

From **Complementary and Alternative Therapies Evidence Based Decision Making Framework**

Appendix B: Acupuncture Guidance and Evidence Base

NHS Leeds considers needle acupuncture (manual or electroacupuncture) may be medically necessary for any of the following indications:

- Postoperative and chemotherapy-induced nausea and vomiting; or
- Nausea of pregnancy; or
- Postoperative dental pain; or
- Temporomandibular disorders (TMD); or
- Migraine headache; or
- Pain from osteoarthritis of the knee or hip (adjunctive therapy); or
- Fetal breech presentation (with Obstetric advice)
- Chronic low back pain. (Maintenance treatment, where the patient's symptoms are neither regressing nor improving, is not medically necessary.)

Leeds considers acupuncture experimental and investigational for all other indications, including but not limited to any of the following conditions, because there is inadequate scientific research assessing the efficacy of acupuncture compared with placebo, sham acupuncture or other modalities of treatment in these conditions:

Addiction	Painful neuropathies
AIDS	Peripheral arterial disease (e.g., intermittent claudication)
Asthma	Phantom leg pain
Acute low back pain	Postherpetic neuralgia
Carpal tunnel syndrome	Psoriasis
Chronic pain syndrome (e.g., RSD)	Psychiatric disorders
Fibromyalgia	Raynaud's disease pain
Fibrotic contractures	Rheumatoid arthritis
Glaucoma	Rhinitis
Hypertension	Sensorineural deafness
Induction of labour	Shoulder pain (e.g., bursitis)
Infertility	Smoking cessation
Insomnia	Stroke rehabilitation
Irritable bowel syndrome	Tennis elbow / epicondylitis
Menstrual cramps/dysmenorrhea	Tension headache
Myofascial pain	Tinnitus
Neck pain / cervical spondylosis	Urinary incontinence
Obesity	Xerostomia
	Whiplash

Note: Further acupuncture treatment is not considered medically necessary if the patient does not demonstrate meaningful improvement in symptoms. Maintenance treatment, where the patient's symptoms are neither regressing nor improving, is considered not medically necessary.

Background

Acupuncture as a therapeutic intervention is widely practiced in the UK. The general theory of acupuncture is based on the premise that there are patterns of energy flow (Qi) through the body that are essential for health. Disruptions of this flow are believed to be responsible for disease. Acupuncture may correct imbalances of flow at identifiable points close to the skin. Findings from basic research have begun to elucidate the mechanisms of action of acupuncture, including the release of opioids and other peptides in the central nervous system and the periphery and changes in neuroendocrine function.

While there have been many studies of its potential usefulness, the vast majority of papers studying acupuncture in the biomedical literature consist of case reports, case series, or intervention studies. One of the difficulties with drawing conclusions from the existing literature is that the term acupuncture is used to describe a variety of treatments that differ in many important aspects according to level of effect (e.g., local, segmental, generalized) and type of acupuncture treatment (e.g., manual versus electrical acupuncture). 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, and by absence of studies comparing acupuncture with conventional biomedical treatments. Some factors needing investigation include frequency, number, and duration of treatments, depth of puncture, number of acupuncture points used, combination with other therapies, sample size, setting, blinding factors, and needle size. Be that as it may, promising results have emerged on the efficacy of acupuncture in adult post-operative and chemotherapy nausea and vomiting and in postoperative dental pain.

The U.S. Department of Health and Human Services, Public Health Service, Agency for Healthcare Research and Quality (AHRQ) recently performed a technology assessment (2003) on "Acupuncture for the treatment of fibromyalgia", it stated that "At this time, therefore, there is insufficient evidence to conclude that acupuncture has efficacy for the treatment of fibromyalgia. Two randomised 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."

Furthermore, an AHRQ technology assessment (2003) on "Acupuncture for osteoarthritis" concluded that "The currently available evidence is insufficient to determine whether acupuncture has a specific beneficial effect in osteoarthritis."

In a large randomised controlled study (n = 401), Vickers, et al. (2004) examined the effects of a policy of "use acupuncture" on headache (predominantly migraine), health status, days off sick, and use of resources in patients with chronic headache compared with a policy of "avoid acupuncture". Patients were randomly allocated to receive up to 12 acupuncture treatments over 3 months or to a control intervention offering usual care. Headache score, SF-36 health status, and use of medication were assessed at baseline, 3, and 12 months. Use of resources was assessed every 3 months. 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). The authors concluded that acupuncture leads to persisting, clinically relevant benefits for primary care patients with chronic headache, particularly migraine.

