained acupuncturists." [69]

In a review of nine separate prospective surveys of acupuncture, involving nearly a quarter of a million treatments, there were two incidents of pneumothorax, the most serious event. Other adverse events were pain from needling, which varied from .03% to 45% incidence, depending on the study. Faintness and syncope occurred only from 0% to .3%. Interestingly, 86% of the patients reporting side effected, also experienced relaxation with treatment. [70]

The same group conducting this review then conducted a prospective, multicenter study of event monitoring of acupuncture treatment. This included 31,822 treatments by 78 acupuncturists. They found that most adverse events were not serious and cleared within one week. Needling pain and bleeding were the most common adverse events. Symptom aggravation occurred in only 96 per 10,000 treatments. [71]

Some of these same researchers then collaborated in a German study of nearly 100,000 patients receiving acupuncture, each of whom averaged 7.8 treatments. This study found 3% incidence of needling pain; 3% incidence of hematoma; and 1% incidence of bleeding. Two pneumothoraces occurred in this study population. [72]

The Guidelines' expert Advisory Council questioned whether there was any consistency in the definitions of the adverse events, or in the training of the practitioners in the nine prospective surveys selected. The Council suggested that slight pain upon needle insertion should not be considered an "adverse event," that needle pain that lasted beyond the duration of the treatment session could be caused by very aggressive and unusual needling technique, but more likely by poorly trained practitioners. They noted that any bleeding that occurs should be confined to a few drops of blood when a needle is withdrawn, and that pricking to release a few drops of blood is a common acupuncture technique. Furthermoe, they felt that tiredness and relaxation can actually be positive outcomes related to the stress of illnesses for which patients commonly seek treatment.

In the words of Edzard Ernst, professor, Complementary Medicine Peninsula Medical School , Exeter, U.K.:

> "***The overall conclusion of this work seems clear: acupuncture is a safe therapy, at least when it is administered by experienced and well-trained professionals.*** "[73]

Another recent study found that incidence of adverse events related to acupuncture treatment had declined since 1988. They therefore concluded: "Declines in adverse reports may suggest that recent practices, such as clean needle techniques and more rigorous acupuncturist training requirements, have reduced the risks associated with the procedure. Therefore, acupuncture performed by trained practitioners using clean needle techniques is a generally safe procedure." [74]

In sum, these studies of over one hundred thousand patients and over a million treatments attest to the safety of acupuncture treatment.

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5. Electroacupuncture

Electroacupuncture (EA) is the application of a small electrical current to conductive needles that have been inserted into various locations of the body, and can be described in more technical terms, such as "percutaneous electroneural stimulation" (PENS) and "percutaneous neuromodulation therapy" (PNT). “Percutaneous” refers to the fact that the needles are inserted “through the skin.” “Electroneural” refers to nerves being stimulated by the electrical current, though sometimes muscles are also directly stimulated. “Neuromodulation” refers to the ability to adjust the electrical current to very specific patterns and strengths.

While the original purpose of the electrical current was to replace traditional manual stimulation, it has the added benefit of making such stimulation repeatable and standardized, since a identical current settings can be reproduced when treating different patients in different locations. Electroacupuncture settings are typically finely adjusted using precalibrated devices.

Having thousands of years experience in treating every known disease affecting the human population by their understanding of the distribution of neurovascular nodes throughout the body, the Chinese simply added electrical stimulation to a few key nodes used in particular treatment protocols to enhance the effect of acupuncture.. Therapeutic use of EA started being popularized around 1958 when China started using small electrical devices attached to needles inserted through the skin to treat a wide range of medical conditions, and even using it to induce surgical analgesia.

A. Background of Electrical Stimulation

The ancient Egyptians and Greeks may have been the first to use electrical stimulation for therapeutic reasons by use of electric fish. A depiction of malopterurus electricus (Nile catfish) is prominently displayed in an Egyptian tomb relief dated to the Fifth Dynasty, ca.2750 BCE. Both gnathonerus petersi and torpedo ray were depicted on ancient green pottery (Greek pinax) which were honored and feared for their unusual ability to numb the senses. In Hippocrates times electric fish could be stepped on or placed on a particular body location, such as the low back or forehead, to treat particular pain conditions.

The term "electric" was coined by the English physician William Gilbert in 1600 to describe some static electrical effects, distinguishing them for the first time from magnetism. This term was derived from the Greek word eleckrom for amber since it had been known from Roman times that rubbing amber with a dry cloth could produce a static electric discharge

Interest in applying electrical devices to treat human ailments in Europe and the United States evolved simultaneously with the exploration and understanding of electrical phenomena from 1600 to the late 1800s. Machines of various types were developed. Sarlandiere le Chevalier (1825) was perhaps the first to hook up an electrical device to inserted needles. This is the first known application of EA. In 1958 the Chinese reintroduced EA and used it to treat many common ailments, dental pain, nerve dysfunction, paralysis, substance withdrawal,

musculoskeletal conditions, and to induce surgical analgesia. Many practitioners of Chinese medicine in the United States and Europe presently use EA in their normal clinical routines.

B. Features of Typical Electrostimulation Devices

Electrostimulation is usually applied by percutaneous means with wire leads and a simple, battery powered, pulse waveform output device connected to inserted needles. Positive and negative wire leads are attached by suitable clips to inserted needles. Output frequency and amplitude of EA units are adjustable and they have several operational modes with respect to output pulse patterns. Many devices are similar to transcutaneous electrical nerve stimulation (TENS) units, although output characteristics may vary. Application of TENS uses conductive pads applied to the skin, in lieu of needles.

1. Output Leads and Clips

Output leads of the EA stimulator usually have a clip device on the terminal end which is capable of grasping the metal shaft of the inserted needle, or needle handle if it is made of metal. These clips sometimes have opposing metal jaws with serrated edges and are referred to as "alligator clips." Other clips have opposing smooth surfaces (duck bill clips) and some are simply constructed from spring steel wire.

2. On-Off Switch Control and Mode Selections

Most EA/PENS devices have a master on/off switch and two or four outputs, with a positive and negative lead associated for each output. Most units also have a mode select function to provide a range of different output pulse patterns usually consisting of:

- Continuous Output
- Discontinuous (Intermittent) Output
- Mixed Frequencies (Dense Disperse)

3. Waveform Characteristics

Units are battery powered (6-9 v.) and use a pulse transformer design to increase output voltage. This type of circuit produces a pulse which has both a positive and negative voltage component (See Figure 1). The pulse wave output can be adjusted in amplitude from zero volts to a level necessary to activate EA/PENS induced processes. Output of typical circuit produces a biphasic waveform consisting of a near square wave positive portion followed by a negative attenuated spike.

4. Pulse Width

Width of the positive pulse is usually a fixed value of 0.2-0.4 ms. Pulse widths greater than 0.6 ms. have a greater potential to induce pain by stimulating nociceptive C fibers. Areas under the positive and negative portions of the waveform are equal and no net electrical energy is imparted to the body. The purpose of the biphasic pulse is to depolarize and repolarize tissue during each pulse cycle and therefore produces no deleterious effects at local site of needle insertion.

5. Amplitude Control

Output circuits should have an individual amplitude control capability (potentiometer) to manipulate the output voltage. Some machines have on/off switches on each circuit. Output can be controlled from zero volts to maximum . Units can typically produce pulses with positive and negative amplitudes of 60 volts, while the current is limited to a negligible value. Some devices, especially when used for TENS application, produce pulses up to +80 v. and negative spikes of -130 v. Both positive and negative amplitudes increase and decrease together proportionately as the output is adjusted.

PRECAUTIONS in controlling Amplitude include:

- It is necessary to make certain that all amplitude settings are at zero volts and unit is turned off before connecting leads to needles.
- It is important to zero out (turn down) the amplitude before disconnecting the leads from needles or turning the unit off.
- During initial application the amplitude is adjusted to the level that the patient can just feel the sensation. Care should be taken not to put the muscle into contraction.
- Be aware that in some cases of pain and also paralysis the patient may have impaired ability to feel the stimulating signal.
- Practitioners should be aware of recruitment phenomena of motor fibers, where electrostimulation of a few muscle fibers eventually causes some of the adjacent fibers in the same muscle to start contracting in unison. More and more fibers can also be recruited until the entire muscle is contracting. This can actually be beneficial for some conditions, such as for releasing a muscle spasm, but harmful or irritating if applied directly to a torm muscle.

6. Frequency Control

Devices usually have a frequency control capability that is common to all outputs in order to select appropriate stimulation in terms of the number of pulses\second. Most biological and neural processes that beneficially respond to acupuncture and EA involve low frequency responses. Most EA devices provide either a range of selectable fixed frequencies or have an adjustable frequency capability. The most commonly selected fixed frequencies with a devices witha rotary switch range from 0.1, 1, 2, 10, 25, and 100 Hz. Some units providing considerably higher frequency settings at 1,000 to 1,500 Hz Increasing the output signal frequency causes an increase in the intensity that the signal has on the body, and the subjective feeling experienced by the patient.

PRECAUTIONS in controlling Frequency include:

- When increasing the frequency during treatment, it is necessary turn down the signal amplitude on all outputs being used before switching to the desired higher frequency.
- After increasing the frequency, the amplitude for all outputs then need to be readjusted as necessary.
- Increasing the frequency without a corresponding reduction of the amplitude can lead to inducing stress analgesia.

7. Pulse Patterns

Most EA / PENS devices provide several different variations in output pulse patterns that offer certain advantages for specific type of treatments. Typical patterns include continuous, intermittent (discontinuous) and mixed (dense dispersed) operating modes.

a. Continuous Pulse Pattern

Continuous wave output pattern is characterized by a steady train of output pulses at a constant frequency selected by the practitioner. This a common and useful operating mode applicable to many standard clinical situations.

b. Discontinuous (Intermittent) Pulse Pattern

The discontinuous or intermittent pulse pattern consists of an output signal at the selected frequency that is on for only about three seconds followed by no output for about three seconds. This on-off pattern continually alternates as long as the discontinuous pattern is selected.

PRECAUTIONS in controlling Discontinuous Mode Adjustment:

- Amplitude in discontinuous mode is adjusted only during the "on cycle" period of operation.
- Frequency is only changed during the "on cycle" period consistent with turning down the output amplitude before increasing the frequency and then readjusting the amplitude.

c. Mixed (Dense Dispersed) Pulse Pattern

In the mixed mode of operation a selected output frequency is provided for a short duration (approximately 3 seconds) followed by lower frequency for the same duration. The high and low frequencies portions of the mixed pattern continually alternate. In mixed mode, most devices only require selection of the high frequency with automatic generation of the low frequency component. Some devices allow selection of the low frequency setting as well.

PRECAUTIONS in controlling Mixed Mode Amplitude:

- Amplitude is only adjusted during the high frequency "on" period of the mixed cycle.

C. General Operational Guidelines

The physiological features of the body allow the use of simple, rational, repeatable rules for the application of EA. This includes proper placement of the output leads to achieve the best therapeutic effect while at the same avoiding unwanted current paths in the body. Perhaps the most important consideration in the use of EA, and acupuncture in general, is the selection of candidate neurovascular nodes (acupoints) to be employed to achieve the best clinical outcome for the patient's condition. Duration of treatment, output amplitude, output frequency, and selection of proper operating mode also need to be considered.
When to Consider Using EA

Generally the application of EA stimulation greatly enhances the effect of needling therapy and can increase level of analgesia and significantly extends the period of treatment effectiveness. Many practitioners apply EA as a primary modality for acute and chronic pain and musculoskeletal problems because of its ability to produce a strong analgesic effect. The application of EA is a primary consideration for pain, muscle spasms, numbness, treating nerve dysfunction, paralysis, and atrophy. EA can also be employed in surgical or dental proceduresas an adjuvant to normal anesthetics. EA is very effective in treating withdrawal symptoms of individuals quitting the use of addictive substances such as nicotine, alcohol, cocaine, opiates, and some prescription drugs. EA can also be used to enhance cervical dilatation and uterine contractions to induce labor. Stimulation promotes tissue repair, healing and regenerating of nerve fibers essential to treat many chronic disorders.

1. Placement of Leads

Physiological organization of the body that is critical to afferent and efferent processes affecting the vessels, viscera, muscles, and peripheral nerves is basically longitudinal and ipsilateral in nature. The ipsilateral nature of the ascending afferent signals dictates placing the positive and negative leads of one particular output channel of the EA/PENS device along vertical pathways on the same side of the body. One principal goal in lead placement is to conform to the segmental and axial organization of the body while making certain to prevent cross currents. Cross currents are to be avoided especially in preventing transcranial current pathways.

This is accomplished by placing the positive and negative leads of one particular output channel of the EA/PENS device along vertical pathways on the same side of the body. If the presenting problem is ipsilateral in nature, such as pain in one shoulder, the positive and negative leads are placed at appropriate locations along the affected muscular pathway. If the problem is bilateral, such as low back pain, then one set of positive and negative leads, are placed on one side of the back, and another set placed at the same relative locations on the other side However, there is about a 40% crossover on the descending control restorative signals. This crossover features allows treatment of the opposite side to the one containing a problem to benefit the affected side, especially where the patient cannot tolerate direct treatment of the affected side.

2. Duration of Stimulation

Typical duration of EA application is 15-30 minutes. In cases of dental or surgical analgesia, the duration may by longer. In treatment of withdrawal from a powerful opiate, the duration may be increased to 45 minutes and applied twice a day for 3-4 days.

3. Amplitude (Strength of Current)

Under most conditions, amplitude of the output signal is only adjusted to the level that the patient can detect a slight sensation that feels like tapping on the skin. In many cases of trauma and pain there may be a deficit in sensory perception. These patients may not feel the electrical signal even though strong muscular contractions are activated. Thus, amplitude is adjusted only to the level where either the patient feels a slight sensation or the practitioner observes small movements of the needle or perhaps very slight muscular contractions. Excess strength of stimulation can induce a stress response After several minutes of stimulation, control signals generated in the body, reduce the response to the stimulus and the patient no longer feels the EA stimulus. Thus, the amplitude is periodically readjusted to maintain an awareness of a slight tapping sensation. The control response generated by the body is mediated by descending neural pathways in the spinal cord. This is the prime effect that is sought in the treatment of all problems, including musculoskeletal and viscera conditions.

4. Frequency and Operating Mode

Care needs to be taken not to induce stress by either excess amplitude or using frequencies that are too high.

Low frequency application (2 Hz.) always invokes the analgesic and restorative processes of acupuncture. This frequency (2 Hz.) is suitable for use in treating all pain conditions, substance abuse, osteoarthritis, rheumatoid arthritis, vascular or blood distribution problems and organ dysfunction. Higher frequencies (25-50 Hz.) are selected where nerve dysfunction or paralysis is involved and this is usually in conjunction with a low frequency (mixed mode). Frequencies of 25 Hz. and above can produce tonic contraction of muscles and is useful in treating certain muscular conditions when applied in discontinuous or mixed mode. General considerations of mode selection involve the following:

Continuous mode: Used for most conditions, especially in treating pain, substance withdrawal symptoms, visceral problems, inducing labor, and using EA/PENS for surgical analgesia. Normal treatment duration is about 20-35 minutes and there is little risk of developing tolerance even if this is applied several times a day. When used for surgical or dental analgesia, the duration may be extended. Tolerance can be produced after many hours of continuous application or in several days with a few hours of daily EA/PENS stimulation

Mixed mode: Is considered when a clinical condition involves paralysis, atrophy, and impairment due to loss of nerve function. Mixed mode can also be applied to enhance segmental levels with the higher frequency component as well as activating axial effects with the lower frequency component.

Discontinuous mode: Employed where a longer period of stimulation is needed and also where stimulation is directed to strengthen particular muscular areas or to treat problems such as scoliosis. In situations of long duration EA/PENS, use of discontinuous mode (about 3 sec. on and 3 sec. off) can be considered to reduce potential of developing tolerance

D. General Precautions and Contraindications for EA:

- Profound analgesia induced by EA puts patient at risk of self injury, therefore the patient must be advised or restricted from strenuous physical activity after treatment.
- Contraindicated in left chest region for patients with cardiac pacemakers, or for areas with imbedded neural stimulators and other electrical devices.
- Not to be used on lower abdomen in pregnant women.
- High frequency or high amplitude application may induce stress, which is contraindicated in cases of hypertension.
- High amplitude EA that causes muscle fiber recruitment (twitching) can irritate or re-injure acute local strains and sprains.
- EA can sedate older or fatigued patients, causing drowsiness after treatment; hence some patients should arrange for others to drive them home after an EA treatment.

6. Medical Necessity

A. What is Medical Necessity?

Medical Necessity means services that are:

- Consistent with professionally recognized standards of practice.
- Appropriate and necessary for the symptoms, diagnosis or treatment of patients medical or other health condition.
- Provided to patients for the diagnosis or direct care and treatment of the medical condition.
- Not primarily for the convenience of the provider or third party.
- Provide the most appropriate level of service in a safest manner possible.

B. Appropriateness

- The most appropriate procedure, supply, equipment or service must satisfy the following requirements:
  - There must be valid evidence basis for the expected health benefits from the procedure, supply, equipment or service to produce a greater likelihood of benefit, including a positive outcome to treatment, without a disproportionately greater risk of harm or complications, for the patient with the particular medical condition being treated than other possible alternatives; and
  - Generally accepted forms of treatment that are less invasive have been considered or tried and found to be ineffective or less suitable for the medical condition.

C. Outcome Expectations

All treatment plans require clinical justification for the type, duration, and intensity of services. Within the context of the natural history of the condition and considering patient compliance, treatment proposals should be evaluated to see if it is expected and likely to:

- Increase rate or quality of tissue repair;
- Accelerated return to functional status;
- Decrease time to reach pre-clinical status;
- Substantially decrease or resolve pain and / or other symptoms;
- Decrease or resolve adverse sequelae or complications;
- Reduce or eliminate risks of relapse or recurrence;
- Stabilize functional capacities.

D. Maximum Therapeutic Benefit

The goals of the clinical decision making process, which occur at both the practitioner-patient interface and often, between the practitioner and third-party payors, are to provide clinical services necessary to return the patient to pre-clinical health status or to stabilize a chronic condition for which complete resolution to pre-clinical functional status has been unsuccessful following multiple and different therapeutic interventions and periods of therapeutic withdrawal. This is the point of Maximum Therapeutic Benefit (MTB).

E. Continuing Care

Once the practitioner has initiated a patient's treatment plan and has determined that additional treatments are appropriate and necessary, additional information must be gathered. In those cases where the practitioner has provided a trial of treatment and more treatment is proposed, the decision to approve additional treatment should be based on the following criteria:

- Measurable outcomes as delineated below have been obtained.
- The patient has made reasonable progress toward pre-clinical status or functional outcomes under the initial treatment plan.
- Additional significant improvement can be reasonably expected by continued treatment.
- The patient has not reached maximum therapeutic benefit (MTB) or maximum medical improvement (MMI).
- There is no indication that immediate care/evaluation is required by other healthcare professionals.
- Occurrence of an exacerbation or flare up of condition during original treatment plan/program.
- The patient's chronic pain is controlled only through acupuncture, as the patient is unable or unwilling or allergic or addicted to drugs. (The analgesic effects of acupuncture are similar to morphine for pain relief (***see WHO study***).
- [For chronic pain, see section on Chronic Pain]

It is the treating practitioner's judgment to either re-examine the patient or refer the patient to other health care practitioners. In general, a re-examination is performed every 8 to 12 treatments, every 30 to 45 days, or as clinically necessary. The goal of re-examination is to objectively monitor patient progress and/or determine the need for treatment modification, possible outside referral or additional diagnostic evaluation.

A re-examination should be rendered if the patient shows no significant clinical progress within the first two to three weeks of treatment in order to determine whether modification to treatment, a referral or additional diagnostic studies is necessary.

F. Evidence Based Medicine

> ***"Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients."*** [75]

The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. Individual clinical expertise means the proficiency and judgment that individual clinicians acquire through clinical experience. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and treatment.

Best available external clinical evidence usually means clinically relevant research, often from the basic sciences of medicine, but especially from patient-centered clinical research into the accuracy and precision of diagnostic tests and procedures, identifying prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. External clinical evidence can be used to invalidate previously accepted diagnostic tests and treatments and replaces them with alternatives that are more powerful, more accurate, more efficacious, and far safer.

1. What Evidence Based Medicine Is Not:

According to the Oxford University Centre for Evidence Based Medicine: [75]

- Evidence-based medicine is neither old-hat nor impossible to practice. Studies show that busy clinicians who devote their scarce reading time to selective, efficient, patient-driven searching, appraisal and incorporation of the best available evidence can practice evidence-based medicine

- Evidence-based medicine is not "cook-book" medicine. External clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision

- Evidence-based medicine is not cost-cutting medicine. Some fear that evidence-based medicine will be hijacked by purchasers and managers to cut the costs of health care. This would not only be a misuse of evidence-based medicine but suggests a fundamental misunderstanding of its financial consequences

- Evidence-based medicine is not restricted to randomized trials and meta-analyses. It involves tracking down the best external evidence with which to answer our clinical questions.

G. Measurable Outcomes

Practicing evidence-based medicine requires the utilization of measurable outcomes. A recommendation for continued treatment is indicated in cases when patient's condition of affected body regions is improving in one or more of the following subjective and objective assessments. These factors identify structural and functional improvement:

Subjective
- Decrease of pain, using Visual Analog Scale, 1-10

- Decrease of frequency of flare-ups or episodes of pain
- Decrease in duration of flare-ups or episodes of pain
- Decrease in sensitivity of pain to triggers and aggravating factors
- Decrease in parasthesias
- Decrease in stiffness
- Decreased effects on mood and sleep
- Decrease in ADL / IDL limitations
- Family / associate perceptions of pain behaviors

Objective
- Decreased pain thresholds and tolerance (algometry)
- Increased range of motion and flexibility
- Decreased joint laxity
- Increased strength
- Increased endurance
- Restored sensory and vascular function
- Increased muscle bulk and tone
- Improvements in posture and symmetry
- Improvements in gait
- Reduction of pathologic movements and signs
- Decreased bruising, discoloration, scars, swelling, tenderness
- Increased body mechanics and ability to perform activities of daily living
- Increased ability to perform job-related duties
- Reduction in medication and aids
- Improvements demonstrated by special studies
- Improved tolerance to sitting and standing.
- Compliance and cooperation.
- Relapse prevention.
- Reduction of hospital visits or other medical interventions.
- Reduced pain behaviors.

H. Treatment Outcome Assessment

Treatment outcome assessment requires the incorporation of a procedure or method that measures and documents the patient's functional and symptomatic response to the treatment provided. The comparison of these measurements before and after treatment enables the practitioner to evaluate the patient's progress in an objective manner. A positive result of the treatment outcome assessment, accompanied by a determination that maximum medical improvement has not been achieved would validate the need for a recommendation for additional treatment.

Treatment outcome assessment requires that:

> "***complete, accurate, uniform, and replicable evaluations be conducted, and that such procedures shall include an evaluation of anatomical loss, functional loss, and the presence of physical complaints to be supported, to the extent feasible, by medical***

> ***findings based on standardized examinations and testing techniques generally accepted by the medical community***." [76]

Some commonly used measures and scales include:

- Visual Analog Scale (VAS) [77]
- Neck Disability Index (NDI) [78]
- Oswestry Low Back Pain [79],[80]
- Waddell Signs [81],[82]

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[75] Sackett, David L, et. al., Evidence-Based Medicine: What It Is and What It Isn't, BMJ 1996; 312: 71-2
[76] Calif. Labor Code 4600 Sec.133, 139, 4603.5 and 5307.3. Under L.C. 3209.3
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7. Chronic Pain

Chronic pain is defined as persistent pain, which can be either continuous or recurrent and of sufficient duration and intensity to adversely affect a persons well being, level of function and Quality of life. Chronic pain may involve any body part or organ system.

Acute pain, an essential biologic signal of the potential for or the extent of injury, is pain that lasts or is anticipated to last a short time, typically < 1 mo. It is often associated with anxiety and with hyperactivity of the sympathetic nervous system (eg, tachycardia, increased respiratory rate and BP, diaphoresis, dilated pupils).

Chronic pain is usually defined broadly and arbitrarily as pain persisting > 1 mo beyond the resolution of an acute tissue injury, pain persisting or recurring for > 3 mo, or pain associated with tissue injury that is expected to continue or progress. Chronic pain has no adaptive biologic role. Vegetative signs (eg, lassitude, sleep disturbance, decreased appetite, loss of taste for food, weight loss, diminished libido, constipation) often develop gradually, and depression may follow.

Pain may be broadly classified as **somatogenic** (organic)--explicable in terms of physiologic mechanisms--or **psychogenic**--occurring without organic pathology sufficient to explain the degree of pain and disability and thought to be related mostly to psychologic issues. A psychogenic cause of pain should not be assumed without evidence; if a somatogenic process cannot be identified and a psychologic process is not clear, the pain should be labeled idiopathic.

Somatogenic pain may be nociceptive or neuropathic. **Nociceptive pain** is judged to be commensurate with ongoing activation of somatic or visceral pain-sensitive nerve fibers. When somatic nerves are affected, pain is typically felt as aching or pressure (eg, most cancer pain).

