

## Review

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# Cost-Effectiveness of Complementary Therapies in the United Kingdom—A Systematic Review<sup>†</sup>

Peter H. Canter, Joanna Thompson Coon and Edzard Ernst

Complementary Medicine, Peninsula Medical School, Exeter Devon EX2 4NT, UK

*Objectives:* The aim of this review is to systematically summarize and assess all prospective, controlled, cost-effectiveness studies of complementary therapies carried out in the UK. *Data sources:* Medline (via PubMed), Embase, CINAHL, Amed (Alternative and Allied Medicine Database, British Library Medical Information Centre), The Cochrane Library, National Health Service Economic Evaluation Database (via Cochrane) and Health Technology Assessments up to October 2005. *Review methods:* Articles describing prospective, controlled, cost-effectiveness studies of any type of complementary therapy for any medical condition carried out in the UK were included. Data extracted included the main outcomes for health benefit and cost. These data were extracted independently by two authors, described narratively and also presented as a table. *Results:* Six cost-effectiveness studies of complementary medicine in the UK were identified: four different types of spinal manipulation for back pain, one type of acupuncture for chronic headache and one type of acupuncture for chronic back pain. Four of the six studies compared the complementary therapy with usual conventional treatment in pragmatic, randomized clinical trials without sham or placebo arms. Main outcome measures of effectiveness favored the complementary therapies but in the case of spinal manipulation (four studies) and acupuncture (one study) for back pain, effect sizes were small and of uncertain clinical relevance. The same four studies included a cost-utility analyses in which the incremental cost per quality adjusted life year (QALY) was less than £10 000. The complementary therapy represented an additional health care cost in five of the six studies. *Conclusions:* Prospective, controlled, cost-effectiveness studies of complementary therapies have been carried out in the UK only for spinal manipulation (four studies) and acupuncture (two studies). The limited data available indicate that the use of these therapies usually represents an additional cost to conventional treatment. Estimates of the incremental cost of achieving improvements in quality of life compare favorably with other treatments approved for use in the National Health Service. Because the specific efficacy of the complementary therapies for these indications remains uncertain, and the studies did not include sham controls, the estimates obtained may represent the cost-effectiveness non-specific effects associated with the complementary therapies.

**Keywords:** complementary medicine – cost effectiveness – acupuncture – spinal manipulation

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## Introduction

<sup>†</sup>This review was previously published as a BMJ short report (1). Here, it is reported in full and has been updated to include studies published up to October 2005.

Despite the fact that the evidence for effectiveness of many complementary therapies remains weak, the increased popularity of privately purchased complementary therapies in the UK and the ongoing debate about provision and integration of complementary medicine within the National Health Service (NHS) has inevitably brought the issue of cost-effectiveness to the fore. The cost-effectiveness of any particular treatment depends not only upon the treatments with which it is compared, but also the health care system in which it is provided. A treatment which is cost-effective in the health

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For reprints and all correspondence: Dr Peter H. Canter, Complementary Medicine, Peninsula Medical School, Universities of Exeter and Plymouth, 25 Victoria Park Road, Exeter Devon EX2 4NT, UK. Tel: +44-1392-424-942; Fax: +44-1392-427-562; E-mail: peter.canter@pms.ac.uk

care system of one country may not be so in another. We have, therefore, carried out a systematic review of the most rigorous studies in order to properly appraise what is currently known about cost-effectiveness of any complementary therapies in the UK system.

A full economic evaluation of a health care strategy involves a comparative analysis of relevant alternative courses of action in terms of both their costs and consequences. This systematic review includes only studies evaluating both costs and consequences of two or more treatment options and therefore excludes cost-minimization studies which assume equal effectiveness between interventions and measure only costs. We justify the exclusion of such studies on the grounds that the effectiveness of any complementary therapy relative to conventional treatments remains insufficiently proven. Terms used to describe different types of economic analyses of health care strategies are sometimes used inconsistently, but we follow the terminology outlined by Drummond (2). Cost-utility analyses frequently estimate cost-effectiveness using the measure cost per quality adjusted life year (QALY) gained. One QALY is a year in perfect health and suboptimal health states are assigned a QALY value between 0 and  $\pm 1$  following a weighting exercise of some kind which may include questionnaires, focus groups or expert opinions. Dimensionally, QALY is a product of incremental gain in quality of life and the length of time over which the gain in quality of life is enjoyed. Increasingly, QALY estimates are based on validated and appropriately weighted responses to health-related, quality of life questionnaires such as the SF-36.

