

The Efficacy of Analgesic Effects of Acupuncture

(1) Some Methodological Problems in Its Scientific Appraisal

Raymond Tsang
MSc(PT)
SPT, AP(MS),
Queen Mary Hospital
7th June 2005

Efficacy of Acupuncture

- Have you ever read an article of RCT on efficacy of analgesic effects of acupuncture?
- Have you tried to critically appraise an article of RCT on efficacy of analgesic effects of acupuncture?

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Efficacy of Acupuncture

- Have you ever tried to systematically search, appraise, integrate the findings of RCTs on efficacy of analgesic effects of acupuncture?

→ **Systematic Review**

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Efficacy of Acupuncture

- Most of us would rely on existing systematic reviews or meta-analyses to obtain the “summary” of evidence for the efficacy of analgesic effects of acupuncture.

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Revised SIGN Grading System (SIGN, 2001)

Levels of evidence	
1++	High quality meta analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High quality systematic reviews of case-control or cohort or studies High quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion

Quality of RCTs

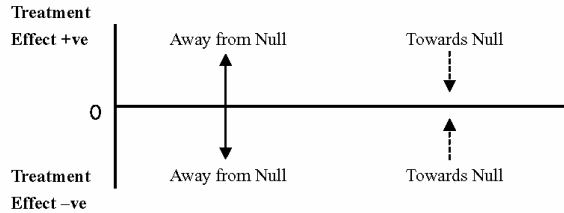
Verhagen et al (2001)

- Defined as “the likelihood of the trial design to generate unbiased results, that are sufficiently precise and allow application in clinical practice.”

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Bias

Effects of Biases on Estimation of Treatment Effect in RCT



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Rationale for Systematic Reviews

Mulrow (1994)

1. Summarizing large quantities of information
2. Integrating pieces of information
3. Efficient
4. Allowing generalizability of findings
5. Assessing consistency of relationships
6. Examining and explaining inconsistencies and conflicts

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Rationale for Systematic Reviews

Mulrow (1994)

7. Increase power in meta-analysis
8. Increased precision in estimates of risks or effect size in meta-analysis
9. Improved accuracy over narrative reviews

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SR & MA of RCTs of Acupuncture for Pain-related Conditions

Table 1. Systematic Reviews and Meta-Analyses of Randomized, Controlled Trials of Acupuncture for Pain-Related Conditions*

Condition	Study (Reference)	Year	RCTs, n	Patients, n	Findings	Conclusions
Chronic pain	Patel et al. (31)	1989	14	720	Overall and in most subgroups pooled: positive; for acupuncture placebo trials: negative	Potential bias precluded conclusive findings, but most results were positive
Chronic pain	ter Riet et al. (32)	1990	51†		24 positive and 27 negative; for acupuncture vs. placebo trials: 15 positive and 17 negative	Highly contradictory evidence; efficacy remains doubtful
Chronic pain	Ezzo et al. (33)	2000	51	2423	21 positive and 27 negative; acupuncture was worse than control in 3 trials	Inconclusive evidence for acupuncture being more effective than placebo or standard care
Chronic neck and back pain	Smith et al. (34)	2000	13	522	All placebo-controlled; 5 positive and 8 negative; most valid trials tended to be negative	No convincing evidence for analgesic efficacy in chronic neck and back pain
Back pain	Ernst and White (35)	1998	12	591 (377 pooled)	9 studies pooled: odds ratio of improvement for acupuncture vs. control, 2.30; for placebo trials, 1.17	Acupuncture superior to various controls, but insufficient evidence to conclude whether superior to placebo
Low back pain	van Tulder et al. (36)	1999	11	542	No evidence that acupuncture was better than no treatment; moderate evidence that acupuncture was not more effective than TENS and trigger-point injections; limited evidence that acupuncture was not more effective than placebo	Effectiveness remains unclear

(Kaptchuk, 2002)

