

Technology Assessment

U.S. Department of Health and
Human Services
Public Health Service



Agency for Healthcare Research and
Quality
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Acupuncture for Osteoarthritis

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INTRODUCTION

The Centers for Medicare and Medicaid Services (CMS) has commissioned a Technology Assessment from The Agency for Healthcare Research and Quality (AHRQ) to review the evidence regarding the use of acupuncture for osteoarthritis.

In order to expedite the review, CMS requested that the review be based on systematic reviews that are published by other groups. The AHRQ review therefore contains:

- a) A review of recent (1995 to present) systematic reviews on the use of acupuncture for osteoarthritis, updated with any RCTs published since the date of the last systematic review (2000 to present).
- b) Information available in the literature on training for persons performing this therapy and the number of physicians certified to perform this therapy.

BACKGROUND

Osteoarthritis

Osteoarthritis is the result of ongoing or chronic deterioration of the joint cartilage. The cartilage degenerates, in part through stress and wear, and in so doing causes a roughening and wearing on the ends of the once-protected bones. Sometime new bone forms, this time as irregular spurs, and contributes to pain and joint dysfunction. The most common sites for osteoarthritis include cervical and lumbar spine, finger, wrist and toe joints, hip and knees. Asymptomatic forms of osteoarthritis can occur between 30 and 40 years of age, but by 70 years old, nearly all persons have some symptoms of osteoarthritis.¹

Description of Acupuncture

In its original form acupuncture was based on the principles of traditional Chinese medicine.²⁻⁴ The general theory of acupuncture is based on the premise that there are patterns of energy flow through the body that are essential for health. Traditional acupuncturists understand health in terms of a vital force of energy called Qi which circulates between the organs along channels called meridians. The traditional Chinese medicine acupuncture practitioner seeks to identify the nature of any imbalance in Qi, and then selects the appropriate acupuncture points from among approximately 360 points distributed along the meridians.^{3, 5, 6}

Acupuncture involves the stimulation of the specific acupuncture points (acupoints) on the skin, usually by the insertion of needles ranging in length from 1 cm to 10 cm. Between 5 and 15 needles are used in a typical treatment, with the point combinations varying during a course of sessions. The acupoints can be chosen based on a standardized "formulary" involving a fixed menu of consistent points for each disease or condition or selected for each patient individually based on a patient's specific symptoms and Qi balance. Depth of puncture can be up to 5 cm.

Other forms of acupuncture include electroacupuncture, heat (including moxibustion), pressure, and laser-generated light.^{4, 5, 7} A glossary of these procedures is found in Appendix A. Generally, studies have addressed either manual needling or electroacupuncture because the stimulation parameters of these procedures are easiest to control.^{3, 5, 6}

FDA's Role

The U.S. Food and Drug Administration (FDA) regulates devices used for acupuncture, such as the needles. Since 1973, the FDA considered acupuncture devices, including needles, as investigational medical devices.⁸ In December of 1994, petitions were filed with the FDA to approve the needles as treatment for five medical conditions: pain, nausea and vomiting, substance abuse, asthma and other respiratory problems, and stroke and paralysis.⁹ As a result of these events, FDA undertook an extensive review of the available evidence regarding the effectiveness of acupuncture.^{5, 9} FDA announced on March 29, 1996 that acupuncture needles had been reclassified from Class III (experimental) medical devices to Class II (non-experimental but regulated) medical devices for "general acupuncture use" by licensed, registered or certified practitioners.¹⁰ As part of this reclassification, FDA determined that the "investigational use" labeling requirements no longer applied. However, the FDA determined that acupuncture needles must comply with the following special controls:

- (1) Labeling for single use only and conformance to the requirements for prescription devices set out in 21 CFR 801.109,
- (2) Device material biocompatibility, and,
- (3) Device sterility.

Class II devices involve less stringent controls by FDA that include good manufacturing procedures and proper labeling. However, clinical data demonstrating clinical effectiveness is not required. To receive marketing clearance as a class II device, acupuncture devices must go through the FDA's 510 (k) process.¹¹

The FDA requires manufacturers of acupuncture needles to label them for single use only. Acupuncture needles must also bear a prescription labeling statement which restricts their use to qualified practitioners as determined by the states. Manufacturers also have to provide information about device material bio-compatibility and sterility.¹²

Adverse events associated with acupuncture

Serious adverse events associated with acupuncture include transmission of infectious disease, pneumothorax, other problems associated with organ punctures, spinal lesions, cardiac tamponade, and broken needles with remnants migrating to other locations.^{6, 7} Minor adverse events include forgotten needles, exacerbation of symptoms, minor bleeding, hematoma, fatigue, sweating, severe nausea, fainting, and headache.^{3, 6, 7} Adverse events may be associated with practitioner competence and training.^{3, 13, 14}

There have been several studies quantifying the rates of adverse events. A few studies compiled case reports. One Japanese systematic review of case reports found 25 cases of pneumothorax, 18 cases of spinal cord injury, 11 cases of acute hepatitis B and two fatalities from infections.¹⁵

This study and other similar studies establish that serious adverse events are possible, but they were not able to measure the frequency of these complications.¹⁶

Two large prospective studies in the U.K. provided estimates of the rates of adverse events. White et al. conducted a prospective survey of 32000 treatments and found that the rate of “significant” events were 14 per 10,000 acupuncture visits.¹⁷ None of these were deemed to be serious. A total of 671 minor events (such as bleeding or needling pain) per 10,000 acupuncture visits were reported in this study. MacPherson et al. conducted a prospective survey of 34000 treatments and found that there were no reports of serious adverse events that required hospital admission or led to permanent disability or death.¹⁸ Minor adverse events such as severe nausea and vomiting occurred in 1.3 out of 1000 visits. Mild transient reactions such as pain or bleeding occurred in 15% of the visits.