## Methods

### Searching

Systematic literature searches were conducted in the following electronic databases: Medline (via PubMed), Embase, CINAHL, Amed (Alternative and Allied Medicine Database, British Library Medical Information Centre), The Cochrane Library, NHS Economic Evaluation Database (via Cochrane) and Health Technology Assessments (via Cochrane (all from their inception to April 2005)). The search terms used were as follows: cost benefit\*, cost util\*, cost effectiv\*, cost minimi\*, AND complementary medicine OR alternative medicine OR chiropract\* OR acupuncture OR homeopathy OR herbal medicine OR phytotherapy OR osteopath\* AND UK OR Britain OR England OR Wales OR Scotland. In the case of the PubMed search the third search term relating to UK origin was restricted to the affiliation field. The same search was carried out in October 2005 to identify any new studies published since April 2005.

### Selection

Only articles describing cost-effectiveness, cost-utility or cost-benefit studies with prospectively collected data for two or more interventions, of which one had to be a complementary

therapy, were included. Cost-minimization studies were excluded because complementary therapies remain insufficiently tested within the NHS to warrant the assumption of equal effectiveness with conventional treatments. Studies had to be carried out in the UK.

### Validity Assessment

Studies were considered valid if the data for health outcome and cost were collected prospectively for two or more interventions. Limitations to the completeness of cost data and methodological problems regarding randomization, and blinding are noted in the discussion.

### Data Abstraction

All articles identified by the search strategy described above were screened by the first author (P.C.) and all studies appearing to meet the inclusion criteria at this stage were retrieved and read in full. Data were extracted by the first author (P.C.) and validated by the second (J.T.C.), with any disagreements being settled by discussion between all three authors.

### Study Characteristics

Studies were grouped according to intervention and indication. Results for the main outcome for health benefit and cost analysis were extracted to a table and described narratively.

### Quantitative Data Synthesis

Because of the expected heterogeneity of treatment interventions and study populations no statistical combination of data was planned.

## Results

After removal of duplicates the initial search carried out in April 2005 generated 453 references. Most failed to meet several of the inclusion criteria, but only the first reason for exclusion identified was recorded (Fig. 1). These were as follows: not complementary medicine ( $n = 255$ ), not UK-based ( $n = 49$ ), presented no primary cost data ( $n = 89$ ), were reviews or commentaries ( $n = 30$ ), did not compare two or more treatment options ( $n = 9$ ). The 11 remaining articles were read in full and two (3,4) were excluded because they did not have a control treatment. The remaining nine articles (5–13) described five discrete studies, four of which were each described by two publications addressing different aspects of the same study.

The subsequent search carried out in October 2005 identified 33 additional articles of which 30 were excluded immediately because they were reviews or commentaries ( $n = 18$ ), were not related to complementary medicine ( $n = 6$ ), included no cost data ( $n = 5$ ) or were surveys ( $n = 1$ ). The other three articles were retrieved and read in full. One was excluded because it did not collect any primary cost data (14) and another because