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SR & MA of RCTs of Acupuncture for Pain-related Conditions

Osteoarthritis	Ernst (37)	1997	131	437	Most trials had methodologic flaws	Highly contradictory evidence
Osteoarthritis of the knee	Ezzo et al. (38)	2001	71	393	2 trials compared acupuncture with wait list; both positive; 3 trials compared acupuncture to placebo; 2 positive; 2 trials compared acupuncture to physical therapy; both negative	Acupuncture may play a role in the treatment of osteoarthritis of the knee; additional research is necessary
Acute dental pain	Ernst and Pittler (39)	1996	16	941	12 trials suggested that acupuncture is more effective than control; 4 trials suggested the contrary	Acupuncture can alleviate dental pain
Neck pain	White and Ernst (40)	1999	14	724	7 positive and 7 negative; acupuncture was not superior to placebo in 4 of 5 trials	Insufficient evidence for damping efficacy
Fibromyalgia	Berman et al. (41)	1999	3	149	All positive, including 1 high-quality study	Acupuncture may be effective; more high-quality trials needed
Headache (tension-type and cervicogenic)	Vernon et al. (42)	1999	8	264	Placebo trials: 2 positive and 4 negative; results of other trials were contradictory	Too few trials, and contradictory evidence precludes conclusions
Headache	Mekhart et al. (43)	1999	22	1042	15 migraine, 6 tension, and 1 mixed; contradictory results in 8 trials that compared acupuncture with other treatments; positive trend in 14 trials that compared acupuncture to placebo	Trend in favor of acupuncture, but evidence not fully convincing

* Positive = significant positive finding for acupuncture compared with control; negative = no significant finding for acupuncture compared with control; RCT = randomized, controlled trial; TENS = transcutaneous electrical nerve stimulation.
† Review and analysis contain some trials that were not randomized.

(Kaptchuk, 2002)

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Problems with RCTs of Acupuncture

Kaptchuk (2002)

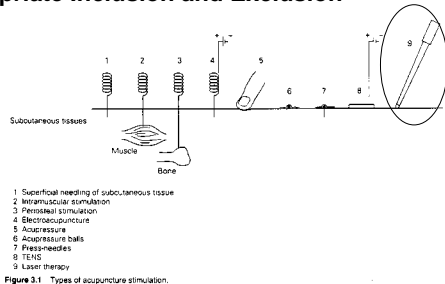
- Insufficient sample size
- Poorly defined conditions with imprecise outcomes
- Inappropriate inclusion and exclusion criteria → heterogeneous study groups
- High dropout rates
- Inadequate follow-up

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Problems with SRs of Acupuncture

Birch (2001, 2003)

1. Inappropriate Inclusion and Exclusion Criteria



Ernst E, White AR (1998) Acupuncture for back pain: a meta-analysis of randomized controlled trials, *Archives of Internal Medicine* 158: 2235-2241.

- A study was included to examine the efficacy of trigger point treatment
- Active treatment
 - single injection of lidocaine or lidocaine and steroid into trigger points for acute low back pain
- Control treatment
 - Single session of “dry needling” or “anaesthetic spray with acupressure”
- Results
 - Favoured “dry needling” or “anaesthetic spray with acupressure”

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Problems with SRs of Acupuncture

Birch (2001, 2003)

2. Adequacy of Acupuncture Treatment

- Inadequate or questionable treatments of acupuncture, regarding selection of points, number of points, number of treatment sessions

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Ernst E, White AR (1998) Acupuncture for back pain: a meta-analysis of randomized controlled trials, *Archives of Internal Medicine* 158: 2235-2241.

