

## The Efficacy of Analgesic Effects of Acupuncture

### (2) An Alternative Explanation of its Efficacy

**Raymond Tsang**  
 MSc(PT)  
 SPT, AP(MS),  
 Queen Mary Hospital  
 14<sup>th</sup> June 2005

## 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, 1.37	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 injection; limited evidence that acupuncture was not more effective than placebo	Effectiveness remains unclear

(Kaptchuk, 2002) 2

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

Osteoarthritis	Ernst (37)	1997	12†	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)	1998	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 8 trials	Insufficient evidence for claiming 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) 3

## Review of 2 RCTs of Acupuncture to:

- Patients with CLBP
- Patients after dental surgery

### With focus on the Effects of Patient Expectations on Treatment Outcomes

4

## Randomized Trial Comparing Traditional Chinese Medical Acupuncture, Therapeutic Massage, and Self-care Education for Chronic Low Back Pain

Daniel C. Cherkin, PhD; David Eisenberg, MD; Karen J. Sherman, PhD; William Barlow, PhD;  
 Ted J. Kaptchuk, OMD; Janet Street, RN, MN, PNP; Richard A. Deyo, MD, MPH  
 Arch Intern Med. 2001;161:1081-1088

- To compare the effectiveness of acupuncture, therapeutic massage, and self-care education for persistent back pain

5

```

    graph TD
      A[693 Potentially Eligible Patients With Back Pain Responded to Invitation Letter] --> B[262 Randomized]
      A --> C[431 Not Randomized:  
• Unable to contact 47  
• Ineligible: 297  
• Not evaluated because enrollment closed: 77  
• Did not consent: 10]
      B --> D[Acupuncture n=94]
      B --> E[Massage n=78]
      B --> F[Self-care n=90]
      D --> G[88 (94%) Received Acupuncture Follow-up:  
4 wk: 92 (98%)  
10 wk: 89 (95%)  
52 wk: 90 (96%)]
      E --> H[74 (95%) Received Massage Follow-up:  
4 wk: 75 (96%)  
10 wk: 77 (99%)  
52 wk: 76 (97%)]
      F --> I[90 (100%) Were Mailed Self-care Materials Follow-up:  
4 wk: 83 (92%)  
10 wk: 83 (92%)  
52 wk: 83 (92%)]
  
```

(Cherkin et al, 2001)

Figure 1. Trial profile. None of the 262 randomized patients withdrew because of adverse events.

6

## Treatment Practitioners

- Licensed acupuncturists and massage therapists as members of CAM practitioner network used by HMO
- 7 acupuncturists and 12 massage therapists with at least 3 years of experience

7

## Treatment Protocols

### 1. Acupuncture

- Basic TCM needling techniques, electrical stimulation and manual manipulation of needles, indirect moxibustion, infrared heat, cupping, and exercise recommendations
- Varying number and location of needles
- Up to 10 visits over 10 weeks

8

## Treatment Protocols

### 2. Massage

- Manipulation of soft tissue (muscles and fascia)
- Swedish, deep-tissue, neuromuscular, trigger and pressure point techniques
- Up to 10 visits over 10 weeks

9

## Treatment Protocols

### 3. Self-care Education

- A book "Back Pain (Recurrent): Self-care Companion for Better Living" and 2 professionally produced videotapes (40-min videotape on self-management of back pain and 25-min videotape demonstrating exercises)

10

Table 1. Baseline Characteristics of 262 Patients With Low Back Pain (LBP) by Treatment Group\*