Neuropathic pain results from dysfunction in the nervous system; it is believed to be sustained by aberrant somatosensory processes in the peripheral nervous system, the CNS, or both Pain may involve the efferent function of the sympathetic nervous system (sympathetically maintained pain) or identifiable peripheral pathology (eg, nerve compression, neuroma formation) or CNS pathology (eg, stroke, spinal cord injury). Usually, the pain is part of a defined neurologic disorder. Pain believed to involve peripheral processes may be subdivided into peripheral mononeuropathies or polyneuropathies; the most common painful polyneuropathy is due to diabetes. Pain believed to involve CNS processes, labeled deafferentation pain, may be subdivided into a variety of types, such as central pain after stroke or phantom pain after amputation.

Some pain syndromes have a multifactorial pathophysiology; eg, most cancer pain syndromes have a prominent nociceptive component but may also include neuropathic pain due to nerve damage by the tumor or its treatment and psychogenic pain related to loss of function and fear of disease progression. Nociceptive pain may predominate in pain syndromes related to chronic joint or bone injury (eg, arthritis, sickle cell disease, hemophilia).

Distinguishing between continuous and recurrent acute pain (as in sickle cell disease) is another important aspect of classification. Treatment plans may differ depending on the temporal description of the pain.

Several pain syndromes are difficult to classify. For example, in most patients, chronic headache probably involves a complex interaction of nociceptive disturbances in muscles and in blood vessels with psychologic factors.

Management of chronic pain is a process wherein patient, physician, non-physician clinician work together to increase function, reduce pain, develop self-management skills and maintain those improvements over time. This process requires active participation by the patient (and significant other's in the person's life) an open ongoing communication among all practitioners involved in the treatment process.

A. Complex Regional Pain Syndrome; Chronic Pain Syndrome: An Example

Complex Regional Pain Syndrome, RSD diagnosis in stage one is usually sympathetically maintained pain in one region, and includes sensory changes, allodynia, hyperpathia, edema, sudomotor, and vasomotor changes. Stage two CRPS or Causalgia increases the symptom profile and include inflammatory changes in the skin, neurodermatitis, bruising, tremor, swelling of joints, insomnia and emotional disturbance. In stage three, spontaneous severe skin ulcers, infection, atrophy of muscles, flexion deformity, osteoporosis, and depression with varying degrees of severity. Diagnostic nerve blocks in the early stages 1 and 2 are used to confirm RSD. Stage 2 and 3 are usually progressed to sympathetically independent pain. [2,3,5,12,13,14]

The first clinical description of Reflex Sympathetic Dystrophy was in 1864 when describing burning pain called Causalgia, in ***"Gunshot Wounds and Other Injuries of Nerves"*** by S.W. Mitchell M.D. [1]

Reflex Sympathetic dystrophy is a neurogenic disease with a multi-symptom medical condition, which affects one or more extremities. RSD was officially recognized and given an ICD-9 code 337.2, in 1993. [8] Generally it is caused by a slight injury, repetitive motion injury, surgery, venipuncture, laceration, burns, Degenerative Joint Disease, compression due to casting, infection and myocardial infarction. RSD is described as an intense severe burning pain, usually with swelling, and color changes to the skin, intense sensitivity to touch and temperature. [2,3,4]

Many patients will have accompanying neuromas, peripheral neuropathies, Temporal Mandibular Joint pain, nerve entrapments, such as carpal tunnel or thoracic outlet syndrome and peripheral nerve compression, RSD will affect up to 5% of these patients.[2,6,7]

RSD is an autonomic nervous system dysfunction involving, in the early stages, a sympathetic component, and may frequently progress and include the somatic nervous system as well. Sensory input of the somatic system terminates in the post central parietal sensory cortex of the brain and perceived as a conscious, focalized, well-defined sensation felt in the nerve root distribution i.e. radiculopathy. Very small sensory nerve fibers (C-fibers) transmit hyperpathic

pain while visceral and neuropathic pain is generated in the afferent portion of the sympathetic reflex arc. This nociceptive propagation in contrast to the somatic pathway generates a spreading and referred type pain by the sympathetic nerves (A-delta), which follow the arteries and small arterial branches resulting in a thermatomal distribution of the pain. Sympathetic input terminates in the limbic part of the brain giving rationale to symptoms of agitation, insomnia, and depression. Vasoconstriction and pain are caused by stimulation of wide dynamic range neurons in the intermediolateral cell column of the spinal cord increasing sympathetic activity to the periphery with the release of norepinephrine. This leads to increased release of Substance P, prostaglandin and nociceptive activity. [2,5,9,10]

Acupuncture works primarily because of its interaction with the spinal afferent processing system, involving somatic nociceptive (pain), proprioceptive (muscle static load, length and position), and autonomic fibers, as well as other nerves of the body that provoke local, spinal, and centrally mediated control. The principal effect of this descending control is to restore autonomic balance and to reduce pain. [9,10]

Voluntary control of muscle tendon can be influenced and altered by the pyramidal tract, which originates in the cerebral cortex (sensory, voluntary), which synapse with Motor neuron Alpha, Gamma and associated neurons from the proprioceptive Cerebellar System (kinesthetic coordination, balance, tonus), and extra pyramidal tract (fine voluntary movement, postural and locomotive). This influence is augmented by the cerebellum, hippocampus, amygdala, and septal area connection (emotion).

Altering the regulated tension of the contractile filaments of the muscle fibers enables the patient to increase range of motion without compromising ligaments or tendons. Muscle fibers are innervated at the neuromuscular junction and the muscle length; muscle tension relationship is regulated in the spinal cord by reciprocal inhibition from Motor neuron Alpha, which control contraction (length) and Motor neuron Gamma, which control tension. Muscle fiber, stretch receptors, sensory neurons, Motor neurons Alpha and Gamma Make up the Gamma Loop.

Golgi Organs and Renshaw cells also regulate tension. Golgi organs relax muscle at the tendon by firing in relation to contraction from Motor neuron Alpha relieving excessive contraction or stretching. Renshaw cells inhibit the Motor neuron Gamma regulating the strength of contraction.

Treatment is complicated with the following (not all inclusive):

Surgeries: Laminectomy, discectomy, decompression, foraminotomy, facetectomy, with or without hardware, IDET – Intradiscal Electrothermal Therapy, spinal endoscopy, implanted spinal cord stimulator, implanted intrathecal pump.

Diagnoses: Failed Back Syndrome, Post-laminectomy Syndrome, Arachnoiditis, Radiculopathy, Facet syndrome, Spondylolisthesis / Spondylosis.

Acupuncture and myofascial release or acupressure enhance the descending inhibition from the central system and brain stem to the trigeminal nucleus, spinal cord and sympathetic ganglia,

providing analgesia, reduction in muscle tension and inhibition of viscerosomatic reflexes achieving decreased pain, muscle spasm and inflammation. With chronic pain patients, acupuncture should be correlated with rehabilitative exercises on the same or alternating days. This treatment protocol blocks A delta and C fibers in order to decrease sympathetic efferent outflow and allow the patient to voluntarily control hyper-tonic muscles as a method of controlling patients pain and disability. Utilizing this protocol improves range of motion and flexibility while managing the barrier pain, allowing mobilization and strengthening in order to return the patient to pre-injury status.

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8. Utilization and Peer Review

A. Utilization Review

'Utilization review' is a system used to manage and improve patient care and decision making through case assessments of frequency, duration, level and appropriateness of medical care. Medically based criteria are used in the utilization review and decision making process.

Medically based criteria are:
1. Based on professionally recognized standards.
2. Developed using sound clinical principles and processes.
3. Developed by experienced practitioners utilizing peer review and standards of practice and treatment protocol determined by medical necessity.

Practitioners of acupuncture and electroacupuncture need to be aware that professional standards of care are coming into play and will affect their practices more and more. While peers can establish practice standards, patients and third-party medial reviewers are insisting that acupuncture services be based upon medical necessity that is verifiable by independent research. Private and public health insurers insist upon standardization, at least for the purposes of utilization.

The following are examples of state workers compensation systems and private insurance carrier policies on acupuncture utilization, which generally address appropriateness for given medical conditions.

HealthNet states that "Acupuncture is covered for treatment of pain as there are scientific studies to validate its effectiveness." [13]

Although some Aetna policies cover any medical diagnosis, Aetna considers needle acupuncture (manual or electroacupuncture) to be "medically necessary" for postoperative and chemotherapy-induced nausea and vomiting, nausea of pregnancy, postoperative dental pain, temporomandibular disorders (TMD), and migraine headache. [15]

For most United Healthcare policies, acupuncture is covered for any medical diagnosis.

Some Blue Cross policies are limited to pain conditions, while others cover acupuncture for any medical diagnosis.

In PPO plans, Cigna Healthcare covers acupuncture for 20 broad medical diagnoses including but not limited to stroke, trigeminal neuralgia, sinusitis, spastic colon, rheumatism, pinched nerve, failed back with intractable pain, dysmenorrhea, sciatica, herpes Zoster, headache, bursitis, bells palsy, back or cervical pain, arthritis of all kinds, tendinitis, and tennis elbow.

In Massachusetts, the state workers compensation system standards allow acupuncture to be utilized as a treatment for various work-related injuries, up to 16 visits per injury. [16]

In Colorado, indications for acupuncture "include joint pain, joint stiffness, soft tissue pain and inflammation, paresthesia, post-surgical pain relief, muscle spasm, and scar tissue pain," and for electroacupuncure, included "chronic pain conditions, radiating pain along a nerve pathway, muscle spasm, inflammation, scar tissue pain, and pain located in multiple sites."

Colorado allows acupuncture and electroacupuncture to be used up to 14 times as a trial course of treatments, but go on to state that "any of the above ***acupuncture treatments may extend longer if objective functional gains can be documented or when symptomatic benefits facilitate progression in the patient's treatment program***. Treatment beyond 14 treatments must be documented with respect to need and ability to facilitate positive symptomatic or functional gains. Such care should be re-evaluated and documented with each series of treatments." [17]

In California, acupuncture and electroacupuncture have been systematically allowed for the treatment of most work-related injuries, usually allowing up to 12 treatments at a time, but requiring re-evaluation to demonstrate functional improvement after 12 visits or 45 days before further treatments are authorized. [83]

B. Peer Review

Acupuncture practitioners need to be aware that the recommendations for treatments that they learned in their formal training was often based upon ideal circumstances in China, where socialized medicine allows patients to be treated daily without interference due to financial hardship or other non-clinical factors. Practice in the United States necessitates that practitioners be aware that third-party payor systems are designed to limit unnecessary expenditures, and should be prepared to have their recommendations reviewed by peers, and based upon standards developed by experts in the field.

One of the primary purposes for any peer review is to educate practitioners on accepted professional practices that are expected no matter what modality is used or what type of professional practitioner that is rendering the care. Education on basic standards enable practitioners to think clearly in care giving and to chart in the clinical setting so that the care is properly defensible should it ever be necessary to do so.

It is important to state here that peer review is not the same as scope of practice. While scope of practice definitions may fall under the realm of peer review, the concept of assuring the quality of the practice of acupuncture and Oriental medicine encompasses a broader concept. Peer review deals more with accepted professional practices, including the level of competence with which care was rendered to the patient, rather than what kind or style of practice the provider chose to use. Peer review deals with the basic standards in the profession such as proper examination, diagnosis, treatment rendered, documentation, cleanliness and orderliness of the office, providing a safe environment for the patient, clear communications verbally and in writing; all of which involve the quality of care. A practitioner can be practicing within the legal scope of practice and still render substandard (unprofessional) care.

Peer Review is the only vehicle by which licensed health care professionals have to observe themselves and learn from their strengths and mistakes.

[83] Treatment Guidelines for the Elbow, Industrial Medical Council, Department of Industrial Relations, State of California, 1997.

9. Treatment Guidelines

Acupuncture and electroacupuncture therapy have been utilized to treat a broad spectrum of illnesses and injuries, and have proven particularly effective at treating anatomically localized neuromusculoskeletal (NMS) injuries caused by repetitive stress or trauma. The anatomical NMS injuries that are most typically treated by acupuncture and electroacupuncture are due to trauma, sports injuries, auto accidents, and work-related repetitive stress injuries of the tendon, ligament, and bursa, and injuries in and around joint areas and the soft tissues (muscles, ligaments, etc) surrounding the spine. Acupuncture and electroacupuncture are also commonly used to treat chronic or post-operative pain, headaches, nausea, menstrual-related pain, and other conditions that may be anatomicallly, neurologically, or physiologically based.

A .Severity and Duration of Conditions

Conditions of illness and injury are generally classified into three or more categories, depending upon severity and duration. The commonly used descriptions of the stages of illness and injuries are acute, sub-acute, chronic, and recurrent.

- Acute -- Having rapid onset, relatively brief duration, and severe symptoms; which have duration within four weeks of onset.
- Sub-Acute -- Somewhat less than acute in severity, intermediate in character between acute and chronic symptoms within three months duration from onset of symptoms.
- Chronic -- Injury of long duration and/or frequent recurrence of longer than three months duration.
- Recurrent/ Flare-Up -- Return of symptoms of original injury at intervals or as a result of aggravating factors.

B. Treatment Frequency and Duration

The effects of acupuncture are generally cumulative. Acupuncture initiates physiologic tissue restorative and regenerative mechanisms. (See Physiological Mechanisms of Action) Frequency and duration of treatment are based on several factors including severity of condition, chronicity (duration of condition), previous episodes, pre-existing conditions, and other complicating factors. Such complicating factors present inherent difficulties in recovery, therefore, extra time and treatment is appropriate in order to observe a therapeutic response. The therapeutic effects of treatment should be assessed by subjective and objective assessments after each course of treatment. (See Measurable Outcomes)

Normally an initial course of treatment consists of 12-18 treatments over a 4-6 week period, depending on complicating factors. For acute conditions, fewer treatments may be necessary to observe a therapeutic effect and to obtain complete recovery. For chronic conditions, and

conditions with complicating factors, extended treatment is recommended to observe response to treatment. As in most types of therapy, the earlier the patient receives treatment, the greater the probability of recovery, and the shorter the time to recovery.

Acupuncture is commonly utilized in chronic conditions because of effectiveness in pain management and limited treatment options. However, it should be noted that acupuncture and electroacupuncture can lead to complete recovery in many NMS conditions when it is offered in the acute and sub-acute stages of injury, particularly when used in conjunction with other therapeutic interventions, such as ROM and strengthening exercises and manual manipulation of the soft tissue.

Acupuncture or electroacupuncture are rarely performed as a single treatment, but are usually prescribed and performed as a series, or "course of treatments." Thus, treatment planning requires a recommendation for the number, frequency, and duration of treatments that is appropriately based upon the nature and extent of the injuries and the prognosis for a progressive and timely recovery from those injuries. Severe injuries, multiple injuries, metabolic disorders, and other complicating factors may require more frequent treatments over a longer duration of time. For example, while some multiple injuries can be treated simultaneously, others must be treated independently and sequentially, requiring increased treatment frequency.

The following recommendations for the frequency and duration of treatment are based upon moderate to severe injuries in an otherwise healthy patient. Individual case recommendations should be scaled accordingly.

- **Acute --** 3 treatments per week, decreasing frequency as symptoms resolve and are reduced.
- **Sub-Acute --** 3 treatments per week for up to four weeks. 2 treatments per week thereafter. This is also the time when a rehabilitation exercise program is usually introduced.
- **Chronic --** 2-3 treatments per week for up to eight weeks as an initial course of treatment, and 1-2 treatment per week thereafter.
- **Recurrent / Flare-Up --** 8-12 visits as needed over a 2 month period

1. Initial Course of Treatments

Table 10: Frequency and Duration for Initial (Trial) Course of Treatments

Stage of Condition	Frequency	Duration	Re-evaluate after:
Acute	3x weekly	4 weeks	12 treatments
Sub-Acute	3x weekly	4 weeks	12 treatments
Chronic	2-3x weekly	6-8 weeks	12 treatments
Recurrent / Flare-up	2 - 3x weekly	4 - 8 weeks	12 treatments

A detailed or focused re-evaluation designed to determine the patient's progress and response to treatment should be conducted at the end of each course of treatment. Additionally, a brief assessment of the patients response to each treatment should be noted after each treatment is

completed, and again before the next one is started, and recorded in progress notes (e.g, SOAP notes). When a patient's condition is not responding to treatment for a period of 2-3 weeks, a more thorough re-evaluation should be conducted immediately to determine if the condition is different or more serious than the initial diagnosis had indicated and/or whether the condition requires further diagnostic testing and/or referral to other diagnostic or treatment specialists.

2. Re-Evaluation and Re-examination

After an initial course of treatment has been concluded, the detailed or focused re-evaluation should determine whether the objectives of the initial treatment plan have been fulfilled, and the extent to which they have been fulfilled by the documentation of subjective and objective assessments. A determination and recommendation must be made as to whether an additional course of treatment would continue to contribute to the patient's recovery or not. In general, if the patient is showing improvement in subjective and objective assessments from the previous evaluation, then continued therapy is indicated. (See Measurable Outcomes). Additionally, if the goals of the treatment are reached, and there is documentation of subjective and objective outcomes in the patient's condition, it is appropriate to continue the therapy. (See Outcome Expectations). If not, the patient should be referred for an alternative treatment or re-evaluation by a specialist after showing no response to the initial course of treatment.

3. Continuing Course of Treatments

Follow-up courses of treatment may be similar in frequency and duration to the initial course of treatment. However, one of the goals of any treatment plan should be to reduce the frequency of treatments to the point where maximum therapeutic benefit continues to be achieved while encouraging more active self-therapy, such as strengthening and ROM exercises, and rehabilitative exercises. The frequency of continued treatment generally depends upon the severity and duration of the condition; treatment benefits are generally stronger and last longer as a condition moves from acute towards complete resolution and as the patient takes a more active role in his or her recovery.

Table 11: Frequency and Duration for Continuing Courses of Treatments

Stage of Condition	Frequency	Duration	Re-evaluate after:
Acute	2-3x weekly	4 weeks	12 treatments
Sub-Acute	2-3x weekly	4 weeks	12 treatments
Chronic	1-2x weekly	6-8 weeks	12 treatments
Recurrence / Flare-up	1 -2x weekly	4 - 8 weeks	12 treatments

When the patient's condition stabilizes, or no longer shows improvement from the therapy, a decision must be made on whether to continue treatment in order to stabilize and maintain the patient's progress, or to discontinue therapy. In some cases of chronic pain, it may be appropriate to utilize acupuncture for pain management, for example, for patients who have adverse reactions to pain medications or when the prescribed pain medications are not sufficient to manage the patient's chronic pain. This decision is based on a number of factors,

including the potential benefit of the therapy and the potential risks involved in that therapy. The research on the effects on pain for acupuncture compares the efficacy of acupuncture for anesthesia comparable to that for morphine. (WHO, 1996).

Table 12: Duration and Frequency for Courses of Treatments for Neuromusculoskeletal Conditions

Stage of Condition	Initial Course		Follow-up Course(s)		Re-evaluate after:
	Frequency	Duration	Frequency	Duration	
Acute	3x weekly	4 weeks	2-3x weekly	4 weeks	12 treatments
Sub-Acute	3x weekly	4 weeks	2-3x weekly	4 weeks	12 treatments
Chronic	2-3x weekly	6-8 weeks	1-2x weekly	6-8 weeks	12 treatments
Recurrent / Flare-up	2 -3x weekly	4 - 8 weeks	1 -2x weekly	4 - 8 weeks	12 treatments

C. Patient Health and Safety

Identification and diagnosis of a condition / disorder is substantiated through historical data related to the chief complaint, onset of the condition, type of symptoms and their character, and previous history related to the condition. In addition, findings from the physical examination assist in defining the severity of involvement and the specific diagnosis.

In order to protect the health and safety of patients, quality of care strategies for reducing clinical errors and improving patient safety should be observed. These strategies include encouraging practitioners to adopt evidence-based health care approaches to patient care, maintain their clinical skills at or above broadly accepted professional standards of care, and follow applicable case management guidelines.

Evidence based healthcare, provided by properly trained providers, is one of the most conservative, least invasive, and safest types of health care. This being said, it is important to note that all forms of treatment carry some risk of harm to the patient and acupuncture and electroacupuncture are no exception. Therefore, implementing basic risk management procedures that recognize, avoid, and manage actual or alleged adverse outcomes, can help clinicians minimize the risk of harm or injury to patients.

1. Improving Patient Health and Safety

The National Patient Safety Foundation's definition of patient safety is:

> "***The avoidance, prevention, and amelioration of adverse outcomes or injury stemming from the processes of health care.***"

The Institute of Medicine “Aims for the 21st Century” recommends [84]:

"The committee proposes six aims for improvement to address key dimensions in which today's health care system functions at far lower levels that it can and should. Health Care should be:

- **Safe -** avoiding injuries to patients from the care that is intended to help them.
- **Effective -** providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit (avoiding underutilization and over utilization, respectively)
- **Patient Centered -** providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
- **Timely -** reducing wait times and sometimes harmful delays for both those who receive and those who give care.
- **Efficient -** avoiding waste, including waste of equipment, supplies, ideas and energy.
- **Equitable -** providing care that does not vary in quality because of patient characteristics such as gender, geographic location or socioeconomic status."

The following goals are useful in improving patient health and safety:

1. Identify types and causes of adverse outcomes;

2. Educate oneself regarding patient safety standards;

3. Decrease the incidence of adverse events through the identification of preventable events and risk factors;

4. Facilitate the reporting of adverse outcomes; and

5. Support or participate in studies to improve patient safety-related clinical outcomes.

2. Cautions and Contraindictations

Besides conditions for which acupuncture and electroacupuncture may not be appropriate or medically necessary, there are also certain clinical situations where acupuncture or electroacupuncture are contraindicated, or where a patient's condition must be co-managed by multiple healthcare specialists.

a. Conditions Contraindicating Acupuncture:

Acupuncture is contraindicated in patients or areas of the body when certain complicating conditions are present, such as:

- Open wound or burn.
- Prolonged bleeding time / hemophilia.

- Artificial joint implants.

- Pacemaker (see section on 5. Electroacupuncture).

b. Conditions Requiring Co-management

Acupuncture should only be used as an adjunct to another form of standard medical intervention, under co-managed care with other health care personnel for certain conditions, such as:

- Cancer pain.
- Chemotherapy-induced nausea.
- Post-operative surgical pain.
- Multiple sclerosis related pain.
- Labor inducement for pregnancy.

c. Conditions Requiring Referral

Patients should be referred to another specialty health care practitioner or to emergecy care in certain instances, such as:

- The patient's condition is not responding to the treatment rendered.
- The patient's condition is worsening with treatment.
- The patient has an unmanaged progressive infectious condition.
- The patient experiences a medical emergency (e.g., heart attack, laceration, pneumothorax).
- A broken needle requires surgical removal.

d. Conditions Requiring Special Care

Conditions for which acupuncture may be contraindicated, or must be modified, due to individual circumstances:

- Pregnancy (avoid strong stimulation of acupoints LI 4, Sp 6, UB 60, UB 67, except to induce labor; avoid low back and abdominal points during last trimester)

3. Informed Consent

Informed consent is the authorization given by a patient to a provider of medical services, to receive a medical procedure, after being adequately informed about the medical procedure and before receiving the medical procedure. The provider of the medical procedure should explain the procedure in writing and verbally, including potential benefits and risks. The patient must be given the opportunity to ask questions and the medical provider should discuss treatment alternatives.

See Appendix E: Informed Consent for sample content of an informed consent form.

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[84] The Institute of Medicine, "Crossing the Quality Chasm; 2001," p. 5.

10. Head and Neck

A. Head

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of head conditions:

- Tension Headache
- Cluster Headache
- Hypertensive Headache
- Head Trauma
- Facial Pain
- Migraine Headache
- Sinus Headache
- Cervicogenic Headache
- Temporomandibular Dysfunction

Quality of Evidence:
Level I - Multiple well-designed, randomized controlled trials, directly relevant to the recommendation, yielded a consistent pattern of findings.

Recommendation Grade:
Grade A - A strong recommendation that was based on an evaluation of the available evidence and general agreement of the expert panel that acupuncture and electroacupuncture treatment is effective, always acceptable, and indicated.

Appropriateness of acupuncture/electroacupuncture was determined by the Advisory Council of expert acupuncturists, based upon general consensus, and after review of the following published research.

Acupuncture for chronic headache in primary care: large, pragmatic, randomised trial.
Vickers AJ, Rees RW, Zollman CE, McCarney R, Smith CM, Ellis N, Fisher P, Van Haselen R. BMJ. Mar 27, 2004; 328(7442):744

Acupuncture in the prophylactic treatment of migraine without aura: a comparison with flunarizine,
Allais G, De Lorenzo C, Quirico PE et al , Headache 42:855-861

Comparison of pharmacological treatment versus acupuncture treatment for migraine without aura
Liguori A, Petti F, Bangrazi A et al, J Trad Chin Med; 20:231-240.

Cost effectiveness analysis of a randomised trial of acupuncture for chronic headache in primary care.
Wonderling D, Vickers AJ, Grieve R, McCarney R, BMJ. Mar 27; 2004; 328(7442):747.

Electroacupuncture for tension-type headache on distal acupoints only: a randomized, controlled, crossover trial.
Xue CC, Dong L, Polus B, English RA, Zheng Z, Da Costa C, Li CG, Story DF, Headache; 44(4):333-41, 2004.