The results of the study by Vickers, et al., (2004) are in agreement with recent findings of Allais, et al., (2003) who reported that acupuncture is effective in reducing the frequency of migraine attacks as well as those by Melchart, et al., (2003) who reported that acupuncture

and sumatriptan were more effective than a placebo injection in the early treatment of an acute migraine attack. Sok and colleagues (2003) stated that further investigation, using a randomised clinical trial design, is necessary to determine the effectiveness of acupuncture for the treatment of insomnia. Furthermore, additional work is also needed to promote the long-term therapeutic effects of acupuncture and to compare it with other therapies for insomnia.

White (2003) performed a review of controlled studies of acupuncture for women's reproductive health care. The author concluded that in view of the small number of studies and their variable quality, doubt remains about the effectiveness of acupuncture for gynaecological conditions. Acupuncture appears promising for dysmenorrhoea and infertility, and further studies are justified.

Acupuncture has also been employed to relieve pain and improve movement in people with osteoarthritis (OA) of the knee. In the largest clinical study of acupuncture reported to date, Berman, et al., (2004) studied 570 patients with an average age of 65 who had OA of the knee. Subjects were randomly assigned to receive one of three treatments for 26 weeks, in addition to standard care such as anti-inflammatory medications and pain relievers: (i) 190 received acupuncture, (ii) 191 underwent sham acupuncture and (iii) 189 participants attended six, 2-hour group sessions over 12 weeks based on the Arthritis Foundation's Arthritis Self-Help Course. Patients' progress was assessed at 4, 8, 14, and 26 weeks. At week 8, patients receiving acupuncture began showing a significant increase in function and by week 14 a significant decrease in pain, compared with the sham and control groups. Overall those who received acupuncture had a 40 % decrease in pain and a nearly 40 % improvement in function compared to baseline assessments. The authors concluded that acupuncture seems to provide improvement in function and pain relief as an adjunctive therapy for OA of the knee when compared with credible sham acupuncture and education control groups. This finding is in agreement with the recent observations of Vas et al (2004), Tukmachi, et al., (2004), as well as that of Stener-Victorin, et al., (2004).

In a randomised, controlled, single blind trial on the use of acupuncture as a complementary therapy to the pharmacological treatment of OA of the knee (n = 97), Vas and colleagues (2004) concluded that acupuncture plus diclofenac is more effective than placebo acupuncture plus diclofenac for the symptomatic treatment of OA of the knee. Tukmachi and associates (2004), in a randomised controlled trial (n = 30), reported that manual and electroacupuncture causes a significant improvement in the symptoms of OA of the knee, either on its own or as an adjunctive therapy, with no loss of benefit after one month. In a randomised controlled study, Stener-Victorin, et al., (2004) evaluated the therapeutic effect of electro-acupuncture (EA) and hydrotherapy, both in combination with patient education or with patient education alone, in the treatment of OA in the hip (n = 45). These investigators found that 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. This finding is in agreement with that of Haslam (2001) who reported that acupuncture is more effective than advice and exercises in the symptomatic treatment of OA of the hip (n = 32) as well as that of Fink and co-workers (2001) who found that placement of acupuncture needle in the area of the affected hip is associated with improvement in the symptoms of OA (n = 67).

In a prospective cohort study, Kukuk, et al., (2005) ascertained the long-term effects 3 and 6 months after the end of a course of acupuncture treatment for chronic low-back pain (LBP) or chronic pain caused by gonarthrosis. A total of 1096 eligible patients with chronic LBP or gonarthrosis pain were identified (68.1 % female) and invited by letter to participate in the study. Ultimately 249 patients remained, with no loss of representativeness. Two telephone interviews were conducted 3 and 6 months after the last acupuncture session using standardized questionnaires, available as electronic case report forms. The primary target criteria were self-assessment of pain tolerability before the start of acupuncture and after the end of treatment, and pain intensity (GCPS) over time. Secondary target criteria were changes to functional impairment (HFAQ for chronic LBP, WOMAC for gonarthrosis), quality of life (SF12), depression (CES-D) and patient global assessment of treatment effectiveness (PGA). For the indication chronic LBP, pain-related fear avoidance beliefs (FABQ) were also

queried. These investigators found that pain tolerability was significantly improved after acupuncture and remained so up to 6 months after treatment. The mean scores of almost all questionnaires did not change significantly between 3 and 6 months. They concluded that acupuncture had a long-term effect on important aspects of cognitive and emotional pain coping.