Characteristic	Patients, No.	Treatment Group			Total
		Acupuncture (n = 94)	Massage (n = 78)	Self-care (n = 90)	
Age, mean (SD), y	262	45.3 (11.5)	45.7 (11.4)	43.8 (11.7)	44.9 (11.5)
Women, %	262	52	69	56	58
Attending some college, %	262	78	82	78	79
White, %	262	82	82	89	84
Family income >\$35,000, %	240	55	59	71	62
Employed or self-employed, %	262	82	90	82	84
SF-12 Physical Health Score score, mean (SD)	257	37.0 (9.4)	37.1 (8.6)	36.3 (9.8)	36.9 (9.2)
SF-12 Mental Health Score score, mean (SD)	257	48.9 (10.7)	49.7 (10.8)	48.8 (10.9)	49.1 (10.8)
First sought LBP care >1 ago, %	261	82	81	85	83
Ever hospitalized for back problem, %	262	11	10	7	9
Have had a lower back operation, %	262	5	5	8	6
Previous acupuncture for LBP, %	262	3	1	4	3
Previous massage for LBP, %	262	14	14	19	16
Pain has faded <4 yr, %	257	37	36	33	31
≥90 d of LBP in the past 6 mo, %	261	63	69	66	66
Pain below the knee, %	262	24	24	29	26
Symptoms most of past 24 h, %	262	33	21	62	61
Symptom bothersomeness during the past week (0-10 scale), mean (SD)	262	6.2 (1.8)	6.2 (1.9)	6.1 (2.0)	6.2 (1.9)
Roland Disability Scale score (0-23 scale), mean (SD)	262	12.8 (5.3)	11.8 (4.4)	12.0 (5.3)	12.2 (5.0)
≥1 Work-loss day due to LBP in the past month, %	233	26	14	26	22
>7 d of restricted activity due to LBP in the past month, %	259	48	36	41	42
Used medication for LBP in the past week, %	262	69	73	63	68
Taking narcotic analgesics, %	262	9	12	9	10
Very satisfied with overall care for LBP, %	232	8	3	6	6

\* There were no significant differences among the 3 treatment groups for any of the characteristics (P > .05).

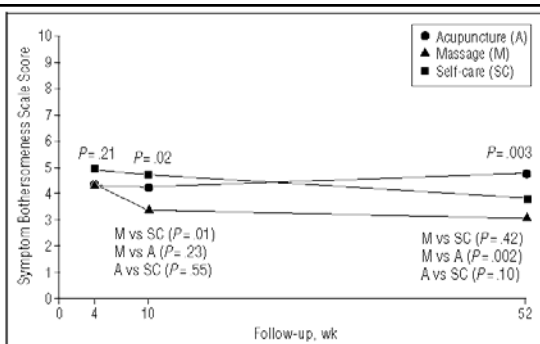
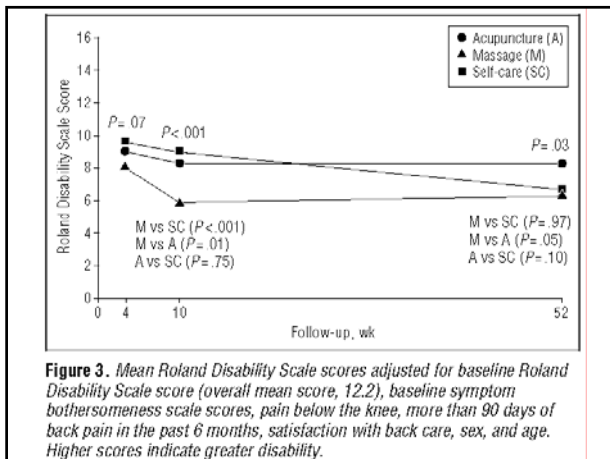


Figure 2. Mean symptom bothersomeness scale scores adjusted for baseline bothersomeness score (overall mean score, 6.2), baseline Roland Disability Scale score, pain below the knee, more than 90 days of back pain in the past 6 months, satisfaction with back care, sex, and age. Higher scores indicate more severe symptoms.



The results of this study suggest that massage is an effective short-term treatment for chronic low back pain, with benefits that persist for at least 1 year. Self-care educational materials had little early effect but, by 1 year, were almost as effective as massage. We were unable to

Because we did not include a “no treatment” or “standard care only” control group, the results might underestimate the value of all 3 treatments. However, if acupuncture has a positive effect, it seems to be concentrated during the first 4 weeks because there was little improvement thereafter. During the first 4 weeks, all 3 groups improved by similar amounts, reflecting either the natural course of back pain, equivalent early effectiveness of all 3 treatments, or both.

SPINE Volume 26, Number 13, pp 1418-1424  
©2001, Lippincott Williams & Wilkins, Inc.

