Appendix 2. Extracted data from studies with relationship constraints

1. Studies of chronic pain with a pain outcome included in the meta-analysis (N=17)

Ref: 21 Scharf (2006)  Country of study Germany  Condition OA (knee)  Trial type RCT
Study details: No. of arms 3. No. randomised 1039. Recruited acupuncture naive participants No How participants recruited GP population, unclear exactly how recruited. Interventions Acupuncture, Sham acupuncture, Care as usual
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Some participants blinded.
Allocation concealment Gold standard - person executing is not person recruiting. Sequence generation method: Computer
Treatment details of main acupuncture group (protocol) 10 treatments in 6 weeks, with 5 more if responding. Number of needles between 7-15. Point selection: Semi-Flexible. Treatment provided by: GPs with A-diploma in acupuncture and 2 years experience. Setting: GP setting.
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: The protocol prescribed the same general procedures, diagnostics and communication with patients in each group. Type of relationship permitted: NR. Fidelity monitored: NR. Practitioners debriefed: NR.

Ref: 22 Martin (2006)  Country of study USA  Condition Fibromyalgia  Trial type RCT
Study details: No. of arms 2. No. randomised 50. Recruited acupuncture naive participants Yes How participants recruited Referrals to Fibromyalgia treatment programme Interventions Acupuncture, Sham acupuncture
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded.
Allocation concealment Not described. Sequence generation method: NR
Treatment details of main acupuncture group (protocol) 6 treatments, approx every 3 days for 2-3 weeks. 18-20 needles. Point selection: Fixed. Treatment provided by: Two ‘acupuncturists’. Setting: Treatment at one ‘facility’
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: Conversation was controlled and neutral in both groups, and limited to topics like family, sports, weather. Any reference to specific treatment or symptoms was deflected or referred to the blinded study coordinator. Type of relationship permitted: Casual talking. Fidelity monitored: NR. Practitioners debriefed: NR.

Ref: 28 Shen (2007)  Country of study USA  Condition Myofascial pain, jaw  Trial type RCT
Study details: No. of arms 2. No. randomised 15. Recruited acupuncture naive participants Yes How participants recruited Patients currently seeking treatment at a University Hospital TMD centre. Interventions Acupuncture, Sham acupuncture
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded.
Allocation concealment Unclear. Sequence generation method: NR
Treatment details of main acupuncture group (protocol) 1 treatment using 1 needle. Point selection: Fixed. Treatment provided by: State certified dental acupuncturist. Setting: NR
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: Acupuncturist instructed not to discuss the treatment during the interventions. Type of relationship permitted: Not talking about treatment. Fidelity monitored: NR. Practitioners debriefed: NR.

Ref: 33 Leibing (2002)  Country of study Germany  Condition Low back pain  Trial type RCT
Study details: No. of arms 3. No. randomised 150. Recruited acupuncture naive participants No How participants recruited Recruited from an outpatient clinic of Orthopaedics at a University Hospital. Interventions Acupuncture, Sham acupuncture, Care as usual
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Some participants blinded.
Allocation concealment Not described. Sequence generation method: Computer
Treatment details of main acupuncture group (protocol) 20 treatments over 12 wks; 2 weeks at 5 x week then 10wks at 1 x week. 26 needles. Point selection: Fixed. Treatment provided by: Taiwanese physician. Setting: Outpatient clinic of Orthopaedics at a University Hospital
Relationship constraint Why constraint used: Blinding. Stated reason: To exclude a potential bias because the acupuncturist had to know the group assignment. Description of constraint: No additional interaction or conversation was done, except for a short explanation of the procedure. Type of relationship permitted: Minimal talking. Fidelity monitored: NR. Practitioners debriefed: NR. Practitioners debriefed: NR.

Ref: 38 Yeung (2003)  Country of study Hong Kong  Condition Low back pain  Trial type RCT
Study details: No. of arms 2. No. randomised 52. Recruited acupuncture naive participants No How participants recruited Recruited from the outpatient clinic of an orthopaedic clinic. Interventions Electro-acupuncture, Exercise
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status No - or obviously can’t be.
Allocation concealment Not described. Sequence generation method: NR
Treatment details of main acupuncture group (protocol) 12 treatments, 3 times a week for 4 weeks and exercise once a week. 3 needles. Point selection: Fixed. Treatment provided by: A physiotherapist certificated in acupuncture. Setting: NR
Relationship constraint Why constraint used: To reduce therapeutic relationship. Stated reason: Not explicit, but described in section concerning therapeutic relationship. Description of constraint: Interaction between patient and acupuncturist was minimised to limit potential bias. Conversation was limited to a short explanation of the procedure at each treatment session. Type of relationship permitted: Other describe,. Describing the treatment. Fidelity monitored: NR. Practitioners debriefed: NR.

Ref: 40 White (2000)  Country of study UK  Condition Tension-type headache  Trial type RCT
Study details: No. of arms 2. No. randomised 50. Recruited acupuncture naive participants Yes How participants recruited Recruited during consultations, disease registers, notice in premises of participating practices and via local media. Interventions Acupuncture, Sham acupuncture
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded to sham nature of control treatment.
Allocation concealment Gold standard - person executing is not person recruiting. Sequence generation method: Computer
Treatment details of main acupuncture group (protocol) 1 x week for 6 weeks (treatment period) then one additional treatment after one month, and another the next month. 4-8 needles. Point selection: Semi-flexible. Treatment provided by: Accredited members of British Medical Acupuncture Society. Setting: Unclear.

Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: The consultation with the physician acupuncturist was standardised in terms of examination, treatment and permitted discussion. Acupuncturist made ambiguous statement at the end of treatment ‘the needles are all out and there is no bleeding’. Type of relationship permitted: Not talking about treatment. Discussion with acupuncturist about treatment not permitted, discussion about headache limited to simple statement of the beneficial or adverse response to the previous treatment. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.


Ref: 60 Harris (2005) Country of study USA Condition Fibromyalgia Trial type RCT Study details: No. of arms 4. No. randomised 118. Recruited acupuncture naive participants Yes How participants recruited Recruited from announcements in local papers and periodicals. Interventions Acupuncture (manual stimulation), Sham acupuncture onpoint (no stimulation), Sham acupuncture offpoint (manu stimulation), Sham acupuncture offpoint (no stimulation) Staff blinding status Outcome observer: Not stated. Statistical analyst: Not stated. Participant blinding status Blinded to sham nature of control treatment. Allocation concealment Not described. Sequence generation method: Computer Treatment details of main acupuncture group (protocol) 18 treatments, 1 x week for 3 weeks, transition, 2 x week for 3 weeks, transition, 3 x week for 3 weeks. 9 needles. Point selection: Fixed. Treatment provided by: 95% by an investigator, licensed acupuncturist with 17 years experience. Setting: NR. Relationship constraint Why constraint used: Blinding. Stated reason: To ensure and to verify adequate blinding. Description of constraint: All subjects were blindfolded during treatment and no verbal communication was allowed between the acupuncturist and the subjects. Type of relationship permitted: Silence. Fidelity monitored: A non-blinded research assistant was present during all study sessions to monitor and ensure treatment integrity. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 61 He (2004) Country of study Norway Condition Neck and shoulder pain Trial type RCT Study details: No. of arms 2. No. randomised 24. Recruited acupuncture naive participants No How participants recruited Recruited from five large companies by the company's occupational physician. Interventions Acupuncture, Sham acupuncture Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded to sham nature of control treatment. Allocation concealment Not described. Sequence generation method: Unclear. Treatment details of main acupuncture group (protocol) 10 treatments, 3 a week for 3-4 weeks. 22 needles (16 body, 6 ear). Point selection: Fixed. Treatment provided by: One of the authors who had more than 10 years acupuncture experience. Setting: NR. Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: All patients were treated as equally as possible in the communications with the acupuncturist. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.
Recruited from NHS patients with shoulder pain attending an urban primary care clinic. Interventions Acupuncture, Sham acupuncture

Allocation concealment Gold standard • person recruiting is not person recruiting. Sequence generation method: Computer

Treatment details of main acupuncture group (protocol) 8 treatments, once a week for 7 weeks. Four needles. Point selection: Fixed. Treatment provided by: Two licenced acupuncturists (3 years training) with four years experience. Setting: Public primary care clinic.

Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: Both groups were treated in the same manner by the acupuncturist who tried not to give or receive any information to or from the patients. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Recruited from patients undergoing treatment in a neurology department or referred from neurosurgical department

Allocation concealment Adequate method but person recruiting may be executing. Sequence generation method: Computer

Treatment details of main acupuncture group (protocol) 23 treatments over 26 weeks, tapering from 16 in first 8 weeks to 1 a month. 8 (one knee) to 16 (both knees) needles. Point selection: Fixed.

Relationship constraint Why constraint used: Blinding. Stated reason: To avoid inadvertently communicate group assignment. Description of constraint: Avoid interactions that could inadvertently communicate group assignment. Type of relationship permitted: Not talking about treatment. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Allocation concealment Adequate method but person recruiting may be executing. Sequence generation method: Computer

Treatment details of main acupuncture group (protocol) 10 treatments over 5 weeks. 9 needles. Point selection: Fixed. Treatment provided by: NR. Setting: NR.