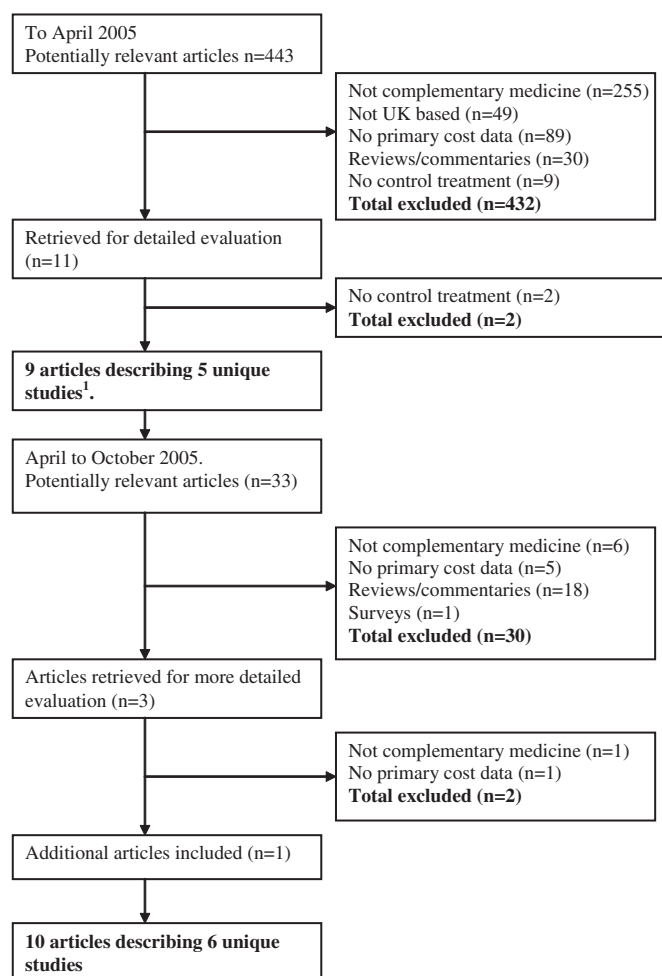


Figure 1. Studies included and excluded from the systematic review.

it did not test a complementary therapy (15). The third study (16) was included meaning that six studies were included overall.

### Study Characteristics

The remaining 10 articles (5–13,16) described 6 discrete studies, 4 of which were each described by two publications addressing different aspects of the same study. Two studies (5,6,16) were concerned with acupuncture and the other four studies (7–13) with spinal manipulation. The included studies are summarized in Table 1 and described below.

### Acupuncture as an Adjunct to Usual Care for Headache

Vickers *et al.* (5,6) carried out a pragmatic randomized trial of acupuncture for chronic headache (mainly migraine) in primary care. Participants received usual care or usual care plus individualized acupuncture. Mean scores calculated from headache diaries fell by 34% in the acupuncture group and 16% in controls between baseline and 12 months ( $P = 0.0002$ ). A 35% reduction in headache score was predefined as clinically relevant and this was achieved by 54% of

acupuncture patients and 32% of usual care patients, equivalent to a number needed to treat 4.6 (95% CI 3.0–9.1). The difference between treatments in days with headaches was equivalent to 22 (8–38) additional headache free days per year with acupuncture.

The associated cost-effectiveness study (6) calculated treatment costs for the 12 months of the study. The cost of prescription drugs was calculated for a subgroup of patients ( $n = 71$ ) but this data were omitted from the analysis because results were sensitive to the regression methods used. Differences in medication cost between groups was small ( $<£50$  per patient) and tended to favor the acupuncture group. Total costs during the 1 year period of the study were on average higher with additional acupuncture (£403) than for usual care (£217) mainly accounted for by the additional costs of the acupuncture practitioners. Mean cost to the NHS per patient excluding prescription costs was £290 in the acupuncture group and £89 in the usual care group. Mean cost to the patient was £114 in the acupuncture group and £129 in the usual care group. Using the health-related quality of life instrument SF-6D, the mean incremental health gain for acupuncture above usual care was 0.021 QALY ( $P = 0.02$ ). The mean incremental cost to the NHS excluding prescription costs was £205 per patient and cost per QALY for acupuncture in addition to usual care and adjusted for baseline differences was £9180. Inclusion of productivity costs at £88 per day of sick leave decreased incremental cost per QALY to £3263. Assuming that there were lasting positive effects on quality of life beyond the 12 month study period persisting for 2, 5 and 10 years reduced cost per QALY to £4730, £1807 and £801, respectively. Using costs of private acupuncture increased cost per QALY to £11 375 and acupuncture delivered by General Practitioners (GP) seeing four patients per hour increased it to £12333. Acupuncture delivered by trained physiotherapists seeing three patients per hour reduced cost per QALY to £5701.

### Cost-Effectiveness of Manipulation Provided by Chiropractors or the NHS for Low Back Pain

Meade *et al.* (7,8) published a clinical trial of 741 patients with low back pain who were randomized to treatments provided by either chiropractic or NHS hospital outpatient clinics. Treatment was at the discretion of the therapists involved; chiropractors used chiropractic manipulation in most patients, hospital staff mostly used Maitland mobilization or manipulation or both. Patients treated by chiropractors received ~44% more treatments than those treated in hospitals. Patients were followed up for 2 years after treatment in the initial study and at 3 years in the follow on. Oswestry questionnaires were administered by post and the results reported initially (6) for 1 and 2 years were based on a much reduced dataset. We report here the more complete data from the follow on (8). At 6 weeks, the difference in Oswestry score was not statistically significant. At 6 and 12 months after treatment cessation, there were small differences in Oswestry score between groups of