**Lessons from a Trial of Acupuncture and Massage for Low Back Pain**

Patient Expectations and Treatment Effects

Donna Kalaoukalani, MD, MPH,\* Daniel C. Cherkin, PhD,† Karen J. Sherman, PhD,‡  
Thomas D. Koepsell, MD, MPH,§ and Richard A. Deyo, MD, MPH||

- **To examine whether patient expectations regarding benefit from a specific treatment were associated with functional improvement**

15

## Data Collection

- **Patient expectations about therapeutic benefit from each of treatment (acupuncture and massage) were assessed before randomization, to reduce bias**
- **Patients were asked to rate how helpful they believed each treatment would be for their current back problems on 11-point scale (0=“not at all helpful” to 10=“extremely helpful”)**

16

## Data Collection

- **Patients were also asked to describe their expectations for improvement of their back pain without regard to treatment using a 7-point Likert scale from “completely gone” to “much worse”**

17

## Expectation Variables

1. Expectation for Treatment Benefit
  - **E<sub>m</sub>**=rating of believed helpfulness of massage for current back problem (0-10)
  - **E<sub>a</sub>**=rating of believed helpfulness of acupuncture for current back problem (0-10)

18

## Expectation Variables

### 1. Expectation for Treatment Benefit

- Ratings of 8-10: higher expectations for benefit
- Ratings of 0-7: lower expectations for benefit

19

## Expectation Variables

### 2. Relative Expectation for Treatment Benefit

- $E_m - E_a$  = difference between ratings of believed helpfulness of massage and ratings of believed helpfulness of acupuncture
- A positive difference implied higher expectations for benefit from massage than from acupuncture

20

## Expectation Variables

### 3. Average Expectation for Treatment Benefit

- $(E_m + E_a)/2$  = average of expectation ratings for massage and acupuncture

21

## Expectation Variables

### 4. General Expectation regarding Prognosis

- “One month from now, do you expect your back or leg pain to be 1 (completely gone), 2 (much better), 3 (moderately better), 4 (a little better), 5 (about the same), 6 (a little worse), or 7 (much worse)?”

22

## Expectation Variables

### 4. General Expectation regarding Prognosis

- Ratings 1 to 3 – expectations of back pain to be at least moderately better in 1 month
- Ratings 4 to 7 – expectations of back pain “not” to be at least moderately better in 1 month

23

**Table 1. Baseline Characteristics of Subjects by Level of Expectation for Treatment Received**

Sociodemographic Characteristics	Expectations about the Helpfulness of the Randomly Assigned Treatment			P
	All Patients	Higher (n = 68)	Lower (n = 69)	
Age, mean years (SD)	44 (11)	45 (12)	43 (10)	0.43
Woman (%)	63	70	57	0.11
Attended some college (%)	79	71	82	0.11
Caucasian (%)	81	83	78	0.48
Family income >\$5,000 (%)	53	48	58	0.45
Employed/self-employed (%)	87	83	91	0.16
Married (%)	64	64	64	0.99
Single/separated (%)	29	24	16	0.23
SF-12 Physical Health Scale, mean (SD)	37.3 (9)	36.7 (9)	38.8 (9)	0.95
SF-12 Mental Health Scale, mean (SD)	46.8 (16.2)	44.6 (14)	50.2 (19)	0.68
Low Back Pain History				
Previous Low Back Surgery (%)	4	3	6	0.44
Previous injection for Back/Leg Pain (%)	17	18	16	0.70
Prior use of Acupuncture (%)	2	2	3	0.59
Prior use of Massage (%)	16	23	19	0.06
Current Back Symptoms				
> 7 days restricted activity due to LBP in past month (%)	41.5	43.9	39.1	0.48
limited regular daily activities or accomplishments in past month (%)	77.8	83.3	72.5	0.13
Mean symptom bothersomeness past week (0-10 scale) (SD)	6.14 (1.9)	6.38 (1.9)	5.33 (1.8)	0.17
Mean Roland Score (0-23 scale) (SD)	12.1 (4.9)	13.2 (4.6)	11.1 (4.9)	0.01
Expect LBP to be at least moderately better in one month (%)	31.5	27.5	36.2	0.26
LBP symptoms more than a year (%)	79.3	83.3	75.4	0.25
Assigned Study Treatment				
Acupuncture (%)	55	48	61	0.15