METHODOLOGY

- We examined two recent Technology Assessments to provide a review of systematic reviews as of 2001 (Table 1).
- We updated this search for systematic reviews and found additional systematic reviews on the use of acupuncture for osteoarthritis from 2001 to the present (included in Table 2).
- We updated the list of controlled trials by searching for RCTs more recently than 2002 (included in Table 3).
- Additionally, we identified ongoing clinical trials in this area from the centralized clinical trials web site at NIH (Table 4).

The search strategy used to identify studies listed in all Tables is summarized in Appendix D.

RESULTS

Literature Search

To evaluate the current evidence for the efficacy of acupuncture we identified two recent methodologically sound Technology Assessments:

“Alberta”: Alberta Health Technology Assessment, *Acupuncture: Evidence from Systematic Reviews and Meta-analyses (2002)*.⁷

“NHS”: United Kingdom National Health Service Center for Reviews and Dissemination: *Effective Health Care on Acupuncture (2001)*.⁶

These reviews systematically assessed available systematic reviews and meta-analyses on acupuncture.

The Alberta assessment referenced one systematic review by Ernst of acupuncture as a symptomatic treatment of osteoarthritis, but excluded it because it did not use a “tool” to

evaluate methodological quality.¹⁹ Therefore, no systematic reviews for acupuncture as a treatment for osteoarthritis are included in the Alberta technology assessment.

The NHS assessment included two systematic reviews on osteoarthritis: the systematic review by Ernst that was excluded by the Alberta report and a systematic review by Ezzo et al. on knee osteoarthritis.²⁰

One systematic review, Berman et al., was found that was published since the NHS review.²¹ Four additional RCTs were found that were published since the last systematic review for osteoarthritis.²²⁻²⁵

Three clinical trials on the use of acupuncture to treat osteoarthritis are currently underway (Table 4).

Issues in Evaluating Acupuncture for Osteoarthritis

In addition to standard design issues such as the number of patients needed for adequate statistical power, the randomization procedures, and the appropriateness of outcome measures, the Alberta report summarized specific issues in designing a study for acupuncture including:

- Selection of control technique: Placebo or “sham” acupuncture in studies of acupuncture typically use non-traditional acupuncture points, superficial puncturing of the skin, or for electroacupuncture, the use of electrical stimulators without connecting the cables. Some researchers believe that inserting a needle anywhere in the body or applying pressure to any site evokes a response.
- Complexities of acupuncture: There are many choices in designing a study including different types of acupuncture, different systems for choosing sites and variability in the technique of needle insertion and manipulation.

In addition, it is important to consider that osteoarthritis is a chronic disease characterized by recurring pain over a period of many months or longer. Long term follow-up would be critical to determine the effectiveness of the treatment.

Clinical data

A total of 19 controlled studies published as full articles were found in the systematic reviews and our update search; some of the studies were cited by multiple systematic reviews but others were cited by only a single systematic review. There is some disagreement among the systematic reviews about the study design of some of the studies. In table 2, basic information from the controlled studies was extracted from the abstracts of the studies; we were unable to retrieve an abstract for two of the articles (citations 30, 35-see table 3).

Ernst reviewed 13 studies, of which 12 were identified as being controlled clinical trials or RCTs.¹⁹ Ernst concluded that most trials suffer from methodological flaws, but that the most rigorous studies suggest that acupuncture is not superior to sham-needling in reducing pain of osteoarthritis; both are equally effective. This would suggest that sham-needling has similar specific effects as acupuncture or both methods are associated with considerable non-specific

effects. Other methodological problems in some of the studies included heterogeneous samples, infrequent therapy sessions, no formal test statistics, groups not equal at entry and essential details missing.

Ezzo et al. reviewed 7 studies of osteoarthritis of the knee, all of which were identified as being RCTs.²⁰ These studies suggested that acupuncture is more effective than being on a waiting list for treatment or treatment as usual. The studies did not find a benefit for acupuncture compared to physical therapy. The studies also did not find a benefit for acupuncture compared to sham acupuncture for improving function. Ezzo et al. reviewed three studies with sham acupuncture as a control. Two studies found larger improvements in pain with acupuncture compared to sham; while the third did not.²⁶⁻²⁸ Ezzo et al. noted that in the two studies that showed a benefit, the sham acupuncture consisted of needles placed at distal non-acupuncture points, which they refer to as “minimal sham”. The third study, which did not show a benefit for sham acupuncture, the sham acupuncture was at sites one inch adjacent to the real points, which the authors note may have inadvertently elicited an analgesic response. They also noted that some studies were small and may be underpowered to find a positive effect. Other methodological problems in some of the studies included lack of blinding of patients and outcomes assessors and lack of description of dropouts and withdrawals.