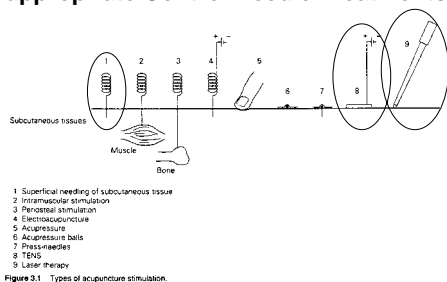
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Problems with SRs of Acupuncture

Birch (2001, 2003)

3. Inappropriate Control Needle Treatments



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Problems with SRs of Acupuncture

Birch (2001, 2003)

3. Inappropriate Control Needle Treatments

- When inadequate treatment (less effective) is compared to an inappropriate control treatment (more effective)
- unfair or unreasonable comparison that tends to bias against acupuncture (towards null)

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Problems with SRs of Acupuncture

Birch (2001, 2003)

4. Inappropriate Use of Jadad Scale

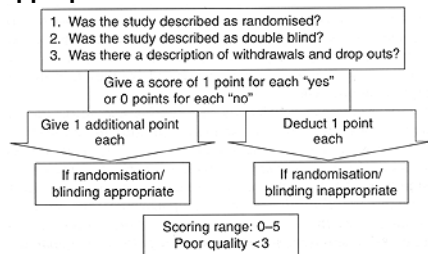


Figure 4.1 Validated quality scale. (From Jadad et al.)

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Problems with SRs of Acupuncture

Birch (2001, 2003)

4. Inappropriate Use of Jadad Scale

- Difficult or may be impossible for double-blind studies in acupuncture
- Bias against finding acupuncture to be effective as fewer acupuncture studies to be judged as high quality (poor quality: score <3)

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Case Study

Rheumatology 1999;38:143-147

A systematic review of randomized controlled trials of acupuncture for neck pain

A. R. White and E. Ernst

Department of Complementary Medicine, School of Postgraduate Medicine and Health Sciences, University of Exeter, 25 Victoria Park Road, Exeter EX2 4NT, UK

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White AR, Ernst E (1999) A systematic review of randomized controlled trials of acupuncture for neck pain, *Rheumatology* 38: 143-147.

1. Search Strategy

A. Databases

- Medline (1966-97)
- Embase (1974-97)
- Cochrane library (Issue 1, 1998)
- CISCOM (Centralized Information Service for Complementary Medicine) (December 1997)
- Personal files and reference lists
- No language restrictions

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White AR, Ernst E (1999) A systematic review of randomized controlled trials of acupuncture for neck pain, *Rheumatology* 38: 143-147.

1. Search Strategy

B. Search terms

- Neck pain, cervical, cervicogenic, osteoarthritis
- Acupuncture
- Controlled trial

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White AR, Ernst E (1999) A systematic review of randomized controlled trials of acupuncture for neck pain, *Rheumatology* 38: 143-147.

2. Selection Strategy

A. Inclusion Criteria

- RCT of neck pain, allocation at random to acupuncture or any control procedure
- Acupuncture – needle acupuncture, electroacupuncture, laser acupuncture
- Studies with neck and/or back pain

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Critique

Rheumatology 2002;41:1224-1231

Review (White et al, 2002a)

Reviews of acupuncture for chronic neck pain: pitfalls in conducting systematic reviews

P. White¹, G. Lewith^{1,2}, B. Berman³ and S. Birch⁴

¹University of Southampton, Royal South Hants Hospital, Southampton, ²University of Southampton, Southampton, UK, ³University of Maryland, School of Medicine, Baltimore, USA and ⁴Stichting (Foundation) for the Study of Traditional East Asian Medicine, W.G. Plein 330, 1054 SG Amsterdam, The Netherlands

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White P, Lewith G, Berman B, Birch S (2002) Reviews of acupuncture for chronic neck pain: pitfalls in conducting systematic reviews, *Rheumatology* 41: 1224-1231.

