

Technology Assessment

**US. Department of Health and
Human Services
Public Health Service**



**Agency for Healthcare Research
and Quality
6010 Executive Blvd., Suite 300
Rockville, Maryland 20852**

June 5, 2003

Acupuncture for Fibromyalgia

Table of Contents

	Page
Introduction	1
Background	
-Fibromyalgia	1
-Description of Acupuncture	1
-FDA's Role	2
-Adverse events associated with acupuncture	3
Methodology	3
Results	
-Literature search	4
-Issues in evaluating acupuncture for fibromyalgia	4
-Clinical data	5
Conclusions	6
Tables 1-4	7
Training, certification & licensing of acupuncture In the United states	11
-Physician acupuncturists	11
-Non-physician acupuncturists	13
Appendices	
-Appendix A: Glossary	14
-Appendix B: NHS Methodology	15
-Appendix C: Alberta Methodology	16
-Appendix D: AHRQ Search Strategy	17
References	20

ACUPUNCTURE FOR THE TREATMENT OF FIBROMYALGIA

The Agency for Healthcare Research and Quality

Center for Practice and Technology Assessment

June 5, 2003

INTRODUCTION

The Centers for Medicare and Medicaid Services (CMS) commissioned an expedited review of the literature on acupuncture for fibromyalgia from the Agency for Healthcare Research and Quality (AHRQ).

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

- a) A review of recent (1995 to present) systematic reviews on the use of acupuncture for fibromyalgia, 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

Fibromyalgia

Fibromyalgia is a syndrome with features that include chronic, widespread musculoskeletal pain and stiffness and associated with fatigue, poor sleep and the presence of discrete tender points. Fibromyalgia affects ~3.7 million people in the U.S.; 75% of patients are women between the ages of approximately 35 to 55 .¹ One small survey estimated that approximately 20% of fibromyalgia patients treated at a university-based clinic in the United States tried acupuncture within 2 years of diagnosis.²

Description of Acupuncture

In its original form acupuncture was based on the principles of traditional Chinese medicine .³⁻⁵ 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.^{4, 6, 7}

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.^{5, 6, 8} 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.^{4, 6, 7}

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.⁹ 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.¹⁰ As a result of these events, FDA undertook an extensive review of the available evidence regarding the effectiveness of acupuncture.^{6, 10} 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.¹¹ 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.¹²

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.¹³

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.^{7, 8} Minor adverse events include forgotten needles, exacerbation of symptoms, minor bleeding, hematoma, fatigue, sweating, severe nausea, fainting, and headache.^{4, 7, 8} Adverse events may be associated with practitioner competence and training.^{4, 14, 15}

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.¹⁶ 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.¹⁷

Two large prospective studies in the U.K. provided estimates of the rates of adverse events. White and colleagues conducted a prospective survey of 32000 treatments and found that the rate of “significant” events were 14 per 10,000 acupuncture visits.¹⁸ 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 and colleagues 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.¹⁹ 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 reviewed two recent Technology Assessments to provide a synopsis of systematic reviews as of 2001 (Table 1).
- We updated the initial review by searching and listing systematic reviews and other reviews on the use of acupuncture for fibromyalgia from 2000 to the present (Table 2).
- We further updated the review by searching for all RCTs published since the last systematic review.
- We reviewed the abstracts of all RCTs identified.
- We searched for ongoing acupuncture clinical trials to treat fibromyalgia from the clinicaltrials.gov web site (Table 3).

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 in treating fibromyalgia we identified two recent methodologically sound Technology Assessments:

“Alberta”: *Alberta Health Technology Assessment, Acupuncture: Evidence from Systematic Reviews and Meta-analyses (2002)*⁸

“NHS”: *United Kingdom National Health Service Center for Reviews and Dissemination: Effective Health Care on Acupuncture (2001)*⁷

These reviews systematically assessed available systematic reviews and meta-analyses on acupuncture. Both of these cited only a single systematic review on fibromyalgia by Berman and colleagues.²⁰ The Alberta report rated the Berman systematic review as “Satisfactory” (on a 3 point rating system from “Good” to “Poor”). The Alberta report criticized the Berman systematic review because it failed to identify the style of acupuncture (e.g. whether the points were individualized to the patient or chosen based on a formula), appropriateness of treatment, or the qualification of the practitioner.

In order to find more recent literature, we searched for reviews or RCTs published since 2000. Two reviews were found: Berman and Bandolier; these did not include any new RCTs.^{21,22} There were no RCTs identified in our search that were published since the last systematic review.

We searched the clinicaltrials.gov website to find current clinical trials on the use of acupuncture for fibromyalgia. Two clinical trials are currently underway (Table 3).