24

**Table 2. 10-week Outcomes According to Treatment Expectations**

Functional Outcome	All Patients	Baseline Expectations for Benefit from the Treatment Received		P
		Higher (n = 66)	Lower (n = 66)	
Mean Baseline Roland score (SD)	12.1 (4.9)	13.2 (4.6)	11.1 (4.9)	0.01
Mean 10-week Roland score (SD)	6.8 (6.2)	6.4 (6.2)	7.1 (6.2)	0.50
Mean Change from Baseline Roland score (SD)	-5.3 (5.3)	-6.8 (5.9)	-4.0 (4.3)	0.00
Improved Roland score (at least 2 points) (%)	77	86	68	0.01
Symptoms				
Mean 10-week symptom bothersomeness score past week (0-10 scale) (SD)	3.7 (3.0)	3.5 (2.8)	3.8 (3.2)	0.50
Mean change from baseline symptom bothersomeness score (SD)	-2.5 (2.9)	-2.9 (2.9)	-2.1 (3.0)	0.12
Satisfaction				
Mostly or very satisfied with care (%)	77	83	71	0.09
Health Status				
SF-12 Physical Health Scale, mean (SD)	44.2 (10.6)	44.0 (11.2)	44.3 (10.4)	0.87
Mean Change from baseline SF-12 Physical Health Scale	6.9 (9.7)	8.5 (9.7)	5.5 (9.5)	0.06
SF-12 Mental Health Scale, mean (SD)	51.5 (10.4)	52.9 (8.4)	50.2 (11.1)	0.14
Mean Change from baseline SF-12 Mental Health Scale	1.7 (9.9)	3.9 (10.5)	-0.35 (8.87)	0.01

■ "... more improved Roland scores were found among participants with higher expectations for benefit from their assigned treatment (86%) than among those with lower expectations (68%) ( $p < 0.01$ )"

25

**Table 2. 10-week Outcomes According to Treatment Expectations**

Functional Outcome	All Patients	Baseline Expectations for Benefit from the Treatment Received		P
		Higher (n = 66)	Lower (n = 66)	
Mean Baseline Roland score (SD)	12.1 (4.9)	13.2 (4.6)	11.1 (4.9)	0.01
Mean 10-week Roland score (SD)	6.8 (6.2)	6.4 (6.2)	7.1 (6.2)	0.50
Mean Change from Baseline Roland score (SD)	-5.3 (5.3)	-6.8 (5.9)	-4.0 (4.3)	0.00
Improved Roland score (at least 2 points) (%)	77	86	68	0.01
Symptoms				
Mean 10-week symptom bothersomeness score past week (0-10 scale) (SD)	3.7 (3.0)	3.5 (2.8)	3.8 (3.2)	0.50
Mean change from baseline symptom bothersomeness score (SD)	-2.5 (2.9)	-2.9 (2.9)	-2.1 (3.0)	0.12
Satisfaction				
Mostly or very satisfied with care (%)	77	83	71	0.09
Health Status				
SF-12 Physical Health Scale, mean (SD)	44.2 (10.6)	44.0 (11.2)	44.3 (10.4)	0.87
Mean Change from baseline SF-12 Physical Health Scale	6.9 (9.7)	8.5 (9.7)	5.5 (9.5)	0.06
SF-12 Mental Health Scale, mean (SD)	51.5 (10.4)	52.9 (8.4)	50.2 (11.1)	0.14
Mean Change from baseline SF-12 Mental Health Scale	1.7 (9.9)	3.9 (10.5)	-0.35 (8.87)	0.01

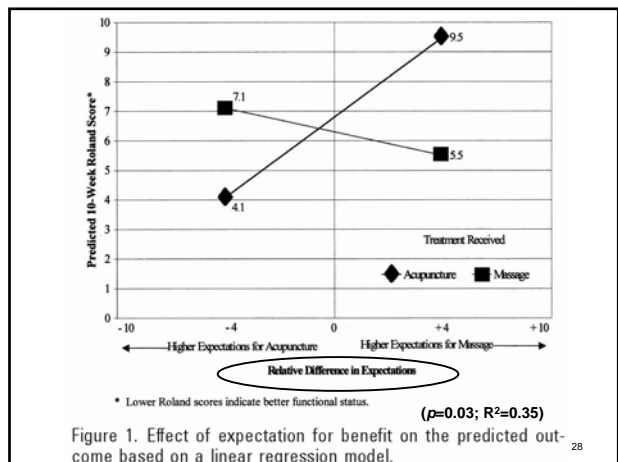
■ "The improvement in Roland disability scores from baseline to follow-up assessment also was significantly greater in the higher expectations group than in the lower expectation group (-6.8 points vs -4.0 points, respectively,  $p < 0.002$ )"