Allocation concealment Gold standard • person recruiting is not person recruiting. Sequence generation method: Computer

Treatment details of main acupuncture group (protocol) 23 treatments over 26 weeks, tapering from 16 in first 8 weeks to 1 a month. 8 (one knee) to 16 (both knees) needles. Point selection: Fixed.

Relationship constraint Why constraint used: Blinding. Stated reason: To avoid inadvertently communicate group assignment. Description of constraint: Avoid interactions that could inadvertently communicate group assignment. Type of relationship permitted: Not talking about treatment. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Allocation concealment Adequate method but person recruiting may be executing. Sequence generation method: Computer

Treatment details of main acupuncture group (protocol) 10 treatments, twice a week for 5 weeks. Max number of needles 15. Point selection: Semi-flexible. Treatment provided by: NR. Setting: NR

Relationship constraint Why constraint used: To reduce therapeutic relationship. Stated reason: To reduce the influence of the acupuncturist. Description of constraint: No conversations about the patient's current complaints nor about the specific characteristics of acupuncture were carried out during the treatment. Questions were prevented by instructing participants to relax throughout the treatment as this was important for the effectiveness of acupuncture. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Allocation concealment Not described. Sequence generation method: NR

Treatment details of main acupuncture group (protocol) 10 treatments, twice a week for 5 weeks. Max number of needles 15. Point selection: Semi-flexible. Treatment provided by: A medical doctor. Setting: Inpatient hospitalisation

Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: The participants were told only to discuss the treatment itself with the acupuncturist and the illness with the other investigator. Type of relationship permitted: Other describe. , Not talking about their illness. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Allocation concealment Not described. Sequence generation method: NR

Treatment details of main acupuncture group (protocol) 10 treatments in 2 weeks, then cross. 3 needles. Point selection: Semi-flexible. Treatment provided by: A medical doctor. Setting: Inpatient hospitalisation

Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: The participants were told only to discuss the treatment itself with the acupuncturist and the illness with the other investigator. Type of relationship permitted: Other describe. , Not talking about their illness. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.
2. Studies of chronic pain with a pain outcome not included in the meta-analysis (N=14)

Ref: 23 Kaptchuk (2006) Country of study USA Condition Repetitive arm strain Trial type RCT Study details: No. of arms 4. No. randomised 246. Recruited acupuncture naive participants No. How participants recruited Recruited from adverts and referral from health professionals Interventions Acupuncture, Sham Acupuncture, Amytriptyline, Sham amytriptyline Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded. Allocation concealment Gold standard - person executing is not person recruiting. Sequence generation method: NR Treatment details of main acupuncture group (protocol) 2 treatments a week for 6 weeks. 5-10 needles. Point selection: Semi-flexible. Treatment provided by: Traditionally trained registered acupuncturists. Setting: In the acupuncturists offices. Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: Limit discussion with patients to what was necessary to evaluate the clinical condition at baseline and changes during treatment. Neutral expectations -this is an experiment- attitude were expected to be maintained. Type of relationship permitted: Minimal talking. Fidelity monitored: Monitored by a research assistant and an acupuncturist monthly. The acupuncturist observed treatments at various points in the study. Three acupuncturists were dropped for failure to adhere to the protocol. Participants debriefed: NR. Practitioners debriefed: A survey was sent out after the trial and results were reported.

Ref: 29 Haake (2007) Country of study Germany Condition Low back pain Trial type RCT Study details: No. of arms 3. No. randomised 1162. Recruited acupuncture naive participants No. Excluded patients who had used acupuncture for low back pain ever, or for any reason in the past year. How participants recruited Recruited from newspaper, magazine, radio and TV. Interventions Acupuncture, Sham acupuncture, Care as usual Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Some blinded and also blinded to sham nature of control treatment. Allocation concealment Gold standard - person executing is not person recruiting. Sequence generation method: Computer Treatment details of main acupuncture group (protocol) 10 treatments, 2 x week or 5 more, depending on efficacy. 14-20 needles Point selection: Semi-flexible. Treatment provided by: Physicians with a 140 min acupuncture training requirement and min 2 years experience. Setting: GP and orthopedic surgeons clinics Relationship constraint Why constraint used: Blinding. Stated reason: NR. Description of constraint: Communication limited to necessary expanations to avoid unblinding the patients by suggestive remarks. Type of relationship permitted: Minimal talking. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 51 White (1996) Country of study UK Condition Tension headache Trial type RCT (Pilot) Study details: No. of arms 2. No. randomised 10. Recruited acupuncture naive participants Yes How participants recruited Recruited via a local neurologist and local newspapers. Interventions Acupuncture, Sham acupuncture Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded to sham nature of control treatment. Allocation concealment Gold standard - person executing is not person recruiting. Sequence generation method: Computer Treatment details of main acupuncture group (protocol) 6 treatments over 6 weeks. Between 2 and 6 points, unclear if bilateral. Point selection: Semi-flexible. Treatment provided by: Most given by aGP who had attended a basic acupuncture course. Setting: NR. Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: After randomisation there was no futher discussion with the treating physician about the condition or the treatment. During the treatment subjects were asked to keep conversation to a minimum. Questions, discussion adn assessments were handled by the assistant who was blinded to allocation. Type of relationship permitted: Minimal talking. Fidelity monitored: Participants debriefed: NR. Practitioners debriefed: NR.


Ref: 86 Godfrey (1978)  Country of study Canada  Condition Musculoskeletal pain  Trial type RCT
Study details: No. of arms 2. No. randomised 140. Recruited acupuncture naïve participants No How participants recruited Recruited from outpatient clinics at a hospital, physician referral and a public announcement; 57% self-referred volunteered.  Interventions Acupuncture, Sham acupuncture
Staff blinding status Outcome observer: Not stated. Statistical analyst: Not stated. Participant blinding status Blinded.
Allocation concealment Not described. Sequence generation method: NR
Treatment details of main acupuncture group (protocol) Number and frequency of treatment, number of needles (protocol): 3-5 treatments over 2-3 weeks. Number of needles NA. Point selection: Flexible. Treatment provided by: A Chinese trained acupuncturist who was a lecturer at a Hong Kong University. Setting: NR.
Relationship constraint Why constraint used: Blinding. Stated reason: To enable blinding of the patient and the practitioner. Description of constraint: A screen separated the patients body from head, so that the acupuncturist and patient could not see each other. All communication was carried out by a 'communicator' who had been instructed who answered questions regarding the treatment in a bland manner. Type of relationship permitted: Silence. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 87 Moore (1976)  Country of study USA  Condition Chronic shoulder pain  Trial type RCT
Study details: No. of arms 2. No. randomised 42. Recruited acupuncture naïve participants No How participants recruited Chosen from those responding to newspaper advertisements. Unclear whether all those with tendonitis or bursitis were chosen or a subsample.  Interventions Acupuncture, Sham acupuncture
Staff blinding status Outcome observer: Yes. Statistical analyst: No. Participant blinding status Blinded to sham nature of control treatment
Allocation concealment Not described. Sequence generation method: NR
Treatment details of main acupuncture group (protocol) Number and frequency of treatment, number of needles (protocol): Three treatments, once a week for 3 weeks. 7 needles. Point selection: Fixed. Treatment provided by: A physician with 2 years of acupuncture experience. Setting: Hospital clinic
Relationship constraint Why constraint used: To reduce therapeutic relationship. Stated reason: A factorial design was used to assess how much of the treatment’s effectiveness depends on the quality of the milieu in which it is administered. Description of constraint: Those in the positive milieu were read a statement emphasizing acupuncture was effective and they could expect a good deal of improvement. The physician called attention to needle sensations and told participant that sensations were signs that the treatment was working. A warm friendly relationship was encouraged by permitting and reinforcing spontaneous interaction. Those in the negative milieu were read a statement emphasizing shortcomings, doubts and inconsistencies surrounding the effectiveness of acupuncture, were warned it may not work and against high expectations. The physician discouraged social communication to stifle any relationship. Type of relationship permitted: Other describe. , Positive milieu: all positive interactions encouraged. Negative milieu: no interactions encouraged. Fidelity monitored: NR. Participants debriefed: Participants asked during the last treatment session how friendly, enthusiastic, competent and empathic their therapist had been four 7 point Likert scales. Group means were moderately enthusiastic (4.9), moderately empathetic (5.0), very competent (5.74) and very friendly (5.64). Factorial analysis revealed no difference between groups except sham group rated friendliness significantly higher than verum. No differences between milieu ratings. Practitioners debriefed: NR.