Issues in evaluating acupuncture for fibromyalgia

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 fibromyalgia 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

The Berman review, which is the basis for all the other reviews of acupuncture for fibromyalgia, cites 7 primary studies²³⁻²⁹, of which 3 are RCTs (Table 4).^{25, 27, 28}

Berman and colleagues considered the Deluze RCT to be the only one of high methodological quality.²⁸ The other two RCTs were considered to be of lower quality because the designs precluded the ability to blind patients to group assignment and the method of randomization concealment was unclear.

The NHS report included fibromyalgia together with the use of acupuncture for other types of chronic pain, and criticized the literature based on three points:

- Quality of the studies was related to study outcomes: lower quality studies were more likely to favor acupuncture.
- Most RCTs of acupuncture in chronic pain have few patients and may be underpowered.
- Active acupuncture and sham techniques may be inadequate; including too few numbers of points, too few treatment sessions, and placement of sham needles in the same body segment as the active needles.

Deluze and colleagues studied 70 patients with electroacupuncture compared to sham. They found statistically significant improvements on several outcome measures such as pain relief. They did not, however, follow patients beyond the three week study period. The two other RCTs had longer term follow-up. Berman et al. reviewed the results of the Lautenschlager et al. study of 50 patients and stated that no significant difference of effect was found between acupuncture and placebo at 3 month follow-up (the translation of the abstract is ambiguous and we could not therefore confirm this statement by Berman et al.) Berman et al. also noted that the data from the RCT was combined with data from a nonrandomized pilot study²⁷ Cassisi and colleagues studied 21 patients and found a long term pain relief benefit at 6 months, but this benefit was quantitatively less than the initial pain relief.²⁵

CONCLUSIONS

There is only one RCT (Deluze et al. ²⁸) on the use of acupuncture for fibromyalgia that was considered to be of high quality by Berman et al, the primary reviewer of fibromyalgia. This study of 70 patients found statistically significant benefits for acupuncture using several outcome measures such as pain relief. This study used electroacupuncture rather than the more traditional needling technique. More importantly, however, Deluze et al. only followed patients for three weeks. Studies of lower methodological quality include two other randomized studies and several other nonrandomized studies.

The reviews interpret the strength of this body of evidence somewhat differently (Table 1 and 2). None of the reviews concluded that the evidence was sufficient to use acupuncture as a first line treatment, although two concluded that the evidence supported the use of acupuncture as adjunctive or second line treatment for fibromyalgia. Even though the study by Deluze et al. found a statistically significant benefit for acupuncture, it only followed patients for three weeks, which is not long enough to draw conclusions about health outcomes for patients with this long-term chronic condition. Longer term studies are necessary to determine the benefit of any treatment for fibromyalgia.

At this time, therefore, there is insufficient evidence to conclude that acupuncture has efficacy for the treatment of fibromyalgia. 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.

Table 1: Acupuncture for Fibromyalgia: A Review of Systematic Reviews*

Systematic Review	Conclusion	Systematic Reviews Included (Quality Rating)
Alberta	The robustness of the effect of acupuncture is debatable and its clinical value questionable.	Berman BM et al. 1999 ¹⁸ (Satisfactory)
NHS	Current levels of evidence from RCTs of acupuncture for chronic pain (including fibromyalgia) 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.	Berman BM et al. 1999 ¹⁸

* The *Alberta Health Technology Assessment, Acupuncture: Evidence from Systematic Reviews and Meta-analyses (2002)*⁸ and the *United Kingdom National Health Service Center for Reviews and Dissemination: Effective HealthCare on Acupuncture (2001)*⁷ systematically assessed available systematic reviews and meta-analyses on acupuncture. This Table provides the systematic review for fibromyalgia.

Table 2: Acupuncture for Fibromyalgia Reviews: 2000- Present*

Clinical condition	Reference	Abstract Conclusions of SR Findings
Fibromyalgia	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	Not yet definitive evidence from large-scale randomized controlled trials; moderately strong evidence supports the use of acupuncture as an adjunctive therapy for fibromyalgia.
	Bandolier. Acupuncture for fibromyalgia. ²²	There is little or no evidence of benefit

*An update of acupuncture systematic reviews found in Table 1 for fibromyalgia: 2000 to the present.