In a multi-center, randomised controlled trial, Thomas, et al., (2005) examined whether patients with persistent non-specific LBP, when offered access to traditional acupuncture care alongside conventional primary care, gained more long-term relief from pain than those offered conventional care only, for equal or less cost. Safety and acceptability of acupuncture care to patients, and the heterogeneity of outcomes were also tested. Patients in the experimental arm were offered the option of referral to the acupuncture service comprising 6 acupuncturists. The control group received usual care from their general practitioner (GP). Eligible patients were randomised in a ratio of 2:1 to the offer of acupuncture to allow between-acupuncturist effects to be tested. Patients were 18 to 65 years of age with non-specific LBP of 4 to 52 weeks' duration, and were assessed as suitable for primary care management by their general practitioner. The trial protocol allowed up to 10 individualized acupuncture treatments per patient. The acupuncturist determined the content and the number of treatments according to patient need. Main outcome measures included the Short Form 36 (SF-36) Bodily Pain dimension (range of 0 to 100 points), assessed at baseline, and 3, 12 and 24 months. Cost-utility analysis was conducted at 24 months using the EuroQoL 5 Dimensions (EQ-5D) and a preference-based single index measure derived from the SF-36 (SF-6D). Secondary outcomes included the McGill Present Pain Index (PPI), Oswestry Pain Disability Index (ODI), all other SF-36 dimensions, medication use, pain-free months in the past year, worry about back pain, satisfaction with care received, as well as safety and acceptability of acupuncture care. A total of 159 patients were in the acupuncture offer arm and 80 in the usual care arm. All 159 patients randomised to the offer of acupuncture care chose to receive acupuncture treatment, and received an average of 8 acupuncture treatments within the trial. These investigators found that traditional acupuncture care delivered in a primary care setting was safe and acceptable to patients with non-specific LBP. Acupuncture care and usual care were both associated with clinically significant improvement at 12- and 24-month follow-up. Acupuncture care was significantly more effective in reducing bodily pain than usual care at 24-month follow-up. No benefits relating to function or disability were identified. They concluded that GP referral to a service providing traditional acupuncture care offers a cost-effective intervention for reducing LBP over a 2-year period.

In a meta-analysis, Manheimer, et al., (2005) evaluated the effectiveness of acupuncture for treating LBP. These researchers concluded that acupuncture effectively relieves chronic LBP. However, no evidence suggests that acupuncture is more effective than other active therapies. This is in agreement with the findings of a Cochrane review on acupuncture for LBP by Furlan, et al., (2005) who stated that the data do not allow firm conclusions about the effectiveness of acupuncture for acute LBP. For chronic LBP, acupuncture is more effective for pain relief and functional improvement than no treatment or sham treatment immediately after treatment and in the short-term only. Acupuncture is not more effective than other conventional and alternative treatments. They concluded that the data suggest that acupuncture may be useful adjuncts to other therapies for chronic LBP.

There is evidence that acupuncture, alone or in combination with moxibustion, may be effective in the treatment of fetal breech presentation. Moxibustion refers to a type of Chinese medicinal practice that involves burning a herb close to the skin of the acupuncture point – urinary bladder 67 (BL67, Chinese name Zhiyin), located at the tip of the 5th toe. Evidence based clinical guidelines from the New Zealand Guidelines Group (2004) state that "[m]oxibustion is an acupuncture technique that involves burning herbal preparations to stimulate the acupoint by the 5th toe. It may be offered to women with breech presentation". Cardini and Weixin (1998) assessed the safety and effectiveness of moxibustion on acupoint BL67 to increase fetal activity and correct breech presentation in a randomised, controlled, open clinical trial (n = 260). The 130 primigravidas in the 33rd week of gestation with normal pregnancy and an ultrasound diagnosis of breech presentation randomised to the intervention group received stimulation of acupoint BL 67 by moxa (Japanese term for *Artemisia vulgaris*) rolls for 7 days, with treatment for an additional 7 days if the fetus persisted in the breech presentation. The 130 subjects randomised to the control group received routine care but no