Acupuncture and physiotherapy in the treatment of myogenic headache patients: pain relief and EMG activity.
Ahonen E, Hakumaki M, Mahlamaki S, Partanen J, Riekkinen P, Sivenius J. Advances in Pain Research and Therapy; 5:571-576.1983

Non-pharmacological approaches to chronic headaches: transcutaneous electrical nerve stimulation, lasertherapy and acupuncture in transformed migraine treatment.
Allais G, De Lorenzo C, Quirico PE, Lupi G, Airola G, Mana O, Benedetto C. Neurol Sci. 24 Suppl 2:S138-42, 2003

Acupuncture treatment of chronic tension headache -- a controlled cross-over trial.
Hansen, P.E., Hansen, J.H. Cephalgia;1985, 5:137-142

The 'dry-needle technique': intramuscular stimulation in tension-type headache

Karakurum B, Karaalin O, Coskun O et al. Cephalalgia; 2001, 21:813-817

Needle acupuncture in tension-type headache: a randomized, placebo-controlled study
Karst M, Reinhard M, Thum P, et al . Cephalalgia, 2001; 21:637-642

Use of percutaneous electrical nerve stimulation (PENS) for treating ECT-induced headaches
Ghoname EA, Craig WF, White PF. Headache; 39(7):502-5. 1999.

Acupuncture: Efficacy, Safety and Practice.
British Medical Association Board of Science and Education. London: Harwood Academic Publishers, 2000.

Acupuncture: Theory, Efficacy and Practice.
Kaptchuk T. Complementary and Alternative Medicine Series, from Annals of Internal Medicine vol. 136, No. 5, March 5, 2002.

Acupuncture: NIH Consensus Statement.
1997 Nov 3-5; 15(5): 1-34. National Institutes of Health.

Acupuncture: NIH Consensus Statement.
1997 Nov 3-5; 15(5): 1-34. National Institutes of Health.

Acupuncture: Review and Analysis of Reports on Controlled Clinical Trials.
World Health Organization, 1999.

B. Neck

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of neck conditions:

- Injuries to the Cervical Spine
- Cervical Radiculopathy
- Herniated Cervical Disc
- Unspecified Neck Pain
- Degenerative Disc Disease
- Cervical Strain and Whiplash
- Cervical Stenosis and Spondylosis
- Torticolis
- Cervical Arthritis
- Muscle Spasm

Quality of Evidence:
Level I - Multiple well-designed, randomized controlled trials, directly relevant to the recommendation, yielded a consistent pattern of findings.

Recommendation Grade:
Grade A - A strong recommendation that was based on an evaluation of the available evidence and general agreement of the expert panel that acupuncture and electroacupuncture treatment is effective, always acceptable, and indicated.

Appropriateness of acupuncture/electroacupuncture was determined by the Advisory Council of expert acupuncturists, based upon general consensus, and after review of the following published research.

Controlled trial of Japanese acupuncture for chronic myofascial neck pain: assessment of specific and nonspecific effects of treatment
Birch S, Jamison RN, Clin J Pain; 1998, 14(3):248-255

Effect of acupuncture treatment on chronic neck and shoulder pain in sedentary female workers: a 6-month and 3-year follow-up study.
He D, Veiersted KB, Hostmark AT, Medbo JI. Pain; 2004: 109(3):299-307.

Randomised trial of acupuncture compared with conventional massage and "sham" laser acupuncture for treatment of chronic neck pain
Irnich D, Behrens N, Molzen H et al , BMJ; 2001: 322:1-6

Immediate effects of dry needling and acupuncture at distant points in chronic neck pain: results of a randomized, double-blind, sham- controlled crossover trial.
Irnich, D.; Behrens, N.; Gleditsch, J.; Stor, W.; Schreiber, M.; Schops, P.; Vickers, A.; Beyer, A. Pain; 2002: 99(1-2): 83.

The acupuncture treatment of neck pain: a randomized controlled study.
Coan RM, Wong G, Coan PL. American Journal of Chinese Medicine; 9:326-332. 1981

Chronic neck pain: a comparison of acupuncture treatment and physiotherapy.
David J, Modi S, Aluko AA, Robertshaw C, Farebrother J. British Journal of Rheumatology; 1998: 37(10):1118-1132.

Randomised trial of acupuncture compared with conventional massage and "sham" laser acupuncture for treatment of chronic neck pain - range of motion analysis
Konig A, Radke S, Molzen H, Haase M, Muller C, Drexler D, Natalis M, Krauss M, Behrens N, Irnich D. Z Orthop Ihre Grenzgeb; 141(4):395-400.,2003.

Treatment of cervical spondylosis. Electroacupuncture versus physiotherapy.
Loy TT, Med J Aust.2(1):32-4, 1983.

Relief of chronic neck and shoulder pain by manual acupuncture to tender points--a sham-controlled randomized trial.
Nabeta T, Kawakita K. Complement Ther Med.; 2002: 10(4):217-22.

Acupuncture in the treatment of chronic cervical pain. A pilot study.
Petrie JP, Langley GB. Clin Exp Rheumatol; 1(4):333-6, 1983.

Electrical stimulation of auricular acupuncture points is more effective than conventional manual auricular acupuncture in chronic cervical pain: a pilot study.
Sator-Katzenschlager SM, Szeles JC, Scharbert G, Michalek-Sauberer A, Kober A, Heinze G, Kozek-Langenecker SA. Anesth Analg. 97(5):1469-73, 2003.

Acupuncture for chronic back and neck pain
Yue, Shyh-Jong., Acupuncture and Electro-Therapeutics; 1978: 3:323-324

A controlled trial on acupuncture for chronic neck pain.
Zhu XM, Polus B. Am J Chin Med; 2002: 30(1):13-28

Acupuncture: Efficacy, Safety and Practice.
British Medical Association Board of Science and Education. London: Harwood Academic Publishers, 2000.

Acupuncture: NIH Consensus Statement.
1997 Nov 3-5; 15(5): 1-34. National Institutes of Health.

Acupuncture: Review and Analysis of Reports on Controlled Clinical Trials.
World Health Organization, 1999.

Acupuncture: Theory, Efficacy and Practice.
Kaptchuk T. Complementary and Alternative Medicine Series, from Annals of Internal Medicine vol. 136, No. 5, March 5, 2002.

Clinical effectiveness of acupuncture: an overveiw of systematic reviews.
Ernst E. In: Ernst E. White A, eds. Acupuncture: A Scientific Appraisal. Oxford. Butterworth-Heinemann. 1999a: 107-127.

Systematic reviews of complementary therapies - an annotated bibliography. Part 1: acupuncture.
Linde K, Vickers A, Hondras M, ter Riet G, Thormahlen J, Berman B, Melchart D. Centre for Complementary Medicine Research, Department of Internal Medicine II, Technische Universitat, Munchen, Kaiserstr 9, 80801 Munchen, Germany. Klaus.Linde@lrz.tu-muenchen.de

11. Upper Extremity

A. Shoulder

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of shoulder conditions:

- Injuries to the Shoulder – General
- Rotator Cuff Tear
- Adhesive Capsulitis (Frozen Shoulder)
- Thoracic outlet syndrome
- Acromioclavicular Joint Separation / Compression
- Biceps Tendon Injury
- Shoulder Tendinitis / Bursitis
- Muscle spasm

Quality of Evidence:
Level II - Evidence was obtained from at least one properly well-designed randomized controlled trial (RCT).

Recommendation Grade:
Grade A - A strong recommendation, based on an evaluation of the available evidence and general consensus of the expert panel, that acupuncture and electroacupuncture treatment is effective, always acceptable, and indicated.

Appropriateness of acupuncture / electroacupuncture was determined by the Advisory Council of expert acupuncturists, based upon general consensus, and after review of the following published research. (II-A)

Acupuncture for frozen shoulder
Sun KO, Chan KC, Lo SL, Fong DY. Hong Kong Med J; 2001: 7(4):381-91

Randomised clinical trial comparing the effects of acupuncture and a newly designed placebo needle in rotator cuff tendonitis
Kleinhenz J, Streitberger K, Windeler J et al ; Pain; 1999: 83:235-241

Acupuncture and Trager psychophysical integration in the treatment of wheelchair user's shoulder pain in individuals with spinal cord injury
Dyson-Hudson TA,Shiflett SC, et al . Arch phys Med Rehabil 82:1038-1046 2001.

Acupuncture: Theory, Efficacy and Practice.
Kaptchuk T. Complementary and Alternative Medicine Series, from Annals of Internal Medicine vol. 136, No. 5, March 5, 2002.

Acupuncture: NIH Consensus Statement.
1997 Nov 3-5; 15(5): 1-34. National Institutes of Health.

Acupuncture: Review and Analysis of Reports on Controlled Clinical Trials.
World Health Organization, 1999.

B. Elbow

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of elbow conditions:

- Lateral Epicondlylitis
- Medial Epicondylitis
- Olecranon Bursitis
- Ulnar Neuritis

In general, the application of acupuncture is recommended in the first 4 weeks of treatment as a part of an overall, initial, conservative, treatment plan. Specifically 3-6 acupuncture treatments over 7-21 days are listed as one Official Disability Guideline "Return-To-Work Pathway" for lateral epicondylitis.[85]

Quality of Evidence:
Level I - Multiple well-designed, randomized controlled trials, directly relevant to the recommendation, yielded a consistent pattern of findings.

Recommendation Grade:
Grade A - A strong recommendation, based on an evaluation of the available evidence and general consensus of the expert panel, that acupuncture and electroacupuncture treatment is effective, always acceptable, and indicated.

Appropriateness of acupuncture/electroacupuncture was determined by the Advisory Council of expert acupuncturists, based upon general consensus, and after review of the following published research.

Acupuncture for the alleviation of lateral epicondyle pain: a systematic review
K. V. Trinh1,5, S.-D. Phillips2, E. Ho3 and K. Damsma4

Acupuncture in chronic epicondylitis: a randomized controlled trial
Fink M, Wolkenstein E, Karst M et al . Rheumatology; 2002: 41:205-209.

Chronic epicondylitis: effects of real and sham acupuncture treatment: a randomised controlled patient- and examiner-blinded long-term trial.
Fink M, Wolkenstein E, Luennemann M, Gutenbrunner C, Gehrke A, Karst M. Forsch Komplementarmed Klass Naturheilkd; 9(4):210-5 2002

Comparison of the effectiveness between manual acupuncture and electro-acupuncture on patients with tennis elbow
Tsui P, Leung MC. Acupunct Electrother Res.; 2002: 27(2):107-17

Acupuncture Therapy for Tennis Elbow
Gunilla Brattberg. Pain, 1983: 16:285-288

Acupuncture: Efficacy, Safety and Practice.
British Medical Association Board of Science and Education. London: Harwood Academic Publishers, 2000.

Acupuncture: NIH Consensus Statement.
1997 Nov 3-5; 15(5): 1-34. National Institutes of Health.

Acupuncture: Review and Analysis of Reports on Controlled Clinical Trials.
World Health Organization, 1999.

C. Forearm, Hand and Wrist

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of forearm, hand, and wrist conditions:

- Forearm sprain / strain
- DeQuervains Syndrome
- Wrist / finger sprain / strain
- Arthritis
- Carpal Tunnel Syndrome
- Trigger Finger
- Tendinitis of forearm / wrist
-

Quality of Evidence:
Level II - Evidence was obtained from at least one properly well-designed randomized controlled trial (RCT).

Recommendation Grade:
Grade B - Recommendation that was based on an evaluation of the available evidence and general consensus of the expert panel that acupuncture and electroacupuncture treatment should be considered acceptable, effective, and indicated..

Appropriateness of acupuncture / electroacupuncture was determined by the Advisory Council of expert acupuncturists, based upon general consensus, and after review of the following published research.

Acupuncture: Theory, Efficacy and Practice.
Kaptchuk T. Complementary and Alternative Medicine Series, from Annals of Internal Medicine vol. 136, No. 5, March 5, 2002.

Acupuncture: NIH Consensus Statement.
1997 Nov 3-5; 15(5): 1-34. National Institutes of Health.

Acupuncture: Review and Analysis of Reports on Controlled Clinical Trials.
World Health Organization, 1999.

Carpal tunnel syndrome pain treated with low-level laser and microamperes transcutaneous electric nerve stimulation: A controlled study
Naeser MA, Hahn KA, Lieberman BE, Branco KF. Arch Phys Med Rehabil; 83:978-988.

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[85] Work Loss Data Institute. Disorders of the elbow. Corpus Christi (TX): Work Loss Data Institute; 2003.

12. Torso and Low Back

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of thorax and low back conditions:

Thoracolumbar Area

- Injuries to the Costals
- Lumbar Facet Syndrome
- Sciatic Neuralgia
- Sacroiliac Sprain / Strain
- Muscle Spasms
- Degenerative Disc Disease
- Low Back Sprain / Strain
- Lumbar Disc Herniation
- Spondylolisthesis
- Spondylosis
- Lumbar Radiculopathy
-

Quality of Evidence:
Level I - Multiple well-designed, randomized controlled trials, directly relevant to the recommendation, yielded a consistent pattern of findings.

Recommendation Grade:
Grade A - A strong recommendation, based on an evaluation of the available evidence and general consensus of the expert panel, that acupuncture and electroacupuncture treatment is effective, always acceptable, and indicated.

Appropriateness of acupuncture/electroacupuncture was determined by the Advisory Council of expert acupuncturists, based upon general consensus, and after review of the following published research.

Acupuncture for chronic low back pain: a randomized placebo-controlled study with long-term follow-up
Carlsson CP, Sjolund BH. Clin J Pain 17:296-305 2001

Acupuncture for chronic low back pain in older patients: a randomized, controlled trial.
Meng CF, Wang D, Ngeow J, Lao L, Peterson M, Paget S. Rheumatology (Oxford); 2003: 42(12):1508-17

Does acupuncture improve the orthopedic management of chronic low back pain - a randomized, blinded, controlled trial with 3 months follow up
Molsberger AF, Mau J, Pawelec DB, et al. Pain; 2002: 99:579-587

Comparison of superficial and deep acupuncture in the treatment of lumbar myofascial pain: a double-blind randomized controlled study.
Ceccherelli F, Rigoni MT, Gagliardi G, Ruzzante L ; Clin J Pain. 2002: 18(3):149-53.

Efficacy of electroacupuncture and TENS in the rehabilitation of chronic low back pain patients.
Lehmann TR et al. Pain; 1986: 26:277-290.

Acupuncture treatment of chronic low-back pain - a randomized, blinded, placebo-controlled trial with 9-month follow-up
Leibing E, Leonhardt U, Koster G et al ; Pain; 2002: 96:189-196.

Importance of modes of acupuncture in the treatment of chronic nociceptive low back pain.
Thomas M, Lundberg T, Acta Anaesthesiol Scand. 1994: 38(1):63-9

Randomised Controlled Trial Comparing the Effectiveness of Electroacupuncture and TENS for Low Back Pain:
Tsukayama H, Yamashita H, Amagai H, Tanno Y. Acupunct Med: 20(4):175-80: 2002

Effect of acupuncture on pain management in patients before and after lumbar disc protrusion surgery - a randomized control study
Wang, R.R., Tronnier, V., American Journal of Chinese Medicine; 2000: 28(1):25-33

The use of electro-acupuncture in conjunction with exercise for the treatment of chronic low-back pain
Yeung CK, Leung MC, Chow DH: J Altern Complement Med. ; 2003: 9(4):479-90.

The acupuncture treatment of low back pain: a randomized controlled treatment.
Coan RM, Wong G, Ku SL, Chan YC, Wang L, Ozer FT, Coan PL. American Journal of Chinese Medicine, 1980: 8:181-189.

A randomized comparative trial of acupuncture versus transcutaneous electrical nerve stimulation for chronic back pain in the elderly.
Grant DJ, Bishop-Miller J, Winchester DM, Anderson M, Faulkner S. Pain.; 1999: 82(1):9-13

Acupuncture in the management of chronic low back pain: a blinded randomized controlled trial
Kerr DP, Walsh DM, Baxter D , Clin J Pain.; 2003: 19(6):364-70

Acupuncture relieves pelvic and low-back pain in late pregnancy.
Kvorning N, Holmberg C, Grennert L, Aberg A, Akeson J. Acta Obstet Gynecol Scand.: 83(3):246-50: 2004

Acupuncture treatment for pain syndrome. I. Treatment for sciatica (report on 90 cases).

Leung SJ. Am J Chin Med. 1973: 1(2):317-26.

Acupuncture treatment of low back pain: a double-blind placebo-controlled trial.
Mendelson G et al. American Journal of Medicine ; 1983: 74:49-55.

The short- and long-term benefit in chronic low back pain through adjuvant electrical versus manual auricular acupuncture.
Sator-Katzenschlager SM, Scharbert G, Kozek-Langenecker SA, Szeles JC, Finster G, Schiesser AW, Heinze G, Kress HG. Anesth Analg. 98(5):1359-642004.

A Multi-center Trial of Percutaneous Neuromodulation Therapy for Low Back Pain Patients with a Subacute Duration of Lower Extremity Pain.
Condon, J., Borg-Stein, J., Revord, J, Schmitt, S., Glassman, J., Bensen, E., Leep, E., Fitzthum, J., Seroussi, R. ; Pain Med. 3(2):172-173, 2002.

Acupuncture for back pain: a meta-analysis of randomized controlled trials.
Ernst E, White AR. Arch Intern Med. 158(20):2235-41. 1998.

Percutaneous electrical nerve stimulation for low back pain: a randomized crossover study
Ghoname EA, Craig WF, White PF, Ahmed HE, Hamza MA, Henderson BN, Gajraj NM, Huber PJ, Gatchel RJ. JAMA. 281(9):818-23, 1999.

Acupuncture and Sciatica??
Ghoname EA, White PF, Ahmed HE, Hamza MA, Craig WF, Noe CE. Pain. 83(2):193-9. 1999.

The effect of stimulus frequency on the analgesic response to percutaneous electrical nerve stimulation in patients with chronic low back pain
Ghoname ES, Craig WF, White PF, Ahmed HE, Hamza MA, Gajraj NM, Vakharia AS, Noe CE. Anesth Analg. 88(4):841-6; 1999.

Acupuncture for low back pain in pregnancy--a prospective, quasi-randomised, controlled study.
Guerreiro da Silva JB, Nakamura MU, Cordeiro JA, Kulay L Jr; Acupunct Med. 22(2):60-7. 2004.

Effect of the duration of electrical stimulation on the analgesic response in patients with low back pain
Hamza MA, Ghoname EA, White PF, Craig WF, Ahmed HE, Gajraj NM, Vakharia AS, Noe CE. Anesthesiology. 91(6):1622-7. 1999

Acupuncture for back pain: a meta-analysis of randomized controlled trials.
Ernst E, White AR, Arch Intern Med.158(20):2235-41. 1998.

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Tait PL, Brooks L, Harstall C, Alberta Heritage Foundation for Medical Research, Edmonton, Alberta, Canada. March, 2002.

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Kaptchuk T. Complementary and Alternative Medicine Series, from Annals of Internal Medicine vol. 136, No. 5, March 5, 2002.

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1997 Nov 3-5; 15(5): 1-34. National Institutes of Health.

Acupuncture: Review and Analysis of Reports on Controlled Clinical Trials.
World Health Organization, 1999.

Systematic reviews of complementary therapies - an annotated bibliography. Part 1: acupuncture.
Linde K, Vickers A, Hondras M, ter Riet G, Thormahlen J, Berman B, Melchart D. Centre for Complementary Medicine Research, Department of Internal Medicine II, Technische Universitat, Munchen, Kaiserstr 9, 80801 Munchen, Germany. Klaus.Linde@lrz.tu-muenchen.de

13. Treatment Guidelines - Lower Extremity

A. Hip and Thigh

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of hip and thight conditions:

- Osteoarthritis
- Tendinitis / Bursitis
- Capsulitis
- Post-Operative Fractures & Hip Replacements
- Muscle Spasm
- Piriformis Syndrome
- Avascular Necrosis

Quality of Evidence:
Level II - Evidence was obtained from at least one properly well-designed randomized controlled trial (RCT).

Recommendation Grade:
Grade A - A strong recommendation, based on an evaluation of the available evidence and general consensus of the expert panel, that acupuncture and electroacupuncture treatment is effective, always acceptable, and indicated.

Appropriateness of acupuncture/electroacupuncture was determined by the Advisory Council of expert acupuncturists, based upon general consensus, and after review of the following published research.

Non-specific effects of traditional Chinese acupuncture in osteoarthritis of the hip
Fink MG, Wipperman B, Gehrke A Complement Ther Med, 9:82-89, 2001.

A comparison of acupuncture with advice and exercises on the symptomatic treatment of osteoarthritis of the hip--a randomised controlled trial
Haslam R, Acupunct Med, 19:19-26, 2001.

Comparison between electro-acupuncture and hydrotherapy, both in combination with patient education and patient education alone, on the symptomatic treatment of osteoarthritis of the hip.
Stener-Victorin E, Kruse-Smidje C, Jung K, Clin J Pain. 20(3):179-85, 2004.

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B. Knee

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of knee conditions:

- Osteoarthritis
- Ligament Injuries
- Patellofemoral Pain
- Bakers Cyst
- Tendinitis
- Meniscus Injuries
- Post-operative pain

Quality of Evidence:
Level I - Multiple well-designed, randomized controlled trials, directly relevant to the recommendation, yielded a consistent pattern of findings.

Recommendation Grade:
Grade A - A strong recommendation, based on an evaluation of the available evidence and general consensus of the expert panel, that acupuncture and electroacupuncture treatment is effective, always acceptable, and indicated.

Appropriateness of acupuncture/electroacupuncture was determined by the Advisory Council of expert acupuncturists, based upon general consensus, and after review of the following published research.

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Berman BM, Singh BB, Lao L, Langenberg P, Li H, Hadhazy V, Bareta J, Hochberg M. Rheumatology (Oxford). 1999 (4):346-54.

The effect of acupuncture on the symptoms of knee osteoarthritis--an open randomised controlled study.
Tukmachi E, Jubb R, Dempsey E, Jones P Acupunct Med. 22(1):14-22, 2004.

Acupuncture treatment of patellofemoral pain syndrome,
Jensen R, Gothesen O, Liseth K et al, J Altern Complement Med, 5:521-527, 1999.

The effects of electro-acupuncture and transcutaneous electrical nerve stimulation on patients with painful osteoarthritic knees: a randomized controlled trial with follow-up evaluation.
Ng MM, Leung MC, Poon DM, J Altern Complement Med. 2003, 9(5):641-9.

Acupuncture and moxibustion as an adjunctive treatment for osteoarthritis of the knee--a large case series
Vas J, Perea-Milla E, Mendez C, Acupunct Med. 22(1):23-8, 2004.

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Naslund J, Naslund UB, Odenbring S, Lundeberg T, J Rehabil Med. 34(5):231-8, 2002.

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C. Ankle and Foot

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of ankle and foot conditions:

- Ankle Sprain
- Plantar Fascitis
- Diabetic Neuropathy
- Osteoarthritis
- Achilles Tendinitis
- Tarsal Tunnel Syndrome
- Reflex Sympathetic Dystrophy
- Post-Operative Pain

Quality of Evidence:
Level IV - Evidence consisted of the opinions of respected authorities, based on clinical experience, descriptive studies in case reports, or reports of expert committees..

Recommendation Grade:
Grade B – The recommendation was based on an evaluation of the available evidence and general consensus of the expert panel that acupuncture and electroacupuncture treatment should be considered acceptable, effective, and indicated.

Appropriateness of acupuncture/electroacupuncture was determined by the Advisory Council of expert acupuncturists, based upon general consensus, and after review of the following published research.

Percutaneous electrical nerve stimulation: a novel analgesic therapy for diabetic neuropathic pain.
Hamza MA, White PF, Craig WF, Ghoname ES, Ahmed HE, Proctor TJ, Noe CE, Vakharia AS, Gajraj N., Diabetes Care., 23(3):365-70, 2000.

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14. Chronic and Postoperative Pain

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of chronic and postoperative pain conditions:

"Acupuncture, in combination with pharmacological interventions, may lower the need for medication and reduce the risk for side effects from these drugs." [86]
"Acupuncture may reduce nausea and vomiting if used in early postoperative period." [87]

Quality of Evidence:
Level II - Evidence was obtained from at least one properly well-designed randomized controlled trial (RCT).

Recommendation Grade:
Grade A - A strong recommendation, based on an evaluation of the available evidence and general consensus of the expert panel, that acupuncture and electroacupuncture treatment is effective, always acceptable, and indicated.

Appropriateness of acupuncture / electroacupuncture was determined by the Advisory Council of expert acupuncturists, based upon general consensus, and after review of the following published research.

Comparative study of the analgesic effect of transcutaneous nerve stimulation (TNS); electroacupuncture (EA) and meperidine in the treatment of postoperative pain
Martelete M, Fiori AM. ,Acupunct Electrother Res., 1985, 10(3):183-93.

Acupuncture and chronic pain mechanisms
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Long-term treatment of chronic pain with acupuncture. Part I.
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Acupuncture and pain: a review of the literature
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[86] National Insitutes of Health, National Center for Complementary and Alternative Medicine. Acupuncture Information and Resources. Gaithersburg, MD; 2001

[87] National Institutes of Health. Acupuncture, NIH Consensus Statement, Nov 3-5 1997. [web page]. Bethesda (MD): National Institutes of Health; 1997 Nov.

15. Systemic and Non-Regional Conditions

A. Fibromyalgia

The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of systemic and non-regional conditions:

- Fibromyalgia

The U.S. Department of Health and Human Services, Public Health Service, Agency for Healthcare Research and Quality (AHRQ) recently performed a technology assessment in 2003 on "Acupuncture for the treatment of fibromyalgia" [88], and found studies to be inadequate and, concluding that "At this time, therefore, there is insufficient evidence to conclude that acupuncture has efficacy for the treatment of fibromyalgia." However, it also stated that "Two randomized controlled clinical trials with a follow-up of at least 13 weeks are currently underway and should provide more useful data about this treatment for fibromyalgia."