Berman et al. reviewed 8 studies of the use of acupuncture in treating osteoarthritis as part of a larger review of the use of acupuncture for rheumatological conditions.²¹ Three of the studies were identified as being RCTs. However, he classified studies by Christensen et al. and their own study as “time series”, although the abstracts of these studies indicate that they were “randomized”.^{27,28} Another study by Junnila is cited by both Berman et al. and Ernst; both refer to it in summary tables, calling it “non-randomized”.²⁹ However, the text of the Berman systematic review describes the Junnila study as “randomly assigning patients”.²¹ The paper describes “successive patients” enrolled in either arm of the study, months apart. Thus two cohorts were formed uniformly from available patients, but in two distinct time periods; leaving open to interpretation whether or not the choice of time of the year constitutes randomization.

Berman found that for the studies they classified as RCTs there were no significant benefits for acupuncture compared to sham acupuncture. None of the studies had sufficient power to detect a difference between acupuncture and sham acupuncture, and there were significant improvements compared to baseline for both acupuncture and sham acupuncture groups. Berman suggests that this may be because puncturing the skin at any position may elicit an analgesic response or that the sham sites chosen were actually active acupuncture sites.²¹

We found four additional RCTs published after the date of the last systematic review.²²⁻²⁵ The results of these trials were consistent with the results of studies previously reviewed. Haslam et al. and Singh et al. compared acupuncture to advice and exercises for the hip or waiting for treatment respectively and found benefit for acupuncture compared to the control.^{23,24} Fink et al. compared acupuncture to sham acupuncture and found that both groups had significant improvements compared to baseline with no differences between the groups.²² Tillu et al. compared acupuncture in the most affected knee to acupuncture in both knees and found a significant reduction in symptoms in both knees in both groups.²⁵

CONCLUSIONS

A key issue in studies of acupuncture is the effect of sham acupuncture. Most studies on acupuncture for osteoarthritis do not find a benefit for acupuncture compared to sham acupuncture. Researchers hypothesize that this may be because placement of a needle anywhere elicits a physiological response or because the sham sites chosen were actually true acupuncture sites. Most studies found a benefit for both acupuncture and sham acupuncture compared to baseline. All the reviewers agree that more research is necessary to understand the effects of sham acupuncture.

The systematic reviews describe other methodological problems with some of the studies. Many studies are small and may be underpowered to measure statistically significant differences between the interventions. Other methodological issues include lack of blinding, lack of description of handling of dropouts and withdrawals, no formal test statistics, heterogeneous samples and groups not equal at entry in some of the studies.

Two studies did find a benefit for acupuncture compared to sham: Petrou et al. and Molsberger et al. Ezzo et al. noted that in these studies the needles were placed superficially, at sites distal to true acupuncture sites.^{30, 31, 20} Ernst also reviewed the study by Petrou et al. and noted that there was a small sample size (31 patients), that it lacked blinding and that not all the variables showed improvement.¹⁹

The systematic reviews had somewhat different conclusions based on their interpretation of the evidence (Table 2). Ernst qualitatively described methodological flaws in most of the studies, and concluded that acupuncture is not superior to sham. Ezzo et al. acknowledged the methodological problems in the studies, but concluded that acupuncture may play a role in the treatment of osteoarthritis; this conclusion was largely based on the two studies showing a positive effect of acupuncture compared to sham.^{30, 31} Berman et al. also found no benefit for acupuncture compared to sham, but they suggest that sham acupuncture may have pain relieving effects and that this may explain the relative equivalence of acupuncture compared to sham acupuncture.²¹ They concluded that there is moderately strong evidence supporting adjunctive use of acupuncture.

Overall, the NHS review concluded that the evidence was probably sufficient to justify the use of acupuncture as a second or third line treatment for a patient who is not responding to conventional management or not tolerating medication or experiencing recurrent pain, but also suggest that the evidence is not sufficient to justify acupuncture as first line treatment.

Three clinical trials on the use of acupuncture in osteoarthritis are currently underway (Table 4). These studies have randomized controlled designs and intend to enroll several hundred patients. Two of the studies are specifically designed to further investigate the effect of sham acupuncture. One of these studies (Table 4, #2) uses a validated placebo needle that does not penetrate the skin.³² A study with this placebo needle suggested that patients who have never had acupuncture could not tell that the technique was a placebo. The needle is designed based on the hypothesis that the beneficial effect of sham acupuncture is due to penetration of the skin by the needle. This study is not testing acupuncture alone but acupuncture in combination with physical therapy. Another study is also designed to further understand the effect of sham acupuncture (Table 4, #3). In this study, patients are randomized to groups with different models for

practitioner-patient interactions. Patients in each interaction group will be further randomized to receive either acupuncture or sham acupuncture. This study is designed to test the hypothesis that placebo effects of sham acupuncture can be enhanced by the practitioner's communicative style, which can affect the patient's expectations and beliefs.

Most studies show a benefit for acupuncture compared to no treatment. It has been more difficult to determine whether the effect observed is a non-specific placebo effect because of the issues around the design of sham acupuncture procedures in randomized controlled trials. These problems arise from the lack of clear definition of what constitutes "acupuncture" and through what mechanisms it is purported to work. The currently available evidence is insufficient to determine whether acupuncture has a specific beneficial effect in osteoarthritis. New studies are underway which were designed with the aim of answering some questions about the effects associated with sham acupuncture. These studies should help to clarify the potential specific effect, if any, of acupuncture for osteoarthritis.