Ref: 89 Kleinhenz (1999)  Country of study Germany  Condition Rotator cuff tenonitis  Trial type RCT
Study details: No. of arms 2. No. randomised 52. Recruited acupuncture naïve participants No How participants recruited Athletes recruited through articles in local newspapers, informing local sports clubs orthopaedic and physiotherapy practices, and posts at sports facilities and university bulletin boards.  Interventions Acupuncture, Sham acupuncture
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded.
Allocation concealment Gold standard - person executing is not person recruiting. Sequence generation method: NR
Treatment details of main acupuncture group (protocol) Number and frequency of treatment, number of needles (protocol): 8 treatments over 4 weeks. 12 points, unclear whether bilateral. Point selection: Semi-flexible. Treatment provided by: 2 acupuncturists. Setting: In a room at the pain treatment unit of the anaesthesiology department.
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: The acupuncturist tried not to give any information to the patients. Questions about acupuncture were answered using an answer catalogue. Type of relationship permitted: Other describe. , Talking about treatment was standardised. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 90 Weinstein (2003)  Country of study USA  Condition Carpal tunnel syndrome  Trial type RCT (reported in an abstract)
Study details: No. of arms 9. No. randomised 140. Recruited acupuncture naïve participants No How participants recruited NR how recruited.  Interventions Acupuncture 1 x week, Irrelevant acupuncture 1 x week, Sham acupuncture1 x week, 6 other arms: 2 x week and 3 x week each group
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded.
Allocation concealment Not described. Sequence generation method: NR
Treatment details of main acupuncture group (protocol) Number and frequency of treatment, number of needles (protocol): 6 treatments, once a week for 6 weeks. 12 needles. Point selection: Fixed. Treatment provided by: NR. Setting: NR.
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: The acupuncturists were mute. Type of relationship permitted: Silence. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Study details: No. of arms 4. No. randomised 52. Recruited acupuncture naïve participants No How participants recruited Recruited from referrals for symptomatic pain treatment from various outpatient clinics.  Interventions Acupuncture, Sham acupuncture, Low frequency electro acupuncture, High frequency electro acupuncture
Staff blinding status Outcome observer: Not stated. Statistical analyst: Not stated. Participant blinding status Not stated but potentially could be Allocation concealment Not described. Sequence generation method: Unclear
Treatment details of main acupuncture group (protocol) Number and frequency of treatment, number of needles (protocol): 2 treatments, twice a week then cross. Twice-weekly long term treatments offered to responders 7 needles. Point selection: Fixed. Treatment provided by: Experienced acupuncturists. Setting: NR
Relationship constraint: Why constraint used: NR. Stated reason: NR. Description of constraint: No communication about expected effects took place. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Staff blinding status: Outcome observer: Not stated.  Statistical analyst: Not stated.  Participant blinding status: Not stated but potentially could be.
Allocation concealment: Not described.  Sequence generation method: NR
Treatment details of main acupuncture group (protocol): Number and frequency of treatment, number of needles (protocol): 3 treatments, twice a week then cross.  Twice-weekly long term treatments offered to responders 6 needles.  Point selection: Fixed.  Treatment provided by: Experienced acupuncturists. Setting: NR.
Relationship constraint: Why constraint used: NR. Stated reason: NR. Description of constraint: No communication about expected effects took place. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Study details: No. of arms: 5.  No. randomised: 43.  Recruited acupuncture naive participants: NR.  How participants recruited: Recruited from referrals for symptomatic pain treatment from various outpatient clinics.  Interventions: Acupuncture 1 min, Acupuncture 5 mins, Acupuncture 15 mins, Acupuncture 30 mins, Acupuncture 60 mins
Staff blinding status: Outcome observer: Not stated.  Statistical analyst: Not stated.  Participant blinding status: No - or obviously can’t be.
Allocation concealment: Not described.  Sequence generation method: NR
Treatment details of main acupuncture group (protocol): Number and frequency of treatment, number of needles (protocol): 2 treatments, twice a week then cross.  Twice-weekly long term treatments offered to responders 4 needles.  Point selection: Fixed.  Treatment provided by: Experienced acupuncturists. Setting: NR.
Relationship constraint: Why constraint used: NR. Stated reason: NR. Description of constraint: No communication about expected effects took place. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Study details: No. of arms: 4.  No. randomised: 125.  Recruited acupuncture naive participants: NR.  How participants recruited: Recruited from a 11 sites of a Community Clinical Research Programme on AIDS.  Interventions: Acupuncture and amitriptyline, Sham acupuncture and amitriptyline, Acupuncture and placebo amitriptyline, Sham acupuncture and placebo amitriptyline
Staff blinding status: Outcome observer: Yes.  Statistical analyst: Not stated.  Participant blinding status: Blinded
Allocation concealment: Adequate method but person recruiting may be executing.  Sequence generation method: NR
Treatment details of main acupuncture group (protocol): Number and frequency of treatment, number of needles (protocol): 20 treatments; twice weekly for 6 weeks then once a week for 8 weeks.  4-10 points, unclear if bilateral.  Point selection: Semi-flexible.  Treatment provided by: NR. Setting: NR
Relationship constraint: Why constraint used: Blinding. Stated reason: To maintain blinding.  Description of constraint: The acupuncturists asked all patients a series of standard questions to ascertain the need for supplemental points. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Staff blinding status: Outcome observer: Yes.  Statistical analyst: Not stated.  Participant blinding status: Blinded
Allocation concealment: Adequate method but person recruiting may be executing.  Sequence generation method: NR
Treatment details of main acupuncture group (protocol): Number and frequency of treatment, number of needles (protocol): 20 treatments; twice weekly for 6 weeks then once a week for 8 weeks.  4-10 points, unclear if bilateral.  Point selection: Semi-flexible.  Treatment provided by: NR. Setting: NR
Relationship constraint: Why constraint used: Blinding. Stated reason: To maintain blinding.  Description of constraint: The acupuncturists asked all patients a series of standard questions to ascertain the need for supplemental points. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

3. All other studies (N=50)

Study details: No. of arms: 2.  No. randomised: Recruited acupuncture naive participants: NR.  How participants recruited: NR how recruited.  Interventions: Acupuncture, Sham acupuncture
Allocation concealment: Not described.  Sequence generation method: NR
Treatment details of main acupuncture group (protocol): Number and frequency of treatment, number of needles (protocol): NR.  Point selection: NR.  Treatment provided by: NR. Setting: NR.
Relationship constraint: Why constraint used: NR. Stated reason: No stated reason for constraint.  Description of constraint: The practitioner was required to treat both verum and sham groups similarly. The practitioner was anxious to avoid discussions that might uncover group allocation. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: The participants were interviewed and it was reported that they were
conscious of being in an experiment. Practitioners debriefed: The acupuncturist was interviewed and reported they were anxious to avoid discussions that might uncover group allocation.

Ref: 24 Huang (2006) Country of study USA Condition Post menopausal hot flushes Trial type RCT (Pilot)
Study details: No. of arms 2. No. randomised 29. Recruited acupuncture naive participants No How participants recruited Recruited from fliers, classified ads, media articles, referrals from community physicians. Interventions Acupuncture, Sham acupuncture
Staff blinding status Outcome observer: Not stated. Statistical analyst: Not stated. Participant blinding status Blinded. Participant blinding tested: Yes, unclear when asked
Allocation concealment Not described. Sequence generation method: Unclear
Treatment details of main acupuncture group (protocol) 9 treatments, 2 a week for 2 weeks, then 1 per week. 10-14 needles. Point selection: Semi-flexible. Treatment provided by: Acupuncturists. Setting: Private offices.
Relationship constraint Why constraint used: To reduce therapeutic relationship. Stated reason: To control for non-specific therapeutic elements. Description of constraint: Limit verbal contact to the most pertinent clinical information and refrain from counselling and offering advice. Type of relationship permitted: Minimal talking. Fidelity monitored: All sessions audio recorded and 5% reviewed by an independent rater to assure adherence to the protocol. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 25 Alecrim-Andrade (2006) Country of study Brazil Condition Migraine Trial type RCT
Study details: No. of arms 2. No. randomised 31. Recruited acupuncture naive participants No How participants recruited Recruited via a media campaign. Interventions Acupuncture, Sham acupuncture
Staff blinding status Outcome observer: Yes. Statistical analyst: Yes. Participant blinding status Blinded.
Allocation concealment Gold standard - person executing is not person recruiting. Sequence generation method: NR
Treatment details of main acupuncture group (protocol) 16 treatments, twice a week for 4 weeks and once a week for 8 weeks. 12-20 needles. Point selection: Semi-flexible. Treatment provided by: General physician who was also an acupuncture specialist. Setting: NR
Relationship constraint Why constraint used: Blinding. Stated reason: Reported under the section on blinding, but not explicit. Description of constraint: The acupuncturist doctor did not give any information to the patients about the acupuncture treatment. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Study details: No. of arms 3. No. randomised 960. Recruited acupuncture naive participants No How participants recruited Recruited from multiple outpatient clinics. Interventions Acupuncture, Sham acupuncture, Care as usual
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Some blinded and also blinded to sham nature of control treatment.
Allocation concealment Adequate method but person recruiting may be executing. Sequence generation method: Computer
Treatment details of main acupuncture group (protocol) Ten treatments over 6 weeks, preferably 2 a week, or 15 over 13 weeks if partially successful. Between 10 to 25 needles. Point selection: Semi-flexible. Treatment provided by: Physicians with at least 140 hours of acupuncture training and 2 years professional training. Setting: Private offices
Relationship constraint Why constraint used: Blinding. Stated reason: To avoid unblinding the patient. Description of constraint: During acupuncture treatment, communications with the patient were restricted to minimum of necessary explanations. Type of relationship permitted: Other describe, Minimal explanation. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Study details: No. of arms 2. No. randomised 58. Recruited acupuncture naive participants Yes How participants recruited Recruited from patients who were scheduled to receive elective lithotripsy for either renal or upper uretal calculi at a hospital. Interventions Electro-acupuncture, Sham electro-acupuncture
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded.
Allocation concealment Unclear. Sequence generation method: Computer
Treatment details of main acupuncture group (protocol) 1 treatment using 4 needles. Point selection: Fixed. Treatment provided by: Board certified anesthesiologist and registered acupuncturist. Setting: Hospital lithotripsy suite.
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: Communication between the acupuncturist and patients was limited to scripted speech. Type of relationship permitted: Other describe, , Scripted. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 30 Nir (2007) 59 Country of study USA Condition Post menopausal hot flushes Trial type RCT (Pilot)
Study details: No. of arms 2. No. randomised 29. Recruited acupuncture naive participants No How participants recruited Recruited by posting study advertisements at community clinics. Interventions Acupuncture, Sham acupuncture
Staff blinding status Outcome observer: Not stated. Statistical analyst: Not stated. Participant blinding status Blinded.
Allocation concealment Not described. Sequence generation method: NR
Treatment details of main acupuncture group (protocol) 9 treatments, twice a week for two weeks then 1 x week for 5 weeks. 10-14 needles. Point selection: Semi-flexible. Treatment provided by: Five licenced acupuncturists. Setting: NR.
Relationship constraint Why constraint used: Blinding and reduce therapeutic relationship. Stated reason: To minimise the potential confounding effect of the acupuncturists awareness of which treatment the participants were receiving. Description of constraint: Acupuncturists were trained to maintain a standardised interaction with all participants. Type of relationship permitted: NR. Fidelity monitored: All sessions were audio taped, 5% randomly selected and reviewed for adherence to the standardised protocol by a blinded rater. The review revealed no significant violations. Participants debriefed: NR. Practitioners debriefed: NR.
Treatment details of main acupuncture group