An additional AHRQ technology assessment on "Acupuncture for osteoarthritis" [89] in 2003 concluded that "The currently available evidence is insufficient to determine whether acupuncture has a specific beneficial effect in osteoarthritis."
1. Quality of Evidence:
Level II - Evidence was obtained from at least one properly well-designed randomized controlled trial (RCT).
2. Recommendation Grade:
Grade A - A strong recommendation, based on an evaluation of the available evidence and general consensus of the expert panel, that acupuncture and electroacupuncture treatment is effective, always acceptable, and indicated.

Appropriateness of acupuncture/electroacupuncture was determined by the Advisory Council of expert acupuncturists, based upon general consensus, and after review of the following published research.

Is acupuncture effective in the treatment of fibromyalgia?
Berman BM, Ezzo J, Hadhazy V, Swyers JP, J Fam Pract., 48(3):213-8, 1999.

Electroacupuncture in fibromyalgia: result of a controlled trial.
Deluze C et al. , British Medical Journal, 1992, 305:1249-1252.

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British Medical Association Board of Science and Education. London: Harwood Academic Publishers, 2000.

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[88] U.S. Department of Health and Human Services, Public Health Service, Agency for Healthcare Research and Quality (AHRQ). Acupuncture for the treatment of fibromyalgia. Technology Assessment. The Agency for Healthcare Research and Quality Center for Practice and Technology Assessment. Rockville, MD: AHRQ; June 5, 2003.

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Appendix A: Practice Guideline References

The standard public resource for evidence-based clinical practice guidelines is the National Guideline Clearinghouse (NGC), which lists nearly 2,000 guidelines from 250 sources in its database. The NGC is an initiative of the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services, and was originally created by AHRQ in partnership with the American Medical Association and the American Association of Health Plans.

A. Clinical Practice Guidelines Defined

The NGC employs the definition of clinical practice guideline developed by the Institute of Medicine (IOM).

> ***Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances***. [90]

B. Criteria for Inclusion of Clinical Practice Guidelines in NGC

All of the criteria below must be met for a clinical practice guideline to be included in NGC.

1. The clinical practice guideline contains systematically developed statements that include recommendations, strategies, or information that assists physicians and/or other health care practitioners and patients make decisions about appropriate health care for specific clinical circumstances.
2. The clinical practice guideline was produced under the auspices of medical specialty associations; relevant professional societies, public or private organizations, government agencies at the Federal, State, or local level; or health care organizations or plans. A clinical practice guideline developed and issued by an individual not officially sponsored or supported by one of the above types of organizations does not meet the inclusion criteria for NGC.
3. Corroborating documentation can be produced and verified that a systematic literature search and review of existing scientific evidence published in peer reviewed journals was performed during the guideline development. A guideline is not excluded from NGC if corroborating documentation can be produced and verified detailing specific gaps in scientific evidence for some of the guideline's recommendations.
4. The guideline is English language, current, and the most recent version produced. Documented evidence can be produced or verified that the guideline was developed, reviewed, or revised within the last five years.

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[90] Institute of Medicine. (1990). Clinical Practice Guidelines: Directions for a New Program, M.J. Field and K.N. Lohr (eds.) Washington, DC: National Academy Press. p. 38.

Appendix B: Standards of Evidence

A. Quality of Evidence

I. Multiple well-designed, randomized controlled trials, directly relevant to the recommendation, yielded a consistent pattern of findings.

II. Evidence was obtained from at least one properly well-designed randomized controlled trial (RCT).

III. Evidence was obtained from well-designed controlled trials without randomization.

IV. Evidence consisted of the opinions of respected authorities, based on clinical experience, descriptive studies in case reports, or reports of expert committees.

B. Recommendation Grades

A. A strong recommendation, based on an evaluation of the available evidence and general consensus of the expert panel, that acupuncture and electroacupuncture treatment is effective, always acceptable, and indicated

B. A recommendation that was based on an evaluation of the available evidence and general consensus of the expert panel that acupuncture and electroacupuncture treatment should be considered acceptable, effective, and indicated.

C. A recommendation that is not well established by evidence, or for which there is conflicting evidence regarding usefulness or efficacy, but which the expert panel has determined that acupuncture and electroacupuncture treatment may be acceptable, effective, and indicated.

D. A recommendation, based on evidence or general agreement, that acupuncture and electroacupuncture treatment may be considered not useful or effective.

E. A strong recommendation, based on evidence or general agreement, that a given procedure or treatment is not useful or effective, or in some cases may be harmful, and should be excluded from consideration.

Appendix C: WHO List of Conditions Treatable by Acupuncture

In 1979, the World Health Organization conducted a symposium on acupuncture in Beijing, China. A follow-up symposium was conducted in 1996 in Italy, which recommneded a critical review of current research literature on acupuncture, and an update of a previous report. The review was limited to 293 qualifying controlled clinical trials that were published through 1998 and early 1999, which stated, "Such trials have only been performed for a limited number of diseases or disorders. This should not be taken to mean, however, that acupuncture treatment of diseases or disorders not mentioned here is excluded…" [91]

A. Level I Standard of Evidence

Diseases, symptoms or conditions for which acupuncture has been proved-through controlled trials-to be an effective treatment:

- Adverse reactions to radiotherapy and / or chemotherapy
- Allergic rhinitis (including hay fever)
- Biliary colic
- Depression (including depressive neurosis and depression following stroke)
- Dysentery, acute bacillary
- Dysmenorrhoea, primary
- Epigastralgia, acute (in peptic ulcer, acute and chronic gastritis, and gastrospasm)
- Facial pain (including craniomandibular disorders)
- Headache
- Hypertension, essential
- Hypotension, primary
- Induction of labour
- Knee pain
- Leukopenia
- Low back pain
- Malposition of fetus, correction of
- Morning sickness
- Nausea and vomiting
- Neck pain
- Pain in dentistry (including dental pain and temporomandibular dysfunction)
- Periarthritis of shoulder
- Postoperative pain
- Renal colic
- Rheumatoid arthritis
- Sciatica
- Sprain
- Stroke
- Tennis elbow

B. Level II Standard of Evidence

This list can be obtained from the WHO report.

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[91] Acupuncture: Review and Analysis of Reports on Controlled Clinical Trials, World Health Organization, 1999.

Appendix D: NIH Consensus Statement

1997: 15(5):1-34.

OBJECTIVE: The objective of this NIH Consensus Statement is to inform the biomedical research and clinical practice communities of the results of the NIH Consensus Development Conference on Acupuncture. The statement provides state-of-the-art information regarding the appropriate use of acupuncture, and presents the conclusions and recommendations of the consensus panel regarding these issues. In addition, the statement identifies those areas of study that deserve further investigation. Upon completion, the reader should possess a clear working clinical knowledge of the state-of-the-art regarding this topic. The target audience of physicians for this statement includes, but is not limited to, family practitioners, medical acupuncturists, psychiatrists, and specialists in pain medicine. PARTICIPANTS: A non-Federal, nonadvocate, 12-member panel representing the fields of acupuncture, pain, psychology, psychiatry, physical medicine and rehabilitation, drug abuse, family practice, internal medicine, health policy, epidemiology, statistics, physiology, biophysics, and the public. In addition, 25 experts from these same fields presented data to the panel and a conference audience of 1,200. EVIDENCE: The literature was searched through Medline, and an extensive bibliography of references was provided to the panel and the conference audience. Experts prepared abstracts with relevant citations from the literature. Scientific evidence was given precedence over clinical anecdotal experience. CONSENSUS PROCESS: The panel, answering predefined questions, developed their conclusions based on the scientific evidence presented in open forum and the scientific literature. The panel composed a draft statement, which was read in its entirety and circulated to the experts and the audience for comment. Thereafter, the panel resolved conflicting recommendations and released a revised statement at the end of the conference. The panel finalized the revisions within a few weeks after the conference. The draft statement was made available on the World Wide Web immediately following its release at the conference and was updated with the panel's final revisions. CONCLUSIONS: Acupuncture as a therapeutic intervention is widely practiced in the United States. While there have been many studies of its potential usefulness, many of these studies provide equivocal results because of design, sample size, and other factors. The issue is further complicated by inherent difficulties in the use of appropriate controls, such as placebos and sham acupuncture groups. However, promising results have emerged, for example, showing efficacy of acupuncture in adult postoperative and chemotherapy nausea and vomiting and in postoperative dental pain. There are other situations such as addiction, stroke rehabilitation, headache, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, and asthma, in which acupuncture may be useful as an adjunct treatment or an acceptable alternative or be included in a comprehensive management program. Further research is likely to uncover additional areas where acupuncture interventions will be useful.

Appendix E: Informed Consent

A typical "Informed Consent" form contains the following information regarding acupuncture:

I hereby request and consent to acupuncture to be performed on me (or my legal charge) by a licensed health care professional.

I understand that success and results of treatment are not assured or guaranteed, that my participation in self-treatment may be necessary for best results, and that there are known and potential risks and complications. I understand that I have the opportunity to discuss the nature of the procedures, and the potential benefits and risks prior to treatment. I choose to rely upon my health care professional to exercise reasonable judgment, based upon known facts, and to act in my best interests. I understand that I may request another person of my choice to be present during the entire appointment.

Acupuncture is the insertion of fine needles into the body to stimulate healing and to reduce pain, and is generally safe and effective. It is normal to feel temporary warm, tight, sore or tingling sensations at the acupuncture site. Acupuncture occasionally causes bruising or a few drops of blood upon the removal of a needle. Bruising should be minimized by immediate direct pressure, and drops of blood can be absorbed with a clean, dry cotton ball. Electroacupuncture is the addition of a small electrical current to the needles, which may cause a tingling, pulsing, or electrial sensation.

Alternatives to treatment and other ways of managing illnesses may range from doing nothing to taking multiple treatment measures, and should be considered. Since you and your acupuncturist have decided upon the appropriate treatment procedures, do not hesitate to discuss the choices and the alternatives available for treatment of similar conditions. The potential effectiveness and risks accompanying any method of treatment should be considered.

I further understand that my other healthcare providers may need to be contacted, especially when a condition needs to be co-managed with specialists. Such conditions that may require co-management include, but are not limited to, pregnancy related nausea, pain associated with multiple sclerosis, neuromusculoskeletal effects of stroke, pain/nausea related to cancer/tumor, chemotherapy related nausea, pain/nausea related to AIDS/ARC, pain or nausea related to surgery. Coordination of care is for the purpose of managing health condition in my best interest and assure the optimal outcome of treatment. Therefore, I give my authorization to my acupuncturist to contact my other healthcare providers when necessary.

I have read, or have had read to me, the above consent, and have had the opportunity to ask questions and discuss this with my acupuncturist. I consent to acupuncture/electroacupuncture for my present condition(s). I have the right to refuse or discontinue treatment at any time and understand that this refusal may affect the expected results.

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References: Research Abstracts

Head and Face Conditions

Acupuncture for chronic headache in primary care: large, pragmatic, randomised trial.
Vickers AJ, Rees RW, Zollman CE, McCarney R, Smith CM, Ellis N, Fisher P, Van Haselen R. BMJ. Mar 27, 2004; 328(7442):744
Acu Research II
Integrative Medicine Service, Biostatistics Service, Memorial Sloan-Kettering Cancer Center, 1275 York Avenue, NY, NY 10021, USA. vickersa@mskcc.org
OBJECTIVE: To determine the effects of a policy of "use acupuncture" on headache, health status, days off sick, and use of resources in patients with chronic headache compared with a policy of "avoid acupuncture." DESIGN: Randomised, controlled trial. SETTING: General practices in England and Wales. PARTICIPANTS: 401 patients with chronic headache, predominantly migraine. Interventions Patients were randomly allocated to receive up to 12 acupuncture treatments over three months or to a control intervention offering usual care. MAIN OUTCOME MEASURES: Headache score, SF-36 health status, and use of medication were assessed at baseline, three, and 12 months. Use of resources was assessed every three months. RESULTS: Headache score at 12 months, the primary end point, was lower in the acupuncture group (16.2, SD 13.7, n = 161, 34% reduction from baseline) than in controls (22.3, SD 17.0, n = 140, 16% reduction from baseline). The adjusted difference between means is 4.6 (95% confidence interval 2.2 to 7.0; P = 0.0002). This result is robust to sensitivity analysis incorporating imputation for missing data. Patients in the acupuncture group experienced the equivalent of 22 fewer days of headache per year (8 to 38). SF-36 data favoured acupuncture, although differences reached significance only for physical role functioning, energy, and change in health. Compared with controls, patients randomised to acupuncture used 15% less medication (P = 0.02), made 25% fewer visits to general practitioners (P = 0.10), and took 15% fewer days off sick (P = 0.2). CONCLUSIONS: Acupuncture leads to persisting, clinically relevant benefits for primary care patients with chronic headache, particularly migraine. Expansion of NHS acupuncture services should be considered.

Acupuncture in the prophylactic treatment of migraine without aura: a comparison with flunarizine,
Allais G, De Lorenzo C, Quirico PE et al , Headache 42:855-861
Acu Research II
Woman's Headache Center, Department of Gynecology and Obstetrics, University of Turin, Turin, Italy.
OBJECTIVES: In a randomized controlled trial extending over 6 months, we evaluated the effectiveness of acupuncture versus flunarizine in the prophylactic treatment of migraine without aura. METHODS: One hundred sixty women with migraines were randomly assigned to acupuncture treatment (group A, n = 80) or to an oral therapy with flunarizine (group F, n = 80). In group A, acupuncture was carried out in weekly sessions for the first 2 months and then once a month for the next 4 months. The same acupoints were used at each treatment: LR3 Taichong, SP6 Sanyinjiao, ST36 Zusanli, CV12 Zhongwan, LI4 Hegu, PC6 Neiguan, GB20 Fengchi, GB14 Yangbai, EX-HN5 Taiyang, GV20 Baihui. In group F, 10 mg flunarizine were given daily for the first 2 months and then for 20 days per month for the next 4 months. RESULTS: The frequency of attacks and use of symptomatic drugs significantly decreased during treatment in both groups. The number of attacks after 2 and 4 months of therapy was significantly lower in group A than in group F, and analgesic consumption was significantly lower in group A at 2 months of treatment. At 6 months no such differences existed between the two treatment groups. Pain intensity was significantly reduced only by acupuncture treatment. Side effects were significantly less frequent in group A. CONCLUSIONS: Acupuncture proved to be adequate for migraine prophylaxis. Relative to flunarizine, acupuncture treatment exhibited greater effectiveness in the first months of therapy and superior tolerability.

Comparison of pharmacological treatment versus acupuncture treatment for migraine without aura
Liguori A, Petti F, Bangrazi A et al, J Trad Chin Med; 20:231-240.
Istituto Paracelso, Italian Center for Non Conventional Medicines, Rome, Italy.

This study was carried out in 120 patients affected by migraine without aura, treated in 4 public health centers and randomly divided into acupuncture group (AG) and conventional drug therapy group (CDTG). The evaluation of clinical results was made 6 and 12 months after the beginning of treatment and was worked out as well according to socio-medical parameters. Acupuncture was applied to the following points: Touwei (ST 8), Xuanlu (GB 5), Fengchi (GB 20), Dazhui (GV 14), Lieque (LU 7), treated with the reducing method. In AG, the figure scoring the entity and frequency of migraine attacks drops from 9,823 before treatment to 1,990 6 months after and 1,590 12 months after; while in CDTG, it drops from 8,405 before treatment to 3,927 6 months after and 3,084 12 months after. In AG, the total absence from work amounted to 1,120 working days / year, with a total cost (private + social costs) of 186,677,000 Italian liras. In CDTG, the absence from work amounted to 1,404 working days / year, with a total cost of 266,614,000 Italian liras. If we consider that in Italy the patients affected by migraine without aura are around 800,000, and that acupuncture therapy is able to save 1,332,000 Italian liras on the total average cost supported for every single patient, the application of acupuncture in the treatment of migraine without aura would allow a saving of the health expenses in Italy of over 1,000 billion liras.

Cost effectiveness analysis of a randomised trial of acupuncture for chronic headache in primary care.

Wonderling D, Vickers AJ, Grieve R, McCarney R, BMJ. Mar 27; 2004; 328(7442):747.
Acu Research II
Health Services Research Unit, London School of Hygiene and Tropical Medicine, London WC1E 7HT.
David.Wonderling@lshtm.ac.uk
OBJECTIVE: To evaluate the cost effectiveness of acupuncture in the management of chronic headache. DESIGN: Cost effectiveness analysis of a randomised controlled trial. SETTING: General practices in England and Wales. PARTICIPANTS: 401 patients with chronic headache, predominantly migraine. Interventions Patients were randomly allocated to receive up to 12 acupuncture treatments over three months from appropriately trained physiotherapists, or to usual care alone. MAIN OUTCOME MEASURE: Incremental cost per quality adjusted life year (QALY) gained. RESULTS: Total costs during the one year period of the study were on average higher for the acupuncture group (403 pounds sterling; 768 dollars; 598 euros) than for controls (217 pounds sterling) because of the acupuncture practitioners' costs. The mean health gain from acupuncture during the one year of the trial was 0.021 quality adjusted life years (QALYs), leading to a base case estimate of 9180 pounds sterling per QALY gained. This result was robust to sensitivity analysis. Cost per QALY dropped substantially when the analysis incorporated likely QALY differences for the years after the trial. CONCLUSIONS: Acupuncture for chronic headache improves health related quality of life at a small additional cost; it is relatively cost effective compared with a number of other interventions provided by the NHS.

Electroacupuncture for tension-type headache on distal acupoints only: a randomized, controlled, crossover trial.
Xue CC, Dong L, Polus B, English RA, Zheng Z, Da Costa C, Li CG, Story DF, Headache; 44(4):333-41, 2004.
RMIT Chinese Medicine Research Group, RMIT University, Bundoora, Victoria, Australia.
OBJECTIVE: To investigate the efficacy of electroacupuncture, applied to distal acupoints only, for tension-type headache. BACKGROUND: Electroacupuncture is commonly used for tension-type headache, but when applied to distal acupoints only, evidence of its efficacy is lacking. DESIGN: A randomized, single-blinded, sham-controlled, crossover clinical trial. Methods.-The trial had 5 stages: baseline (2 weeks), phases I and II (each 4 weeks), washout period (2 weeks), and follow-up (3 months after phase II). Forty patients were randomly assigned to either group A or group B. Group A received real electroacupuncture during phase I, then sham electroacupuncture in phase II. Group B received the treatments in reverse order. Outcome measures were headache frequency and duration, pain intensity using a visual analog scale, mechanical pain threshold, headache disability, and sickness impact. Data were analyzed by univariate 2-way analysis of variance. RESULTS: Thirty-seven patients completed the trial. There were no significant differences between the 2 groups at baseline. At the end of phase I, group A, but not group B, demonstrated significant improvement in mean (standard error of the mean [SEM]) headache frequency (3.0 per month [0.3] versus 12.0 per month [1.7]), duration (13.3 hours [3.5] versus 32.0 hours [6.2]), pain intensity (32.8 mm [4.1] versus 47.5 mm [2.7]), pain threshold (right side, 2.9 kg/second [0.1] versus 0.9 kg/second [0.1]; left side, 2.4 kg/second [0.1] versus 1.1 kg/second [0.1]), headache disability score (6.0 [1.0] versus 16.3 [1.6]), and sickness impact score (288.7 [48.0] versus 687.1 [77.2]). For each parameter, significant differences also were demonstrated for both groups between baseline and phase II, and baseline and follow-up. There were no significant differences between the groups at the end of follow-up (P >.05). CONCLUSION: Electroacupuncture to distal points alone is effective for short-term symptomatic relief of tension-type headache

Acupuncture and physiotherapy in the treatment of myogenic headache patients: pain relief and EMG activity.
Ahonen E, Hakumaki M, Mahlamaki S, Partanen J, Riekkinen P, Sivenius J. Advances in Pain Research and Therapy; 5:571-576.1983
WHO study
Twenty-two tension-neck and headache patients were divided into acupuncture and physiotherapy groups. The quantity of muscle tension (motor unit potential spikes per time unit) was estimated three times before the beginning of the therapy, four times during a therapy period of four weeks, and two times during the follow-up period of 28 weeks. Pain level was also estimated using a visual analogue scale. In both of the groups a significant reduction of muscle tension was observed during the therapy period. After a follow-up period of 28 weeks, there was still a significant reduction of EMG activity in both groups. Also, the subjective level of headache decreased in these groups during the therapy period, and it was also significantly lowered after 28 weeks of follow-up. It is concluded that either acupuncture therapy or physiotherapy relieves pain in tension-neck and headache patients.

Non-pharmacological approaches to chronic headaches: transcutaneous electrical nerve stimulation, lasertherapy and acupuncture in transformed migraine treatment.
Allais G, De Lorenzo C, Quirico PE, Lupi G, Airola G, Mana O, Benedetto C. Neurol Sci. 24 Suppl 2:S138-42, 2003
Woman's Headache Center, Department of Gynecology and Obstetrics, Via Ventimiglia 3, I-10126 Turin, Italy.
In an open, randomized trial, we evaluated transcutaneous electrical nerve stimulation (TENS), infrared lasertherapy and acupuncture in the treatment of transformed migraine, over a 4-month period free of prophylactic drugs. Sixty women suffering from transformed migraine were assigned, after a one month run-in period, to three different treatments: TENS (Group T; n=20), infrared lasertherapy (Group L; n=20) or acupuncture (Group A; n=20). In each group the patients underwent ten sessions of treatment and monthly control visits. In Group T patients were treated for two weeks (5 days/week) simultaneously with three TENS units with different stimulation parameters (I: pulse rate = 80 Hz, pulse width = 120 micros; II: 120 Hz, 90 micros; III: 4 Hz, 200 micros). In Group L an infrared diode laser (27 mW, 904 nm) was applied every other day on tender scalp spots. In Group A acupuncture was carried out twice a week in the first two weeks and weekly in the next 6 weeks. A basic formula (LR3, SP6, LI4, GB20, GV20 and Ex-HN5) was always employed; additional points were selected according to each patient's symptomatology. The number of days with headache per month significantly decreased during treatment in all groups. The response in the groups differed over time, probably due to the different timing of applications of the three methods. TENS, lasertherapy and acupuncture proved to be effective in reducing the frequency of headache attacks. Acupuncture showed the best effectiveness over time.

Acupuncture treatment of chronic tension headache -- a controlled cross-over trial.

Hansen, P.E., Hansen, J.H. Cephalgia;1985, 5:137-142
PubMed update search
Acu Research II
In a controlled trial the effect of traditional Chinese acupuncture v. placebo acupuncture was evaluated in 18 patients with chronic tension headache (mean disease duration 15 years). All patients suffered from daily or frequently recurring headache, the intensity of which was recorded by the patient over a period of 15 weeks. Each patient was treated by traditional Chinese acupuncture as well as by placebo acupuncture in a cross-over design following randomization. Each period of treatment comprised six treatments. Traditional Chinese acupuncture was found to be significantly more pain-relieving than placebo acupuncture, according to the pain registration of the patients themselves. The pain reduction was 31%. Acupuncture is therefore found to be a reasonable treatment for chronic tension headache.

The 'dry-needle technique': intramuscular stimulation in tension-type headache
Karakurum B, Karaalin O, Coskun O et al. Cephalalgia; 2001, 21:813-817
Acu Research II
The Ministry of Health Ankara Hospital, Department of Neurology, Ankara, Turkey.
The 'dry-needle technique', an intramuscular stimulation technique carried out by using a fine solid, 1-inch long, 30-gauge needle, was investigated in the treatment of tension-type headache (TTH) in a randomized, placebo-controlled trial. Fifteen patients with TTH received intramuscular needle insertions into six designated trigger points, while 15 controls received subcutaneous insertions. Headache indices, muscle tenderness and neck ROMs were evaluated before and after treatment. Mean headache indices improved significantly after treatment, both in the treatment group and in the placebo group, but the difference between the two groups was insignificant. In the treatment group the tenderness score and the neck ROM limitation score were significantly improved after treatment, while there was no significant improvement in the placebo group. We conclude that more and larger controlled, comparative trials are needed to show whether the dry-needle technique is an effective non-pharmacological alternative for the treatment of TTH.

Needle acupuncture in tension-type headache: a randomized, placebo-controlled study
Karst M, Reinhard M, Thum P, et al . Cephalalgia, 2001; 21:637-642
Acu Research II
Department of Anaesthesiology, Medical School of Hannover, Hannover, Germany. Karst.Matthias@MH-Hannover.de
A study with needle acupuncture was performed in tension-type headache employing a new placebo acupuncture METHOD: Sixty-nine patients (mean age 48.1 years, SD = 14.1) fulfilling the International Headache Society criteria for tension-type headache were randomly assigned to verum or placebo condition. No significant differences between placebo and verum with respect to visual analogue scale and frequency of headache attacks could be observed immediately, 6 weeks and 5 months after the end of treatment. There was a significant but weak improvement in quality of life parameters (clinical global impressions, Nottingham Health Profile) after verum treatment. In decision tree analyses, the changes in clinical global impressions and headache frequency depended significantly on primary headache frequency with a limit value of 24.5 days headache per month. High values in the von Zerssen Depression Score resulted in high mean visual analogue scale values.