Table 1. Included cost-effectiveness studies of complementary medicine in the UK

Modality Year (reference)	Participants & indication	Design & interventions	Results for main outcome measures of effectiveness	Economic analysis
Acupuncture 2004 (5) 2005 (6)	GP patients (18-65 years). chronic headache mainly migraine ( <i>n</i> = 401)	12-month RCT. UC: usual care, A: usual care + acupuncture (up to 3 sessions in 3 months)	12-month headache score (patient diary) reduced by 34% in A, 16% in UC ( <i>p</i> = 0.0002)	Total costs: UC £217; A £403. NHS costs: UC £89; A £290. Patient costs: UC £129; A £114. Incremental cost to NHS excluding prescriptions: £205. Incremental health gain 0.021 QALY ( <i>p</i> = 0.02). Cost per QALY: £9180
Manipulation 1990 (6) 1995 (7)	Patients attending hospital or chiropractic clinics (18-65 years) back pain. ( <i>n</i> = 741)	12-month RCT. C: individualised chiropractic manipulation (up to 10 sessions in 12 months). H: individualised Maitland mobilisation and/or manipulation by hospital staff	Oswestry back pain questionnaire: NS at 6 weeks, favoured C at 6 months [3.31 95% CL 0.51 to 6.11; <i>p</i> < 0.05], NS at 12 months, favoured C at 2 years [3.02 95% CL 0.08 to 5.96; <i>p</i> < 0.02] and at 3 years [3.18 95% CL 0.16 to 6.20, <i>p</i> < 0.05]	Direct treatment costs: C: £165; H: £111
Manipulation 2000 (9)	Orthopaedic patients (18-60 years) symptomatic lumbar disc herniation ( <i>n</i> = 40)	12-month RCT. CN: Chemonucleolysis, M: Osteopathic manipulation (variable number of 15-minute sessions over 12 weeks)	Leg pain: NS at 2 weeks, 6 weeks & 12 months. Back pain: favoured M at 2 weeks & 6 weeks ( <i>p</i> = ?), NS at 12 months. Roland Disability Questionnaire: favoured M at 2 weeks ( <i>p</i> = ?), NS at 6 weeks & 12 months	Direct treatment costs: CN: £800, M: £220. Estimated incremental cost of CN over M in 1 year including cost of therapeutic failures £300/patient
Manipulation 2003 (10) 2004 (11)	GP patients (16-25 years) subacute spinal pain ( <i>n</i> = 210)	6-month RCT UC: usual GP care M: usual GP care + osteopathic spinal manipulation (3 sessions)	Extended Aberdeen Spine Pain Scale: favoured M at 2 months [95% CL 0.7 to 9.8], NS at 6 months.	Mean health care costs for spinal pain for 6 month of trial: M: £129, UC: £64. Total mean health care costs: M: £328, UC: £307. Cost per QALY: M relative to UC: £3560
Manipulation and exercise 2004 (12) 2005 (13)	GP patients (18-65 years) chronic back pain ( <i>n</i> = 1334)	12-month RCT. BC: GP best care, M: GP best care + manipulation (2-8 sessions in 12 weeks), E: GP best care + exercise classes (up to 8 in 4-8 weeks & refresher at 12 weeks) EM: GP best care + manipulation (up to 8 in 6 weeks) + exercise classes (up to 8 in next 6 weeks & refresher at 12 weeks)	Roland Morris disability score: E > BC at 3m [1.4, 95% CL 0.6 to 2.1], NS at 12 months. M > BC at 3 months [1.6, 95% CL 0.8 to 2.3] and 12 months [1.0, 95% CL 0.2 to 1.8]. EM > BC at 3 months (1.9, 95% CL 1.2 to 2.6) & 12 months (1.3, 95% CL 0.5 to 2.1)	Incremental cost relative to BC: E: £140; M: £195; EM: £125. Cost per QALY: E dominated by EM & excluded, M relative to BC: £4800, M relative to EM £8,700, EM relative to BC: £3,800
Acupuncture 2005 (16)	GP patients (18-65 years) non-specific low back pain ( <i>n</i> = 241)	24-month RCT UC: usual GP care A: usual GP care plus up to 10 individualised acupuncture sessions with various adjunctive treatments	SF-36 bodily pain NS at 3 months & 12 months, favoured A at 24 months (8.0 95% CI 0.7-15.3)	Mean NHS costs UC: £332, A: £471, difference £139 ( <i>p</i> < 0.05, 95% CI £23 to £255). Total healthcare costs UC: £367, A: £525, difference £158 (NS). Total social costs UC: £2470, A: £2135 (NS) cost per QALY A relative to UC £4,241 (95% CI £191 to £28,026) SF-6D data £3,598 [95% CI £189 to £22,035] EQ-5D data

RCT: randomised clinical trial, NS: not statistically significant, QALY: quality of life adjusted years, CL: confidence limits.