1. Inappropriate Inclusion and Exclusion Criteria

A. Inappropriate Treatment

- Laser acupuncture (Emery & Lythgoe, 1986; Kreczi & Klingler, 1986)

B. Inappropriate Conditions

- Neck &/or back pain (Emery & Lythgoe, 1986; Gallacchi et al, 1981; Junnila, 1982; Kreczi & Klingler, 1986)

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White P, Lewith G, Berman B, Birch S (2002) Reviews of acupuncture for chronic neck pain: pitfalls in conducting systematic reviews, *Rheumatology* 41: 1224-1231.

C. Inadequate Treatment

- Too few treatment sessions
- Too few needles
- Unusual or unacceptable needling technique

(Coan et al, 1982; Emery & Lythgoe, 1986; Irnich et al, 1997; Kreczi & Klingler, 1986; Loy, 1983; Lundeberg et al, 1991; Thomas et al, 1991)

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White P, Lewith G, Berman B, Birch S (2002) Reviews of acupuncture for chronic neck pain: pitfalls in conducting systematic reviews, *Rheumatology* 41: 1224-1231.

D. Inappropriate Control

- Gallacchi et al (1981) used sham acupuncture which might not be inactive
- Lundeberg et al (1991) & Thomas et al (1991) used superficial acupuncture which might have some physiological effect

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White P, Lewith G, Berman B, Birch S (2002) Reviews of acupuncture for chronic neck pain: pitfalls in conducting systematic reviews, *Rheumatology* 41: 1224-1231.

D. Inappropriate Control

- David et al (1998), Loy (1983) and Kisiel & Lindh (1996) used an active control (physiotherapy)
- Coan et al (1982) used a waiting list control

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White P, Lewith G, Berman B, Birch S (2002) Reviews of acupuncture for chronic neck pain: pitfalls in conducting systematic reviews, *Rheumatology* 41: 1224-1231.

E. Inappropriate Study Design

- Crossover studies might have carry-over effects that could contaminate the results (Emery & Lythgoe, 1986; Irnich et al, 1997; Kreczi & Klingler, 1986; Thomas et al, 1991)
- Only Petrie & Langley (1983) and Petrie & Hazleman (1986) should be included

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White P, Lewith G, Berman B, Birch S (2002) Reviews of acupuncture for chronic neck pain: pitfalls in conducting systematic reviews, *Rheumatology* 41: 1224-1231.

2. Inappropriate Quality Scale

- Modified Jadad scale was not validated
- Studies could be scored differently by different investigators
- Moderate to low interrater reliability of Jadad scale ($\kappa=0.37-0.39$; Clark et al, 1999)

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White P, Lewith G, Berman B, Birch S (2002) Reviews of acupuncture for chronic neck pain: pitfalls in conducting systematic reviews, *Rheumatology* 41: 1224-1231.

2. Inappropriate Quality Scale

- Too much emphasis on randomization and blinding without considering other aspects of “quality” of RCT in Jadad scale → RCTs with high Jadad score might in fact have low internal validity due to other methodological problems/errors

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Recommendations for Appraising SRs of Acupuncture

1. Complete Literature Search

- Inclusion of non-English studies (esp. Chinese, Japanese & Korean), grey literature to reduce biases (e.g. language bias)
(White et al, 2002b)

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2. Proper Inclusion & Exclusion Criteria

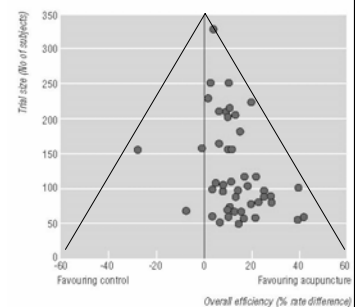
- Clear definition of acupuncture
- Restricting inclusion of studies to those using standard methods found in acupuncture books
- Separate (or subgroup) analysis for those controversial methods if included
(Birch, 2003)

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3. Proper Assessment of Quality of RCTs

A. Publication Bias

(Tang et al, 1999)



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3. Proper Assessment of Quality of RCTs

A. Publication Bias

Do Certain Countries Produce Only Positive Results? A Systematic Review of Controlled Trials

(Vickers et al, 1998)

Andrew Vickers, Niraj Goyal, Robert Harland, and Rebecca Rees

Research Council for Complementary Medicine, London, UK (A.V., R.R.); and Queen Mary & Westfield College, London, UK (N.G., R.H.)