Use of percutaneous electrical nerve stimulation (PENS) for treating ECT-induced headaches
Ghoname EA, Craig WF, White PF. Headache; 39(7):502-5. 1999.
Acu-Research IV
Department of Anesthesiology and Pain Management, University of Texas Southwestern Medical Center at Dallas, 5161 Harry Hines Boulevard, Suite CS2.202, Dallas, TX 75235-9068, USA.
Five patients who experienced migrainelike attacks associated with electroconvulsive therapy (ECT) were treated using a novel nonpharmacologic therapy known as percutaneous electrical nerve stimulation (PENS). In this sham-controlled preliminary evaluation, PENS therapy proved to be a useful alternative to opioid analgesics for the acute treatment and/or prevention of ECT-induced headache.

Neck Conditions

Controlled trial of Japanese acupuncture for chronic myofascial neck pain: assessment of specific and nonspecific effects of treatment
Birch S, Jamison RN, Clin J Pain; 1998, 14(3):248-255
Acu Research II
Anglo-Dutch Institute of Oriental Medicine, IJmuiden, The Netherlands.
OBJECTIVE: This article examines the specific and nonspecific effects of Japanese acupuncture on chronic myofascial neck pain in a randomized single-blind trial. DESIGN: Forty-six patients were randomly assigned to receive relevant acupuncture, irrelevant acupuncture, or no-acupuncture control treatment consisting of nonsteroidal anti-inflammatory medication. The two acupuncture groups underwent comparable light shallow needling. The irrelevant acupuncture group received acupuncture at specific sites not relevant for cervical pain. OUTCOME MEASURES: The study measures included the McGill Pain Questionnaire-Short Form (SF-MPQ), the Short-Form Health Survey (SF-36), the Symptom Checklist 90-Revised (SCL-90-R), medication diary, and physiologic

measures. The factors examined as predictors of outcome pain ratings were experience with, beliefs about, and knowledge of acupuncture before treatment; perceived efficacy, credibility, and logic of acupuncture; perceived competence of the acupuncturist; and painfulness of acupuncture. RESULTS: No differences were found among the three groups at baseline, except that the relevant acupuncture group reported having had more previous acupuncture treatments. No significant differences in terms of perceived credibility or perceived effectiveness of treatment were found between the two acupuncture groups. The relevant acupuncture group had significantly greater pre-/posttreatment differences in pain than the irrelevant acupuncture and control groups ($p < .05$). The nonspecific effects of confidence in the acupuncturist, willingness to try any treatment, mood, and physiologic effect of needling were not predictive of treatment outcome, whereas confidence in the treatment and past experiences with acupuncture did correlate significantly with a decrease in pain. CONCLUSIONS: Relevant acupuncture with heat contributes to modest pain reduction in persons with myofascial neck pain. Previous experience with and confidence in treatment help to predict benefit. Measurement of nonspecific effects of alternative therapy is recommended in future clinical trials.

Effect of acupuncture treatment on chronic neck and shoulder pain in sedentary female workers: a 6-month and 3-year follow-up study.

He D, Veiersted KB, Hostmark AT, Medbo JI. Pain; 2004: 109(3):299-307.

PubMed update search

Acu Research II

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The study was carried out to examine whether acupuncture treatment can reduce chronic pain in the neck and shoulders and related headache, and also to examine whether possible effects are long-lasting. Therefore, 24 female office workers (47+/-9 years old, mean+/-SD) who had had neck and shoulder pain for 12+/-9 years were randomly assigned to a test group (TG) or a control group (CG). Acupuncture was applied 10 times during 3-4 weeks either at presumed anti-pain acupoints (TG) or at placebo-points (CG). A physician measured the pain threshold (PPT) in the neck and shoulder regions with algometry before the first treatment, and after the last one and six months after the treatments. Questionnaires on muscle pain and headache were answered at the same occasions and again 3 years after the last treatment. The intensity and frequency of pain fell more for TG than for CG (Pb < or = 0.04) during the treatment period. Three years after the treatments TG still reported less pain than before the treatments (Pw < 0.001) contrary to what CG did (Pb < 0.04) The degree of headache fell during the treatment period for both groups, but more for TG than for CG (Pb=0.02) Three years after the treatments the effect still lasted for TG (Pw < 0.01) while the degree of headache for CG was back to the pre-treatment level (Pb < 0.001) PPT of some muscles rose during the treatments for TG and remained higher 6 months after the treatments (Pw < 0.05) which contrasts the situation for CG. Adequate acupuncture treatment may reduce chronic pain in the neck and shoulders and related headache. The effect lasted for 3 years.

Randomised trial of acupuncture compared with conventional massage and "sham" laser acupuncture for treatment of chronic neck pain

Irnich D, Behrens N, Molzen H et al , BMJ; 2001: 322:1-6

Acu Research II

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OBJECTIVES: To compare the efficacy of acupuncture and conventional massage for the treatment of chronic neck pain. DESIGN: Prospective, randomised, placebo controlled trial. Setting: Three outpatient departments in Germany. PARTICIPANTS: 177 patients aged 18-85 years with chronic neck pain. Interventions: Patients were randomly allocated to five treatments over three weeks with acupuncture (56), massage (60), or "sham" laser acupuncture (61). MAIN OUTCOME MEASURES: Primary outcome measure: maximum pain related to motion (visual analogue scale) irrespective of direction of movement one week after treatment. Secondary outcome measures: range of motion (3D ultrasound real time motion analyser), pain related to movement in six directions (visual analogue scale), pressure pain threshold (pressure algometer), changes of spontaneous pain, motion related pain, global complaints (seven point scale), and quality of life (SF-36). Assessments were performed before, during, and one week and three months after treatment. Patients' beliefs in treatment were assessed. RESULTS: One week after five treatments the acupuncture group showed a significantly greater improvement in motion related pain compared with massage (difference 24.22 (95% confidence interval 16.5 to 31.9), P=0.0052) but not compared with sham laser (17.28 (10.0 to 24.6), P=0.327). Differences between acupuncture and massage or sham laser were greater in the subgroup who had had pain for longer than five years (n=75) and in patients with myofascial pain syndrome (n=129). The acupuncture group had the best results in most secondary outcome measures. There were no differences in patients' beliefs in treatment. CONCLUSIONS: Acupuncture is an effective short term treatment for patients with chronic neck pain, but there is only limited evidence for long term effects after five treatments.

Immediate effects of dry needling and acupuncture at distant points in chronic neck pain: results of a randomized, double-blind, sham- controlled crossover trial.

Irnich, D.; Behrens, N.; Gleditsch, J.; Stor, W.; Schreiber, M.; Schops, P.; Vickers, A.; Beyer, A. Pain; 2002: 99(1-2): 83.

Acu Research II

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To evaluate immediate effects of two different modes of acupuncture on motion-related pain and cervical spine mobility in chronic neck pain patients compared to a sham procedure. Thirty-six patients with chronic neck pain and limited cervical spine mobility participated in a prospective, randomized, double-blind, sham-controlled crossover trial. Every patient was treated once with needle acupuncture at distant points, dry needling (DN) of local myofascial trigger points and sham laser acupuncture (Sham). Outcome measures were motion-related pain intensity (visual analogue scale, 0-100 mm) and range of motion (ROM). In addition, patients scored changes of general complaints using an 11-point verbal rating scale. Patients were assessed immediately before and

after each treatment by an independent (blinded) investigator. Multivariate analysis was used to assess the effects of true acupuncture and needle site independently. For motion-related pain, use of acupuncture at non-local points reduced pain scores by about a third (11.2 mm; 95% CI 5.7, 16.7; P = 0.00006) compared to DN and sham. DN led to an estimated reduction in pain of 1.0 mm (95% CI -4.5, 6.5; P = 0.7). Use of DN slightly improved ROM by 1.7 degrees (95% CI 0.2, 3.2; P = 0.032) with use of non-local points improving ROM by an additional 1.9 degrees (95% CI 0.3, 3.4; P = 0.016). For patient assessment of change, non-local acupuncture was significantly superior both to Sham (1.7 points; 95% CI 1.0, 2.5; P = 0.0001) and DN (1.5 points; 95% CI 0.4, 2.6; P = 0.008) but there was no difference between DN and Sham (0.1 point; 95% CI -1.0, 1.2; P = 0.8). Acupuncture is superior to Sham in improving motion-related pain and ROM following a single session of treatment in chronic neck pain patients. Acupuncture at distant points improves ROM more than DN; DN was ineffective for motion-related pain. Copyright 2002 International Association for the Study of Pain

The acupuncture treatment of neck pain: a randomized controlled study.
Coan RM, Wong G, Coan PL. American Journal of Chinese Medicine; 9:326-332. 1981
WHO study / FAR Rolling Database
Thirty patients with cervical spine pain syndromes persisting a mean of 8 years were assigned randomly into equal treatment and control groups. After 12 weeks, 12 of 15 (80%) of the treated group felt improved, some dramatically, with a mean 40% reduction of pain score, 54% reduction of pain pills, 68% reduction of pain hours per day and 32% less limitation of activity. Two of 15 (13%) of the control group reported slight improvement after 12.8 weeks. The control group had a mean 2% worsening of the pain score, 10% reduction in pain pills, no lessening of pain hours and 12% less limitation of activity.

Chronic neck pain: a comparison of acupuncture treatment and physiotherapy.
David J, Modi S, Aluko AA, Robertshaw C, Farebrother J. British Journal of Rheumatology; 1998: 37(10):1118-1132.
WHO study / FAR Rolling /
Acu Research II
Royal Berkshire Hospital NHS Trust and University of Reading.
OBJECTIVE: To evaluate the effectiveness of acupuncture, as compared with physiotherapy, in the management of chronic neck pain. DESIGN: Seventy adult patients with non-inflammatory neck pain of >6 weeks duration and with no abnormal neurology were randomly assigned to receive either of the treatments. Thirty-five patients were included in each group. OUTCOME MEASURES: Pain by visual analogue scale and neck pain questionnaire, improvement in range of movement of neck relative to baseline, and well-being (general health questionnaire). Measurements were recorded at the start of treatment, at 6 weeks and at 6 months. RESULTS: Both treatment groups improved in all criteria. Acupuncture was slightly more effective in patients who had higher baseline pain scores. CONCLUSIONS: Both acupuncture and physiotherapy are effective forms of treatment. Since an untreated control group was not part of the study design, the magnitude of this improvement cannot be quantified.

Randomised trial of acupuncture compared with conventional massage and "sham" laser acupuncture for treatment of chronic neck pain - range of motion analysis
Konig A, Radke S, Molzen H, Haase M, Muller C, Drexler D, Natalis M, Krauss M, Behrens N, Irnich D. Z Orthop Ihre Grenzgeb; 141(4):395-400.,2003.
PubMed update search
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AIM: The aim of this study was to compare the effects of acupuncture on active motion of the cervical spine in patients with chronic neck pain with those of "sham" laser acupuncture and massage. MATERIAL AND METHODS: 177 patients with chronic neck pain were included in this prospective, randomized, placebo-controlled study. The patients were allocated by external randomization to five treatments over three weeks with acupuncture, massage and "sham" laser acupuncture. The range of active motion was measured by means of a 3D ultrasound real time motion analyzer. RESULTS: The analysis of cervical motion in three directions showed the largest increase in range of motion 14 days after acupuncture. Compared to massage, a significant improvement in total range of motion was seen in those patients treated by acupuncture immediately (p = 0,03) and one week (p = 0,03) weeks after therapy. There was no significant difference in those patients treated by sham laser acupuncture. CONCLUSION: The results of the study indicate that acupuncture is superior to conventional massage for improving active range of motion in patients with chronic neck pain. Because of its positive effects, its acceptance among patients and the lack of severe side effects, acupuncture can be recommended for the treatment of chronic neck pain, although there was no significant difference in results between "sham" laser acupuncture and acupuncture.

Treatment of cervical spondylosis. Electroacupuncture versus physiotherapy.
Loy TT, Med J Aust.2(1):32-4, 1983.
A prospective, controlled clinical trial was undertaken to assess the relative efficacies of physiotherapy and electroacupuncture in the treatment of cervical spondylosis. The results suggested that, while both methods were effective, electroacupuncture produced an earlier symptomatic improvement with increased neck movement, especially in patients with mild degenerative changes of the cervical spine.

Relief of chronic neck and shoulder pain by manual acupuncture to tender points--a sham-controlled randomized trial.
Nabeta T, Kawakita K. Complement Ther Med.; 2002: 10(4):217-22.
PubMed update search
Acu Research II

Meiji School of Oriental Medicine, Osaka, Japan.
OBJECTIVES: To compare the effects of real acupuncture to tender points for neck and shoulder pain and stiffness (Japanese: katakori) with those of sham acupuncture. DESIGN: Randomized-controlled trial. METHODS: Thirty-four volunteers from an acupuncture school with complaints of chronic pain and stiffness, who had no arm symptoms and gave informed consent, were randomly allocated to acupuncture or sham groups. Acupuncture or sham acupuncture was applied to the tender points once a week for 3 weeks. In the acupuncture group the acupuncture needle was inserted to the muscle, then the sparrow pecking technique was applied five times. Sham acupuncture was done without insertion of the needle. Dull pain and stiffness were evaluated by visual analog scale (VAS) before, and every 2 days after the first needling for 1 month. Pressure pain threshold on the tender points was measured before and after each treatment. RESULTS: There was no statistical difference of VAS scores between acupuncture and sham groups 9 days after the last treatment. However, the acupuncture group showed significant reduction of VAS scores immediately after and / or 1 day after the real acupuncture treatments ($P<0.01$). The effect tended to be prolonged after repeated treatment. Pressure pain thresholds tended to increase after real acupuncture treatment but not after sham acupuncture. CONCLUSIONS: Acupuncture applied to tender points appears to have short-term effects on neck and shoulder pain and stiffness, but this study was unable to demonstrate any long-term superiority over sham acupuncture.

Acupuncture in the treatment of chronic cervical pain. A pilot study.
Petrie JP, Langley GB. Clin Exp Rheumatol; 1(4):333-6, 1983.
PubMed update search
Thirteen patients with neck pain of at least two years' duration participated in the study. Patients were randomly assigned to either an acupuncture group or a placebo TNS (transcutaneous nerve stimulation) group. Initial pain scores revealed no significant difference between the groups with respect to pain severity. Patients were treated twice weekly for four weeks, at the end of which pain relief was measured using a simple descriptive scale. Even though an attempt was made to maximize the effect of placebo TNS using strong verbal suggestion, acupuncture still proved superior to placebo in the relief of cervical pain (p less than 0.01). The implications of these findings are discussed.

Electrical stimulation of auricular acupuncture points is more effective than conventional manual auricular acupuncture in chronic cervical pain: a pilot study.
Sator-Katzenschlager SM, Szeles JC, Scharbert G, Michalek-Sauberer A, Kober A, Heinze G, Kozek-Langenecker SA. Anesth Analg. 97(5):1469-73, 2003.
PubMed update search
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In this prospective, randomized, double-blinded, controlled study, we tested the hypothesis that auricular electroacupuncture relieves pain more effectively than conventional manual auricular acupuncture. We studied 21 chronic cervical pain patients without radicular symptoms with insufficient pain relief (visual analogue scale >5) treated with standardized analgesic therapy. All patients received disposable acupuncture needles on the dominant side on the following acupuncture points: cervical spine, shen men, and cushion. In 10 patients, needles were continuously stimulated (2-mA constant current, 1 Hz monophasic) by using the electrical point stimulation device P-STIM. In 11 control patients, no electrical stimulation was administered. All needles were withdrawn 48 h after insertion. Acupuncture was performed once a week for 6 wk. Patients had to complete a questionnaire assessing pain intensity, psychological well-being, activity, sleep, and demand for rescue medication (lornoxicam and tramadol). The reduction in pain scores was significant in the electrical acupuncture group. Similarly, psychological well-being, activity, and sleep were significantly improved in patients receiving electrical acupuncture, and consumption of rescue medication was significantly less. These results demonstrate that continuous electrical stimulation of auricular acupuncture points by using the new point stimulation device P-STIM improves the treatment of chronic cervical pain in an outpatient population. IMPLICATIONS: Continuous electrical stimulation of auricular acupuncture points by using the new point stimulation device P-STIM significantly decreases pain intensity and significantly improves psychological well-being, activity, and sleep in chronic cervical pain patients.

Acupuncture for chronic back and neck pain
Yue, Shyh-Jong., Acupuncture and Electro-Therapeutics; 1978: 3:323-324
Acu-Research I
This is a preliminary report of the research in acupuncture conducte at the Rehabilitation Medicine Service of St. Luke's Hospital Center. In a controlled study, classical accepted-site acupuncture, off-site acupuncture, and conventional physical therapy were compared. Patients who were randomly assigned to these treatment conditions had chronic back or neck pain with objective findings. Improvement was evaluated by a rheumatologiist, who was unaware of the type of treatment the patient received; by the treating physician; and by a range of motion tests. The patients also participated in a battery of psychiatric and psychological tests including hypmotic susceptibility. Some preliminary findings of interest are: acupuncture was superior to convetional physical therapy; accepted-site acupuncture and off-site acupuncture did not differ significantly, and the score on the Hamilton Pschiatric Rating Scale for Depression accurately predicted the results of acupuncture therapy.

A controlled trial on acupuncture for chronic neck pain.
Zhu XM, Polus B. Am J Chin Med; 2002: 30(1):13-28
PubMed update search
Acu-Research II
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To evaluate the efficacy of Chinese medicine (CM) acupuncture for chronic neck pain (CNP), a single blind, controlled, crossover, clinical trial was undertaken. Twenty-nine volunteers with CNP were randomly recruited into two groups. Both groups received

two phases of treatment with a washout period between the two phases. Group A (14 volunteers) received CM acupuncture in the first phase and sham acupuncture in the second, while Group B (15 volunteers) received sham in the first and real in the second. CM acupuncture was individualized and consisted of nine sessions on both local and distal points. Manual twisting of the needle was applied on all points plus strong electrical stimulation of distal points in CM acupuncture. Sham acupoints (lateral to the real) and sham (weak) electrical stimulation was used in the control group. Comparison of subjective and objective measures between the two groups was made at different periods, including baseline, after each phase of treatment, after washout, and after the 16th week follow-up. The subjective measures included pain intensity, duration per day, analgesic medication count, visual analogue scales (VAS) and neck disability index (NDI). The objective measures consisted of neck range of motion (ROM) and pain threshold (PT). Both the real and sham treatments significantly reduced subjective pain, without significant differences between groups for most subjective measures. Objective measures showed no significant change for either group before and after each period or by inter-groups analysis. A minimum 16-week effect of both real and sham acupuncture was found for subjective measures in the follow-up periods. Further study is recommended with an increased sample size, a longer washout period, and a longer baseline period.

Shoulder Conditions

Acupuncture for frozen shoulder
Sun KO, Chan KC, Lo SL, Fong DY. Hong Kong Med J; 2001: 7(4):381-91
Acu Research II
Department of Anaesthesiology and Operating Theatre Services, Kwong Wah Hospital, 25 Waterloo Road, Kowloon, Hong Kong.
This randomised controlled trial was undertaken to evaluate the effectiveness of acupuncture as a treatment for frozen shoulder. Thirty-five patients with a diagnosis of frozen shoulder were randomly allocated to an exercise group or an exercise plus acupuncture group and treated for a period of 6 weeks. Functional mobility, power, and pain were assessed by a blinded assessor using the Constant Shoulder Assessment, at baseline, 6 weeks and 20 weeks. Analysis was based on the intention-to-treat principle. Compared with the exercise group, the exercise plus acupuncture group experienced significantly greater improvement with treatment. Improvements in scores by 39.8% (standard deviation, 27.1) and 76.4% (55.0) were seen for the exercise and the exercise plus acupuncture groups, respectively at 6 weeks (P=0.048), and were sustained at the 20-week re-assessment (40.3% [26.7] and 77.2% [54.0], respectively; P=0.025). We conclude that the combination of acupuncture with shoulder exercise may offer effective treatment for frozen shoulder.

Randomised clinical trial comparing the effects of acupuncture and a newly designed placebo needle in rotator cuff tendonitis
Kleinhenz J, Streitberger K, Windeler J et al ; Pain; 1999: 83:235-241
Acu Research II
Clinic of Anesthesiology, University of Heidelberg, Im Neuenheimer Feld 110, 69120, Heidelberg, Germany.
Acupuncture has gained increasing attention in the treatment of chronic pain. The lack of a satisfying placebo method has made it impossible to show whether needling is an important part of the method or whether the improvement felt by the patient is due to the therapeutic setting and psychological phenomena. Also, the effectiveness of acupuncture has not been demonstrated sufficiently. We treated 52 sportsmen with rotator cuff tendinitis in a randomised single-blind clinical trial using a new placebo-needle as control. Patients were treated for 4 weeks. The primary endpoint of the trial was the change in the modified Constant-Murley-score from the baseline. Assessment of the treatment outcome was made by experienced orthopaedists not informed of the treatment allocation. Acupuncture with penetration of the skin was shown to be more effective than a similar therapeutic setting with placebo needling in the treatment of pain. The acupuncture-group improved 19.2 Constant-Murley-score points (SD 16.1, range from -13 to 50), the control-group improved 8.37 points (SD 14.56, range from -20 to 41), (P=0.014; C.I. 2.3;19.4). This study showed that needling is an important part of the acupuncture effect in the treatment of chronic shoulder pain in athletes. No conclusions can be derived from this study concerning the importance of choosing points and the rules of Traditional Chinese Medicine. Using the new placebo method as control for other ailments could improve the evidence of specific acupuncture effects beyond pain treatment.

Acupuncture and Trager psychophysical integration in the treatment of wheelchair user's shoulder pain in individuals with spinal cord injury
Dyson-Hudson TA,Shiflett SC, et al . Arch phys Med Rehabil 82:1038-1046 2001.

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OBJECTIVE: To determine the effectiveness of acupuncture and Trager Psychophysical Integration (a form of manual therapy) in decreasing chronic shoulder pain in wheelchair users with spinal cord injury (SCI). DESIGN: A prospective clinical trial, with subjects randomized to acupuncture or Trager treatment condition. Subjects served as their own controls by including a 5-week pretreatment baseline period and a 5-week posttreatment follow-up period. SETTING: Rehabilitation hospital research department. PARTICIPANTS: Eighteen subjects with chronic SCI and chronic shoulder pain who used manual wheelchairs as their primary means of mobility. INTERVENTION: Ten acupuncture or 10 Trager treatments over a 5-week period. MAIN OUTCOME MEASURES: Changes in performance-corrected Wheelchair User's Shoulder Pain Index (PC-WUSPI) scores during baseline, treatment, and follow-up periods were assessed by using analysis of variance. RESULTS: The mean PC-WUSPI score +/- standard deviation of the 18 subjects at entry was 48.9 +/- 24.6 (range, 8.0-94). No significant change in mean PC-WUSPI scores occurred

during the pretreatment baseline period. Mean PC-WUSPI scores decreased significantly during the treatment period in both the acupuncture (53.4%; 23.3 points) and Trager (53.8%; 21.7 points) treatment groups. The reduced PC-WUSPI scores were maintained in both groups throughout the 5-week posttreatment follow-up period. CONCLUSION: Acupuncture and Trager are both effective treatments for reducing chronic shoulder pain associated with functional activities in persons with SCI.

Elbow Conditions

Acupuncture in chronic epicondylitis: a randomized controlled trial
Fink M, Wolkenstein E, Karst M et al . Rheumatology; 2002: 41:205-209.
Acu Research II
Department of Physical Medicine and Rehabilitation, Hannover Medical School, Hannover, Germany.
OBJECTIVE: To evaluate the clinical efficacy of acupuncture in the treatment of chronic lateral epicondylitis. METHODS: In a randomized, investigator- and patient-blinded, controlled clinical study, 23 patients were treated with real acupuncture and 22 patients received sham acupuncture. Patients each received 10 treatments, with two treatments per week. The primary outcome variables were maximal strength, pain intensity (verbal rating scale) and disability scale (Disabilities of the Arm, Shoulder and Hand questionnaire). Patients were examined at baseline (1 week before the start of treatment) and at follow-up 2 weeks and 2 months after the end of treatment. RESULTS: There was no significant difference between the groups at baseline for any outcome parameter. Two weeks and 2 months after the end of treatment, there were significant reductions in pain intensity and improvements in the function of the arm and in maximal strength in both treatment groups. At the 2-week follow-up these differences were significantly greater for all outcome parameters in the group treated with real acupuncture. At 2 months the function of the arm was still better in this group than in the sham acupuncture group; however, the differences in pain intensity and maximal strength between the groups were no longer significant. CONCLUSION: In the treatment of chronic epicondylopathia lateralis humeri, acupuncture in which real acupuncture points were selected and stimulated was superior to non-specific acupuncture with respect to reduction in pain and improvement in the functioning of the arm. These changes are particularly marked at early follow-up.