Table 3. Acupuncture Clinical Trials for Fibromyalgia*

Acupuncture Clinical Trial	Condition	Study Duration	Target Number of Patients
Acupuncture for Fibromyalgia Principle investigator: Thomas R. Cupps, MD Sponsor: NCCAM	<i>Fibromyalgia Pain</i>	13 weeks active treatment; no mention of longer term follow-up	phase III trial**
Efficacy of Acupuncture in the Treatment of Fibromyalgia Principle Investigator: Debra S. Buchwald, MD Sponsor: NCCAM, NHLBI	<i>Fibromyalgia</i>	12 week treatments; follow up at 1 and 6 months post treatment	96

* The information provided in this Table comes from searching the ClinicalTrials.gov web site for acupuncture. 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.

** Phase III trials typically involve >1000 patients (see clinicaltrials.gov)

Table 4: RCTs cited by Berman, et al. 1999

Trial	Number of Patients	Treatment	Duration	Results
Cassisi 1994 ²⁵	21 (7 patients per group)	Mianserine Acupuncture Mianserine plus acupuncture	10 weeks treatment 6 month follow-up	Huskisson test, McGill pain questionnaire, pressure alometry, Krug and Laughlin test for depression, electric algometry and daily analysis of pain and sleep were all used in evaluating efficacy. All three groups showed improvement from baseline. Six of 7 in the acupuncture group, 3 of 7 in the mianserine group and 6 of 7 in the combined group showed improvement. Six month follow-up showed lasting but decaying efficacy.
Deluze 1992 ²⁸	70	Sham electro-acupuncture Electro-acupuncture	3 weeks	Seven of 8 outcomes parameters showed a significant improvement in the active treatment group compared to sham group. Differences were significant for 5 of 8 parameters. Parameters included pain threshold, analgesia use, sleep quality, and morning stiffness.
Lautenschlager 1989 ²⁷	50	6 placebo acupuncture treatments (sham-disconnected laser equipment) 6 acupuncture treatments	3 months	Change in pain threshold was documented before and after treatment using pain scales (visual analog scale and dolorimetry). Significant differences between treatment and sham in all 3 methods of pain evaluation were found. Three month follow-up found no changes in the effect of treatment, despite upward trends in the treatment group (however, the meaning of the translation is ambiguous).

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.⁸

Acupuncture, in the strictest sense, refers to insertion of dry needles, at specially chosen sites for the treatment or prevention of symptoms and conditions.⁸

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.⁸

Cupping is a technique by which a vacuum force is applied to acupuncture sites.⁸

Electroacupuncture refers to the technique of introducing an electrical current to the inserted needles at various frequencies.⁸

Fire needle techniques insert red-hot needles at an acupuncture point.⁸

Intramuscular stimulation is a technique of applying needles to areas of tenderness.⁸

Laser acupuncture directs and stimulates a laser beam directed at the acupuncture site.⁸

Medical acupuncture is a medical discipline that integrates traditional and modern acupuncture techniques into contemporary biomedical practice.³⁰

Physician Acupuncturist is one who has acquired specialized knowledge and experience related to the integration of acupuncture within a biomedicine practice.⁵

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.⁸

Staple puncture is the application of a metal staple to an acupuncture point where it remains for a prolonged period of time.⁸

Zhejiu is the Chinese term and refers to both acupuncture and moxibustion.⁸

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 stapleacupuncture OR staple-acupuncture OR staple acupuncture 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 designation 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

1. Search Strategy for Acupuncture RCT's

Database Searched	Subject Headings	Date Searched
Pub Med	(acupuncture² OR acupressure² OR electroacupuncture[tw] OR electro-acupuncture[tw] OR (staple[tw] AND acupuncture[tw]) OR staple-acupuncture[tw] OR 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	8/5/2002
CINAHL (Ovid)		8/15/2002
AMED (Ovid)		8/15/2002

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

2. Search Strategy for Systematic Reviews

Database Searched	Subject Heading	Date Searched
APC Journal Club (EBM Reviews)	Acupuncture (Exploded) (acupuncture OR acupressure OR electroacupuncture 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
Pub Med	Acupuncture (MESH) (acupuncture OR acupressure OR electroacupuncture 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 electroacupuncture 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