Controlled Clinical Trials 19:159-166 (1998)

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Table 1 Results of Controlled Clinical Trials of Acupuncture by Country of Research

Country	Total Trials Analyzed	Favoring Test Treatment	
		Number	Percentage
USA	47	25	53
China	36	36	100
Sweden	27	16	59
UK	20	12	60
Denmark	16	8	50
Germany	16	10	63
Canada	11	3	27
Russia/USSR	11	10	91
Austria	9	8	89
Italy	9	8	89
Australia	6	1	17
France	6	5	83
Taiwan	6	6	100
Japan	5	5	100
Finland	4	2	50
Hong Kong	3	3	100
Netherlands	3	1	33
New Zealand	3	2	67
Poland	3	2	67
Switzerland	3	1	33
Bulgaria	2	2	100
Brazil	1	1	100
Croatia	1	1	100
Israel	1	1	100
Nigeria	1	1	100
Sri Lanka	1	0	0
Vietnam	1	1	100
Total	252	171	68

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3. Proper Assessment of Quality of RCTs

B. Recruitment of Homogeneous Patients

(Lewith, 2003)

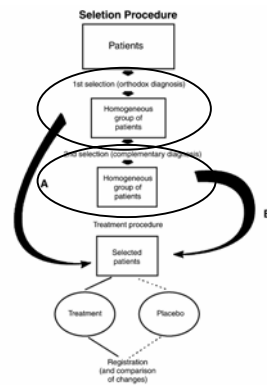


Fig. 3 A possible procedure employ the selection of patients for inclusion in clinical trials.

3. Proper Assessment of Quality of RCTs

C. Adequacy of Treatment

Establishing an Adequate Dose (Lao et al, 2001)

Establishing an adequate treatment/dose of acupuncture is one of the fundamental first steps of a trial. In the past, many acupuncture treatments used in trials have been shown to be inadequate according to minimal criteria [6 and see Chapt. 10]. The fundamental decisions a researcher must make when establishing an adequate acupuncture treatment pertain to:

1. Type of acupuncture treatment (e.g., TCM, Japanese, five-element)
2. Formulaic vs. individualized treatments
3. Qualifications/experience of the acupuncturist
4. Point selection
5. Depth and techniques of needle manipulation, i.e., manual (reinforced or reducing technique) or electrical stimulation (frequency and intensity)
6. Whether de qi will be pursued
7. Duration of each treatment
8. Number of treatments per week and spacing between treatments
9. Total number of treatments.

3. Proper Assessment of Quality of RCTs

C. Adequacy of Treatment

■ Use of BRITS method (Stux & Birch, 2001)

Selecting and Validating Test (Relevant) Treatment Points

The BRITS methodology for determining relevant treatment points uses the following guidelines:

1. Review treatment texts or papers directly related to the method or tradition of practice being tested. Confirm that all acupoints to be treated are recommended for the condition in a minimum number of sources, e.g., at least six.
2. Review other treatment texts to confirm that the treatment points are generally indicated in these other texts for the condition at hand. This step enhances the potential generalizability of the results and is optional, but preferred.
3. Test the treatment in a pilot study before going to a full-scale study. Data from the pilot study can help fine-tune the design and size of the larger follow-up studies. This step is preferable but not always necessary.