Allocation

Staff b

newspaper adverts and partly referrals from GPs

was limited to the time required for detection and needling of the points

by:

Treatment details of main acupuncture group

Allocation concealment

Participants debriefed:

1 treatment. 2 needles.

Staff b

Acupuncture

Study details

REF:

and sham protocols

Treatment details of main acupuncture group

Allocation concealment

Gold standard - person executing is not person recruiting. Sequence generation method: Computer

Treatmen

t details of main acupuncture group (protocol) Up to 12 treatments in 6-8 weeks. 10-14 needles. Point selection: Semi-flexible. Treatment provided by: Licensed acupuncturists with a minimim of 1 year experience. Two sets of acupuncturists were used, one for diagnosing and deciding which points to use and one for treating. Setting: Private treatment room in a hospital clinic.

Relationship constraint

Why constraint used: NR. Stated reason: NR. Description of constraint: Interaction limited to the time required for the placement of needles. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Study details

No. of arms 2. No. randomised 192. Recruited acupuncture naive participants NR. How participants recruited NR. Recruited from advertising in media and public transport, and through mass mailings to age-eligible city residents. Interventions Individualised acupuncture, Standardised acupuncture, Sham acupuncture

Staff blinding status


Allocation concealment

Gold standard - person executing is person recruiting. Sequence generation method: Computer

Treatmen
t details of main acupuncture group (protocol) Up to 12 treatments in 6-8 weeks. 10-14 needles. Point selection: Semi-flexible. Treatment provided by: Licensed acupuncturists with a minimim of 1 year experience. Two sets of acupuncturists were used, one for diagnosing and deciding which points to use and one for treating. Setting: Private treatment room in a hospital clinic.

Relationship constraint

Why constraint used: NR. Stated reason: NR. Description of constraint: Patients were given an opportunity to ask the acupuncturists questions related to the placement of needles only. Type of relationship permitted: Other describe. Related to placement of needles. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Study details

No. of arms 2. No. randomised 200. Recruited acupuncture naive participants NR. How participants recruited NR. Recruited through a rehabilitation hospital's database, letters to local hospital neurologists, nursing homes and stroke support group leaders, and newspaper advertising. Interventions Acupuncture, Sham acupuncture

Staff blinding status

Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded.

Allocation concealment

Adequate method but person recruiting may be executing. Sequence generation method: Computer

Treatmen
t details of main acupuncture group (protocol) 20 treatments, 2 x week for 10 weeks. 5-7 needles. Point selection: Semi-flexible. Treatment provided by: 2 acupuncturists trained in China with an average of 20 years experience treating stroke patients. Setting: NR.

Relationship constraint

Why constraint used: To reduce therapeutic relationship. Stated reason: To minimise nonspecific differences between active and sham protocols. Description of constraint: A standard operating procedure was developed that was in all practitioner-patient interactions. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Study details

No. of arms 2. No. randomised 220. Recruited acupuncture naive participants NR. How participants recruited NR. Excluded those with acupuncture treatment in last 6 months. Interventions Acupuncture, Sham acupuncture

Staff blinding status

Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded.

Allocation concealment

Adequate method but person recruiting may be executing. Sequence generation method: NR

Treatmen
t details of main acupuncture group (protocol) NR 1 treatment. 2 needles. Point selection: Fixed. Treatment provided by: Two trained acupuncturists. Setting: Pre-surgery suite

Relationship constraint

Why constraint used: Blinding. Stated reason: No explicit, but reported under blinding section. Description of constraint: The acupuncturists asked questions about acupuncture using an identical list of answers. Type of relationship permitted: NR. Fidelity monitored: NR. Practitioners debriefed: NR. Participants debriefed: NR.

Study details

No. of arms 2. No. randomised 61. Recruited acupuncture naive participants NR. How participants recruited NR. Recruited from participants scheduled for elective total hip arthroplasty at a hospital. Interventions Auricular acupuncture, Sham auricular acupuncture

Staff blinding status

Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded.

Allocation concealment

Unclear. Sequence generation method: Random number table

Treatmen
t details of main acupuncture group (protocol) 1 treatment with 4 needles in-situ for 2-3 days. Point selection: Fixed. Treatment provided by: Two certified and experienced acupuncturists, with more than 5 years clinical experience. Setting: In-patient prior to surgery.

Relationship constraint

Why constraint used: NR. Stated reason: NR. Description of constraint: Interaction between the patient and acupuncturist was limited to the time required for detection and needling of the points. Type of relationship permitted: Other describe. , Unclear. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Study details

No. of arms 2. No. randomised 85. Recruited acupuncture naive participants NR. How participants recruited NR. Recruited from newspaper adverts and partly referrals from GPs. Interventions Dry needling and placebo tablets, Sham dry needling and metoprolol

Staff blinding status

Outcome observer: Yes. Statistical analyst: Yes. Participant blinding status Blinded.

Allocation concealment

Not described. Sequence generation method: NR

Treatmen
t details of main acupuncture group (protocol) 6-8 treatments over 17 weeks. Number of needles 4-6. Point selection: Flexible. Treatment provided by: NR. Setting: NR.
### Relationship constraint

- **Why constraint used:** NR. Stated reason: NR. Description of constraint: The therapist endeavoured to adopt a neutral and uniform attitude to all patients. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

### Ref: 39 David (1999)  
**Country of study:** UK  
**Condition:** RA  
**Trial type:** RCT

**Study details:** No. of arms 2. No. randomised 64. Recruited acupuncture naïve participants. Yes How participants recruited Recruited from rheumatology outpatient attendees. Interventions Acupuncture, Sham acupuncture.

**Staff blinding status** Outcome observer: Yes. Statistical analyst: Not stated. **Participant blinding status** Blinded.

**Allocation concealment** Gold standard - person executing is not person recruiting. Sequence generation method: Random number table.

**Treatment details of main acupuncture group (protocol)**
- Treatments, once a week for 5 weeks, then cross-2 needles. Point selection: Fixed. Treatment provided by: NR. Setting: NR.

**Relationship constraint** Why constraint used: NR. Stated reason: NR. Description of constraint: There was minimal conversation between patient and acupuncturist. Type of relationship permitted: Minimal talking. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

### Ref: 41 Lao (1994)  
**Country of study:** USA  
**Condition:** Post-operative oral surgery pain  
**Trial type:** RCT (Pilot)

**Study details:** No. of arms 2. No. randomised 12. Recruited acupuncture naïve participants. Yes How participants recruited Recruited from the outpatient clinic of a Dental School. Interventions Acupuncture, Sham acupuncture.