Chronic epicondylitis: effects of real and sham acupuncture treatment: a randomised controlled patient- and examiner-blinded long-term trial.
Fink M, Wolkenstein E, Luennemann M, Gutenbrunner C, Gehrke A, Karst M. Forsch Komplementarmed Klass Naturheilkd; 9(4):210-5 2002
PubMed update search
Department of Physical Medicine and Rehabilitation, Hannover Medical School.
OBJECTIVE: The clinical long-term effectiveness of real and sham acupuncture treatment on differentiated pain measurement was evaluated in chronic lateral epicondylitis, an example of a tendomyotic disorder. METHODS: Randomised, examiner- and patient-blinded controlled clinical study. Outcome measurement: pain at rest, pain on movement, pain on exertion, frequency and duration of pain. Real acupuncture (n = 23) was tested versus invasive sham acupuncture (n = 22). Ten treatments were given (2 treatments / week). Patients were examined at baseline (E1) as well as 2 weeks (E2), 2 months (E3) and 1 year (E4) after the end of treatment. In the treatment with real acupuncture, acupuncture points were selected and mechanically stimulated while in the sham group non-acupuncture points were selected. RESULTS: There was no significant difference between the groups at baseline for any outcome parameter. Two weeks, 2 months and 1 year after the end of treatment there were significant reductions in all pain variables compared to baseline. At the first follow-up, significant group differences were registered for pain on motion and pain on exertion in favour to the real acupuncture group. These differences in pain intensity between the groups were no longer significant at the 2 months and 12 months follow-ups. CONCLUSION: The results suggest that, in the treatment of chronic epicondylitis, the selection of so-called real acupuncture points gives better results than invasive sham acupuncture at early follow-up. This additional effect can be interpreted as a specific effect of real acupuncture. Copyright 2002 S. Karger GmbH, Freiburg

Comparison of the effectiveness between manual acupuncture and electro-acupuncture on patients with tennis elbow
Tsui P, Leung MC. Acupunct Electrother Res.; 2002: 27(2):107-17
Acu-Research I
Department of Rehabilitation Sciences, The Hong Kong Polytechnic University, Hung Hom, Kowloon, China.
This is a single-blinded randomized controlled trial to compare the relative effectiveness between manual acupuncture (MA) and electro-acupuncture (EA) on the patients with chronic tennis elbow. Twenty patients recruited in the study were first introduced into control group for 2 weeks waiting period. Then, they were randomly assigned into either MA or EA group for acupuncture treatment. The acupuncture points of GB34 and ST38 were used in both treatment groups. In the MA group, the needle was retained for 20 minutes after the Deqi sensation obtained. In the EA group, electrical stimulation with 4 pulses / second frequency was applied and treatment lasted for 20 minutes. After 6 treatments within 2 weeks duration, significant differences were observed between groups favoring the electro-acupuncture in relation to pain relief (Pain visual analogue scale) and pain free hand grip strength (PFG). This study showed that electro-acupuncture is superior to manual acupuncture in treating patients with tennis elbow.

Acupuncture Therapy for Tennis Elbow
Gunilla Brattberg. Pain, 1983: 16:285-288

Acu Research II
Acupuncture therapy for patients suffering from tennis elbow has shown itself to be an excellent alternative to steroid injections. Twenty-one out of 34 patients who were treated with acupuncture became much better--completely free of pain. Many of them had previously been given one or more steroid injections without improvement. In a control group of 26 patients who received only steroid injections, 8 patients reported a corresponding improvement. The ancient Chinese technique adapted to Western conditions has, in the above cases, neither caused any side effects nor worsened the condition of any patient, and is well worth trying as therapy for this disabling complaint.

Wrist and Hand

Carpal tunnel syndrome pain treated with low-level laser and microamperes transcutaneous electric nerve stimulation: A controlled study
Naeser MA, Hahn KA, Lieberman BE, Branco KF. Arch Phys Med Rehabil; 83:978-988.
Acu Research II
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OBJECTIVE: To investigate whether real or sham low-level laser therapy (LLLT) plus microamperes transcutaneous electric nerve stimulation (TENS) applied to acupuncture points significantly reduces pain in carpal tunnel syndrome (CTS). DESIGN: Randomized, double-blind, placebo-control, crossover trial. Patients and staff administered outcome measures blinded. SETTING: Outpatient, university-affiliated Department of Veterans Affairs medical center. PARTICIPANTS: Eleven mild to moderate CTS cases (nerve conduction study, clinical examination) who failed standard medical or surgical treatment for 3 to 30 months. INTERVENTION: Patients received real and sham treatment series (each for 3-4wk), in a randomized order. Real treatments used red-beam laser (continuous wave, 15mW, 632.8nm) on shallow acupuncture points on the affected hand, infrared laser (pulsed, 9.4W, 904nm) on deeper points on upper extremity and cervical paraspinal areas, and microamps TENS on the affected wrist. Devices were painless, noninvasive, and produced no sensation whether they were real or sham. The hand was treated behind a hanging black curtain without the patient knowing if devices were on (real) or off (sham). MAIN OUTCOME MEASURES: McGill Pain Questionnaire (MPQ) score, sensory and motor latencies, and Phalen and Tinel signs. RESULTS: Significant decreases in MPQ score, median nerve sensory latency, and Phalen and Tinel signs after the real treatment series but not after the sham treatment series. Patients could perform their previous work (computer typist, handyman) and were stable for 1 to 3 years. CONCLUSIONS: This new, conservative treatment was effective in treating CTS pain; larger studies are recommended. Copyright 2002 by the American Congress of Rehabilitation Medicine and the American Academy of Physical Medicine and Rehabilitation

Thorax and Low Back

Acupuncture for chronic low back pain: a randomized placebo-controlled study with long-term follow-up
Carlsson CP, Sjolund BH. Clin J Pain 17:296-305 2001
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OBJECTIVE: The authors sought to determine whether a series of needle acupuncture treatments produced long-term relief of chronic low back pain. DESIGN: A blinded placebo-controlled study with an independent observer. The patients were randomized to receive manual acupuncture, electroacupuncture, or active placebo (mock transcutaneous electrical nerve stimulation). Subjects were examined and monitored by an investigator who was blinded to the treatment given. SETTING: A tertiary-level pain clinic at a Swedish university hospital. PATIENTS: Fifty consecutive patients (33 women, 17 men; mean age, 49.8 years) with chronic low back pain (mean pain duration, 9.5 years) and without rhizopathy or history of acupuncture treatment were included in the study. INTERVENTIONS: Treatments were given once per week for 8 weeks. Two further treatments were given during the follow-up assessment period of 6 months or longer. OUTCOME MEASURES: The independent observer made a global assessment of the patients 1, 3, and 6 months after treatment. The patients kept pain diaries to score pain intensity twice daily, analgesic intake, and quality of sleep daily, and activity level weekly. RESULTS: At the 1-month independent assessment, 16 of 34 patients in the acupuncture groups and 2 of 16 patients in the placebo group showed improvement ($p < 0.05$). At the 6-month follow-up assessment, 14 of 34 patients in the acupuncture groups and 2 of 16 patients in the placebo group showed improvement ($p < 0.05$). A significant decrease in pain intensities occurred at 1 and 3 months in the acupuncture groups compared with the placebo group. There was a significant improvement in return to work, quality of sleep, and analgesic intake in subjects treated with acupuncture. CONCLUSIONS: The authors found a long-term pain-relieving effect of needle acupuncture compared with true placebo in some patients with chronic nociceptive low back pain.

Acupuncture for chronic low back pain in older patients: a randomized, controlled trial.
Meng CF, Wang D, Ngeow J, Lao L, Peterson M, Paget S. Rheumatology (Oxford); 2003: 42(12):1508-17
Acu-Research II
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OBJECTIVE: To determine if acupuncture is an effective, safe adjunctive treatment to standard therapy for chronic low back pain (LBP) in older patients. METHODS: The inclusion criteria for subjects were: (i) LBP > or =12 weeks and (ii) age > or =60 yr; the exclusion criteria were (i) spinal tumour, infection or fracture and (ii) associated neurological symptoms. The subjects were

randomized to two groups. The control group of subjects continued their usual care as directed by their physicians, i.e. NSAIDs, muscle relaxants, paracetamol and back exercises. Subjects in the acupuncture group in addition received biweekly acupuncture with electrical stimulation for 5 weeks. Outcome was measured by the modified Roland Disability Questionnaire (RDQ) at weeks 0, 2, 6 and 9. The primary outcome measure was change in RDQ score between weeks 0 and 6. RESULTS: Fifty-five patients were enrolled, with eight drop-outs. Twenty-four subjects were randomized to the acupuncture group and 23 were randomized to the control group. Acupuncture subjects had a significant decrease in RDQ score of 4.1 +/- 3.9 at week 6, compared with a mean decrease of 0.7 +/- 2.8 in the control group (P = 0.001). This effect was maintained for up to 4 weeks after treatment at week 9, with a decrease in RDQ of 3.5 +/- 4.4 from baseline, compared with 0.43 +/- 2.7 in the control group (P = 0.007). The mean global transition score was higher in the acupuncture group, 3.7 +/- 1.2, indicating greater improvement, compared with the score in the control group, 2.5 +/- 0.9 (P < 0.001). Fewer acupuncture subjects had medication-related side-effects compared with the control group. CONCLUSIONS: Acupuncture is an effective, safe adjunctive treatment for chronic LBP in older patients.

Does acupuncture improve the orthopedic management of chronic low back pain - a randomized, blinded, controlled trial with 3 months follow up

Molsberger AF, Mau J, Pawelec DB, et al. Pain; 2002: 99:579-587

Acu Research II

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This prospective, randomised controlled trial, with three parallel groups, patient and observer blinded for verum and sham acupuncture and a follow up of 3 months raises the question: "Does a combination of acupuncture and conservative orthopedic treatment improve conservative orthopedic treatment in chronic low back pain (LBP). 186 in-patients of a LBP rehabilitation center with a history of LBP >or=6 weeks, VAS >or=50mm, and no pending compensation claims, were selected; for the three random group 4 weeks of treatment was applied. 174 patients met the protocol criteria and reported after treatment, 124 reported after 3 months follow up. Patients were assorted 4 strata: chronic LBP, <or=0.5 years, 0.5-2 years, 2-5 years, >or=5 years. Analysis was by intention to treat. Group 1 (Verum+COT) received 12 treatments of verum acupuncture and conservative orthopedic treatment (COT). Group 2 (Sham+COT) received 12 treatments of non-specific needling and COT. Group 3 (nil+COT) received COT alone. Verum- and Sham acupuncture were blinded against patient and examiner. The primary endpoints were pain reduction >or=50% on VAS 3 months after the end of the treatment protocol. Secondary endpoints were pain reduction >or=50% on VAS and treatment efficacy on a four-point box scale directly after the end of the treatment protocol and treatment efficacy after 3 months. In the whole sample a pain relief of >or=50% on VAS was reported directly after the end of treatment protocol: Verum+COT 65% (95%CI 51-77%), Sham+COT 34% (95%ci 22-49%), nil+COT 43% (95%ci 29-58%) - results are significant for Verum+COT over Sham+COT (P<or=0.02). The results after 3 months are: Verum+COT 77% (95%ci 62-88%), Sham+COT 29% (95%ci 16-46%), nil+Cot 14% (95%ci 4-30%) - effects are significant for Verum+COT over Sham+COT (P<or=0.001) and for Verum+COT over nil+COT (P<0.001). No difference was found in the mobility of the patients nor in the intake of NSAID diclofenac. Our conclusion is that acupuncture can be an important supplement of conservative orthopedic treatment in the management of chronic LBP.

Comparison of superficial and deep acupuncture in the treatment of lumbar myofascial pain: a double-blind randomized controlled study.

Ceccherelli F, Rigoni MT, Gagliardi G, Ruzzante L ; Clin J Pain. 2002 18(3):149-53.

Acu-Research I

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OBJECTIVE: The aim of the study was to compare the therapeutic effect of the superficial and in-depth insertion of acupuncture needles in the treatment of patients with chronic lumbar myofascial pain. DESIGN: A prospective randomized double-blind study of superficial and deep acupuncture was conducted. SETTING: The study was conducted in the Pain Service Unit of the University of Padova. PATIENTS: The study comprised 42 patients with lumbar myofascial pain who were divided into two equal groups (A and B). INTERVENTION: In group A, the needle was introduced in the skin at a depth of 2 mm, whereas in group B the needle was placed deeply into muscular tissue. The treatment was planned for a cycle of eight sessions. OUTCOME MEASURES: The intensity of pain was evaluated with the McGill Pain Questionnaire before and after treatment and at the 3-month follow-up examination. RESULTS: Although at the end of the treatment there was no evidence of significant statistical differences between the two different groups, pain reduction was greater in the group treated with deep acupuncture. A statistical difference existed between the two groups at the 3-month follow up, with a better result in the deeply stimulated group. CONCLUSIONS: Clinical results show that deep stimulation has a better analgesic effect when compared with superficial stimulation.

Efficacy of electroacupuncture and TENS in the rehabilitation of chronic low back pain patients.

Lehmann TR et al. Pain; 1986: 26:277-290.

WHO study

Acu Research II

Fifty-four patients treated in a 3-week inpatient rehabilitation program were randomly assigned to and accepted treatment with electroacupuncture (n = 17), TENS (low intensity transcutaneous nerve stimulation, n = 18), and TENS dead-battery (placebo, n = 18). Outcome measures included estimates of pain (on a Visual Analogue Scale) and disability by both physician and patient, physical measures of trunk strength and spine range of motion, as well as the patient's perceptions of the relative contribution of the education, exercise training, and the electrical stimulation. Analyses of variance were utilized to determine effects of treatment (electroacupuncture, TENS, placebo) across time (admission, discharge, and return) for the outcome measures. There were no

significant differences between treatment groups with respect to their overall rehabilitation. All 3 treatment groups ranked the contribution of the education as being greater than the electrical stimulation. However, the electroacupuncture group consistently demonstrated greater improvement on the outcome measures than the other treatment groups. For the visual analogue scale measure of average pain, there was a statistical trend at the return visit suggesting that the acupuncture group was experiencing less pain.

Acupuncture treatment of chronic low-back pain - a randomized, blinded, placebo-controlled trial with 9-month follow-up
Leibing E, Leonhardt U, Koster G et al ; Pain; 2002
96:189-196
Acu Research II
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There is some evidence for the efficacy of acupuncture in chronic low-back pain (LBP), but it remains unclear whether acupuncture is superior to placebo. In a randomized, blinded, placebo-controlled trial, we evaluated the effect of traditional acupuncture in chronic LBP. A total of 131 consecutive out-patients of the Department of Orthopaedics, University Goettingen, Germany, (age=48.1 years, 58.5% female, duration of pain: 9.6 years) with non-radiating LBP for at least 6 months and a normal neurological examination were randomized to one of three groups over 12 weeks. Each group received active physiotherapy over 12 weeks. The control group (n=46) received no further treatment, the acupuncture group (n=40) received 20 sessions of traditional acupuncture and the sham-acupuncture group (n=45) 20 sessions of minimal acupuncture.Changes from baseline to the end of treatment and to 9-month follow-up were assessed in pain intensity and in pain disability, and secondary in psychological distress and in spine flexion, compared by intervention groups.Acupuncture was superior to the control condition (physiotherapy) regarding pain intensity (P=0.000), pain disability (P=0.000), and psychological distress (P=0.020) at the end of treatment. Compared to sham-acupuncture, acupuncture reduced psychological distress (P=0.040) only. At 9-month follow-up, the superiority of acupuncture compared to the control condition became less and acupuncture was not different to sham-acupuncture.We found a significant improvement by traditional acupuncture in chronic LBP compared to routine care (physiotherapy) but not compared to sham-acupuncture. The trial demonstrated a placebo effect of traditional acupuncture in chronic LBP.

Importance of modes of acupuncture in the treatment of chronic nociceptive low back pain.
Thomas M, Lundberg T, Acta Anaesthesiol Scand. 1994: 38(1):63-9
Acu-Research I
Department of Physiology II, Karolinska Institute, Stockholm, Sweden.
A controlled study of different modes of acupuncture stimulation was conducted on patients fulfilling clinical criteria for chronic low back pain of nociceptive origin. Forty patients were randomly entered into the study. Thirty had three trial treatments with manual stimulation of needles (MS), electrical low frequency stimulation at 2 Hz (LF), and high-frequency stimulation at 80 Hz (HF), and then continued treatment with the mode they felt most benefitted them. Ten patients were put on the waiting list for treatment but served as the untreated control group. The results were evaluated after 6 weeks and at 6 months for: activity related to pain; mobility; verbal descriptors of pain and the patient's subjective assessment of his condition. After 6 weeks, patients receiving treatment showed significant improvement ($P < 0.05$ to $P < 0.001$) on three of the four measures compared to the untreated controls. After 6 months a similar measure of significant improvement was seen in patients continuing with low-frequency (LF) acupuncture, but not in those groups continuing with manual stimulation (MS) or high-frequency (HF) acupuncture. The results suggest that 2 Hz electrical stimulation is the mode of choice when using acupuncture in the treatment of chronic nociceptive low back pain.

Randomised Controlled Trial Comparing the Effectiveness of Electroacupuncture and TENS for Low Back Pain:
Tsukayama H, Yamashita H, Amagai H, Tanno Y. Acupunct Med: 20(4):175-80: 2002
Tsukuba College of Technology Clinic, Tsukuba City, Japan. tsukayama@k.tsukuba-tech.ac.jp
The objective of this study was to compare the effectiveness of electroacupuncture and TENS for low back pain when the electroacupuncture is applied in a clinically realistic manner. The study was designed as an evaluator-blinded randomised controlled trial (RCT). The study was performed at the Tsukuba College of Technology Clinic in Japan. Twenty subjects, who suffered from low back pain (LBP) without sciatica, were recruited, using leaflets in Tsukuba city. Subjects were allocated to either an electroacupuncture (EA) group (10 patients) or a transcutaneous electrical nerve stimulation (TENS) group (10 patients). The procedure for EA was in accordance with standard practice at our clinic. The main outcome measures were a pain relief scale (100 mm visual analogue scale: VAS) and a LBP score recommended by the Japanese Orthopaedic Association (JOA Score). Mean VAS value during the 2-weeks experimental period of the EA group was significantly smaller than that of the TENS group (65 mm vs 86 mm; 95% CI, 4.126 - 37.953). JOA Score in the EA group improved significantly while that in the TENS group showed no change. Although some placebo effect may be included, EA appeared more useful than TENS in the short-term effect on low back pain. We suggest that more realistic acupuncture interventions based on standard practice should be employed in pragmatic RCTs.

Effect of acupuncture on pain management in patients before and after lumbar disc protrusion surgery - a randomized control study
Wang, R.R., Tronnier, V., American Journal of Chinese Medicine; 2000: 28(1):25-33
Acu Research II
Department of Neurosurgery, University of Heidelberg, Germany.
Management of acute and chronic low back and leg pain often includes the use of acupuncture. The effectiveness of this form of therapy is dependent upon compliance, which in turn is dependent on availability, response, treatment of proper acupoints, and the placebo effect. We hypothesized that classical acupuncture would be more effective than placebo acupuncture. One hundred and

thirty-two patients with acute and chronic low back and leg pain were examined before and after surgery for lumbar disc protrusion. Diagnosis was based on CT and MRT findings. Patients received acupuncture drug-free throughout the study period. The visual analogue scale was used to assess pain intensity before and after (i.e. 30 min. 60 min. 2 h and 6 h) acupuncture. Classical acupuncture resulted in a significant reduction in pain that become increasingly stronger during the 6h study period. Placebo acupuncture lead to same early pain relief that did not reach statistic significant and then declined thereafter.

The use of electro-acupuncture in conjunction with exercise for the treatment of chronic low-back pain
Yeung CK, Leung MC, Chow DH: J Altern Complement Med. ; 2003: 9(4):479-90.
PubMed update search
Acu-Research II
Department of Rehabilitation Sciences, The Hong Kong Polytechnic University, Hung Hom, Hong Kong.
OBJECTIVES: To determine the effect of a series of electro-acupuncture (EA) treatment in conjunction with exercise on the pain, disability, and functional improvement scores of patients with chronic low-back pain (LBP). DESIGN: A blinded prospective randomized controlled study. Subjects and interventions: A total of 52 patients were randomly allocated to an exercise group (n = 26) or an exercise plus EA group (n = 26) and treated for 12 sessions. OUTCOME MEASURES: Numerical Rating Scale (NRS), Aberdeen LBP scale, lumbar spinal active range of movement (AROM), and the isokinetic strength were assessed by a blinded observer. Repeated measures analysis of variance (R-ANOVA) with factors of group and time was used to compare the outcomes between the two groups at baseline (before treatment), immediately after treatment, 1-month follow-up, and 3-month follow-up. The level of significance was set at p = 0.05. RESULTS: Significantly better scores in the NRS and Aberdeen LBP scale were found in the exercise plus EA group immediately after treatment and at 1-month follow-up. Higher scores were also seen at 3-month follow-up. No significant differences were observed in spinal AROM and isokinetic trunk concentric strength between the two groups at any stage of follow-up. CONCLUSIONS: This study provides additional data on the potential role of EA in the treatment of LBP, and indicates that the combination of EA and back exercise might be an effective option in the treatment of pain and disability associated with chronic LBP.

The acupuncture treatment of low back pain: a randomized controlled treatment.
Coan RM, Wong G, Ku SL, Chan YC, Wang L, Ozer FT, Coan PL.
American Journal of Chinese Medicine, 1980: 8:181-189.
WHO study,
Acu-Research I
The acupuncture treatment situation was beneficial to the majority of people with low back pain. This was shown by the use of short-term controls and long-term controls, although the latter were not intended in the study design. After acupuncture, there was a 51% pain reduction in the average pain score in the Immediate Treatment Group. The short-term controls, the Delayed Treatment Group, had no reduction whatsoever in their pain scores at the comparable followup period. Later, the Delayed Treatment Group bere also treated by acupuncturists, and reported 62% less pain. When these two treatment groups were compared at 40 weeks with long-term controls (Inadequate Treatment Group), the Inadequate Treatment Group still had the same pain scores, on the average, as when they enrolled in the study. Both treatment groups, on the average, had 30% lower pain scores. Furthermore, 58% of the treatment groups felt that they were definitely improved at 40 weeks, while only 11% of the Inadequate Treatment Group felt definitely improved at 40 weeks.

A randomized comparative trial of acupuncture versus transcutaneous electrical nerve stimulation for chronic back pain in the elderly.
Grant DJ, Bishop-Miller J, Winchester DM, Anderson M, Faulkner S. Pain.; 1999: 82(1):9-13
PubMed update search
Acu Research II
Liberton Hospital, Edinburgh, UK. d.j.grant@btinternet.com
Sixty patients aged 60 or over with back pain for at least 6 months were recruited from General Practitioner referrals and randomized to 4 weeks of treatment with acupuncture or transcutaneous electrical nerve stimulation (TENS). All treatments were administered by the same physiotherapist and both groups had the same contact with him. The following were measured at baseline, completion and at a 3-month follow-up by an independent observer blinded to treatment received: (1) pain severity on visual analogue scale (VAS); (2) pain subscale of Nottingham Health Profile (NHP); (3) number of analgesic tablets consumed in previous week; (4) spinal flexion from C7 to S1. Thirty-two patients were randomized to acupuncture and 28 to TENS; only three withdrew (two from acupuncture, one from TENS). Significant improvements were shown on VAS ($P < 0.001$), NHP ($P < 0.001$) and tablet count ($P < 0.05$) between baseline and completion in both groups, these improvements remaining significant comparing baseline with follow-up with a further non-significant improvement in VAS and NHP in the acupuncture group. The acupuncture but not the TENS patients showed a small but statistically significant improvement ($P < 0.05$) in mean spinal flexion between baseline and completion which was not maintained at follow-up. Thus in these elderly patients with chronic back pain both acupuncture and TENS had demonstrable benefits which outlasted the treatment period. Acupuncture may improve spinal flexion. This trial cannot exclude the possibility that both treatments are 'placebos'.

Acupuncture in the management of chronic low back pain: a blinded randomized controlled trial
Kerr DP, Walsh DM, Baxter D , Clin J Pain.; 2003: 19(6):364-70
PubMed update search
AcuResearch II

Rehabilatation Sciences Research Group, School of Rehabilitation Sciences, University of Ulser at Jordanstown, County Antrim, Northern Ireland.
OBJECTIVE: To assess the efficacy of acupuncture in the treatment of chronic low back pain. METHODS: Patients (n = 60) with chronic low back pain were recruited and randomly allocated to either Acupuncture therapy or Placebo transcutaneous electrical nerve stimulation (TENS) groups. Patients were treated weekly for 6 weeks, and blinded assessments were carried out pre- and post-treatment using the McGill Pain Questionnaire (MPQ) and visual analog scales (VAS) for pain, the Short-form 36 quality-of-life questionnaire, and a simple range of motion measurement. A total of 46 patients completed the trial and were followed up at 6 months. RESULTS: Analysis of results using t tests showed that in both groups there were significant pre-post improvements for all scores, except for MPQ scores in the Placebo-TENS group. There was no significant difference between the 2 groups for any of the outcome measures at the end of treatment. Results from the 6-month follow-up would suggest that the response was better in the acupuncture group. DISCUSSION: Further research is necessary to fully assess the efficacy of this treatment in combating chronic low back pain using larger sample sizes or alternative control groups.

Acupuncture relieves pelvic and low-back pain in late pregnancy.
Kvorning N, Holmberg C, Grennert L, Aberg A, Akeson J. Acta Obstet Gynecol Scand.: 83(3):246-50: 2004
PubMed update search
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BACKGROUND: The study was designed to evaluate the analgesic effect and possible adverse effects of acupuncture for pelvic and low-back pain during the last trimester of pregnancy. METHODS: Following individual informed consent, 72 pregnant women reporting pelvic or low-back pain were randomized during pregnancy weeks 24-37 to an acupuncture group (n = 37) or to a control group (n = 35) at three maternity wards in southern Sweden. Traditional acupuncture points and local tender points (TP) were chosen according to individual pain patterns and stimulated once or twice a week until delivery or complete recovery in acupuncture patients. Control patients were given no sham stimulation. Throughout the study period each patient made weekly visual analog scale (VAS) evaluations of maximal and minimal pain intensity as well as three-point assessments of pain intensity during various activities. RESULTS: During the study period, VAS scorings of pain intensity decreased over time in 60% of patients in the acupuncture group and in 14% of those in the control group ($p < 0.01$). At the end of the study period, 43% of the acupuncture patients were less bothered than initially by pain during activity compared with 9% of control patients ($p < 0.01$). No serious adverse effects of acupuncture were found in the patients, and there were no adverse effects at all in the infants. CONCLUSION: Acupuncture relieves low-back and pelvic pain without serious adverse effects in late pregnancy.