REFERENCES

1. Leventhal LJ. Management of Fibromyalgia. *Annals of Internal Medicine*. 7 December 1999;131(11):850-858.
2. Bombardier CH, Buchwald D. Chronic fatigue, chronic fatigue syndrome, and fibromyalgia. Disability and health-care use. *Med Care*. 1996;34(9):924-930.
3. National Institutes of Health. Acupuncture. NIH Consensus statement Online. 1997 Nov 3-5;15(5):1-34.
4. Kaptchuk T. Acupuncture: theory, efficacy, and practice. *Ann Intern Med*. 2002 Mar;136(5):374-383.
5. National Center for Complementary and Alternative Medicine. Acupuncture Information and Resources. Available at: <http://nccam.nih.gov/health/acupuncture>.
6. Mayer DJ. Acupuncture: an evidence-based review of the clinical literature. *Annu Rev Med*. 2000;51:49-63.
7. United Kingdom National Health Service Center for Reviews and Dissemination. Effective Health Care on Acupuncture. *Effective Health Bulletins*. Vol 7; 2001 Nov:1-12.
8. Alberta Heritage Foundation for Medical Research Health Technology Assessment Unit. *Acupuncture: Evidence from systematic reviews and meta-analyses* 2002 Mar.
9. Lytle CD. History of the food and drug administration's regulation of acupuncture devices. *J Altern Complement Med*. 1996;2(1):253-256.
10. Turner JS. The regulation of acupuncture needles by the United States food and drug administration. *J Altern Complement Med*. 1995;1(1):15-16.
11. GuidePoints. ACU Field Crosses Fingers on N.I.H. Panel Outcome. *Guidepoints: Acupuncture in Recovery*, 1997 Sep 30;Health Watch, Nexis: 1.
12. Center for Devices and Radiological Health USFaDA. List of Devices for Third Party Review under the FDA Modernization Act of 1997. Feb 7, 2002. Available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdparty/current.cfm?panel=HO>.
13. Center for Devices and Radiological Health USFaDA. Code of Federal Regulations Title 21 Food and Drugs Database.
14. Norheim AJ. Adverse effects of acupuncture: a study of the literature for the years 1981-1994. *J Altern Complement Med*. 1996;2(2):291-297.
15. Vickers A, Zollman C. ABC of Complementary Medicine. Acupuncture. *BMJ*. 1999;319:973-976.
16. Yamashita H, Tsukayama H, White AR, Tanno Y, Sugishita C, Ernst E. Systematic review of adverse events following acupuncture: the Japanese literature. *Complement Ther Med*. 2001;9(2):98-104.
17. Vincent C. The safety of acupuncture. *BMJ*. 2001;323(7311):467-468.
18. White A, Hayhoe S, Hart A, Ernst E. Adverse events following acupuncture: prospective survey of 32 000 consultations with doctors and physiotherapists. *BMJ*. 2001;323(7311):485-486.
19. MacPherson H, Thomas K, Walters S, Fitter M. A prospective survey of adverse events and treatment reactions following 34,000 consultations with professional acupuncturists. *Acupunct Med*. 2001;19(2):93-102.
20. Berman BM, Ezzo J, Hadhazy V, et al. Is acupuncture effective in the treatment of fibromyalgia. *J Fam Pract*. 1999;48(3):213-218.

21. Berman BM, Swyer J, Ezzo J. The evidence for acupuncture as a treatment for rheumatologic conditions. *Rheum Dis Clin North Am*. 2000;26(1):103-115, ix-x.
22. Bandolier. Acupuncture for fibromyalgia: Bandolier; 2003.
23. Sprott H, Franke S, Kluge H, Hein G. Pain treatment of fibromyalgia by acupuncture (abstract). *Arthritis Rheum*. 1996;39:S91.
24. Radaelli E, Buzzi GP. Trattamento mediante agopuntura delle fibromiositi del trapezio. *Min Med*. 1978;69:3017-3019.
25. Cassisi G, Roncaglione A, Ceccherelli F, Donolato C, Gagliardi G, Todesco S. Trattamento agopunturale della fibromyalgia primaria. Confronto con mianserina. *G. Ital. Riflessot. Agopunt*. 9-10 September 1994 1995;7(1):33-35.
26. Pasotti D, Montanari E, Capobianchi B. Lagopuntura nella Syndrome Fibromyalgia primaria. *G Ital Riflessot Agopunt*. 1990;2:23-31.
27. Lautenschlager J, Schnorrenberger CC, Muller W. Akupunktur bei generalisierter Tendomyopathie (Fibromyalgie-Syndrom). *Deutsche Zeitschrift fur Akupunktur*. 1989 1989;6:122-128.
28. Deluze C, Bosia L, Zirbs A, Chantraine A, Vischer TL. Electroacupuncture in fibromyalgia: results of a controlled trial. *BMJ*. 1992;305(6864):1249-1252.
29. Waylonis G.W. Long-term follow-up on patients with fibrocystitis treated with acupuncture. *Ohio State Medical Journal*. 1977;17:299-302.
30. An Overview Of Medical Acupuncture, American Academy of Medical Acupuncture, June 2, 2003. Available at:
http://www.medicalacupuncture.org/acu_info/articles/helmsarticle.html