interventions for breech presentation. Subjects with persistent breech presentation after 2 weeks of treatment could undergo external cephalic version (ECV) anytime between 35 weeks' gestation and delivery. The intervention group experienced a mean of 48.45 fetal movements versus 35.35 in the control group ($p < 0.001$). During the 35th week of gestation, 98 (75.4 %) of 130 fetuses in the intervention group were cephalic versus 62 (47.7 %) of 130 fetuses in the control group ($p < 0.001$). Despite the fact that 24 subjects in the control group and 1 subject in the intervention group underwent ECV, 98 (75.4 %) of the 130 fetuses in the intervention group were cephalic at birth versus 81 (62.3 %) of the 130 fetuses in the control group ($p = 0.02$). The authors concluded that among primigravidas with breech presentation during the 33rd week of gestation, moxibustion for 1 to 2 weeks increased fetal activity during the treatment period and cephalic presentation after the treatment period and at delivery.

Kanakura, et al., (2001) discussed their findings on the use of moxibustion or electrical stimulation for the treatment of breech. Only patients with breech pregnancies at the 28th week or later were entered into the study. With moxibustion treatment, the control group had a spontaneous correction rate of 165/224 (73.7 %), and the treatment group had a correction rate of 123/133 (92.5 %) ($p < 0.0001$). With low-frequency percutaneous electrical stimulation, the correction rate was 20/941 (83.9 %) in the control group and 171/191 (89.5 %) in the treatment group ($p = 0.094$). The controls in the moxibustion study did no exercises and received no external manipulation to correct breech presentation whereas those in the electrical stimulation study experienced both. Acupuncture stimulation, especially with moxibustion, is expected to serve as a safe and effective modality in the management of breech presentation in a clinical setting.

Habek et al (2003) evaluated the value of acupuncture in the conversion of foetal breech presentation into vertex presentation in a randomised prospective controlled clinical study that included 67 pregnant women with foetal breech presentation: 34 women with singleton pregnancies treated with manual acupuncture (Zhiyin) and a control group which included 33 women with singleton pregnancies without acupuncture treatment. The acupuncture treatment lasted 30 minutes a day, and was conducted during and after 34 weeks of pregnancy with simultaneous cardiotocography. The success rate of the acupuncture correction of foetal breech presentation is 76.4 % (26 women), and spontaneous conversion without acupuncture in vertex presentation is observed in 15 women (45.4 %; $p < 0.001$). The authors concluded that acupuncture correction of foetal malpresentation is a relatively simple, efficacious and inexpensive method associated with a lower percentage of operatively completed deliveries, which definitely reflects in improved parameters of vital and perinatal statistics.

In a controlled study by Neri, et al., (2004), a total of 240 women at 33 to 35 weeks of gestation carrying a foetus in breech presentation were randomised to receive active treatment (acupuncture plus moxibustion) or to be assigned to the observation group. Bilateral acupuncture plus moxibustion was applied at the BL67 acupoint. The primary outcome of the study was fetal presentation at delivery. Fourteen cases dropped out. The final analysis was thus made on 226 cases, 114 randomised to observation and 112 to acupuncture plus moxibustion. At delivery, the proportion of cephalic version was lower in the observation group (36.7 %) than in the active-treatment group (53.6 %) ($p = 0.01$). Hence, the proportion of Cesarean sections indicated for breech presentation was significantly lower in the treatment group than in the observation group (52.3 % versus 66.7 %, $p = 0.03$). The authors concluded that acupuncture plus moxibustion is more effective than observation in revolving foetuses in breech presentation. Such a method appears to be a valid option for women willing to experience a natural birth.