Acupuncture treatment for pain syndrome. I. Treatment for sciatica (report on 90 cases).
Leung SJ. Am J Chin Med. 1973: 1(2):317-26.
Acu-Research I
The analgesic effect of acupuncture is well known throughout the world. In China, acupuncture for analgesia has been used for thousands of years, and was used for thousands of years before the introduction of analgesic medicine.As a matter of fact, the analgesic effect of acupuncture produces much more benefit than any medicine, a conclusion drawn after we observed a number of acute and chronic pain cases treated by acupuncture only. These cases consisted of sciatica, trigeminal neuralgia, low-back pain, intercostal neuralgia, post herpetic neuralgia, painful keloids, paraplegia arachnoiditis, migraine headache, hypoglossus neuralgia, cervical and brachiplex neuralgia, frozen shoulder, rheumatoid arthritis and osteoid arthritis, etc. A good result in many of these cases has been recorded. Reports on treatment of these pain cases are grouped under different diseases.
Sciatic neuralgia is one of the most severe neuralgic diseases ... In this paper, 90 cases of sciatic neuralgia which were treated by acupuncture only are reported ...

Acupuncture treatment of low back pain: a double-blind placebo-controlled trial.
Mendelson G et al. American Journal of Medicine ; 1983: 74:49-55.
WHO study /
Acu-Research I
Acupuncture treatment of chronic low back pain was studied in a placebo-controlled double-blind crossover trial completed by 77 patients. The patients had significantly increased depression, neuroticism, and hypochondriasis scores. Initial pain levels correlated with state-anxiety, depression, pain duration, and abnormal illness behavior measures, as well as with the intake of psychotropic but not analgesic medication. Overall reduction in pain score was 26 percent for acupuncture and 22 percent for placebo treatment; the difference was not significant (p greater than 0.6). Analgesic drug intake was reduced to a similar extent in both groups. During the first phase of treatment, patients receiving acupuncture had a greater but not significantly different reduction in pain rating scores compared with those receiving placebo ($t = 0.52$; p greater than 0.6). This group showed significantly lower pain scores (p less than 0.05) in the second phase of the trial while receiving placebo treatment. Overall reduction in individual patient's pain score was best predicted by initial pain severity ($r = 0.43$; p less than 0.001) and psychotropic drug intake ($r = 0.37$; p less than 0.001). None of the variables tested predicted which patients would specifically respond to acupuncture or placebo.

The short- and long-term benefit in chronic low back pain through adjuvant electrical versus manual auricular acupuncture.
Sator-Katzenschlager SM, Scharbert G, Kozek-Langenecker SA, Szeles JC, Finster G, Schiesser AW, Heinze G, Kress HG. Anesth Analg. 98(5):1359-642004.
PubMed update search
Department of Anesthesiology and Intensive Care Medicine (B), Outpatient Pain Center, University of Vienna, Vienna, Austria. sabine.sator@univie.ac.at
Acupuncture is an established adjuvant analgesic modality for the treatment of chronic pain. Electrical stimulation of acupuncture

points is considered to increase acupuncture analgesia. In this prospective, randomized, double-blind, controlled study we tested the hypothesis that auricular electroacupuncture (EA) relieves pain more effectively than conventional manual auricular acupuncture (CO) in chronic low back pain patients with insufficient pain relief (visual analogue scale [VAS] > or = 5) treated with standardized analgesic therapy. Disposable acupuncture needles were inserted in the auricular acupuncture points 29, 40, and 55 of the dominant side and connected to a newly developed battery-powered miniaturized stimulator worn behind the ear. Patients were randomized into group EA (n = 31) with continuous low-frequency auricular EA (1 Hz biphasic constant current of 2 mA) and group CO (n = 30) without electrical stimulation (sham-electroacupuncture). Treatment was performed once weekly for 6 wk, and in each group needles were withdrawn 48 h after insertion. During the study period and a 3-mo follow-up, patients were asked to complete the McGill questionnaire. Psychological well being, activity level, quality of sleep, and pain intensity were assessed by means of VAS; moreover, analgesic drug consumption was documented. Pain relief was significantly better in group EA during the study and the follow-up period as compared with group CO. Similarly, psychological well-being, activity, and sleep were significantly improved in group EA versus group CO, the consumption of analgesic rescue medication was less, and more patients returned to full-time employment. Neuropathic pain in particular improved in patients treated with EA. There were no adverse side effects. These results are the first to demonstrate that continuous EA stimulation of auricular acupuncture points improves the treatment of chronic low back pain in an outpatient population. IMPLICATIONS: Continuous electrical stimulation of auricular acupuncture points using the new point stimulation device P-stim significantly decreases pain intensity and improves psychological well-being, activity, and sleep in chronic low back pain patients.

A Multi-center Trial of Percutaneous Neuromodulation Therapy for Low Back Pain Patients with a Subacute Duration of Lower Extremity Pain.
Condon, J., Borg-Stein, J., Revord, J, Schmitt, S., Glassman, J., Bensen, E., Leep, E., Fitzthum, J., Seroussi, R. ; Pain Med. 3(2):172-173, 2002.
Acu-Research IV
Joseph Condon, MD, Southern California Orthopedic Institute; Joanne Borg-Stein, MD, Spaulding Rehabilitation-Wellesley; John Revord, MD, NeuroSpine Center of Wisconsin; Susan Schmitt, MD, The Everett Spine Center; Jerel Glassman, DO, St. Mary's Hospital and Spine Center; Elizabeth Bensen, MD, Agnesian Healthcare; Eric Leep, DO, Hastings Orthopedic Clinic; Jeffery Fitzthum, MD, Northwest Hospital; Richard Seroussi, MD MSc; Bradford Fowler, MSc, Vertis Neuroscience.
INTRODUCTION: We performed a prospective multi-center trial of percutaneous neuromodulation therapy (PNT) for low back pain patients (LBP) with a subacute duration of radiating pain. PNT is a more standardized method of delivering percutaneous electrical stimulation, previously validated for chronic LBP patients in randomized, controlled crossover trials [JAMA 1999; 281:818-23].
METHODS: Our study involved a multi-center study with 83 enrolled patients. Patients were recruited from clinical practice or advertisement, with inclusion criteria of: 1) buttock and/or leg pain duration of 1-6 months, and 2) pain intensity of at least 4/10 on a visual analog scale (VAS). PNT was administered once a week for at least 4 weeks, and consisted of 30-minute sessions with the patient prone, receiving electrical stimulation through 5 percutaneous electrode pairs deployed 3 centimeters into the lumbar paraspinal tissues. Outcome measures included VAS scores for pain, sleep and activity, as well as an Oswestry Disability Questionnaire.
RESULTS: At 5-week follow-up, leg/buttock pain scores improved from 6.6 +/- 1.7 to 4.0 +/- 2.6 ($p < 0.001$), activity levels improved from 6.0 +/- 2.2 to 3.6 +/- 2.2 ($p < 0.001$), sleep scores improved from 4.8 +/- 3.0 to 3.1 +/- 2.5 ($p < 0.001$), and Oswestry scores improved from 43 +/- 15 to 33 +/- 16 ($p < 0.001$). 63% of patients had >/=30% improvement in leg/buttock pain scores.
CONCLUSION: PNT appears promising for treating LBP patients with a subacute duration of radiating pain. November 16, 2001.

Acupuncture for back pain: a meta-analysis of randomized controlled trials.
Ernst E, White AR. Arch Intern Med. 158(20):2235-41. 1998.
Acu-Research IV
Department of Complementary Medicine, Postgraduate Medical School, University of Exeter, England. E.Ernst@ex.ac.uk
BACKGROUND: Acupuncture is commonly used to treat back pain, but there is no published meta-analysis of trials of its effectiveness for this condition. OBJECTIVE: To perform a meta-analysis of trials of acupuncture for the treatment of back pain. METHODS: A systematic literature search was conducted to retrieve all randomized controlled trials of any form of acupuncture for any type of back pain in humans. The adequacy of the acupuncture treatment was assessed by consulting 6 experienced acupuncturists. The main outcome measure for the meta-analysis was numbers of patients whose symptoms were improved at the end of treatment. RESULTS: Twelve studies were included, of which 9 presented data suitable for meta-analysis. The odds ratio of improvement with acupuncture compared with control intervention was 2.30 (95% confidence interval, 1.28-4.13). For sham-controlled, evaluator-blinded studies, the odds ratio was 1.37 (95% confidence interval, 0.84-2.25). CONCLUSION: Acupuncture was shown to be superior to various control interventions, although there is insufficient evidence to state whether it is superior to placebo.

Percutaneous electrical nerve stimulation for low back pain: a randomized crossover study
Ghoname EA, Craig WF, White PF, Ahmed HE, Hamza MA, Henderson BN, Gajraj NM, Huber PJ, Gatchel RJ. JAMA. 281(9):818-23, 1999.
Acu-Research IV
Eugene McDermott Center for Pain Management, Department of Anesthesiology and Pain Management, University of Texas Southwestern Medical Center, Dallas 75235-9068, USA.
CONTEXT: Low back pain (LBP) contributes to considerable disability and lost wages in the United States. Commonly used opioid and nonopioid analgesic drugs produce adverse effects and are of limited long-term benefit in the management of this patient

population.
OBJECTIVE: To compare the effectiveness of a novel nonpharmacologic pain therapy, percutaneous electrical nerve stimulation (PENS), with transcutaneous electrical nerve stimulation (TENS) and flexion-extension exercise therapies in patients with long-term LBP.
DESIGN: A randomized, single-blinded, sham-controlled, crossover study from March 1997 to December 1997.
SETTING: An ambulatory pain management center at a university medical center.
PATIENTS: Twenty-nine men and 31 women with LBP secondary to degenerative disk disease.
INTERVENTIONS: Four therapeutic modalities (sham-PENS, PENS, TENS, and exercise therapies) were each administered for a period of 30 minutes 3 times a week for 3 weeks.
MAIN OUTCOME MEASURES: Pretreatment and posttreatment visual analog scale (VAS) scores for pain, physical activity, and quality of sleep; daily analgesic medication usage; a global patient assessment questionnaire; and Health Status Survey Short Form (SF-36).
RESULTS: PENS was significantly more effective in decreasing VAS pain scores after each treatment than sham-PENS, TENS, and exercise therapies (after-treatment mean +/- SD VAS for pain, 3.4+/-1.4 cm, 5.5+/-1.9 cm, 5.6+/-1.9 cm, and 6.4+/-1.9 cm, respectively). The average +/- SD daily oral intake of nonopioid analgesics (2.6+/-1.4 pills per day) was decreased to 1.3+/-1.0 pills per day with PENS (P<.008) compared with 2.5+/-1.1, 2.2+/-1.0, and 2.6+/-1.2 pills per day with sham-PENS, TENS, and exercise, respectively. Compared with the other 3 modalities, 91 % of the patients reported that PENS was the most effective in decreasing their LBP. The PENS therapy was also significantly more effective in improving physical activity, quality of sleep, and sense of well-being (P<.05 for each). The SF-36 survey confirmed that PENS improved posttreatment function more than sham-PENS, TENS, and exercise.
CONCLUSIONS: In this sham-controlled study, PENS was more effective than TENS or exercise therapy in providing short-term pain relief and improved physical function in patients with long-term LBP.

Acupuncture and Sciatica??
Ghoname EA, White PF, Ahmed HE, Hamza MA, Craig WF, Noe CE. Pain. 83(2):193-9. 1999.
Acu-Research IV
McDermott Center for Pain Management, Department of Anesthesiology and Pain Management, University of Texas Southwestern Medical Center at Dallas, Dallas, USA.
INTRODUCTION: Sciatica is a common pain problem and current pharmacologic therapies have proven inadequate for many patients.
OBJECTIVE: The objective of this sham-controlled investigation was to compare a novel non-pharmacologic technique, percutaneous electrical nerve stimulation (PENS), to transcutaneous electrical nerve stimulation (TENS) in the management of the radicular pain associated with sciatica.
METHODS: Sixty-four consenting patients with sciatica due to lumbar disc herniation were treated with PENS, TENS and sham-PENS according to a randomized, single-blinded, cross-over study. All patients had been maintained on a stable oral non-opioid analgesic regimen for at least 6 weeks prior to entering the study. Each treatment modality was administered for a period of 30 min three times per week for 3 weeks, with 1 week 'off' between each modality. Both PENS and TENS treatments were administered using a stimulation frequency of 4 Hz. The pre-treatment assessment included the health status survey short form (SF-36), as well as visual analog scales (VAS) for radicular pain, physical activity and quality of sleep. The pain VAS was also repeated after each treatment session. At the end of each 3-week treatment block, the SF-36 was repeated. After receiving all three treatment modalities, a global assessment questionnaire was completed.
RESULTS: Both PENS (42%) and TENS (23%) were significantly more effective than the sham (8%) treatments in decreasing VAS pain scores. The daily oral analgesic requirements were also significantly reduced compared to the pre-treatment values with PENS (P<0.01) and TENS (P<0.05). However, PENS was significantly more effective than TENS (and sham-PENS) in improving physical activity and quality of sleep. The SF-36 evaluation confirmed the superiority of PENS (versus TENS and sham-PENS) with respect to post-treatment functionality. In the overall assessment, 73% of the patients reported that PENS was the most desirable modality (versus 21% for TENS and 6% for sham-PENS). Finally, 71% of the patients stated that they would be willing to pay extra to receive PENS therapy compared to 22% and 3% for TENS and sham-PENS, respectively.
CONCLUSION: In this sham-controlled study, we concluded that PENS was more effective than TENS when administered at a stimulation frequency of 4 Hz in providing short-term pain relief and improved functionality in patients with sciatica.

The effect of stimulus frequency on the analgesic response to percutaneous electrical nerve stimulation in patients with chronic low back pain
Ghoname ES, Craig WF, White PF, Ahmed HE, Hamza MA, Gajraj NM, Vakharia AS, Noe CE. Anesth Analg. 88(4):841-6; 1999.
Acu-Research IV
Eugene McDermott Center for Pain Management, Department of Anesthesiology & Pain Management, University of Texas Southwestern Medical Center at Dallas, 75235-9068, USA.
INTRODUCTION: Low back pain (LBP) is one of the most common medical problems in our society. Increasingly, patients are turning to nonpharmacologic analgesic therapies such as percutaneous electrical nerve stimulation (PENS).
OBJECTIVE: We designed this sham-controlled study to compare the effect of three different frequencies of electrical stimulation on the analgesic response to PENS therapy.
METHODS: Sixty-eight consenting patients with LBP secondary to degenerative lumbar disc disease were treated with PENS therapy at 4 Hz, alternating 15 Hz and 30 Hz (15/30 Hz), and 100 Hz, as well as sham-PENS (0 Hz), according to a randomized, cross-over study design. Each treatment was administered for a period of 30 min three times per week for 2 wk. The pre- and posttreatment assessments included the health status survey short form and visual analog scales for pain, physical activity, and

quality of sleep. After receiving all four treatments, patients completed a global assessment questionnaire.
RESULTS: The sham-PENS treatments failed to produce changes in the degree of pain, physical activity, sleep quality, or daily intake of oral analgesic medications. In contrast, 4-Hz, 15/30-Hz, and 100-Hz stimulation all produced significant decreases in the severity of pain, increases in physical activity, improvements in the quality of sleep, and decreases in oral analgesic requirements ($P < 0.01$). Of the three frequencies, 15/30 Hz was the most effective in decreasing pain, increasing physical activity, and improving the quality of sleep ($P < 0.05$). In the global assessment, 40% of the patients reported that 15/30 Hz was the most desirable therapy, and it was also more effective in improving the patient's sense of well-being. We conclude that the frequency of electrical stimulation is an important determinant of the analgesic response to PENS therapy. Alternating stimulation at 15-Hz and 30-Hz frequencies was more effective than either 4 Hz or 100 Hz in improving outcome measures in patients with LBP. Implications:
CONCLUSIONS: The frequency of electrical stimulation seems to be an important determinant of the analgesic efficacy of percutaneous electrical nerve stimulation. Mixed low- and high-frequency stimulation was more effective than either low or high frequencies alone in the treatment of patients with low back pain.

Acupuncture for low back pain in pregnancy--a prospective, quasi-randomised, controlled study.
Guerreiro da Silva JB, Nakamura MU, Cordeiro JA, Kulay L Jr; Acupunct Med. 22(2):60-7. 2004.
Acu-Research IV
Medicine School of Sao, Jose do Rio Preto, Brazil. jbgsilva@hotmail.com
This study was undertaken to investigate the effects of acupuncture in low back and pelvic pain during pregnancy under real life conditions, as compared with patients undergoing conventional treatment alone. A total of 61 conventionally treated pregnant women were allocated randomly into two groups to be treated or not by acupuncture. Twenty-seven patients formed the study group and 34 the control group. They reported the severity of pain using a Numerical Rating Scale from 0 to 10, and their capacity to perform general activities, to work, and to walk. We also assessed the use of analgesic drugs. Women were followed up for eight weeks and interviewed five times, at two-week intervals. All women completed the study. In the study group the average pain during the study period showed a larger reduction (4.8 points) than the control group (-0.3 points) ($P < 0.0001$). Average pain scores decreased by at least 50% over time in 21 (78%) patients in the acupuncture group and in five (15%) patients in the control group ($P < 0.0001$). Maximum pain and pain at the moment of interview were also less in the acupuncture group compared with the control group. The capacity to perform general activities, to work and to walk was improved significantly more in the study group than in the control group ($P < 0.05$). The use of paracetamol was lower in the acupuncture group ($P < 0.01$). These results indicate that acupuncture seems to alleviate low back and pelvic pain during pregnancy, as well as to increase the capacity for some physical activities and to diminish the need for drugs, which is a great advantage during this period.

Effect of the duration of electrical stimulation on the analgesic response in patients with low back pain
Hamza MA, Ghoname EA, White PF, Craig WF, Ahmed HE, Gajraj NM, Vakharia AS, Noe CE. Anesthesiology. 91(6):1622-7. 1999
Acu-Research IV
Eugene McDermott Center for Pain Management, Department of Anesthesiology and Pain Management, University of Texas Southwestern Medical Center, Dallas 75235-9068, USA.
BACKGROUND: Electrical stimulation of peripheral nerves produces acute analgesic effects. This randomized, sham-controlled, crossover study was designed to evaluate the effect of differing durations of electrical stimulation on the analgesic response to percutaneous electrical nerve stimulation in 75 consenting patients with low back pain. METHODS: All patients received electrical stimulation for four different time intervals (0, 15, 30, and 45 min) in a random sequence over the course of an 11-week study period. All active percutaneous electrical nerve stimulation treatments were administered using alternating frequencies of 15 and 30 Hz three times per week for 2 consecutive weeks. The prestudy assessments included the health status survey short form questionnaire and 10-cm visual analog scale scores for pain, physical activity, and quality of sleep, with 0 being the best and 10 being the worst. The pain scoring was repeated 5-10 min after each 60-min study session and 24 h after the last treatment session with each of the four methods. The daily oral analgesic requirements were assessed during each of the four treatment blocks. At the end of each 2-week treatment block, the questionnaire was repeated. RESULTS: Electrical stimulation using percutaneously placed needles produced short-term improvements in the visual analog scale pain, physical activity, and quality of sleep scores, and a reduction in the oral analgesic requirements. The 30-min and 45-min durations of electrical stimulation produced similar hypoalgesic effects (48+/-21% and 46+/-19%, respectively) and were significantly more effective than either 15 min (21+/-17%) or 0 min (10+/-11%). The 30- and 45-min treatments were also more effective in improving physical activity and sleep scores over the course of the 2-week treatment period. In contrast to the sham treatment (0 min), the health status survey short form revealed that electrical stimulation for 15 to 45 min three times per week for 2 weeks improved patient function. CONCLUSION: The recommended duration of electrical stimulation with percutaneous electrical nerve stimulation therapy is 30 min.

Acupuncture for back pain: a meta-analysis of randomized controlled trials.
Ernst E, White AR, Arch Intern Med.158(20):2235-41. 1998.
Acu-Research IV
Department of Complementary Medicine, Postgraduate Medical School, University of Exeter, England. E.Ernst@ex.ac.uk
BACKGROUND: Acupuncture is commonly used to treat back pain, but there is no published meta-analysis of trials of its effectiveness for this condition. OBJECTIVE: To perform a meta-analysis of trials of acupuncture for the treatment of back pain. METHODS: A systematic literature search was conducted to retrieve all randomized controlled trials of any form of acupuncture for any type of back pain in humans. The adequacy of the acupuncture treatment was assessed by consulting 6 experienced acupuncturists. The main outcome measure for the meta-analysis was numbers of patients whose symptoms were improved at the end of treatment. RESULTS: Twelve studies were included, of which 9 presented data suitable for meta-analysis. The odds ratio of improvement with acupuncture compared with control intervention was 2.30 (95% confidence interval, 1.28-4.13). For sham-

controlled, evaluator-blinded studies, the odds ratio was 1.37 (95% confidence interval, 0.84-2.25). CONCLUSION: Acupuncture was shown to be superior to various control interventions, although there is insufficient evidence to state whether it is superior to placebo.
Publication Types:
ï Meta-Analysis

Hip and Thigh

Non-specific effects of traditional Chinese acupuncture in osteoarthritis of the hip
Fink MG, Wipperman B, Gehrke A
Complement Ther Med 9:82-89 2001
Department for Physical Medicine and Rehabilitation, Hannover Medical School, Hannover, 30625, Germany. Fink.matthias@mh-hannover.de
OBJECTIVES: The effectiveness of acupuncture treatment in patients with osteoarthritis of the hip was tested. DESIGN: This is a prospective, randomized, controlled, patient- and investigator-blinded clinical trial. PATIENTS AND SETTING: The study was performed at a university department for physical medicine and rehabilitation. Sixty-seven patients were separated into two treatment groups. INTERVENTIONS: Group 1 (treatment) had traditional needle placement and manipulation, whereas in group 2 (control) needles were placed away from classic positions and not manipulated. In both groups needles were placed within the L2 to L5 dermatomes. Outcome parameters were: pain (VAS), functional impairment (hip score), activity in daily life (ADL) and overall satisfaction before treatment, and 2 weeks and 2 months after treatment. RESULTS: For all parameters there was a significant improvement versus baseline in both groups 2 weeks and 2 months following treatment, but no significant difference between the two treatment groups. CONCLUSIONS: We conclude from these results that needle placement in the area of the affected hip is associated with improvement in the symptoms of osteoarthritis. It appears to be less important to follow the rules of traditional acupuncture techniques.

A comparison of acupuncture with advice and exercises on the symptomatic treatment of osteoarthritis of the hip--a randomised controlled trial
Haslam R, Acupunct Med, 19:19-26, 2001.
Princess Margaret Hospital Swindon. haslamroisin@hotmail.com
Acupuncture is becoming a common technique within the physiotherapy profession as a treatment modality for pain relief; however, few randomised controlled trials have been undertaken to assess the effectiveness of acupuncture, particularly in the treatment of osteoarthritis (OA) of the hip. Therefore, a randomised trial to compare the effectiveness of acupuncture with advice and exercises on the symptomatic treatment of OA of the hip was carried out. Thirty-two patients awaiting a total hip arthroplasty were randomly allocated to either the experimental group, (A), to have six sessions of acupuncture each lasting up to 25 minutes, or the control group, (B), to be given advice and exercises for their hip over a six week period. Group A consisted of three men and 13 women, and group B consisted of four men and eight women. The average age in group A was 66 years and in group B it was 68 years. Patients were assessed for pain and functional ability, using a modified version of the WOMAC questionnaire, pre-treatment, immediately post-treatment and at eight weeks post-treatment. The pre-treatment WOMAC scores in the two groups were similar (p=0.85). There was a significant improvement in group A (decrease in WOMAC score) immediately post-treatment (p=0.002) and this was maintained at the eight-week follow-up (p=0.03). There were no significant changes in group B. When the changes in WOMAC scores were compared between groups, a significantly greater improvement was found between pre-treatment and immediately post-treatment in group A, compared with group B (p=0.02). The changes between pre-treatment and the eight-week follow-up also showed a significant improvement in group A compared with group B (p=0.03). In conclusion, this trial supports the hypothesis that acupuncture is more effective than advice and exercises in the symptomatic treatment of OA of the hip.