26

**Expectations – Higher vs Lower**

■ "Using logistic regression and adjusting for potential confounders (baseline Roland score, treatment, age, gender, education, physical health status, and prior use of massage), the relative odds [OR] of improvement for a participant with higher expectations as compared with a participant who had lower expectations was 5.3 (95% CI 1.9-15.4,  $p = 0.002$ )"

27



**Relative Strength of Expectation**

Among the participants with higher relative expectations for massage (e.g., a relative expectation score of +4), estimates of 10-week Roland scores were better (lower) if the participants had received massage than if they had received acupuncture. Alternatively, the 10-week Roland score estimates for the participants with higher relative expectations for acupuncture (e.g., a relative expectation score of -4) were better if the participants had received acupuncture than if they had received massage. Thus, regardless of the treatment received, the effect of the treatment depended on the magnitude of relative expectations.

29

**Relative Strength of Expectation**

more, the analyses suggest that the strength of expectation for benefit from one treatment versus another treatment modified the effect of the treatment received. Thus, the participants with strong relative expectations for a specific treatment had significantly better functional outcomes if they received that treatment.

30

## Importance of Effective Blinding in RCTs

These results also highlight the importance of effectively masking the treatment received in clinical trials. This masking is relatively easy in some drug trials, but more difficult in trials of physical treatments, devices, or procedures. Nonetheless, control treatments not only should mimic the active treatment as closely as possible, but also should seek to mimic levels of expectations. Innovation and pilot testing

31

## IS ACUPUNCTURE ANALGESIA AN EXPECTANCY EFFECT?

Preliminary Evidence Based on Participants' Perceived Assignments in Two Placebo-Controlled Trials

R. BARKER BAUSELL  
*University of Maryland School of Nursing*  
LIXING LAO  
*University of Maryland School of Medicine*  
STEWART BERGMAN  
*University of Maryland School of Dentistry*  
WEN-LIN LEE  
BRIAN M. BERMAN  
*University of Maryland School of Medicine*

EVALUATION & THE HEALTH PROFESSIONS, Vol. 28 No. 1, March 2005 9-26

■ To evaluate the analgesic efficacy of acupuncture for dental pain after surgery, compared to 3 different placebo conditions

■ To assess the degree to which these sham procedures were distinguishable from actual therapy

32

## Experiment 1

### 1. Active acupuncture

- TCM acupuncture – acupuncture needles (2.5cm, 32 gauge) inserted to a depth of 0.8 to 1.3cm into 4 points, with a piece of tape placed next to each needle
  - 3 in face (Jiache 頰車 ST6; Xiaguan 下關 ST7; Yifeng 翳風 TE17)
  - 1 in hand (Hegu 合谷 LI 4)
- One sham non-insertion at medial aspect of knee (1cm posterior to Ququan 曲泉 LR 8)

33

## Experiment 1

### 1. Active acupuncture

- Needles were manipulated 3 times to elicit “De Qi” at:
  - during initial insertion
  - at mid-point of 20-min treatment
  - at the end of treatment session
- All treatments were performed by one of 4 licensed acupuncturists

34

## Experiment 1

### 2. Placebo 1

- Sham non-insertion adjacent to acupuncture points; distal sham shallow insertion at non-point
- 5 points were employed – sham non-insertion at same 4 classic acupuncture points and one sham shallow insertion (0.3 to 0.8cm) in the classic mode at non-active point of knee

35

## Experiment 1

### 3. Placebo 2

- Sham shallow insertion adjacent to acupuncture points; distal sham non-insertion at non-point
- 5 points were employed – sham shallow insertion at 4 non-acupuncture points (at least 3cm away from classic points) and one sham non-insertion at the non-active point of knee

36

## Experiment 1

- All participants' eyes were covered during the application of all procedures, true or sham
- A mock electrical stimulation unit equipped with a blinking light was employed for all participants in all conditions to further facilitate masking
- Patients were told that they might or might not feel electrical current because of the nature of the device