Table 1: Acupuncture for Osteoarthritis: A Review of Systematic Reviews Through 2001*

Systematic Review of review literature	Conclusion	Systematic Reviews Included (Good quality rating)
Alberta	No specific conclusions were drawn about Osteoarthritis because no reviews on the use of acupuncture for osteoarthritis were included.	None
NHS	Current levels of evidence from RCTs of acupuncture for chronic pain (including osteoarthritis) are probably sufficient to justify the use of acupuncture as second or third line treatment for a patient who is not responding to conventional management, not tolerating medication or experiencing recurrent pain; however, there is insufficient evidence to warrant first-line treatment of chronic pain.	Ernst 1997 Ezzo et al 2001

* The *Alberta Health Technology Assessment, Acupuncture: Evidence from Systematic Reviews and Meta-analyses (2002)*⁷. and the *United Kingdom National Health Service Center for Reviews and Dissemination: Effective HealthCare on Acupuncture (2001)*⁶ systematically assessed available systematic reviews and meta-analyses on acupuncture. This Table provides those systematic reviews for osteoarthritis.

Table 2: Systematic Reviews on the use of Acupuncture for Osteoarthritis

Clinical condition	Reference	Abstract Conclusions of SR Findings
Osteoarthritis	Ernst E. Acupuncture as a Symptomatic Treatment of Osteoarthritis ¹⁹	The most rigorous studies suggest that acupuncture is not superior to sham needling
Knee Osteoarthritis	Ezzo J et al. Acupuncture for osteoarthritis of the knee: a systematic review ²⁰	Evidence strong that real acupuncture is more effective than sham acupuncture for pain; inconclusive evidence for function. Insufficient evidence to determine whether the efficacy of acupuncture is similar to other treatments. The existing evidence suggests that acupuncture may play a role in the treatment of knee OA. Future research should define an optimal acupuncture treatment
Osteoarthritis	Berman BM, Swyers JP, Ezzo J. The evidence for acupuncture as a treatment for rheumatic conditions. <i>Rheu Dis Clin North Am.</i> 2000;26(1):103-15,ix-x ²¹	In all the studies that employed sham acupuncture as a placebo control, there were no significant between-group differences. Moderately strong evidence supports the use of acupuncture as an adjunctive therapy for osteoarthritis.

Table 3: Acupuncture Controlled Trials

Trial Name	Cited by	Indication	Number of Patients	Follow up	Treatment	Results
Gaw et al., 1975 ³³	Ernst, 1997 Berman et al., 2000	Not specified	40	Not specified	Treatment at standard acupuncture points Treatment at placebo points	Significant (p<0.05) improvement in tenderness and subjective report of pain in both groups compared to baseline No significant differences between groups
Coan et al., 1981 ³⁴	Ernst, 1997	Cervical (neck)	30	12 weeks	Not specified	12/15 of treatment group felt improved: mean 40% reduction in pain score, 54% reduction in pain pills, 68% reduction of pain hours per day, 32% less limitation of activity 2/15 of the control group reported improvement: mean 2% worsening in pain score, 10% reduction in pain pills, no lessening of pain hours and 12% less limitation of activity
Milligan et al., 1981 ³⁵	Ezzo et al., 2001	Abstract unavailable				
Junnila et al., 1982 ²⁹	Ernst, 1997 Berman et al., 2000	large joints	32	4 months	Acupuncture Piroxicam	Acupuncture reported to have a greater pain reducing effect than Piroxicam
Loy et al., 1983 ³⁶	Ernst, 1997	Cervical (neck)	Not specified	Not specified	Electroacupuncture Physiotherapy	Both methods were effective, electroacupuncture produced an earlier symptomatic improvement

Trial Name	Cited by	Indication	Number of Patients	Follow up	Treatment	Results
Loy et al., 1983 ³⁶ (continued)						with increased neck movement
Petrie et al., 1983 ³⁷	Ernst, 1997	Cervical (neck)	13	4 weeks	Acupuncture Placebo transcutaneous nerve stimulation Treatment twice weekly	Acupuncture superior to placebo (p<0.01)
Petrie et al., 1986 ³⁸	Ernst, 1997	Cervical (neck)	25	Not specified	Acupuncture Placebo transcutaneous nerve stimulation	No significant difference found either post-treatment or at follow-up
Petrou et al., 1988 ³⁰	Ernst, 1997 Ezzo et al., 2001	Abstract unavailable				
Ammer and Petschnig, 1988 ³⁹	Ernst, 1997 Ezzo et al., 2001	Knee	Not specified	4 weeks	Acupuncture Physical therapy	Patients treated with acupuncture showed 2/10 parameters improved after 4 weeks of therapy. Patients treated with physical therapy showed 4/10 parameters improved after 2 weeks and 7/10 parameters improved after 4 weeks.