**Staff blinding status** Outcome observer: Yes. Statistical analyst: Not stated. **Participant blinding status** Blinded.

**Allocation concealment** Not described. Sequence generation method: NR.


**Relationship constraint** Why constraint used: Blinding. Stated reason: Not explicit, but mentioned under section discussing blinding. Description of constraint: The acupuncturist had little verbal contact with any of the patients. (It is possible that this was not by design). Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

### Ref: 42 Avants (1995)  
**Country of study:** USA  
**Condition:** Cocaine addiction.  
**Trial type:** RCT (Reason for the trial was to investigate the appropriateness of the control)

**Study details:** No. of arms 2. No. randomised 40. Recruited acupuncture naïve participants. No How participants recruited Recruited from people enrolled in an inner-city methadone programme, referred by their counselors. Interventions Acupuncture, Sham acupuncture.

**Staff blinding status** Outcome observer: Yes. Statistical analyst: Not stated. **Participant blinding status** Blinded.

**Allocation concealment** Not described. Sequence generation method: NR.

**Treatment details of main acupuncture group (protocol)** 30 treatments, one each weekday for 6 weeks. 8 needles. Point selection: Fixed. Treatment provided by: An acupuncturist trained in China with NADA certification and 16 years of experience. Setting: Quiet room in an outpatient clinic, two beds per room.

**Relationship constraint** Why constraint used: NR. Stated reason: NR. Description of constraint: Beyond performing the acupuncture procedure, the acupuncturist had minimal contact with the patients. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

### Ref: 44 Kelliler (1994)  
**Country of study:** UK  
**Condition:** Irritative bladder.  
**Trial type:** RCT

**Study details:** No. of arms 2. No. randomised 39. Recruited acupuncture naïve participants. No How participants recruited NR how recruited. Interventions Acupuncture, Drug.

**Staff blinding status** Outcome observer: Not stated. Statistical analyst: Not stated. **Participant blinding status** No - or obviously can’t be.

**Allocation concealment** Not described. Sequence generation method: Random number table.

**Treatment details of main acupuncture group (protocol)** Six treatments, once a week for 6 weeks. 15 needles. Point selection: Fixed. Treatment provided by: An experienced acupuncturist. Setting: NR.

**Relationship constraint** Why constraint used: NR. Stated reason: NR. Description of constraint: As far as possible, no feedback was allowed between the acupuncturist and the patient. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

### Ref: 45 Koenfal (1994)  
**Country of study:** USA  
**Condition:** Substance abuse  
**Trial type:** RCT

**Study details:** No. of arms 3. No. randomised 568. Recruited acupuncture naïve participants. No How participants recruited Recruited from either self-referred or assigned by the court to undergo a drug counseling and substance abuse treatment programme located in a primarily Black and Hispanic community. Interventions Auricular acupuncture and frequent urine testing, Frequent urine testing, Standard drug treatment programme.

**Staff blinding status** Outcome observer: Not stated. Statistical analyst: Not stated. **Participant blinding status** No - or obviously can’t be.

**Allocation concealment** Not described. Sequence generation method: NR.

**Treatment details of main acupuncture group (protocol)** 48 treatments. 5 x week for 2 weeks, 3 x week for 10 weeks, 2 x week for 4 weeks. 10 needles. Point selection: Fixed. Treatment provided by: NR. Setting: Group setting in chairs.

**Relationship constraint** Why constraint used: NR. Stated reason: NR. Description of constraint: There was a general policy of silence in the group setting. Some clients wanted to relate their personal drug stories to the acupuncturists or other clients but were discouraged by the acupuncturists from doing so. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

### Ref: 46 Lipton (1994)  
**Country of study:** USA  
**Condition:** Crack cocaine abuse.  
**Trial type:** RCT

**Study details:** No. of arms 2. No. randomised 192. Recruited acupuncture naïve participants. Yes How participants recruited Recruited from either self-referred or assigned by the court to undergo a drug counseling and substance abuse treatment programme located in a primarily Black and Hispanic community. Interventions Auricular acupuncture, Sham auricular acupuncture.

**Staff blinding status** Outcome observer: Not stated. Statistical analyst: Not stated. **Participant blinding status** Blinded.

**Allocation concealment** Not described. Sequence generation method: A code based on the subjects social security number, described as random.

**Treatment details of main acupuncture group (protocol)** Up to 48 treatments over one month. 8 needles. Point selection: Fixed. Treatment provided by: Five acupuncturists. Setting: Group setting with chairs.

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Relationship constraint Why constraint used: Blinding. Stated reason: Since the acupuncturists were not blind to subject condition assignment, contact between acupuncturists and participants were strictly monitored. Description of constraint: Acupuncturists were instructed not to converse with participants during treatment and not to respond to any questions concerning the type of acupuncture treatment provided. Type of relationship permitted: Other describe. Not talking about the treatment and minimal talking. Fidelity monitored: A nonacupuncturist staff person monitored acupuncturist-participants interactions to ensure that minimal verbal communication occurred. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 47 Cristian (2005) Country of study USA Condition Parkinson's disease Trial type RCT (Pilot)
Study details: No. of arms 2. No. randomised 14. Recruited acupuncture naïve participants Yes How participants recruited Recruited from a movement disorders clinic in a large inner city VA medical centre. Interventions Acupuncture, Sham acupuncture
Staff blinding status Outcome observer: Unclear. Statistical analyst: Not stated. Participant blinding status Blinded to sham nature of control treatment. Participant blinding tested: NR
Allocation concealment Not described. Sequence generation method: Coin toss
Treatment details of main acupuncture group (protocol) 5 treatments over 2 weeks. 29 needles. Point selection: Fixed. Treatment provided by: A physician acupuncturist. Setting: NR.
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: Reported that the participants were instructed using similar language as to what they could potentially experience. Unclear whether this referred to the informed consent process or interactions with the acupuncturist. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 49 Bullock (1989) Country of study USA Condition Alcoholic recidivism Trial type RCT
Study details: No. of arms 2. No. randomised 80. Recruited acupuncture naïve participants Yes How participants recruited Recruited from free severe recidivist detoxification clinic. Interventions Acupuncture, Sham acupuncture
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded.
Allocation concealment NA. Sequence generation method: Alternated; participants went into treatment area where names entered into a ledger, then consecutive names allocated in pairs to each arm.
Treatment details of main acupuncture group (protocol) 26 treatments; (I) 5 a week for 2 weeks, (II) 3 a week for 4 weeks, (III) 2 a week for 2 weeks. 8 needles. Point selection: Fixed. Treatment provided by: Acupuncturists. Setting: Group setting in a long-term chemical dependency unit
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: Interaction between the acupuncturists and the patients was limited to the time required for needle placement and casual group (never individual) conversation. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 50 Bullock (1987) Country of study USA Condition Alcoholic recidivism Trial type RCT (Pilot)
Study details: No. of arms 2. No. randomised 54. Recruited acupuncture naïve participants No How participants recruited Recruited from free severe recidivist detoxification clinic. Interventions Acupuncture, Sham acupuncture
Staff blinding status Outcome observer: Unclear, Unblinded acupuncturist asked outcome questions but these were evaluated by blinded personnel. Statistical analyst: Not stated. Participant blinding status Blinded.
Allocation concealment Not described. Sequence generation method: NR
Treatment details of main acupuncture group (protocol) 30 treatments; (I) 5 in 1 week, (II) 3 a week for 4 weeks, (III) 2 a week for 6.5 weeks. Number of needles unclear. Point selection: Fixed. Treatment provided by: An experienced acupuncturist. Setting: Group setting in a board and care facility
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: Interaction between the acupuncturist with the patients was limited to the time required for needle placement, casual group conversation during the treatment period, and brief interviews with patients after each completed study phase. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Study details: No. of arms 2. No. randomised 64. Recruited acupuncture naïve participants No How participants recruited Recruited from patients scheduled to undergo a total hip arthroplasty. Interventions Acupuncture, Sham acupuncture
Staff blinding status Outcome observer: Yes. Statistical analyst: No. Participant blinding status Blinded.
Allocation concealment Unclear. Sequence generation method: Computer
Treatment details of main acupuncture group (protocol) 1 treatment, 4 needles. Point selection: Fixed. Treatment provided by: Physician with more than 5 years of acupuncture experience. Setting: NR.
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: Interaction between the patient and acupuncturist was limited to the time required for detection and needling of the acupuncture or sham points. Unclear whether this was an actual limitation. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 54 Hollifield (2007) Country of study USA Condition PTSD Trial type RCT (Pilot)
Study details: No. of arms 3. No. randomised 84. Recruited acupuncture naïve participants No How participants recruited Recruited from repose to flyers, distributing brochures to physicians and advertisements in local media. Interventions Acupuncture, Group CBT, Waiting list
Staff blinding status Outcome observer: No. Statistical analyst: Not stated. Participant blinding status No - or obviously can’t be.
Allocation concealment Adequate method but person recruiting may be executing. Sequence generation method: Computer
Treatment details of main acupuncture group (protocol) 24 treatments, twice a week for 12 weeks. 11-25 needles. Point selection: Semi-flexible. Treatment provided by: Doctor of Oriental Medicine with 4 years clinical experience. Setting: NR.
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: Lifestyle advice was limited and only given in response to direct questions by participants or if a behaviour was seriously affecting symptoms related to diagnosis and constitution. Type of relationship permitted: Other describe. Limited lifestyle advice. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.
### Ref: 55  Yu (2006)  Country of study China  Condition Vascular dementia  Trial type RCT