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3. Proper Assessment of Quality of RCTs

C. Adequacy of Treatment

■ Use of BRITS method (Stux & Birch, 2001)

Selecting and Validating Control (Irrelevant) Treatment Points

To determine control treatment points, the BRITS method uses the following steps:

1. Review the same treatment texts and papers used to validate the test acupoints and pick out the same number of inappropriate points as test points.
2. The selection criteria for these points should be:
 - A. They are hardly or not at all mentioned as being good for the condition or related conditions being treated in the study.
 - B. They are in similar regions of the body. The credibility of the control treatment will likely decrease if the treatment is perceived as being ridiculous or unrelated to the pain. Needling in the proximity of the pain will tend to appear more credible.
 - C. Always test the control treatment in a pilot study before going to a full-scale study. This will allow estimates of relative effectiveness of the control treatment to be made. These can then be used to determine the appropriateness of the control and make sample size calculations for larger scale studies [4, 6]. If the control treatment appears almost as effective as the test treatment, it may be an inappropriate control treatment. Additional steps may be required to investigate this further [49, 50].

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3. Proper Assessment of Quality of RCTs

C. Adequacy of Treatment

■ Examples (Stux & Birch, 2001)

Table 2. Recommended treatment outlines for low back pain

Source	Recommended number of treatment points	
Kwok et al. 1991	4/6/7/5/5/5/6 (7-14)	(18 texts)
Manaka 1970	6/3/2 (3-10)	
Shanghai Institute of TCM, n.d.	8-10/8-10/8-11/8-10/8-13 (10-26)	
O'Connor, Bensky 1981	6-10 (10-18) [10 or more sessions]	
Anon 1980	3/6/3 (5-10)	
Cheng 1987	5/5/3 (5-9)	
Feit, Zmiewski 1990	6/6/6 (10-11)	
Liu 1988	5/5/3 (6-10)	
Qiu, Su 1985	8/4/6/5 (7-15)	
Chen, Wang 1988	6 (12) (actual cases) [15 sessions]	
So 1987	5 (9) [over 10 sessions for chronic pain]	
Miao 1974	6 (12)	
Tianjin Chinese Med Coll 1988	6/4 (7-10)	
Stux, Pommeranz 1988	5+3+4 (10-14)	
Nagahama et al 1982	Up to 14 depending on pressure pain (probably 10-16)	
Kinoshita 1983	7/6/8/up to 5 (10-14)	
Ikeida 1985	10-14/8-12/6/10-13/12 (12-28)	
Lee, Cheung 1978	6/5 (10-11)	

The entry "6/6/5" indicates three alternative treatments (including treatments according to differential diagnostic patterns) with six, six, and five points listed, respectively. The entry "10-11" indicates that from 10 to 11 discrete sites are treated. N.d., no year given.

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3. Proper Assessment of Quality of RCTs

C. Adequacy of Treatment

■ Examples (Stux & Birch, 2001)

Table 3. Summary of low back pain treatments in TCM related acupuncture texts [12]

Source	N patterns	N points	(16 texts)
1. Kwok et al 1991	7	Mean 5.7 points (10.3-10.5 discrete sites)	
2. Manaka 1970	3	Mean 3.7 points (6.3 discrete sites)	
3. Shanghai Institute of TCM, n.d.	5	Mean 8.2 points (14.6 discrete sites)	
4. O'Connor, Bensky 1981	3	Mean 6 points (11-12 discrete sites)	
5. Anon 1980	3	Mean 4.7 points (7.7 discrete sites)	
6. Chang 1987	4	Mean 5 points (8.3-8.5 discrete sites)	
7. Feit, Zmiewski 1990	4	Mean 6 points (10.3-10.5 discrete sites)	
8. Liu 1988	4	Mean 3.8 points (6.3-7.3 discrete sites)	
9. Qiu, Su 1985	3	Mean 4 points (6.7-7.3 discrete sites)	
10. Wiseman, Feng 1998	19	Mean 7.6 points (12.9-13.8 discrete sites)	
11. Ying, De 1997	4	Mean 5 points (9.3-9.5 discrete sites)	
12. Liu 1996	4	Mean 9.5 points (17-17.5 discrete sites)	
13. Geng, Su 1991	3	Mean 5.7 points (9.3-10.3 discrete sites)	
14. Maccioia 1994	3	Mean 12 points (15-19 discrete sites)	
15. Zheng 1990	3	Mean 6 points (11-11.3 discrete sites)	
16. Wu, Fischer 1997	5	Mean 6.2 points (10.6-10.8 discrete sites)	