Comparison between electro-acupuncture and hydrotherapy, both in combination with patient education and patient education alone, on the symptomatic treatment of osteoarthritis of the hip.
Stener-Victorin E, Kruse-Smidje C, Jung K, Clin J Pain. 20(3):179-85, 2004.
PubMed update search
Department of Physiology and Pharmacology, Goteborg University, Goteborg, Sweden. elisabet.stener-victorin@fhs.gu.se
OBJECTIVES: The aim of the study was to evaluate the therapeutic effect of electro-acupuncture (EA) and hydrotherapy, both in combination with patient education or with patient education alone, in the treatment of osteoarthritis in the hip. METHODS: Forty-five patients, aged 42-86 years, with radiographic changes consistent with osteoarthritis in the hip, pain related to motion, pain on load, and ache were chosen. They were randomly allocated to EA, hydrotherapy, both in combination with patient education, or patient education alone. Outcome measures were the disability rating index (DRI), global self-rating index (GSI), and visual analogue scale (VAS). Assessments were done before the intervention and immediately after the last treatment and 1, 3, and 6 months after the last treatment. RESULTS: Pain related to motion and pain on load was reduced up to 3 months after last the treatment in the hydrotherapy group and up to 6 months in the EA group. Ache during the day was significantly improved in both the EA and hydrotherapy group up to 3 months after the last treatment. Ache during the night was reduced in the hydrotherapy group up to 3 months after the last treatment and in the EA group up to 6 months after. Disability in functional activities was improved in EA and hydrotherapy groups up to 6 months after the last treatment. Quality of life was also improved in EA and hydrotherapy groups up to 3 months after the last treatment. There were no changes in the education group alone. DISCUSSION: In conclusion, EA and hydrotherapy, both in combination with patient education, induce long-lasting effects, shown by reduced pain

and ache and by increased functional activity and quality of life, as demonstrated by differences in the pre- and post-treatment assessments.

Knee

A randomized trial of acupuncture as an adjunctive therapy in osteoarthritis of the knee.
Berman BM, Singh BB, Lao L, Langenberg P, Li H, Hadhazy V, Bareta J, Hochberg M. Rheumatology (Oxford). 1999 (4):346-54.
Acu Research II
Complementary Medicine Program, University of Maryland School of Medicine, Baltimore 21207-6697, USA.
OBJECTIVE: The purpose of this study was to investigate the efficacy of acupuncture as an adjunctive therapy to standard care for the relief of pain and dysfunction in elderly patients with osteoarthritis (OA) of the knee. METHODS: Seventy-three patients with symptomatic OA of the knee were randomly assigned to treatment (acupuncture) or standard care (control). Analysis was performed on last score carried forward to account for patients who dropped out before completion. Patients self-scored Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Lequesne indices at baseline and at 4, 8 and 12 weeks. Patients in the control group were offered acupuncture treatment after 12 weeks. The data for these patients are pooled with those from the original acupuncture group for within-group analysis. RESULTS: Patients randomized to acupuncture improved on both WOMAC and Lequesne indices compared to those who received standard treatment alone. Significant differences on total WOMAC Scale were seen at 4 and 8 weeks. There appears to be a slight decline in effect at 4 weeks after cessation of treatment (12 weeks after first treatment). No adverse effects of acupuncture were reported. CONCLUSION: These data suggest that acupuncture is an effective and safe adjunctive therapy to conventional care for patients with OA of the knee.

The effect of acupuncture on the symptoms of knee osteoarthritis--an open randomised controlled study.
Tukmachi E, Jubb R, Dempsey E, Jones P Acupunct Med. 22(1):14-22, 2004.
PubMed update search
Selly Oak Hospital, Birmingham, UK.
BACKGROUND: Using an open randomised controlled study, we examined the effectiveness of manual and electroacupuncture on symptom relief for patients with osteoarthritis of the knee. METHODS: Patients with symptomatic osteoarthritis of the knee were randomised to one of three treatment groups. Group A had acupuncture alone, group B had acupuncture but continued on their symptomatic medication, and group C used their symptomatic medication for the first five weeks and then had a course of acupuncture added. Patients receiving acupuncture were treated twice weekly over five weeks. Needles were inserted (with manual and electrical stimulation) in acupuncture points for pain and stiffness, selected according to traditional acupuncture theory for treating Bi syndrome. Patients were assessed by a blinded observer before treatment, after five weeks' treatment and at one month follow up, using a visual analogue pain scale (VAS) and the Western Ontario McMaster (WOMAC) questionnaire for osteoarthritis of the knee. RESULTS: The 30 patients in our study were well matched for age, body mass index, disease duration, baseline VAS pain score and baseline WOMAC scores. Repeated measure analyses gave a highly significant improvement in pain (VAS) after the courses of acupuncture in groups A (P = 0.012) and B (P=0.001); there was no change in group C until after the course of acupuncture, when the improvement was significant (P = 0.001). Similarly significant changes were seen with the WOMAC pain and stiffness scores. These benefits were maintained during the one month after the course of acupuncture. Patients' rating of global assessment was higher than that of the acupuncturist. CONCLUSION: We conclude that manual and electroacupuncture causes a significant improvement in the symptoms of osteoarthritis of the knee, either on its own or as an adjunct therapy, with no loss of benefit after one month.

Acupuncture treatment of patellofemoral pain syndrome,
Jensen R, Gothesen O, Liseth K et al, J Altern Complement Med, 5:521-527, 1999.
Jensen Fysikalske Institutt, Bergen, Norway.
OBJECTIVE: To evaluate the effect of acupuncture treatment in patellofemoral pain syndrome. DESIGN: A controlled trial where patients were randomly assigned either to acupuncture treatment or no treatment. Evaluation of the result was blinded. SETTING: An acupuncture/physiotherapy treatment practice in Bergen, Norway. SUBJECTS: A total of 75 patients with patellofemoral pain syndrome were included, of whom 44 were female. INTERVENTION: Individualized acupuncture treatment twice weekly for 4 weeks. MAIN OUTCOME MEASURE: Patients were followed for 1 year with the Cincinnati Knee Rating System (CKRS) scale as the main outcome measure. Other tests used were the Stairs-Hopple test, quadriceps atrophy, and evaluating level pain after activity by a visual analogue scale. RESULTS: At inclusion patients, aged 18-45 (mean 31.0) years, reported persistent pain on activity (mean 6.6 years) and at rest (mean 4.3 years). CRS scores at baseline were similar (acupuncture group 58.0 versus no treatment group 56.1). At 12 months there was a significant difference in the CRS score between the groups (acupuncture 75.2 versus no treatment 61.7, p = 0.005). When analyzing for worst case, the difference persisted (68.1 versus 54.4, p = 0.03). Results were then dichotomized as to whether the patient was cured or not at 12 months. A patient was defined as cured if he/she scored "slight" or "none" on the "pain" or "limitation to activity" subscales. The Number Necessary to Treat (NNT) to cure one patient was NNT = 3.0 for the CRS pain subscale and NNT = 3.7 for the CRS function subscale. CONCLUSION: We conclude that acupuncture may be an alternative treatment for patellofemoral pain syndrome.

The effects of electro-acupuncture and transcutaneous electrical nerve stimulation on patients with painful osteoarthritic knees: a randomized controlled trial with follow-up evaluation.
Ng MM, Leung MC, Poon DM, J Altern Complement Med. 2003, 9(5):641-9.

PubMed update search
Acu Research II
Department of Rehabilitation Sciences, The Hong Kong Polytechnic University, Hong Kong, China.
OBJECTIVES: To examine the relative effectiveness of electro-acupuncture (EA) and transcutaneous electrical nerve stimulation (TENS) in alleviating osteoarthritic (OA)-induced knee pain. DESIGN: Single-blinded, randomized controlled study. SUBJECTS: Twenty-four (24) subjects (23 women and 1 man), mean age 85, were recruited from eight subsidized Care & Attention Homes for the elderly. INTERVENTIONS: Subjects were randomly assigned to the EA, TENS, or control groups. Subjects in the EA group (n = 8) received low-frequency EA (2 Hz) on two acupuncture points (ST-35, Dubi and EX-LE-4, Neixiyan) of the painful knee for 20 minutes. Subjects in the TENS group (n = 8) received low-frequency TENS of 2 Hz and pulse width of 200 micros on the same acupuncture points for 20 minutes. In both treatment groups, electrical treatment was carried out for a total of eight sessions in 2 weeks. Eight subjects received osteoarthritic knee care and education only in a control group. All subjects were evaluated before the first treatment, after the last treatment, and at 2-week follow-up periods. RESULTS: After eight sessions of treatment, there was significant reduction of knee pain in both EA group and TENS group, as measured by the Numeric Rating Scale (NRS) of pain ($p < 0.01$). Prolonged analgesic effect was maintained in the EA and the TENS groups at a 2-week follow-up evaluation. The Timed Up-and-Go Test (TUGT) score of the EA group was significantly lower than that of the control group ($p < 0.05$), but such change was not observed in the TENS group. CONCLUSIONS: Both EA and TENS treatments were effective in reducing OA-induced knee pain. EA had the additional advantage of enhancing the TUGT results as opposed to TENS treatment or no treatment, which did not produce such corollary effect.

Acupuncture and moxibustion as an adjunctive treatment for osteoarthritis of the knee--a large case series
Vas J, Perea-Milla E, Mendez C, Acupunct Med. 22(1):23-8, 2004.
PubMed update search
Centro de Salud de Dos Hermanas, Sevilla, Spain. jvas@acmas.com
BACKGROUND: In 1997, the first Pain Management Unit, which was set up as part of primary health care within the Andalusian Public Health System, offered acupuncture among other therapies. This observational study was conducted in preparation for a randomised controlled trial. METHODS: We conducted a descriptive study of patients who had been diagnosed with osteoarthritis of the knee. The patients received weekly acupuncture treatment, and related techniques, from November 1997 to November 2000. We recorded: socio-demographic data; measures of effectiveness, including intensity and frequency of pain; the daily dose of analgesic and anti-inflammatory medication; the degree of incapacity; and sleep disorders caused by pain in the knee. RESULTS: The 563 patients who presented were mainly female (88%) with an average age of 65 years (+/- 10.7); the average age of the male patients was 67 years (+/- 11.8). The condition in most patients (95%) was chronic: 54% had the condition for 5-10 years and a further 23% for more than 10 years. Of the total, 85 (15%) abandoned treatment and were excluded from the evaluation, while 75% of the remainder achieved a reduction in pain of 45% or more. This study is intended to form the basis for a subsequent controlled clinical trial of the effectiveness of acupuncture as a treatment for osteoarthritis of the knee. CONCLUSION: The degree of pain relief experienced by patients from acupuncture justifies a more rigorous study.

Sensory stimulation (acupuncture) for the treatment of idiopathic anterior knee pain
Naslund J, Naslund UB, Odenbring S, Lundeberg T, J Rehabil Med. 34(5):231-8, 2002.
PubMed update search
Department of Physiology and Pharmacology, Karolinska Institutet, Stockholm, Sweden. j.naslund@mailbox.calypso.net
A randomized controlled study was conducted to evaluate the effect of acupuncture treatment in idiopathic anterior knee pain, a pain syndrome without known aetiology. Fifty-eight patients, clinically and radiologically examined, were randomly assigned to either deep or minimal superficial acupuncture treatment. The patients were treated twice weekly for a total of 15 treatments. The main outcome measurements were one leg vertical jump, functional score, daily VAS recording and skin temperature. Fifty-seven patients completed the study. Pain measurements on VAS decreased significantly within both groups; in the deep acupuncture group from 25 before treatments to 10 afterwards, and in the superficial (placebo) acupuncture group from 30 to 10. There was no significant difference between the groups. The improvement on the VAS recordings remained significant even after 3 and 6 months. Even though the pain decreased after sensory stimulation, neither the ability to jump on one leg, the functional score nor the skin temperature changed. This study shows that patients with idiopathic anterior knee pain benefit from both electroacupuncture treatment and subcutaneous needling. The pain-relieving effect remains for at least 6 months. Central pain inhibition, caused by either afferent stimulation or by non-specific therapeutic (placebo) effects, is a plausible explanation behind the treatment effects.

Clinical decisions in the use of acupuncture as an adjunctive therapy for osteoarthritis of the knee
Singh BB, Berman BM, Hadhazy V, Bareta J, Lao L, Zarow FM, Hochberg M. Altern Ther Health Med.7(4):58-65 2001
PubMed update search
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OBJECTIVE: To determine whether demographic, medical history, or arthritis assessment data may influence outcome and rate of decay for patients with osteoarthritis treated with acupuncture. DESIGN: Seventy-three persons with symptomatic osteoarthritis of the knee were recruited for this randomized controlled trial. Both treatment and crossover control groups received acupuncture treatments twice weekly for 8 weeks. Patients self-scored on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Lequesne Algofunctional Index at baseline and 4, 8, and 12 weeks. Sample size for this outcome analysis was 60 patients at 4 weeks, 58 at 8 weeks, and 52 at 12 weeks. RESULTS: Patients' scores on both indexes improved at 4, 8, and 12 weeks. Scores were stable regardless of the baseline severity of the osteoarthritis. Despite some decay in outcomes at week 12, measures were significantly improved over baseline. With WOMAC scores partitioned into equal quartiles, a strong effect on outcome was apparent at 12 weeks (4 weeks after treatment) related to initial WOMAC scores. The group with the least disability and pain

rebounded to original levels to a greater degree than did those who initially were more disabled. The more disabled groups retained the benefits of acupuncture treatment through the 12-week period. CONCLUSION: Acupuncture for patients with osteoarthritis of the knee may best be used early in the treatment plan, with a methodical decrease in frequency in treatment once the acute treatment period is completed to avoid a rebound effect. Demographic and medical history data were not mediating variables.

Acupuncture for osteoarthritis of the knee: a systematic review.
Ezzo J, Hadhazy V, Birch S, Lao L, Kaplan G, Hochberg M, Berman B, Arthritis Rheum. 44(4):819-25, 2001.
Acu-Research III - pulled 7.28
Project LEAD, Washington, DC, USA.
OBJECTIVE: To evaluate trials of acupuncture for osteoarthritis (OA) of the knee, to assess the methodologic quality of the trials and determine whether low-quality trials are associated with positive outcomes, to document adverse effects, to identify patient or treatment characteristics associated with positive response, and to identify areas of future research. METHODS: Eight databases and 62 conference abstract series were searched. Randomized or quasi-randomized trials of all languages were included and evaluated for methodologic quality using the Jadad scale. Outcomes were pain, function, global improvement, and imaging. Data could not be pooled; therefore, a best-evidence synthesis was performed to determine the strength of evidence by control group. The adequacy of the acupuncture procedure was assessed by 2 acupuncturists trained in treating OA and blinded to study results. RESULTS: Seven trials representing 393 patients with knee OA were identified. For pain and function, there was limited evidence that acupuncture is more effective than being on a waiting list for treatment or having treatment as usual. For pain, there was strong evidence that real acupuncture is more effective than sham acupuncture; however, for function, there was inconclusive evidence that real acupuncture is more effective than sham acupuncture. There was insufficient evidence to determine whether the efficacy of acupuncture is similar to that of other treatments. CONCLUSION: The existing evidence suggests that acupuncture may play a role in the treatment of knee OA. Future research should define an optimal acupuncture treatment, measure quality of life, and assess acupuncture combined with other modalities.
Publication Types:
- Evaluation Studies
- Review
- Review, Tutorial

Ankle and Foot

Percutaneous electrical nerve stimulation: a novel analgesic therapy for diabetic neuropathic pain.
Hamza MA, White PF, Craig WF, Ghoname ES, Ahmed HE, Proctor TJ, Noe CE, Vakharia AS, Gajraj N., Diabetes Care., 23(3):365-70, 2000.
Acu-Research IV
Eugene McDermott Center for Pain Management, Department of Anesthesiology and Pain Management, University of Texas Southwestern Medical Center at Dallas, 75235, USA.
OBJECTIVE: To evaluate the use of percutaneous electrical nerve stimulation (PENS) in the management of patients with painful diabetic peripheral neuropathy.
RESEARCH DESIGN AND METHODS: A total of 50 adult patients with type 2 diabetes and peripheral neuropathic pain of >6 months duration involving the lower extremities were randomly assigned to receive active PENS (needles with electrical stimulation at an alternating frequency of 15 and 30 Hz) and sham (needles only) treatments for 3 weeks. Each series of treatments was administered for 30 min three times a week according to a standardized protocol. After a 1-week washout period, all patients were subsequently switched to the other modality. A 10-cm visual analog scale (VAS) was used to assess pain, physical activity, and quality of sleep before each session. The changes in VAS scores and daily requirements for oral analgesic medication were determined during each 3-week treatment period. Patients completed the MOS 36-Item Short-Form Health Survey (SF-36), the Beck Depression Inventory (BDI), and the Profile of Mood States (POMS) before and after completion of each treatment modality. At the end of the crossover study, a patient preference questionnaire was used to compare the effectiveness of the two modalities.
RESULTS: Compared with the pain VAS scores before active (6.2 +/- 1.0) and sham (6.4 +/- 0.9) treatments, pain scores after treatment were reduced to 2.5 +/- 0.8 and 6.3 +/- 1.1, respectively. With active PENS treatment, the VAS activity and sleep scores were significantly improved from 5.2 +/- 1.0 and 5.8 +/- 1.3 to 7.9 +/- 1.0 and 8.3 +/- 0.7, respectively. The VAS scores for pain, activity, and sleep were unchanged from baseline values after the sham treatments. Patients' daily oral nonopioid analgesic requirements decreased by 49 and 14% after active and sham PENS treatments, respectively. The post-treatment physical and mental components of the SF-36, the BDI, and the POMS all showed a significantly greater improvement with active versus sham treatments. Active PENS treatment improved the neuropathic pain symptoms in all patients.
CONCLUSIONS: PENS is a useful nonpharmacological therapeutic modality for treating diabetic neuropathic pain. In addition to decreasing extremity pain, PENS therapy improved physical activity, sense of well-being, and quality of sleep while reducing the need for oral nonopioid analgesic medication.

Chronic and Postoperative Pain

Comparative study of the analgesic effect of transcutaneous nerve stimulation (TNS); electroacupuncture (EA) and meperidine in the treatment of postoperative pain
Martelete M, Fiori AM. ,Acupunct Electrother Res., 1985, 10(3):183-93.
Acu-Research I
Seventy two patients, from 15 to 60 years old, in good physical status and submitted to surgery in the upper or lower abdominal, rectal or lumbar areas were studied. In the immediate postoperative period, they were randomly divided in three groups and each group was submitted to one of the following treatments: intravenous meperidine, transcutaneous nerve stimulation (TNS) or electroacupuncture (EA). Each treatment was divided in two phases with one hour interval between them. Each phase was constituted of 30 minutes of stimulation in case of TNS and EA and fractionated administration of meperidine in all groups. The pain level was evaluated through a visual analogue scale before and after each phase of treatment. The results were compared among groups and, on each group, between the phases of treatment. In all surgery types, the postoperative pain relief presented by TNS and EA groups of patients was greater than that of meperidine treated group. But, the analgesia presented by the EA treated group of patients lasted longer and increased with the repetition of treatment. The differences of behaviour of TNS and EA analgesia suggest that their neurochemical mechanisms may not be the same.

Acupuncture and chronic pain mechanisms
Ghia JN, Mao W, Toomey TC, Gregg JM , Pain. 1976, 2(3):285-99.
Acu-Research I
Forty patients with chronic pain below the waist level not amenable to conventional medical and/or surgical treatment were randomly assigned to one or two different methods of acupuncture, after studying the underlying pain mechanisms using a Multidisciplinary Pain Clinic approach and the differential spinal block (DSB). One group received acupuncture needling in the classical acupuncture points referred to as meridian loci needling (MLN) and the other group received tender area needling (TAN) with needles inserted in the dermatomal distribution of the painful areas. The responses between the two groups showed no significant difference. Results were then related to the predetermined somatopsychological basis of the individual's pain problems as classified by the DSB. A group of patinets in whom pain relief occurred upon subarachnoid injection of 0.25% procaine followed by sympathetic blockade or 0.5% procaine injection followed by hypalgesia without motor loss, also reported maximum subjective improvement in their pain level following acupuncture therapy performed at a later time. The other group of patients in whom pain persisted despite sensory and motor blockade (1% procaine) responded very poorly to acupuncture therapy. DSB was found to be complimentary to acupuncture therapy in that it facilitated patient selection for the therapy.

Long-term treatment of chronic pain with acupuncture. Part I.
Junnila SY, Acupunct Electrother Res., 12(1):23-36. 1987.
PubMed update search
A 5-year trial of acupuncture therapy in the Finnish NHS is surveyed. In total 348 patients attending Halikko Health Centre in SW Finland were treated with needle-stimulation for a wide variety of chronic pain syndromes. The mean number of acupuncture sessions was 5 in the primary series and 41% of patients received more than one series. An analysis of results showed significant relief of pain (more than 40% reduction on the visual analogue scale) in myofascial syndromes affecting the head, neck, shoulder and arm. Osteoarthrosis of major joints, and backache, responded less favourably. In total 65% of those patients who had taken analgesics before acupuncture therapy, either stopped totally or reduced their dose considerably. Those with headache could significantly more often reduce their drug intake than those with arthritis or osteoarthrosis. More results and discussion will be published in part II later in this Journal.

Acupuncture: Review and Analysis of Reports on Controlled Clinical Trials
World Health Organization, 1999
2.1 Pain
The effectiveness of acupuncture analgesia has already been established in controlled clinical studies. As mentioned previously, acupuncture analgesia works better than a placebo for most kinds of pain, and its effective rate in the treatment of chronic pain is comparable with that of morphine.* In addition, numerous laboratory studies have provided further evidence of the efficacy of acupuncture's analgesic action as well as an explanation of the mechanism involved. In fact, the excellent analgesic effects of acupuncture have stimulated research on pain.
Because of the side-effects of long-term drug therapy for pain and the risks of dependence, acupuncture analgesia can be regarded as the method of choice for treating many chronically painful conditions.

Acupuncture and pain: a review of the literature
Eshkevari L, AANA J. 71(5):361-370, 2003.
PubMed update search Acu-Research III - pulled 7.31
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In the United States today, as many as one third of the population suffers from chronic pain conditions. These syndromes cost an estimated $80 billion and are a major source of burden to the healthcare system as well as to the suffering patients. According to a study by Harvard Medical School in 1997, visits to alternative medicine providers had reached 629 million, mostly for these pain conditions. The action of acupuncture as an analgesic, although widely accepted, remains somewhat of an enigma. In reviewing the literature it became evident that many investigators have had conflicting data; however, with regard to acupuncture in pain management, quite a few results were found to be positive. Many now believe that acupuncture should be considered a valuable asset in the specialty of pain, and that it can be of value in comprehensive pain clinics as well as physical therapy practice.

Acupuncture is certainly not a cure-all; however, researchers and experienced clinicians both attest to its benefits. This article is a review of the literature with regard to acupuncture as a modality for pain management.
Publication Types:
* Review
* Review, Academic

Fibromyalgia

Is acupuncture effective in the treatment of fibromyalgia?
Berman BM, Ezzo J, Hadhazy V, Swyers JP, J Fam Pract., 48(3):213-8, 1999.
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BACKGROUND: We conducted this study to assess the effectiveness of acupuncture in the treatment of fibromyalgia syndrome (FMS), report any adverse effects, and generate hypotheses for future investigation. METHODS: We searched MEDLINE, EMBASE, Manual Therapy Information System, the Cochrane registry, the University of Maryland Complementary and Alternative Medicine in Pain, the Centralized Information Service for Complementary Medicine, and the National Institutes of Health Office of Alternative Medicine databases for the key words "acupuncture" and "fibromyalgia." Conference abstracts, citation lists, and letters supplemented the search. We selected all randomized or quasi-randomized controlled trials, or cohort studies of patients with FMS who were treated with acupuncture. Methodologic quality, sample characteristics, type of acupuncture treatment, and outcomes were extracted. Statistical pooling was not performed because of the differences in control groups. RESULTS: Seven studies (3 randomized controlled trials and 4 cohort studies) were included; only one was of high methodologic quality. The high-quality study suggests that real acupuncture is more effective than sham acupuncture for relieving pain, increasing pain thresholds, improving global ratings, and reducing morning stiffness of FMS, but the duration of benefit following the acupuncture treatment series is not known. Some patients report no benefit, and a few report an exacerbation of FMS-related pain. Lower-quality studies were consistent with these findings. Booster doses of acupuncture to maintain benefit once regular treatments have stopped have been described anecdotally but not investigated in controlled trials. CONCLUSIONS: The limited amount of high-quality evidence suggests that real acupuncture is more effective than sham acupuncture for improving symptoms of patients with FMS. However, because this conclusion is based on a single high-quality study, further high-quality randomized trials are needed to provide more robust data on effectiveness.

Electroacupuncture in fibromyalgia: result of a controlled trial.
Deluze C et al. , British Medical Journal, 1992, 305:1249-1252.
Acu Research II
Division of Physical Medicine and Rehabilitation, University Hospital, Geneva, Switzerland.

OBJECTIVE--To determine the efficacy of electroacupuncture in patients with fibromyalgia, a syndrome of unknown origin causing diffuse musculoskeletal pain. DESIGN--Three weeks' randomised study with blinded patients and evaluating physician. SETTING--University divisions of physical medicine and rehabilitation and rheumatology, Geneva. PATIENTS--70 patients (54 women) referred to the division for fibromyalgia as defined by the American College of Rheumatology. INTERVENTIONS--Patients were randomised to electroacupuncture (n = 36) or a sham procedure (n = 34) by means of an electronic numbers generator. MAIN OUTCOME MEASURES--Pain threshold, number of analgesic tablets used, regional pain score, pain recorded on visual analogue scale, sleep quality, morning stiffness, and patient's and evaluating physician's appreciation. RESULTS--Seven of the eight outcome parameters showed a significant improvement in the active treatment group whereas none were improved in the sham treatment group. Differences between the groups were significant for five of the eight outcome measures after treatment. CONCLUSIONS--Electroacupuncture is effective in relieving symptoms of fibromyalgia. Its potential in long term management should now be studied.