3.31 (0.51–6.11,  $P < 0.02$ ,  $n = 607$ ) and 2.04 (–0.71 to 4.79;  $P = \text{NS}$ ,  $n = 579$ ), respectively, in favor of chiropractic. At 2 years, the difference had increased to 3.02 (0.08–5.96,  $P < 0.05$ ,  $n = 541$ ) and by 3 years it was 3.18 (0.16–6.20,  $P < 0.05$ ,  $n = 529$ ). Only direct costs of treatment provided during the intervention period were considered; mean costs of chiropractic and hospital-based treatments were £165 and £111 per patient, respectively. The follow-on (7) showed that a higher proportion of patients in the chiropractic group than the hospital group sought further treatment of any kind for back pain after completion of the trial treatment. Between 1 and 2 years after trial entry 42% of patients treated with chiropractic and 31% of hospital-treated patients sought such treatment but the additional cost of this further treatment was not accounted for.

### Comparison of Osteopathic Manipulation and Chemonucleolysis in Lumbar Disc Herniation

Burton *et al.* (9) conducted a 12 month single-blind, randomized trial comparing chemonucleolysis (injection of the enzyme chymopapain) and osteopathic manipulation delivered by a private practitioner in 40 patients with symptomatic lumbar disc herniation resulting in sciatica. Patients were recruited from the orthopaedic department of a hospital in the north of England. The manipulative treatment consisted of a number of 15 min treatment sessions over a period not exceeding 12 weeks, with most sessions occurring in the first 6 weeks. The mean number of manipulation treatments received was 11 (range 6–18) at a cost of £20 per session. The treatments followed a typical protocol for osteopathic management of sciatica. Chemonucleolysis was administered as an inpatient procedure under general anesthesia and the cost including hospital and drug costs was £800. Outcomes were assessed at baseline, 2 weeks, 6 weeks and 12 months. At 12 months, both treatment groups showed significant improvements for mean scores for leg pain, back pain and the Roland Disability Questionnaire with no significant differences between groups. There was a statistically significant benefit of manipulation at 2 and 6 weeks for back pain and at 2 weeks for mean disability score. The authors considered only the direct costs of the interventions for the 30 patients with complete data at 12 months (15 in each group) and the costs incurred for treating therapeutic failures (5 in the manipulation group and 3 in the chemonucleolysis group); they estimated that the saving per patient over 1 year associated with manipulation would be ~£300.

### Cost-Effectiveness of Manipulation in Addition to Usual Care for Spinal Pain

Williams (10,11) assessed the effectiveness and health care costs of manipulation for subacute spinal pain in a primary care-based osteopathy clinic accepting referrals from 14 neighboring practices in Wales. It included 210 patients aged 16–65, with back or neck pain of 2–12 weeks duration who were randomly assigned to usual GP care with or without three

sessions of osteopathic spinal manipulation. The primary outcome measure was the Extended Aberdeen Spine Pain Scale (EASPS) which, at 2 months, showed a significantly greater improvement in the osteopathy group than in the usual care group (95% CI 0.7–9.8). This difference was no longer significant at 6 months (95% CI –1.5 to 10.4).

Data on health care use were collected for 6 months preceding and 6 months following randomization and costs were calculated for primary care consultations, investigations, prescribing and referrals. Mean health care costs attributed to spinal pain for the 6 months of the trial were £129 (SD £283) in the osteopathy group and £64 (SD £90) in the usual care group, a significant difference of £65 (95% CI £32–£155). Mean total health care costs in the same period were £328 (£564) in the osteopathy group and £307 (£687) in the usual care group, a non-significant difference of £22 (95% CI –£159 to £142).