37

## Experiment 1

- VAS on pain was administered immediately on a fixed, 15-min schedule for 6 hours
- Patients with a report of a pain rating of  $\geq 3/10$  and "moderate/severe pain" on a supplementary 4-point rating scale would be given the same acupuncture treatment second time, followed by a second blinding check
- Pain assessments were resumed for 2 hr unless patient requested rescue medication

38

## Experiment 1

### End-points

- Pain-free time from initial acupuncture session until reporting of moderate or severe pain (or a total of 360 min for those patients without moderate/severe pain)
- Mean of all pain VAS assessed prior to the second acupuncture session or end of the experiment

39

## Experiment 2

- Same inclusion criteria, randomization and blinding protocol, end-points, assessment procedures, and acupuncture intervention
- 180 patients were recruited
- First placebo condition was replaced using a sham non-insertion procedure next to all 5 acupuncture points
- Setting from UMB Dental Clinic to a private research clinic for dental trials

40

TABLE 1  
Effects of Acupuncture on Postoperative Dental Pain

	True Acupuncture (Experimental)		Placebo Acupuncture (Combined Controls)		p
	Mean (95% CI)	n	Mean (95% CI)	n	
Experiment 1					
Pain-free time	163.5 (125.4-201.6)	40	160.2 (132.9-187.5)	80	.89
Mean of pain VAS: first to second treatment	24.1 (18.3-29.9)	40	24.9 (20.2-29.6)	120	.83
Experiment 2					
Pain-free time	215.6 (180.8-250.4)	59	177.5 (152.5-202.4)	117	.08
Mean of pain VAS: first to second treatment	24.7 (19.6-29.8)	60	28.7 (24.3-33.2)	120	.27
Experiments 1 and 2					
Pain-free time	194.6 (168.7-220.5)	99	170.5 (152.1-188.9)	197	.14
Mean of pain VAS: first to second treatment	24.5 (20.7-28.2)	100	27.2 (24.0-30.5)	200	.30

NOTE: VAS = visual analogue scale.

The authors stated that "... acupuncture was not effective for reducing pain following dental surgery." (p.17)

41

## Blinding Success

TABLE 2  
Combined Results for Patient Beliefs Regarding Group Membership (Blinding Success)

	Patients Who Believed They Were Receiving True Acupuncture	Patients Who Were Unsure Which Treatment They Were Receiving	Patients Who Believed They Were Receiving One of the Placebo Treatments	p
	n (%)	n (%)	n (%)	
True (acupuncture)	43 (43.0%)	53 (53.0%)	4 (4.0%)	.001
Placebo groups (C)	61 (30.5%)	100 (50.0%)	39 (19.5%)	

"... the experimental procedures were more effective in disguising group membership for placebo than for experimental patients." (p.18)

42

## Patient Beliefs on Pain

TABLE 3  
Effects of Patient Belief on Pain

	Patients Who Believed They Were Receiving True Acupuncture		Patients Who Were Unsure Which Treatment They Were Receiving		Patients Who Believed They Were Receiving One of the Placebo Treatments		p
	Mean (95% CI)	n	Mean (95% CI)	n	Mean (95% CI)	n	
Experiment 1							
Pain-free time	196.0 (149.2-242.9)	31	153.5 (125.7-181.3)	71	132.3 (74.2-190.4)	18	.14
Mean of pain VAS: first to second treatment	17.5 (13.6-21.3)	31	24.7 (20.1-29.3)	71	36.8 (22.6-51.0)	18	.004
Experiment 2							
Pain-free time	221.1 (190.4-251.8)	72	190.6 (159.0-222.2)	79	100.5 (61.6-139.5)	25	.001
Mean of Pain VAS: first to second treatment	22.5 (17.3-27.6)	73	27.0 (22.5-31.5)	82	42.9 (31.7-54.1)	25	.001
Experiment 1 and 2							
Pain-free time	215.5 (188.2-238.9)	103	173.1 (151.9-194.2)	150	113.8 (81.7-145.9)	43	<.001
Mean of pain VAS: first to second treatment	21.0 (17.2-24.8)	104	26.0 (22.8-29.2)	153	40.4 (31.9-48.8)	43	<.001

NOTE: VAS = visual analogue scale.