While the majority of evidence supports the use of acupuncture/moxibustion in correcting fetal breech presentation, recent publications are less clear in its role for the management of this condition. In a single-blind randomised controlled study, Cardini, et al. (2005) assessed the effectiveness of moxibustion for the correction of fetal breech presentation in a non-Chinese population. Healthy non-Chinese nulliparous pregnant women at 32 to 33 weeks + 3 days of gestational age with the foetus in breech presentation were randomly assigned to treatment or observation. Treatment consisted of moxibustion (stimulation with heat from a stick of *Artemisia vulgaris*) at the Zhiyin for 1 or 2 weeks. Subjects in the control group received no

moxibustion but were observed. Two weeks after recruitment, each participant was subjected to an ultrasonic examination of the fetal presentation. The main outcome measure was number of participants with cephalic presentation in the 35th week. The study was interrupted when 123 participants had been recruited (46 % of the planned sample). Intermediate data monitoring revealed a high number of treatment interruptions. At this point no difference was found in cephalic presentation in the 35th week (treatment group: 22/65, 34 %; control group: 21/58, 36 %). The authors stated that the results underline the methodological problems evaluating of a traditional treatment transferred from a different cultural context. They do not support either the effectiveness or the ineffectiveness of moxibustion in correcting fetal breech presentation.

In a Cochrane review, Coyle and colleagues (2005) examined the safety and effectiveness of moxibustion on changing the presentation of an unborn baby in the breech position, the need for ECV, mode of birth, and perinatal morbidity and mortality for breech presentation. These investigators concluded that there is insufficient evidence from randomised controlled clinical trials to support the use of moxibustion to correct a breech presentation. The authors stated that moxibustion may be beneficial in reducing the need for ECV, and decreasing the use of oxytocin; however there is a need for well-designed randomised controlled trials to evaluate moxibustion for breech presentation which report on clinically relevant outcomes as well as the safety of the intervention.

In women with a 3rd trimester breech presentation Caesarean section is the mode of delivery of 1st choice, especially when ECV has failed to turn the foetus to cephalic (RCOG 2006). According to the American College of Obstetricians and Gynecologists (ACOG, 2002), ECV may not be for some women and it can pose risks including pre-term labour, placental abruption, umbilical cord entanglement, premature rupture of the membranes, as well as severe maternal discomfort. Currently, neither Royal College of Obstetricians and Gynaecologists nor the ACOG have a policy statement/recommendation on the use of acupuncture/moxibustion for managing foetal breech presentation (RCOG, 2006). However, since ECV is complex, time consuming, and carries increased risk of Obstetric intervention, acupuncture/moxibustion may be a possible option for the management of foetal breech presentation with Obstetric advice.

Jedel (2005) evaluated the effectiveness of acupuncture in the management of xerostomia. Articles of controlled clinical studies assessing the effectiveness of acupuncture in the management of xerostomia were obtained by searching through the databases MEDLINE and Cochrane Central Register of Controlled Trials. Three articles met the criteria for inclusion and a criteria list was used to assess the quality of these studies. The studies were considered to be of high quality or low quality in accordance with the criteria list utilized. The results of the trials were considered positive, negative or indifferent based on statistically significant between group differences. The criteria list utilized indicate that one of the three studies was of high quality and it presents indifferent results. One of the two studies of low quality presents positive results and one presents indifferent results. An analysis of the results degree of evidence resulted in no evidence for the effectiveness of acupuncture in the management of xerostomia. The authors concluded that this systematic review showed that there is no evidence for the effectiveness of acupuncture in the management of xerostomia, and there is a need for future high quality randomised controlled trials.

In a Cochrane review, Lim et al (2006) examined if acupuncture is more effective than no treatment, more effective than 'sham' (placebo) acupuncture, and as effective as other interventions used to treat irritable bowel syndrome. The authors concluded that most of the trials included in this review were of poor quality and were heterogeneous in terms of interventions, controls, and outcomes measured. Thus, it is still inconclusive if acupuncture is more effective than sham acupuncture or other interventions for treating irritable bowel syndrome.

Passalacqua et al (2006) noted that complementary-alternative medicines (CAM) are extensively used in the treatment of allergic rhinitis and asthma, but evidence-based recommendations are lacking. These researchers carried out a systematic review on CAM for these two indications. Meta-analyses provided no clear evidence for the effectiveness of

acupuncture in rhinitis and asthma. Some positive results were described with homeopathy in good-quality trials in rhinitis, but a number of negative studies were also found. Therefore it is not possible to provide evidence-based recommendations for homeopathy in the treatment of allergic rhinitis, and further trials are needed. A limited number of studies of herbal remedies showed some effectiveness in rhinitis and asthma, but the studies were too few to make recommendations. There are also unresolved safety concerns. The authors concluded that the effectiveness of CAM (e.g., acupuncture) for rhinitis and asthma is not supported by currently available evidence.

The above framework is based on the following references:

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