Trial Name	Cited by	Indication	Number of Patients	Follow up	Treatment	Results
Ammer and Petschnig, 1988 ³⁹ (continued)						Physical therapy was superior in objective measurements, but no significant difference in subjective judgment by patients.
Dickens and Lewith, 1989 ⁴⁰	Ernst, 1997 Berman et al., 2000	Trapezio-metacarpal (hand)	12 patients	Not specified	Acupuncture Placebo transcutaneous nerve stimulation 6 sessions over two week period	Acupuncture group: 76.01% pain reduction Placebo group: 20% pain reduction Statistically significant within groups but not between groups; study likely underpowered
Thomas et al., 1991 ⁴¹	Ernst, 1997 Berman et al., 2000	Cervical (neck)	Not specified	Not specified	Acupuncture Sham acupuncture Diazepam Placebo-diazepam	Acupuncture significantly (p<0.05) more effective than placebo-diazepam Acupuncture not significantly more effective than sham acupuncture or diazepam.
Christensen et al., 1992 ²⁷ Christensen et al., 1992 ²⁷	Ernst, 1997 Berman et al., 2000 Ezzo et al., 2001	knee	29	49 weeks	Treatment No treatment control for 9 weeks, then crossed over into treatment In second part of study 17 patients continued treatment once a month	Treatment group had significant reduction in pain and analgesic use compared to no treatment group. Benefit was maintained in the second part of the study Patients were all initially waiting for arthroplasty; 7 patients no longer wanted surgery after acupuncture treatment

Trial Name	Cited by	Indication	Number of Patients	Follow up	Treatment	Results
(continued)						
Molsberger et al., 1994 ³¹	Ezzo et al., 2001	knee	97	3 months	Acupuncture Sham acupuncture at non-acupuncture points Treatment 2x per week for 5 weeks	47.5% pain reduction for acupuncture groups vs. 26.1% for control after treatment period 48.2% pain reduction for acupuncture group vs. 26.1% for control at 3 month follow up p<0.05; Functional parameters had no significant change
Takeda and Wessel, 1994 ²⁶	Ernst, 1997 Berman et al., 2000 Ezzo et al., 2001	knee	40	3 weeks	Real acupuncture Sham acupuncture Treatment 3x per week for 3 weeks	Both real and sham acupuncture significantly reduced pain, stiffness and physical disability compared to baseline No significant difference between groups
Berman et al., 1999 ²⁸	Ezzo et al., 2001 Berman et al., 2000	knee	73 elderly patients	12 weeks	Acupuncture Standard care	Significant improvement for acupuncture patients compared to control at 4 and 8 weeks. Slight decline in effect at 4 weeks after cessation of treatment No adverse effects reported
Fink et al., 2001 ²²	Update search	hip	67	2 months	Traditional needle placement and	Both groups had significant improvement compared to baseline

Trial Name	Cited by	Indication	Number of Patients	Follow up	Treatment	Results
					manipulation Needles placed away from classic positions and not manipulated	No significant difference between groups
Haslam et al., 2001 ²³	Update search	hip	32	8 weeks	Acupuncture (six sessions each lasting up to 25 minutes) Advice and exercises for the hip	Significant improvement in acupuncture group immediately post treatment (p=0.002) which was maintained at the 8 week follow up (p=0.03) compared to baseline. Significant improvement in acupuncture group compared to control immediately post treatment (p=0.02) and at 8 week follow up (p=0.03)
Singh et al., 2001 ²⁴	Update search	knee	73	12 weeks	Acupuncture treatments twice weekly for 8 weeks Crossover control group	Scores on two functional indexes improved at 4, 8, and 12 weeks. Some decay in scores at week 12, but measures significantly improved over baseline
Tillu et al., 2001 ²⁵	Update search	knee	44	6 months	Acupuncture to most affected knee Acupuncture to both knees	Significant reduction of symptoms in both groups. Improvement sustained for 6 months.
Tillu et al., 2001 ²⁵					Acupuncture to four local points and one	No statistical significance between the groups.

Trial Name	Cited by	Indication	Number of Patients	Follow up	Treatment	Results
(continued)					distal point on the ipsilateral hand	

- For *osteoarthritis*, we updated systematic reviews for osteoarthritis (Table 1& Table 2) by identifying all RCTs published since the last systematic review.

Table 4: Current Clinical Trials Studying Acupuncture for Osteoarthritis*

Acupuncture Clinical Trial	Condition	Study Duration	Intervention	Target Number of Patients
1. Acupuncture Safety/Efficacy in Knee Osteoarthritis Principle Investigator: Dr. Brian Berman Sponsor: NCCAM	Knee osteoarthritis	Not specified	Traditional Chinese acupuncture Education and attention comparison group Sham Traditional Chinese Acupuncture	525
2. Efficacy of Acupuncture with Physical Therapy for Knee Osteoarthritis Principle Investigator: Dr. John Farrar Sponsor: NCCAM	Knee osteoarthritis	Not specified	Acupuncture with exercise physical therapy Validated blinded placebo needle with exercise physical therapy	300
3. Interaction Between Patient and Health Healthcare Provider: Response to Acupuncture in Knee Osteoarthritis Principle Investigator: Dr. Maria Suarez-Almazor Sponsor: NIAMS and NCCAM	Osteoarthritis	6 weeks of biweekly treatment visits 6 month follow-up	Acupuncture Sham acupuncture Each group will also be randomized to different models for practitioner-patient interactions.	760

*The information provided in this Table comes from searching the ClinicalTrials.gov web site for acupuncture (search term “acupuncture” and search term “osteoarthritis”). The National Institutes of Health (NIH), through its National Library of Medicine (NLM), has developed the ClinicalTrials.gov web site in collaboration with all NIH Institutes and the Food and Drug Administration (FDA) to provide current information about clinical research studies. The site currently contains approximately 7,100 clinical studies sponsored by the National Institutes of Health, other Federal agencies, and the pharmaceutical industry in over 77,000 locations worldwide. Studies listed in the database are conducted primarily in the United States and Canada.