“... beliefs regarding group membership significantly predicted both the amount of pain experienced and pain-free time (i.e., time to moderate pain) for the combined data ( $p < 0.001$ ).” (p.18)

43

## Effects of Second Acupuncture Treatment

Effects of the second acupuncture treatment. Because slightly more than two thirds of the sample received a second acupuncture treatment (due to their experiencing significant levels of pain over the course of the experiments), the analyses depicted in Tables 1 and 3 were repeated with the following exceptions: (a) The average pain experience following the second acupuncture session served as the outcome (pain-free time could no longer be employed because individuals were given rescue medication once they reported experiencing a moderate degree of pain) and (b) patient guesses regarding which treatment they believed that they were receiving following two acupuncture sessions served as the three belief groups.

44

## Effects of Second Acupuncture Treatment

Based on the results already presented, the following a posteriori hypotheses appeared appropriate:

1. There should be no actual treatment effect for pain based on the second acupuncture procedure. As expected, there were no statistically significant differences between patients who actually received a second acupuncture treatment versus a second placebo treatment ( $t < 1$  [ $df = 205$ ],  $p = .42$ ).
2. Given that 46% of patients changed their beliefs regarding the treatment they received from the first to the second acupuncture treatment, initial beliefs regarding the treatment received should no longer be predictive of the pain experienced following the second acupuncture treatment. For the 208 patients who received a second treatment, there were no statistically significant differences with respect to whether these individuals had initially believed that they were receiving real acupuncture, placebo, or were not sure and the pain they experienced following the second treatment administration ( $F < 1$  [2, 204],  $p = .98$ ).

## Effects of Second Acupuncture Treatment

3. Beliefs regarding treatment received following the second treatment administration should be significantly associated with subsequent pain (mirroring the direction presented in Table 3). As compared to the first treatment, more patients were uncertain regarding the treatment that they were receiving following their second treatment and were more likely to believe that they had actually received acupuncture. The numbers believing that they were receiving a placebo treatment, however, were almost identical across the two administrations (39 vs. 38). As shown in Table 4, although the pain had increased in all three groups (due to the time-limited effect of the local anesthetic), patients' beliefs regarding treatment receipt significantly predicted the amount of pain that they experienced following their second acupuncture/placebo treatment ( $F = 10.5$  [2, 204],  $p < .001$ ). As was the case for beliefs regarding the first treatment administration, post hoc tests indicated that it was only the individuals who believed that they were receiving a placebo who differed significantly from the other two groups.

## Effects of Second Acupuncture Treatment

TABLE 4  
Effects of Patient Belief on Pain for the Second Treatment Administration

	Patients Who Believed They Were Receiving True Acupuncture		Patients Who Were Unsure Which Treatment They Were Receiving		Patients Who Believed They Were Receiving One of the Placebo Treatments		p
	Mean (95% CI)	n	Mean (95% CI)	n	Mean (95% CI)	n	
Experiment 1							
Mean of pain VAS following second treatment	37.8 (30.7-44.8)	26	45.0 (38.7-51.3)	44	61.6 (51.8-71.3)	22	<.001
Experiment 2							
Mean of pain VAS following second treatment	45.0 (40.6-52.2)	49	51.3 (45.6-56.0)	49	61.2 (51.1-71.4)	17	.033
Experiment 1 and 2							
Mean of pain VAS: first to second treatment	43.1 (38.3-47.9)	75	48.3 (44.1-52.5)	93	61.4 (54.7-68.2)	39	<.001

NOTE: VAS = visual analogue scale.

47

## Patient Beliefs on Pain

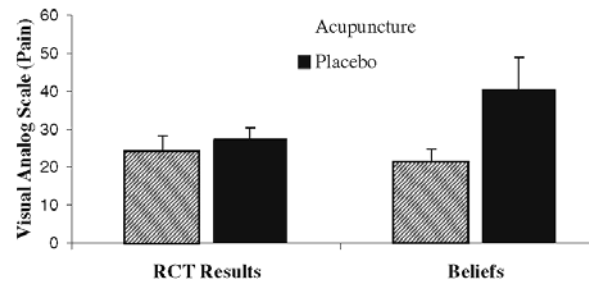


Figure 1: Differences Between Beliefs and Reality: Acupuncture Versus Placebo Effects on Pain

## Trial Conclusion

in this context, an impotent treatment (see Figure 1). We also believe that these experiments have provided additional evidence supporting the importance of (a) employing credible controls for the placebo effect in all clinical trials (Miller, Emanuel, Rosenstein, & Straus, 2004) and (b) actually checking the credibility of those controls. And, finally, until a reasonable body of evidence accrues from such research to the contrary, it may well be that the most parsimonious explanation for our results is that acupuncture analgesia is in reality nothing more than an expectancy effect.