**Study details: No. of arms 2. No. randomised 60. Recruited acupuncture naive participants No How participants recruited Recruited (chosen) from inpatients of an acupuncture department at a University Hospital.**  
**Interventions** Specialised Acupuncture, Conventional acupuncture  
**Staff blinding status** Outcome observer: Yes. Statistical analyst: Yes. **Participant blinding status** Blinded.  
**Allocation concealment** Not described. Sequence generation method: NR  
**Treatment details of main acupuncture group (protocol)** 42 treatments, once daily for 6 weeks. 8 points, unclear if bilateral. Point selection: Fixed. Treatment provided by: Two experienced acupuncturists. Setting: Hospital inpatient setting.  
**Relationship constraint** Why constraint used: NR. Stated reason: Not explicit, but discusses in the context of the acupuncturist not being blinded.  
Description of constraint: All participants were treated as equally as possible, in treatment procedure and communication with the acupuncturists. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

### Ref: 56  Linde (2004)  Country of study Sweden  Condition Menstrually related migraine  Trial type RCT

**Study details: No. of arms 2. No. randomised 31. Recruited acupuncture naive participants Yes How participants recruited Recruited from a specialist clinic.**  
**Interventions** Acupuncture, Sham acupuncture  
**Staff blinding status** Outcome observer: Not stated. Statistical analyst: Yes. **Participant blinding status** Blinded.  
**Allocation concealment** Not described. Sequence generation method: Other Method of lottery  
**Treatment details of main acupuncture group (protocol)** 9 sessions over 3 months, 3 sessions a month within 8 days of menstrual period. 12 needles. Point selection: Semi-Flexible. Treatment provided by: Experienced physiotherapist and stand-in. Setting: NR.  
**Relationship constraint** Why constraint used: NR. Stated reason: NR. Description of constraint: All patients were treated identically and great emphasis was on the acupuncturist not behaving more or less enthusiastically. They were instructed to not discuss the needling technique or the effect. Type of relationship permitted: Other describe. , Not talking about the treatment or the effect. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

### Ref: 57  Worner (1992)  Country of study USA  Condition Alcoholism  Trial type RCT

**Study details: No. of arms 3. No. randomised 56. Recruited acupuncture naive participants No How participants recruited Recruited from enrollees in a comprehensive outpatient alcoholism treatment programme.**  
**Interventions** Acupuncture, Sham TENS, Care as usual  
**Staff blinding status** Outcome observer: Other. Statistical analyst: Not stated. **Participant blinding status** Some participants blinded.  
**Allocation concealment** Not described. Sequence generation method: NR  
**Treatment details of main acupuncture group (protocol)** Treatments, 3 times a week for 3 months. 13 needles. Point selection: Fixed. Treatment provided by: Licensed acupuncturist. Setting: Group setting in a large open room.  
**Relationship constraint** Why constraint used: NR. Stated reason: NR. Description of constraint: Interaction of the acupuncturist and the patient was limited to the time required for placement of the needles. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

### Ref: 58  Washburn (1993)  Country of study USA  Condition Herion detox  Trial type RCT

**Study details: No. of arms 2. No. randomised 100. Recruited acupuncture naive participants No How participants recruited Recruited from a city locality, possibly from a drug treatment programme?.**  
**Interventions** Acupuncture, Sham acupuncture  
**Staff blinding status** Outcome observer: Not stated. Statistical analyst: Not stated. **Participant blinding status** Blinded.  
**Allocation concealment** Not described. Sequence generation method: Unclear  
**Treatment details of main acupuncture group (protocol)** Daily for 21 days. 4 points [unclear whether bilateral]. Point selection: Fixed. Treatment provided by: Acupuncturist. Setting: Group setting in a large room at a substance abuse facility.  
**Relationship constraint** Why constraint used: NR. Stated reason: NR. Description of constraint: Interaction between the patient and the therapist was limited to the time it took to place the needles and collect sign and symptom data. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

### Ref: 63  Knight (2001)  Country of study UK  Condition Nausea in pregnancy.  Trial type RCT

**Study details: No. of arms 2. No. randomised 55. Recruited acupuncture naive participants Yes How participants recruited Recruited from a hospital maternity unit.**  
**Interventions** Acupuncture, Sham acupuncture  
**Staff blinding status** Outcome observer: Yes. Statistical analyst: Yes. **Participant blinding status** Blinded.  
**Allocation concealment** Gold standard - person executing is not person recruiting. Sequence generation method: Computer  
**Treatment details of main acupuncture group (protocol)** 4 treatments, twice a week for one week then once a week for two weeks. 5-7 needles. Point selection: Semi-Flexible. Treatment provided by: Acupuncture practitioner. Setting: NR.  
**Relationship constraint** Why constraint used: NR. Stated reason: NR, but mentioned in the same paragraph as blinding. Description of constraint: The acupuncturist followed standardised procedures for all interactions. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