CMS REQUEST

- III** Provide a review of any information available in the literature on training of the persons to perform this therapy and the number of physicians certified to perform this therapy.

Training, certification & licensing of acupuncturists in the United States

In 1976, California became the first state to license acupuncture as an independent health care profession. Since then, 40 states and the District of Columbia have adopted similar laws. Most states allow herbal medicine within the scope of acupuncture practice; only a few states require the supervision of a physician for the almost 11,000 practicing non-physician acupuncturists.

The number of acupuncturists is rapidly growing and is projected to double by 2005 and quadruple by 2015. The typical education standard for an acupuncturist is between 2,000 and 3,000 hours of training in independently accredited master's degree 4-year schools. Although some states allow physicians to practice acupuncture without additional education, most states require between 200 and 300 hours of special training. There are approximately 3,000 acupuncturists with medical degrees practicing in the United States.

Physician acupuncturists

State regulations

Most states regard acupuncture as being within the scope of practice for licensed physicians, but many require that physician acupuncturists receive additional training and in some cases pass an examination. A table published by the American Academy of Medical Acupuncture in 1999 outlines various state requirements. This table can be viewed at:

http://www.medicalacupuncture.org/acu_info/licensure.html.

Professional societies

The American Academy of Medical Acupuncture (AAMA) is the sole physician-only professional acupuncture society in North America, accepting members from a diversity of training backgrounds. Membership requirements for the Academy have been established in accordance with the training guidelines created by the World Federation of Acupuncture-Moxibustion Societies. The AAMA training guidelines can be viewed at:

http://www.medicalacupuncture.org/aama_marf/aama.html.

There are two categories of Practice Members of the AAMA. All AAMA Practice Members receive a formal certificate recognizing their level of training and experience. A detailed listing of AAMA membership requirements can be found at:

http://www.medicalacupuncture.org/aama_marf/aama_membership.html.

Full membership

Physicians who desire Full Membership in the AAMA must fulfill all three of the following requirements:

- Possess an active M.D. or D.O. license (or equivalent) to practice medicine under U.S. or Canadian jurisdiction;

- Have completed a minimum of 220 hours of formal training in Medical Acupuncture (120 hours didactic, 100 hours clinical), or the equivalent in an apprenticeship program acceptable to the Membership Committee;
- Have two years of experience practicing medical acupuncture.

Associate membership

Associate Membership is available to physicians that satisfy either of the following requirements:

- Have at least 200 hours of formal training, but do not have at least two years of experience practicing medical acupuncture;
 - Have two years of clinical experience in acupuncture, but lack sufficient hours of formal training approved by the Membership Committee.
- Associate Members may apply for Full Membership whenever they have met the experience and education requirements for Full Members.

The AAMA maintains a Physician Acupuncturist Referral Service that contains listings for 1,031 Practice Members of the AAMA. This listing can be viewed at:

<http://www.medicalacupuncture.org/findadoc/index.html>.

Board certification

The American Board of Medical Acupuncture (ABMA) was formally established on April 26, 2000 as an independent entity within the American Academy of Medical Acupuncture. Its mission is to promote safe, ethical, efficacious medical acupuncture to the public by maintaining high standards for the examination and certification of physician acupuncturists as medical specialists.

A physician who desires certification by the ABMA must complete a formal course of study and training designed for physicians that, as a minimum, meets the guidelines and standards set forth by The World Health Organization and the World Federation of Acupuncture and Moxibustion Societies (WFAS). Programs must be a minimum of 200 hours of acupuncture specific training, post-medical school, of which 100 hours should be clinical. More information about the ABMA can be found at: http://www.medicalacupuncture.org/cme/cme/abma_info.html. A current listing of ABMA-approved training programs can be found at:

http://www.medicalacupuncture.org/cme/cme/abma_info.html#trainingprograms.

Currently 200 American Academy of Medical Acupuncture (AAMA) members have qualified for ABMA Board Certification.

Non-physician acupuncturists

State licensing requirements

Legislative and regulatory policies that affect non-physician acupuncture practitioners vary from state to state. In their Final Report of March 2002, the White House Commission on Complementary and Alternative Medicine Policy published a table (in Chapter 6: Access and Delivery) that provides a brief overview of these policies. A table detailing licensing regulations by state and specialty can be viewed at: <http://www.whccamp.hhs.gov/fr6.html>.

United States Acupuncture Laws by State is a comprehensive survey of state policies affecting both non-physician and physician acupuncturists, with links in many instances to the relevant laws, regulations and agencies of that state. This site can be viewed at: <http://acupuncture.com/StateLaws/StateLaws.htm>.