The cost-utility analysis found that differences between groups in mean QALY calculated from EuroQol EQ-5D data favored osteopathy but were not statistically significant when using data from only patients with complete data (0.006, 95% CL –0.033 to 0.046,  $n = 108$ ), using estimated values for missing EQ-5D data (0.018, 95% CL –0.017 to 0.052,  $n = 146$ ) or patients with estimated EQ-5D values and complete cost data (0.025, 95% CL –0.012 to 0.060,  $n = 136$ ). Based on the third, and most optimistic of these, mean QALY and total costs were 0.031 and £215 with usual GP care, and 0.056 and £303 with additional osteopathy. Cost per QALY gain in the osteopathy group was estimated as £3560. The median bootstrap cost-utility estimate was £3760 per QALY gained (80% CL £542–£77100). A sensitivity analysis omitting data from three outliers (one in GP group, two in osteopathy group) gave a bootstrapped estimate of £1390 for cost per QALY (upper 80% CL £13400). When only spine-related costs were considered, the median bootstrapped estimate was £2870 per QALY gained (80% CL £998–£36500). These findings suggest an increase in mean QALY and a small increase in cost associated with the addition of osteopathy to usual GP care but the estimates for cost per QALY are subject to a high level of random error. The cost-utility plot does not suggest that incremental increases in spending on osteopathy are associated with incremental gains in QALY.

### The UK Beam Trial: Manipulation and Exercise for Low Back Pain

In the UK Beam trial (12,13) patients with low back pain ( $n = 1334$ ) were randomized to GP best care (emphasis on normal activity and avoiding rest), GP care plus manipulation (delivered by chiropractors, osteopaths or physiotherapists), GP care plus exercise classes (delivered by a physiotherapist) or GP care plus manipulation followed by exercise classes. Patients allocated to manipulation were further randomized between manipulation in private premises and in NHS premises to give a  $3 \times 2$  factorial design. Manipulation comprised a package of techniques agreed by a panel of UK

chiropractors, osteopaths and physiotherapists. Outcomes were measured at baseline, 3 months and 12 months.

The main outcome measure was the Roland Morris disability questionnaire in which changes of 2.5 are usually considered clinically important. Compared to GP care alone, the exercise group showed statistically significant improvement at 3 months (1.4, 95% CL 0.6–2.1) but not at 12 months. Manipulation was significantly better than GP care at 3 months (1.6, 0.8–2.3) and 12 months (1.0, 0.2–1.8). Manipulation followed by exercise was significantly better than GP care at 3 months (1.9, 1.2–2.6) and 12 months (1.3, 0.5–2.1). The authors describe the effect sizes as small to moderate. There was no significant difference on any measure between manipulation delivered in private or NHS premises.

The cost-utility analysis (13) was based on participants with sufficient cost data ( $n = 1287$ ) and assumed the lower costs of manipulation delivered in NHS premises. Based on EQ-5D data, the mean (SD) QALY was 0.618 (0.232) for best care, 0.635 (0.245) for best care plus exercise, 0.659 (0.241) for best care plus manipulation and 0.651 (0.237) for best care plus combined treatment. Mean incremental QALY generated per participant relative to best care was therefore 0.041 (95% credibility interval 0.016–0.066) for manipulation, 0.017 (–0.017 to 0.051) for exercise and 0.033 (–0.001 to 0.067) for combined treatment. The mean incremental treatment cost above best care was £195 (£85–£308) for manipulation, £140 (£3–£278) for exercise and £125 (£21–£228) for combined treatment. The lower incremental cost for the combined additional treatment resulted from lower subsequent hospital costs. The cost-utility analysis shows that cost per QALY for combined treatment is £3800. Exercise alone was more expensive and achieved less, i.e. was ‘dominated’ by combined treatment and was excluded as a treatment option. For manipulation alone, cost per QALY was £4800 relative to best care and £8700 relative to best care plus combined treatment. Several sensitivity analyses were performed. Excluding outliers whose health care costs exceeded £2000 (best care,  $n = 9$ ; exercise,  $n = 16$ ; manipulation,  $n = 16$ ; combined treatment,  $n = 10$ ) caused manipulation to achieve dominance over both exercise and combined treatment with a cost per additional QALY of £3000. Cost per QALY relative to best care was £6600 for combined treatment and £8700 for manipulation when private costs were substituted for the manipulation carried out in private premises and were £8600 for combined treatment and £10 600 for manipulation when private costs were substituted for all manipulation given in the trial. The authors note that shortage of trained manipulators within the NHS means that in the short-term at least, manipulation would have to be bought in from the private sector.