### Ref: 65  McConaghy (1996)  Country of study Australia  Condition PONV  Trial type RCT

**Study details: No. of arms 2. No. randomised 30. Recruited acupuncture naive participants No How participants recruited Recruited from patients on surgical waiting list.**  
**Interventions** Acupuncture, Sham acupuncture  
**Staff blinding status** Outcome observer: Not stated. Statistical analyst: Not stated. **Participant blinding status** Blinded. Participant blinding tested: NR  
**Allocation concealment** Not described. Sequence generation method: NR  
**Treatment details of main acupuncture group** 1 treatment using 2 needles. Point selection: Fixed. Treatment provided by: NR. Setting: Post-operative suite  
**Relationship constraint** Why constraint used: NR. Stated reason: To reduce bias. Description of constraint: An attempt was made to standardise the interactions between acupuncturist and patients. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.
Ref: 67 Avants (2000) Country of study USA Condition Cocaine dependence Trial type RCT 
Study details: No. of arms 3. No. randomised 82. Recruited acupuncture naïve participants No. How participants recruited Recruited from an inner city methadone maintenance programme. Interventions Acupuncture, Sham acupuncture, Relaxation 
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Some participants blinded. 
Allocation concealment Not described. Sequence generation method: Computer 
Treatment details of main acupuncture group (protocol) 40 treatments, 5 days a week for 8 weeks. 8 needles. Point selection: Fixed. Treatment provided by: A NADA trained acupuncturist with more than 10 years acupuncture experience, with 4 back-ups. Setting: In a group setting. 
Relationship constraint Why constraint used: NR. Stated reason: To diminish the possibility that acupuncturists might knowingly or unknowingly attempt to influence outcome in favour of the active treatment. Description of constraint: Acupuncturist was provided with a standardised script which proscribed answering questions clearly and succinctly without additional information volunteered beyond that needed to answer the question. Participants told not to engage acupuncturist in conversation and were told at onset that lack of interaction was not a sign that the acupuncturist was uncaring about them or their recovery. Type of relationship permitted: Other describe. Answering questions only. Fidelity monitored: A research assistant observed the treatment sessions. Fidelity NR. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 69 Manber (2004) Country of study USA Condition Depression in pregnancy Trial type RCT (Pilot) 
Study details: No. of arms 3. No. randomised 61. Recruited acupuncture naïve participants No. How participants recruited Recruited from obstetric clinics and from advertisements in local and parenting magazines. Interventions Acupuncture, Sham (non-specific) acupuncture, Massage 
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Some participants blinded. 
Allocation concealment Not described. Sequence generation method: NR 
Treatment details of main acupuncture group (protocol) 12 sessions over 8 weeks, responders to continue for 8 sessions well past postpartum. Number of needles NA. Point selection: Flexible. Treatment provided by: Acupuncturists. Setting: NR. 
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: Acupuncture (and massage) sessions included minimal verbal contact. Type of relationship permitted: Minimal talking. Fidelity monitored: All sessions were audiotaped and randomly inspected to ensure compliance. Results NR. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 70 Gilbertson (2003) Country of study USA Condition Recovery after arthroscopic acromioplasty Trial type RCT 
Study details: No. of arms 2. No. randomised 40. Recruited acupuncture naïve participants No. How participants recruited Recruited from patients scheduled for arthroscopic acromioplasty. Interventions Acupuncture, Sham acupuncture 
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded. 
Allocation concealment Adequate method but person recruiting may be executing. Sequence generation method: Lots in a container 
Treatment details of main acupuncture group (protocol) 12 treatments, 3 times a week for a month. Number of needles NA. Point selection: Semi-flexible. Treatment provided by: A physician acupuncturist. Setting: NR. 
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: Subjects were instructed not to discuss acupuncture with anyone. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Study details: No. of arms 2. No. randomised 80. Recruited acupuncture naïve participants No. How participants recruited Recruited from patients assigned to high dose chemotherapy treatment and autologous peripheral blood stem cell transplantation at a University Hospital. Interventions Acupuncture, Sham acupuncture 
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded. 
Allocation concealment Adequate method but person recruiting may be executing. Sequence generation method: NR 
Treatment details of main acupuncture group (protocol) 2 treatments, 2 needles. Point selection: Fixed. Treatment provided by: Two trained acupuncturists. Setting: Administered prior to infusions, but NR where in the hospital. 
Relationship constraint Why constraint used: Blinding. Stated reason: Not explicit, but reported in the discussion on blinding. Description of constraint: Acupuncturists answered questions about acupuncture using an identical answer catalogue. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 72 Trümppler (2003) Country of study Switzerland Condition Alcohol withdrawal. Trial type RCT (Pilot) 
Study details: No. of arms 3. No. randomised 48. Recruited acupuncture naïve participants No. How participants recruited Recruited from admissions to an inpatient alcohol unit in alcohol withdrawal. Interventions Auricular acupuncture, Laser, Sham laser 
Staff blinding status Outcome observer: Other. Statistical analyst: Not stated. Participant blinding status Some participants blinded. 
Allocation concealment Adequate method but person recruiting may be executing. Sequence generation method: Other. Drawing lots 
Treatment details of main acupuncture group (protocol) Treatment daily until withdrawal complete (survival analysis). 2 to 10 points (unclear if one or both ears). Point selection: Semi-flexible. Treatment provided by: Two acupuncturists. Setting: In a quiet room on an inpatient unit. 
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: Interaction between acupuncturists and participants was limited to the time required for the stimulation procedures. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Study details: No. of arms 2. No. randomised 20. Recruited acupuncture naïve participants No. How participants recruited Participants recruited from those being treated at a hearing centre at a hospital. Interventions Acupuncture, Sham acupuncture 
Allocation concealment Not described. Sequence generation method: NR 
Treatment details of main acupuncture group (protocol) 6 treatments, twice a week for 3 weeks, then cross. 6 needles. Point selection: Semi-flexible. Treatment provided by: Acupuncturist. Setting: NR.
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: Participants were told to discuss only the treatment with the acupuncturist, and their illness with another investigator. Type of relationship permitted: Other describe. Only talking about the treatment. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 75 Gilbey (1977) Country of study Canada Condition Smoking Trial type RCT
Study details: No. of arms 2. No. randomised 92. Recruited acupuncture naïve participants No How participants recruited Recruited through newspapers advertisements. Interventions Auricular acupuncture in Lung area, Auricular acupuncture in Kidney area
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded.
Allocation concealment Not described. Sequence generation method: NR
Treatment details of main acupuncture group (protocol) 1 treatment: 2 needles, retained. Point selection: Fixed. Treatment provided by: A radiologist who had received training as an acupuncturist in Hong Kong. Setting: Single treatment room, NR where.
Relationship constraint Why constraint used: Blinding and reduce therapeutic relationship. Stated reason: Psychological support was minimised in order to determine the effect of acupuncture, and limited interaction also discussed under blinding section in methods. Description of constraint: There was minimal interaction between the acupuncturist and the patient. Type of relationship permitted: Minimal talking. Fidelity monitored: Another person was with the acupuncturist during the entire treatment. Not explicit whether this person was monitoring the constraint. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 76 White (1998) Country of study UK Condition Nicotine withdrawal Trial type RCT
Study details: No. of arms 2. No. randomised 76. Recruited acupuncture naïve participants Yes How participants recruited Recruited through media invitations. Interventions Acupuncture, Superficial acupuncture / Sham TENS
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded to sham nature of control treatment.
Allocation concealment Gold standard - person executing is not person recruiting. Sequence generation method: Computer
Treatment details of main acupuncture group (protocol) Number and frequency of treatment, number of needles (protocol): 3 treatments over one week, 1 needle. Point selection: Fixed. Treatment provided by: An acupuncturist with 14 years clinical and teaching experience. Setting: In a separate room, NR where.
Relationship constraint Why constraint used: Blinding. Stated reason: Not explicit, but mentioned under ‘masking and randomisation’ section of methods. Description of constraint: The acupuncturist maintained a neutral attitude towards all participants, with minimal verbal and nonverbal interaction. Type of relationship permitted: Minimal talking. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 77 Bier (2002) Country of study USA Condition Smoking Trial type RCT
Study details: No. of arms 3. No. randomised 141. Recruited acupuncture naïve participants No How participants recruited Recruited from advertisements on radio and local print media. Interventions Acupuncture, Acupuncture and smoking cessation education, Sham acupuncture and smoking cessation education
Staff blinding status Outcome observer: Not stated. Statistical analyst: Not stated. Participant blinding status Blinded. Participant blinding tested: NR
Allocation concealment Adequate method but person recruiting may be executing. Sequence generation method: Random number table
Treatment details of main acupuncture group (protocol) Number and frequency of treatment, number of needles (protocol): 3 treatments over one week, 1 needle. Point selection: Fixed. Treatment provided by: Highly trained and experienced acupuncturists, members of NCCAO and NADA. Setting: Seated in comfortable chairs, NR where.
Relationship constraint Why constraint used: NR. Stated reason: To ensure that no bias occurred. Description of constraint: Interaction was limited to the time required for needle placement and withdrawal, and only essential verbal communication took place between participants and acupuncturists. Type of relationship permitted: Other describe. Essential verbal communication. Fidelity monitored: A blinded research assistant supervised the treatment to ensure that only essential communication took place. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 78 Margolin (2002) Country of study USA Condition Cocaine addiction Trial type RCT
Study details: No. of arms 3. No. randomised 83. Recruited acupuncture naïve participants No How participants recruited Recruited from an inner city methadone maintenance programme. Interventions Acupuncture, Sham acupuncture, Relaxation
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded. Participant blinding tested: NR
Allocation concealment Not described. Sequence generation method: Computer
Treatment details of main acupuncture group (protocol) Number and frequency of treatment, number of needles (protocol): 6 treatments over 8 weeks, 6 needles. Point selection: Fixed. Treatment provided by: A NADA trained acupuncturist with more than 10 years acupuncture experience, with 4 back-ups. Setting: In a group setting.
Relationship constraint Why constraint used: NR. Stated reason: To diminish the possibility that acupuncturists might knowingly or unknowingly attempt to influence outcome in favour of the active treatment. Description of constraint: Acupuncturist was provided with a standardised script which proscribed answering questions clearly and succinctly without additional information volunteered beyond that needed to answer the question. Participants told not to engage acupuncturist in conversation and were told at onset that lack of interaction was not a sign that the acupuncturist was uncaring about them or their recovery. Type of relationship permitted: Other describe. Answering questions only. Fidelity monitored: A research assistant observed the treatment sessions. Fidelity NR. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 80 Rampes (1997) Country of study UK Condition Alcohol abuse Trial type RCT
Study details: No. of arms 3. No. randomised 59. Recruited acupuncture naïve participants Yes How participants recruited Recruited from a community alcohol programme. Interventions Auricular acupuncture, Sham auricular acupuncture, Usual care
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Some participants blinded.
Allocation concealment Adequate method but person recruiting may be executing. Sequence generation method: Random number table
Treatment details of main acupuncture group (protocol) Number and frequency of treatment, number of needles (protocol): 6 treatments, once a week for 6 weeks. 6 needles. Point selection: Fixed. Treatment provided by: An acupuncturist. Setting: At the community alcohol facility, two participants in a room.
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: Conversation with the acupuncturist was solely restricted to enable the acupuncture to be done. Type of relationship permitted: Other describe. Only to enable the treatment to be carried out. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.
Ref: 82 Tam (2007) Country of study Hong Kong Condition Rheumatoid arthritis Trial type RCT (Pilot)
Allocation concealment Not described. Sequence generation method: Computer
Treatment details of main acupuncture group (protocol) Number and frequency of treatment, number of needles (protocol): 20 treatments, two a week for 10 weeks. 6 points, unclear if bilateral. Point selection: Fixed. Treatment provided by: A registered acupuncturist with 10 years experience. Setting: NR.
Relationship constraint Why constraint used: NR. Stated reason: To minimise bias. Description of constraint: The acupuncturist had the least possible communication with the participants. Type of relationship permitted: Minimal talking. Fidelity monitored: NR. Participants debriefed: NR.
Practitioners debriefed: NR.