In those states that license non-physician acupuncturists, education and testing requirements vary. An outline of formal education and examination requirements for licensure in these states has been posted on the Acupuncture Alliance website at: <http://www.acupuncturealliance.org/examrequ.htm>. The Acupuncture Alliance is an advocacy group that works to support and develop acupuncture and Oriental medicine through encouraging research, assisting in creating and amending state laws and regulations, and creating practice standards.

Most states require that applicants, trained in the U.S., must have graduated from a program accredited by the Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM). Recognized by the U.S. Department of Education as a “specialized and professional” accrediting agency, ACAOM’s primary purposes are to establish comprehensive educational and institutional requirements for acupuncture and Oriental medicine programs, and to accredit programs and institutions that meet these requirements. More information about ACAOM can be found at: <http://www.acaom.org/AboutUs.htm>. A list of ACAOM accredited institutions can be found at: <http://www.acaom.org/SchoolistNov2001.htm>.

Typically, a licensing board will also require passage by the applicant of the National Certification Commission of Acupuncture and Oriental Medicine (NCCAOM) certification examination. The National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) is a non-profit organization established in 1982. Its mission is to promote nationally recognized standards of competency and safety in acupuncture and Oriental medicine for the purpose of protecting the public.

More information about NCCAOM and the certification process can be found at: <http://www.nccaom.org/about.html>. The NCCAOM published a table in January 2001 that outlines how various states use its certification examination in their acupuncturist licensing requirements. State licensure requirements can be viewed at: <http://www.nccaom.org/states.html>. Since its inception in 1982, the NCCAOM has certified close to 10,000 Diplomates in Acupuncture, Chinese Herbology and Asian Bodywork Therapy

APPENDICES

Appendix A: GLOSSARY

Acupressure refers to the stimulation of a point manually with pressure.⁷

Acupuncture, in the strictest sense, refers to insertion of dry needles, at specially chosen sites for the treatment or prevention of symptoms and conditions.⁷

Bloodletting refers to the pricking of the skin for the purpose of releasing blood. This may be aided with the application of a cup over the site.⁷

Cupping is a technique by which a vacuum force is applied to acupuncture sites.⁷

Electroacupuncture refers to the technique of introducing an electrical current to the inserted needles at various frequencies.⁷

Fire needle techniques insert red-hot needles at an acupuncture point.⁷

Intramuscular stimulation is a technique of applying needles to areas of tenderness.⁷

Laser acupuncture directs and stimulates a laser beam directed at the acupuncture site.⁷

Medical acupuncture is a medical discipline that integrates traditional and modern acupuncture techniques into contemporary biomedical practice.⁴²

Physician Acupuncturist is one who has acquired specialized knowledge and experience related to the integration of acupuncture within a biomedicine practice.⁴

Moxibustion refers to heat stimulation and the use of the herb *Artemisia vulgaris* (mugwort) which is burned over the acupuncture site for purposes of warming.⁷

Staple puncture is the application of a metal staple to an acupuncture point where it remains for a prolonged period of time.⁷

Zhejiu is the Chinese term and refers to both acupuncture and moxibustion.⁷

Appendix B: NHS Methodology

Systematic reviews on acupuncture were located as part of an attempt by the Cochrane Complementary Medicine Field to locate all reviews on acupuncture, herbal medicine and homeopathy. The field registry is a specialized complementary medicine database compiled from searcher of other databases including Embase, AMED and Medline; approximately 4,700 RCTs of complementary medicine are included on the database. Another 5,700 controlled trials have been identified for which the randomization status is unknown. RCTs have also been identified through hand searching of 31 alternative medicine journals. In addition to searches of the field registry, the following searches were conducted:

- Medline 1989 to July 2000 using a standard strategy to identify systematic reviews;
- The Cochrane Library Issue 2 2000;
- Bibliographies of articles obtained and relevant textbooks were screened for further potentially relevant articles.

A search of Medline and the Cochrane Library (2001:1) was made in March 2001 to find further reviews and RCTs published subsequently to each review. All searches used strategies developed by the Complementary Medicine field of the Cochrane Collaboration and published on the Cochrane Library. Where no review was available, all RCTs on that topic were included.

To be included, systematic reviews had to meet the following criteria:
Included clinical trials of acupuncture; describe review methods explicitly; had to be published; had to focus on treatment effects.

Quality assessment was undertaken by two reviewers working independently for the systematic reviews. Data extraction and assessment of methodological quality of the additional RCTs were undertaken by one reviewer and checked by a second reviewer.

Appendix C: Alberta Methodology

Two searches were performed - in January and July 2001. The following outlines the search strategy and the databases used. Effort was made to find criteria accepted by the acupuncture community as well as the scientific community for use in the critical appraisal of the quality of systematic reviews for acupuncture. No quality assessment tool specific to acupuncture was found.

Two of the co-authors (LB and CH) selected the articles based on the inclusion and exclusion criteria while two co-authors (LB and PLT) extracted data from the reviews and evaluated their methodological quality using criteria by Greenhalgh²¹ as outlined in Appendix B. The authors of the reviews were not contacted for missing information.