49

## Observed Treatment Effects

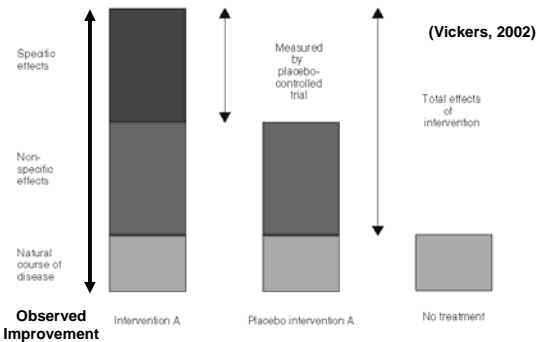


Figure 2: Elements of an Apparent Treatment Effect: Placebo-Controlled Trials Measure on the Specific Effects of an Intervention

## Acupuncture as Complex Intervention

(Paterson & Britten, 2004)

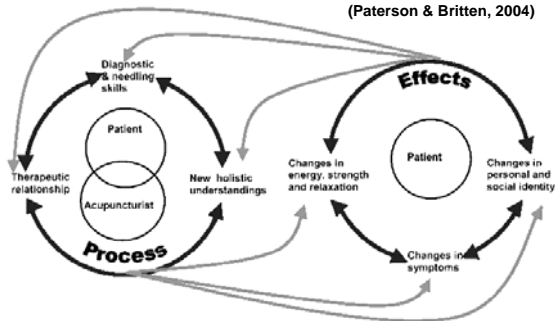
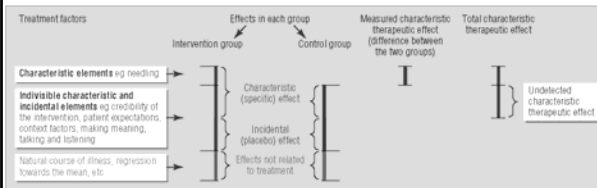


FIG. 1. Model of treatment by professional acupuncturist.

## Acupuncture as Complex Intervention



Application of randomised controlled design to trial of non-pharmaceutical intervention such as acupuncture

(Paterson & Dieppe, 2005)

52

## Take-Home Messages

- “Expectancy effect” or “non-specific effect” can be a confounding variable in explaining the efficacy of acupuncture analgesia
- In order to understand the influence of “expectancy effect” in RCTs of analgesic effect of acupuncture, subjects’ expectations have to be measured

53

## References

- Bausell RB, Lao L, Bergman S, Lee WL, Berman BM (2005) Is acupuncture analgesia an expectancy effect? Preliminary evidence based on participants’ perceived assignments in two placebo-controlled trials, *Evaluation & Health Professions* 28: 9-26.
- Cherkin DC, Eisenberg D, Sherman KJ, Barlow W, Kaptchuk TJ, Street J, Deyo RA (2001) Randomized trial comparing traditional Chinese medical acupuncture, therapeutic massage, and self-care education for chronic low back pain, *Archives of Internal Medicine* 161: 1081-1088.
- Kalaoukalani D, Cherkin DC, Sherman KJ, Koepsell TD, Deyo RA (2001) Lessons from a trial of acupuncture and massage for low back pain: patient expectations and treatment effects, *Spine* 26: 1418-1424.
- Kaptchuk TJ (2002) Acupuncture: theory, efficacy, and practice, *Annals of Internal Medicine* 136: 374-383.

54

## References

- Paterson C, Britten N (2004) Acupuncture as a complex intervention: a holistic model, *Journal of Alternative and Complementary Medicine* 10: 791-801.
- Paterson C, Dieppe P (2005) Characteristic and incidental (placebo) effects in complex interventions such as acupuncture, *British Medical Journal* 330: 1202-1205.
- Vickers AJ (2002) Placebo controls in randomized trials of acupuncture, *Evaluation & Health Professions* 25: 421-435.