N.d., no year given. (Minimum: 10 discrete sites; 10 sessions)

3. Proper Assessment of Quality of RCTs

C. Adequacy of Treatment

■ Examples (Stux & Birch, 2001)

Table 4. Summary of neck pain, headache, and asthma treatment recommendations

Condition	N sources consulted	N points recommended	N sessions recommended	Minimal adequate treatment
Neck pain	12 Chinese, Japanese, and English	4-11 points, mean 6-7.5 points, 7-20 discrete sites; mean 10.5-13.8 sites	At least 10	At least 11 sites in each of at least 10 sessions
Headache	15 Chinese, Japanese, and English	4-21 points, mean 7.3-11.4 points; 5-24 discrete sites, mean 10.8-14.5 sites	At least 10	At least 11 sites in each of at least 10 sessions
Asthma (long-term treatment, not relief of acute attack)	22 Chinese, Japanese, and English	4-17 points, mean 8.3-8.9 points; 5-30 discrete sites, mean 12.2-16.8 sites	At least 10 and probably more than 20	At least 12 sites each in more than 10 sessions

3. Proper Assessment of Quality of RCTs

C. Adequacy of Treatment

■ Survey of 136 Italian MDs (Romoli et al, 2003)

Table 1 Median of the scores > 8

	All	Teachers	Non-teachers	Practice <13 years	Practice ≥13 years
Individualized treatment	10	10	10	10	10
Needle sensation induced	9	10	9	9	9
Selection points TCM	8	10	8	8	9
Depth of needling	8	9	8	8	9, 10
WHO Int. nomenclature of points (1987)	8	8, 9	8	8	8
Duration of needling	8	8	8	8	8
Number of repetitions	8	8	8	8	8
Frequency of repetitions	8	8	8	8	8
Stimulation chosen (manual, electrical and moxa)	8	8	8	8	8
Changing of points from one session to the other	8	8	8	8	8
Electrical stimulation	8	8	8	8	9
Duration of stimulation	8	8	8	8	8
Strength of stimulation	8	8	7	8	8
Wave-form	8	7	8	8	7

3. Proper Assessment of Quality of RCTs

C. Adequacy of Treatment

■ Standards for Reporting Interventions in Controlled Trials of Acupuncture – STRICTA Recommendations

Table 1 Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) - Items to include when reporting on the interventions in a randomised controlled trial of acupuncture.

Intervention	Item	Description	Reported on page #
Acupuncture rationale	1	Style of acupuncture Rationale for treatment (e.g. syndrome patterns, segmental levels, trigger points) and individualisation if used Literature sources to justify rationale	
Needling details	2	Points used (uni/bilateral) Numbers of needles inserted Depths of insertion (e.g. tissue level, mm or cun) Responses elicited (e.g. de qi or twitch response) Needle stimulation (e.g. manual or electrical) Needle retention time Needle type (gauge, length, and manufacturer or material)	(MacPherson et al, 2001)
Treatment regimen	3	Number of treatment sessions Frequency of treatment	
Co-interventions	4	Other interventions (e.g. moxibustion, cupping, herbs, exercises, life-style advice)	
Practitioner background	5	Duration of relevant training Length of clinical experience Expertise in specific condition	
Control intervention(s)	6	Intended effect of control intervention and its appropriateness to research question and, if appropriate, blinding of participants (e.g. active comparison, minimally active penetrating or non-penetrating sham, inert) Explanations given to patients of treatment and control interventions Details of control intervention (precise description, as for Item 2 above, and other items if different) Sources that justify choice of control	