### Traditional Acupuncture in Low Back Pain

The most recent study (16) tested the hypothesis that patients with persistent non-specific low back pain, offered traditional acupuncture as an adjunct to conventional primary care, would

gain more long-term relief from pain than those offered conventional care alone for equal or less cost. The study was carried out in three non-NHS acupuncture clinics taking referrals from 39 GPs in 16 practices in York. Patients ( $n = 241$ ) aged 18–65 years with non-specific low back pain of 4–52 weeks duration, assessed as suitable for primary care management by their GP were randomized to the offer of acupuncture or usual care with a 2:1 allocation ratio. In addition to usual care as provided at the discretion of their GP, patients in the acupuncture group were offered up to 10 individualized treatment sessions with one of six non-NHS acupuncturists and adjunctive treatments including moxa, cupping, acupressure, massage, Chinese herbs and advice on diet, rest and exercise. Usual care entailed a mixture of physiotherapy, medication and recommended back exercises. The primary outcome measure was the SF-36 Bodily Pain dimension assessed at baseline, 3, 12 and 24 months. Cost-utility analysis was carried out at 24 months using quality of life assessments from both the EuroQol-5D and a measure derived from the SF-36 (SF-6D).

All 159 patients randomized to acupuncture took up the offer and of these 9 did not receive any acupuncture treatment. Patients received an average of eight acupuncture treatments, mostly within the first 3 months of the study. Changes from baseline on the SF-36 Bodily Pain dimension were not statistically different at 3 months (95% CI –1.5 to 11.6) or 12 months (95% CI –1.3 to 12.5) and were significantly different at 24 months with a treatment effect of 8.0 points (95% CI 0.7–15.3). An analysis of heterogeneity in the main outcome found that 35% of the variability was associated with the acupuncturist at 12 months but with no significant difference between the six practitioners. At 24 months the variability was 2%. The difference in treatment effect at 24 months did not significantly differ between subacute patients (4–12 weeks of back pain) and chronic patients (12–48 weeks). At baseline, 50.3% of acupuncture patients and 37.5% of usual care patients expected their back pain to be better in 6 months time and there was a non-significant interaction such that acupuncture patients had their initial optimism reinforced.

Among the secondary outcome measures there was a significant difference favoring acupuncture on the McGill Present Pain Intensity scale (PPI) at 3 months ( $P = 0.02$ ) but not at 12 or 24 months. There were no significant differences between groups on the other seven dimensions of the SF-36 or on the Oswestry Low Back Pain Disability Questionnaire (ODI). At 24 months, the acupuncture group reported significantly more months free of pain in the preceding 12 months ( $P = 0.03$ ) and a lower proportion (40 versus 60%) reported using medication for back pain in the previous 4 weeks ( $P = 0.03$ ). By 24 months more acupuncture patients than usual care patients reported being ‘much less’ or ‘less’ worried about their back pain and were more likely to attribute their improvements to the treatment received ( $P < 0.001$ ). At 3 months more acupuncture patients reported being very satisfied with their treatment ( $P = 0.01$ ) and their overall care ( $P = 0.04$ ).

Cost-effectiveness was calculated from both NHS and societal perspectives including NHS costs, private treatment costs and the cost of lost productivity. The total mean NHS costs for back pain were £471 for acupuncture and £332 for the usual care group a difference of £139 ( $P < 0.05$ , 95% CI £23–£255). The mean cost of the study acupuncture was £214. This was offset by higher costs in the control group for hospitalizations, GP, outpatient and other health care visits. Curiously, the mean cost of medication for back pain was over twice as high in the acupuncture group (£34 SD £114) as in the control group (£16 SD £27).

Total health care costs for back pain including private treatment were £525 for acupuncture and £367 for usual care, a statistically non-significant difference of £158 (95% CI –£28 to £320). The total social costs including estimates of lost productivity for time-off work were lower for the acupuncture group (£2135) than the usual care group (£2470), but not significantly so.

There were no significant intergroup differences in incremental quality of life scores on the SF-6D scores at 3, 12 or 24 months or on the EQ-5D at 12 and 24 months. The EQ-5D data favored acupuncture at 3 months ( $P < 0.05$ ). Imputing missing values in the EQ-5D data from regression analysis of the SF-36 data did not change this pattern of results, but an area under the curve (AUC) analysis found a statistical difference favoring acupuncture at 24 months ( $P < 0.05$ ).

At 24 months the estimated incremental cost per QALY for acupuncture relative to usual care was £4241 (95% CI £191–£28 026) using the SF-6D measure and £3598 (£189–£22 035) using the EQ-5D data. Cost per QALY was estimated using the AUC data available for quality of life and NHS treatment costs for acupuncture patients ( $n = 78$ ) and usual care patients ( $n = 44$ ).

### Quantitative Data Synthesis

None planned or executed.