Search Strategy

Databases Searched	Subject headings (Bolded) and Textwords combinations
MEDLINE (Ovid) 1990-May2001 and PreMEDLINE to July 21, 2001	Acupuncture (exploded) OR acupuncture acupressure OR Electroacupuncture OR electro-acupuncture OR staple acupuncture OR staple-acupuncture OR stapleacupuncture OR staple puncture OR staple-puncture OR staplepuncture OR moxibustion
HealthSTAR (Ovid) 1991- Jan 2000 – database discontinued	
Best evidence (Ovid) Jan/Feb 2001	
CINAHL (Ovid) 1990-March 2001	
EMBASE (Ovid) 1990-April 2001	
AMED (Ovid) May 2001	
Cochrane Database of Systematic Reviews 1st Quarter 2001	Acupunctur* OR acupressure OR electroacupuncture OR electro-acupuncture OR staple acupuncture OR staple-acupuncture OR stapleacupuncture OR staple puncture OR staple-puncture OR staplepuncture OR moxibustion
CMA practice guidelines- CPG infobase June 22, 2001	acupuncture OR moxibustion
National guideline clearinghouse June 22, 2001	acupuncture OR moxibustion
DARE, HTA, EED June, 2001	Acup OR moxibustion

Databases Searched	Subject headings (Bolded) and Textwords combinations
WWW: ECRI, Bandolier, and other HTA agencies websites	acupuncture OR acupressure OR electroacupuncture OR electro-acupuncture OR staple acupuncture OR staple-acupuncture OR stapleacupuncture OR staple puncture OR staple-puncture OR staplepuncture OR moxibustion

Two other databases, ISTAHC, PsycInfo (February 2001), were searched but there were no relevant studies found. Articles were submitted by various people interested in acupuncture, and access was granted to a private collection of journals of acupuncture. This ‘grey literature’ was hand searched for articles that complied with the inclusion criteria. Reference lists of retrieved reviews were search for systematic reviews and meta analyses.

Publication type limits (where available): meta-analysis, systematic review

“A systematic review is an overview of primary studies that use explicit and reproducible methods”²¹.

“A meta-analysis is a mathematical synthesis of the results of two or more primary studies that addressed the same hypothesis in the same way”²¹.

These publication types were searched as textwords and where publication type limiting was not available by using this search string: (Subject headings OR Textwords) AND (systematic review OR meta analysis OR critical appraisal OR metaanaly\$ OR meta-analy\$ OR metanaly\$ OR critical\$ apprais\$ OR systematic\$ review\$)

Inclusion criteria: Articles were selected if they were systematic reviews, a category which includes but is not limited to meta-analyses. The study must have human participants, but with no restriction of age group or nationality. Reviews were required to have an intervention of acupuncture as being the primary treatment intervention in the study. Studies addressing any medical indication were included if they were published within the past 11 years (1990 – 2001). Only reviews available in English were evaluated.

Exclusion criteria: Reviews were excluded if the use of a tool to evaluate the methodological quality of the primary studies was not apparent. If reviews used the same methodological criteria and had the majority of primary studies in common, the older publications were excluded.

Appendix D: AHRQ Search Strategy

Search Strategies for Acupuncture

Search Strategy for Acupuncture RCT's

Database Searched	Subject Headings	Date Searched
PubMed	(acupuncture[tw] OR acupressure[tw] OR	8/5/2002
	electroacupuncture[tw] OR electro-	
CINAHL (Ovid)	acupuncture[tw] OR (staple[tw] AND	8/15/2002
	acupuncture[tw]) OR staple-	
AMED (Ovid)	acupuncture[tw] OR	8/15/2002
	stapleacupuncture[tw] OR (staple[tw]	
	AND puncture[tw]) OR staple-puncture[tw]	
	OR staplepuncture[tw] OR	
	moxibustion[tw])	
	Limits: Pub. Dates 1995-2002, English,	
	Human	

Inclusion criteria: Acupuncture, acupressure, electro-acupuncture, staple acupuncture, moxibustion, human, adult, English language, RCT

Search Strategy for Systematic Reviews

Database Searched	Subject Heading	Date Searched
APC Journal Club (EBM Reviews)	Acupuncture (Exploded) (acupuncture OR acupressure OR electro acupuncture OR electro- acupuncture OR (staple AND acupuncture) OR staple-acupuncture OR stapleacupuncture OR (staple AND puncture) OR staple-puncture OR staplepuncture OR moxibustion) Limits: Pub. Date 2001-2002	7/31/2002
HealthSTAR (Ovid)		7/31/2002
PubMed	Acupuncture (MESH) (acupuncture OR acupressure OR electro acupuncture OR electro- acupuncture OR (staple AND acupuncture) OR staple-acupuncture OR stapleacupuncture OR (staple AND puncture) OR staple-puncture OR staplepuncture OR moxibustion) Limits: Pub. Date 2001-2002	7/31/2002
CINAHL	Acupuncture (Exploded) (acupuncture OR acupressure OR electro acupuncture OR electro- acupuncture OR (staple AND acupuncture) OR staple-acupuncture OR stapleacupuncture OR (staple AND puncture) OR staple-puncture OR staplepuncture OR moxibustion) Limits: Pub. Date 2001-2002	7/31/02
INAHTA		8/1/2002
MANTIS		8/1/2002
AMED		8/1/2002
DARE		8/2/2002

Inclusion criteria: Acupuncture, acupressure, moxibustion, systematic review, meta-analysis

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