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3. Proper Assessment of Quality of RCTs

D. Credibility of Control

Use of placebo control

- To facilitate blinding
- To control for placebo effect

Table 2 Overview of sham interventions used in the 47 trials

Category	(Dincer & Linde, 2003)	Trials
I	Superficial needling of "true" acupuncture points	2
II	Irrelevant acupuncture points	4
III	Non-acupuncture points	27
	Sum of trials with a 'penetrating' sham	33
IV	Placebo needles	5
V	Pseudo-interventions	9
	Sum of trials without skin penetration	14

3. Proper Assessment of Quality of RCTs

D. Credibility of Control

(Lao et al, 2001)

Type of control	Questions asked	Advantages	Disadvantages
Waiting list (delayed treatment)	Is acupuncture more effective than no treatment?	Controls for disease remissions all patients receive treatment	Does not control for placebo effects
Nonacupuncture inert controls (sham TENS, sugar pills)	Is acupuncture more effective than a placebo?	Controls for some placebo effects	Does not resemble acupuncture; cannot blind patients
Placebo acupuncture (noninserted needle)	Is acupuncture more effective than placebo?	Resembles real acupuncture; patients can be blinded; eliminates the possibility of non-specific needling effects	Difficult to implement in long-term studies; may be effective only for acupuncture-naïve patients; does not test for specificity of acupuncture
Sham acupuncture (inserted needle)	Is real acupuncture more effective than sham acupuncture? Does real acupuncture have point-specific effects on the condition under investigation?	Resembles real acupuncture; patients can be blinded	Likely to produce non-specific physiological effects of needling
Combined controls (e.g. placebo acupuncture plus sham acupuncture)	What is the magnitude of placebo acupuncture (no treatment vs. placebo)? What is the magnitude of nonspecific effects (placebo vs. sham)?	The two treatments resemble each other, so patients can be blinded; can minimize nonspecific needling effects of sham	If placebo acupuncture is used, it may be difficult to implement in long-term studies
Positive controls (standard medical care)	Is acupuncture equivalent superior to standard medical care or is it, when combined with standard care, more effective than standard care alone?	Compares the effectiveness of acupuncture as replacement or adjunctive care; has practical value, since cost effectiveness, adverse effects, and efficacy can be compared	Cannot blind patients or practitioners; may risk a type II error (where the two treatments are believed to be equivalent but, in reality, one is better)

3. Proper Assessment of Quality of RCTs

D. Credibility of Control

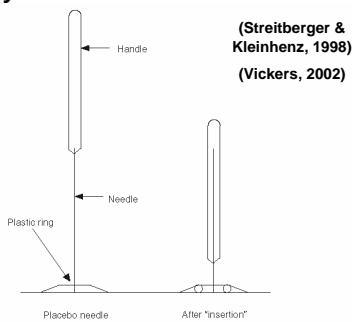


Figure 1: The Placebo Needle Appears to Have Been Inserted But Does Not Actually Penetrate the Skin. 57

3. Proper Assessment of Quality of RCTs

E. Success in Patient Blinding

■ Credibility of Treatment Rating Scale

- 5-point Likert Scale (Strongly disagree to Strongly agree)

- 1 How confident do you feel that this treatment can alleviate your complaint?
- 2 How confident would you be in recommending this treatment to a friend who suffered from similar complaints?
- 3 How logical does this treatment seem to you?
- 4 How successful do you think this treatment would be in alleviating other complaints?

(Vincent & Lewith, 1995)

- Direct question: Do you think you are receiving active treatment?

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Take-Home Messages

- Beware of pitfalls in SRs of RCTs of acupuncture
- Need to appraise SRs of RCTs of acupuncture critically
- High-quality RCTs of acupuncture in studying efficacy of analgesic effects of acupuncture are urgently needed

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