### Discussion

Our search located only six prospective, controlled, cost-effectiveness studies of complementary therapies conducted in the UK. The studies are restricted to two modalities and two medical conditions within the broad spectrum of complementary and alternative medicine and many indications for which it is used: spinal manipulation for back pain, acupuncture for headache and acupuncture for back pain. Given the paucity of good data, it is premature to draw firm conclusions about the cost-effectiveness of using any complementary therapy in the UK health system. The general question 'is complementary medicine cost-effective?' is of course unanswerable. Cost-effectiveness can only be assessed for a specific complementary therapy in a particular indication within a particular health care system.

Of the six studies meeting our inclusion criteria, four (4,5,10,11–13,16) made useful comparisons between the

complementary therapy and usual care and also estimated cost per QALY. The other two studies did not make such useful comparisons. Meade *et al.* (6,7) compared the cost-effectiveness of different forms of spinal manipulation carried out in private and NHS settings and Burton *et al.* (9) compared osteopathic manipulation with chemonucleolysis, a procedure used only when other standard treatments have failed.

All four studies comparing complementary therapy with usual care indicate that use of the complementary therapy in addition to, or as an alternative to, usual or conventional treatment represents an increase in total health care costs. There is presently no direct evidence from prospectively conducted and controlled studies that the use of any complementary medicine modality used in addition to or instead of routine care, reduces costs in the UK health care system.

In the case of spinal manipulation, the health benefits observed in these studies were small to moderate and of questionable clinical significance. The effectiveness of spinal manipulation in back pain remains controversial and the most rigorous RCTs fail to demonstrate its usefulness (17,18). Similarly, the efficacy of acupuncture in the indications studied remains uncertain. In the trial comparing adjunctive acupuncture with usual care for chronic back pain (16) the difference between groups on the main clinical outcome measure did not reach statistical significance until the 24 month measurement. Data from the most recent systematic reviews of acupuncture for pain appear to indicate that effect sizes diminish as clinical trials become more rigorous and include larger samples (19). Large-scale trials conducted in Germany and due to report their findings shortly, are expected to show similar effectiveness for real and sham acupuncture in pain (19). More specifically, real and sham acupuncture appear to be equally effective in treating migraine (20).

Previous decisions taken by the National Institute for Clinical Excellence (NICE) (21), the body which advises government and the NHS on the cost-effectiveness of new treatments, imply an upper limit above those for acupuncture and manipulation in this review here at £10 000 per QALY or considerably less. However, it may be misleading to compare these pragmatic studies with studies of other treatments accepted by for use in the NHS. The absence of blinding and control treatments in these trials and the use of subjective quality of life measures upon which the cost-effectiveness analyses are based, may have enhanced non-specific treatment effects, particularly placebo effects attributable to differential expectations of patients randomized to different treatments. It will be argued that this does not matter because cost-effectiveness analyses should take such effects into account by reflecting how treatments are likely to be delivered in 'real life'. However, such effects may not operate in a situation where the complementary therapy is offered routinely, is not offered in the novel situation of a clinical trial, or where disappointment associated with allocation to usual care is not generated. The use of pragmatic cost-effectiveness studies is justified in treatments where appropriately blinded and



sham-controlled randomized clinical trials have already demonstrated efficacy in the indication concerned, but this is not the case for the interventions included in this review.

The picture emerging from the most rigorous cost-effectiveness studies of complementary medicine in the UK is a rather consistent one. First, their use represents an additional cost to the NHS. Second, estimates of cost-effectiveness based on data from clinical trials without sham controls compare favorably with other treatments approved for use in the NHS. Third, the specific treatment effects of the complementary therapies for the indications in question remains uncertain. We therefore strongly suspect that such studies may be estimating the cost-effectiveness of non-specific treatment effects. We recommend that future cost-effectiveness studies of complementary therapies include a sham treatment arm.

## Conclusions

There are presently very few prospective, controlled studies of the cost-effectiveness of complementary therapies in the UK and those published are confined to two modalities: spinal manipulation and acupuncture. The evidence that is available suggests that the use of these complementary therapies represents an additional cost and there is no evidence that their use leads to savings. Cost-utility analyses included in these studies compare favorably in terms of cost per QALY with other treatments accepted for use in the NHS, but because the specific efficacy of the complementary therapies for these indications remains uncertain, and the studies did not include sham controls, the estimates obtained may represent the cost-effectiveness non-specific effects associated with the complementary therapies.

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