Ref: 83 Ballegaard (1986) Country of study Denmark Condition Angina Pectoris Trial type RCT
Study details: No. of arms 2. No. randomised 26. Recruited acupuncture naive participants Yes How participants recruited Recruited from cocaine substance abuse clinics and methadone maintenance clinics. Interventions Auricular acupuncture, Sham auricular acupuncture, Relaxation 
Staff blinding status Outcome observer: No. Statistical analyst: Not stated. Participant blinding status Blinded.
Allocation concealment Not described. Sequence generation method: NR
Treatment details of main acupuncture group (protocol) Number and frequency of treatment, number of needles (protocol): 7 treatments over an unspecified period. 6 needles. Point selection: Fixed. Treatment provided by: NR. Setting: Outpatient hospital clinic.
Relationship constraint Why constraint used: Blinding. Stated reason: To increase the participants confidence that they were receiving the correct acupuncture treatment. Description of constraint: The acupuncturist used a electrically resistant measurement device that beeped when the needle was inserted. Setting: XR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 84 Margolin (2002) Country of study USA Condition Cocaine abuse Trial type RCT
Study details: No. of arms 3. No. randomised 620. Recruited acupuncture naive participants No How participants recruited Recruited from inpatient substance abuse treatment unit of a Veterans hospital. Interventions Acupuncture, Sham acupuncture, Symptom based acupuncture, Care as usual (substance abuse treatment) 
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Some participants blinded.
Allocation concealment Not described. Sequence generation method: Computer
Treatment details of main acupuncture group (protocol) Number and frequency of treatment, number of needles (protocol): 40 treatments, one each weekday for 8 weeks. 8 needles. Point selection: Fixed. Treatment provided by: Licensed acupuncturists with NADA certification. Setting: NR.
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: The acupuncturists were not permitted to converse with the patients. Type of relationship permitted: Silence. Fidelity monitored: NR. Participants debriefed: Participants were asked to fill in a therapeutic alliance scale (28) after the 1st treatment and during weeks 4-8 (scale 10-70). Acupuncture 56.04 (SD 10.7), sham 53.02 (11.95) relaxation 57.13 (10.2) (NR timepoint of this data). Practitioners debriefed: NR.

Ref: 85 Bullock (2002) Country of study USA Condition Alcohol dependence Trial type RCT
Study details: No. of arms 4. No. randomised 503. Recruited acupuncture naive participants No How participants recruited Recruited from a residential inpatient programme at a university medical centre. Interventions Acupuncture, Sham acupuncture, Symptom based acupuncture, Care as usual (substance abuse treatment) 
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Some participants blinded.
Allocation concealment Not described. Sequence generation method: NR
Treatment details of main acupuncture group (protocol) Number and frequency of treatment, number of needles (protocol): 18 treatments, 6 days a week, from 3 weeks. Some extended the treatment for up to another 3 weeks. 4 points, unclear if bilateral. Point selection: Fixed. Treatment provided by: 7 highly trained and experienced acupuncturists. Setting: Inpatient substance abuse treatment centre.
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: Interaction in the specific acupuncture and sham groups was limited to the time required for placement and withdrawal and for essential verbal exchange only. In the symptom-based acupuncture group acupuncturists were free to explain the points they use and the intended effect of each. Type of relationship permitted: Other describe., Essential exchange for specific acupuncture and sham, taking about treatment in symptom-based group. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 88 Otto (1998) Country of study USA Condition Cocaine addiction Trial type RCT (Pilot)
Study details: No. of arms 2. No. randomised 36. Recruited acupuncture naive participants No How participants recruited Recruited from cocaine-dependent patients in the inpatient substance abuse treatment unit of a Veterans hospital. Interventions Auricular acupuncture, Sham auricular acupuncture 
Staff blinding status Outcome observer: Yes. Statistical analyst: Not stated. Participant blinding status Blinded.
Allocation concealment Not described. Sequence generation method: NR
Treatment details of main acupuncture group (protocol) Number and frequency of treatment, number of needles (protocol): 24+ treatment; 5 times a week for 2 wks, then 3 times a wk for 2 weeks, then once a week 8 wks, then as needed. 10 needles. Point selection: Fixed. Treatment provided by: An acupuncturist trained at the Lincoln clinic. Setting: Group setting at an inpatient substance abuse treatment programme.
Relationship constraint Why constraint used: NR. Stated reason: NR. Description of constraint: The treatments were arranged in a group setting to enable the acupuncturist to avoid individual conversation with any patient. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

Ref: 91 Bullock (1999) Country of study USA Condition Cocaine abuse Trial type RCT
Study details: No. of arms 3. No. randomised 236. Recruited acupuncture naive participants No How participants recruited Recruited from residents of a substance abuse treatment centre. Interventions Acupuncture, Sham acupuncture, Care as usual (Addiction care model)
**Staff blinding status** Outcome observer: Yes. Statistical analyst: Not stated. **Participant blinding status** Some participants blinded.

**Allocation concealment** Not described. Sequence generation method: NR

**Treatment details of main acupuncture group (protocol)** Number and frequency of treatment, number of needles (protocol): 28 treatments over 56 days. 3 points, unclear whether bilateral. Point selection: Fixed. Treatment provided by: Nationally board certified acupuncturists. Setting: Inpatient substance abuse programme, group setting with comfortable chairs

**Relationship constraint** Why constraint used: NR. Stated reason: NR. Description of constraint: Interaction was limited to the time required for needle placement and withdrawal. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

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Ref: 91 Baulsell (1999) Country of study USA Condition Cocaine abuse Trial type RCT

Study details: No. of arms 3. No. randomised 202. Recruited acupuncture naive participants No How participants recruited Recruited from outpatients of a substance abuse treatment centre. **Interventions** Acupuncture (28 sessions), Acupuncture (16 sessions), Acupuncture (8 sessions)

**Staff blinding status** Outcome observer: No. Statistical analyst: Not stated. **Participant blinding status** Some participants blinded.

**Allocation concealment** Not described. Sequence generation method: NR

**Treatment details of main acupuncture group (protocol)** Number and frequency of treatment, number of needles (protocol): 28 treatments over 56 days. 5 points, unclear whether bilateral. Point selection: Fixed. Treatment provided by: Nationally board certified acupuncturists. Setting: Outpatient substance abuse programme, group setting with comfortable chairs.

**Relationship constraint** Why constraint used: NR. Stated reason: NR. Description of constraint: Interaction was limited to the time required for needle placement and withdrawal. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

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Ref: 92 Baulsell (2005) Country of study USA Condition Dental surgery Trial type RCT

Study details: No. of arms 3. No. randomised 120. Recruited acupuncture naive participants Yes How participants recruited Recruited from a university dental clinic. **Interventions** Acupuncture, Sham acupuncture (adjacent non-insertion, distal shallow insertion), Sham acupuncture (adjacent shallow insertion, distal non-insertion)

**Staff blinding status** Outcome observer: Yes. Statistical analyst: Yes. **Participant blinding status** Blinded.

**Allocation concealment** Gold standard - person executing is not person recruiting. Sequence generation method: Computer

**Treatment details of main acupuncture group (protocol)** Number and frequency of treatment, number of needles (protocol): 1 treatment, 2 if required by pain level. 4 needles plus one sham. Point selection: Fixed. Treatment provided by: Four licenced acupuncturists trained the protocol. Setting: A university dental clinic.

**Relationship constraint** Why constraint used: NR. Stated reason: NR. Description of constraint: The participants eyes were covered. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

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Ref: 93 Baulsell (2005) Country of study USA Condition Dental surgery pain Trial type RCT

Study details: No. of arms 3. No. randomised 180. Recruited acupuncture naive participants Yes How participants recruited Recruited from an independent dental research facility. **Interventions** Acupuncture, Sham acupuncture 1, Sham acupuncture 2

**Staff blinding status** Outcome observer: Yes. Statistical analyst: Yes. **Participant blinding status** Blinded.

**Allocation concealment** Gold standard - person executing is not person recruiting. Sequence generation method: Computer

**Treatment details of main acupuncture group (protocol)** Number and frequency of treatment, number of needles (protocol): 1 treatment, 2 if required by pain level. 4 needles plus one sham. Point selection: Fixed. Treatment provided by: Four licenced acupuncturists trained the protocol. Setting: A private dental clinic.

**Relationship constraint** Why constraint used: NR. Stated reason: NR. Description of constraint: The participants eyes were covered. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

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Study details: No. of arms 2. No. randomised 16. Recruited acupuncture naive participants NR How participants recruited Recruited from referrals for symptomatic pain treatment from various outpatient clinics. **Interventions** De qi acupuncture, Sham acupuncture

**Staff blinding status** Outcome observer: Not stated. Statistical analyst: Not stated. **Participant blinding status** Not stated but potentially could be Blinded.

**Allocation concealment** Not described. Sequence generation method: NR

**Treatment details of main acupuncture group (protocol)** Number and frequency of treatment, number of needles (protocol): 5 treatments, twice a week then cross. Twice-weekly long term treatments offered to responders 6 needles. Point selection: Fixed. Treatment provided by: Experienced acupuncturists. Setting: NR.

**Relationship constraint** Why constraint used: NR. Stated reason: NR. Description of constraint: No communication about expected effects took place. Type of relationship permitted: NR. Fidelity monitored: NR. Participants debriefed: NR. Practitioners debriefed: NR.

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**Abbreviations**

EA electro-acupuncture

NR not reported

NA not applicable

RCT randomised controlled trial