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Randomized osteopathic manipulation study (ROMANS): pragmatic trial for spinal pain in primary care

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Background. Spinal pain is common and frequently disabling. Management guidelines have encouraged referral from primary care for spinal manipulation. However, the evidence base for these recommendations is weak. More pragmatic trials and economic evaluations have been recommended.

Objectives. Our aim was to assess the effectiveness and health care costs of a practice-based osteopathy clinic for subacute spinal pain.

Methods. A pragmatic randomized controlled trial was carried out in a primary care osteopathy clinic accepting referrals from 14 neighbouring practices in North West Wales. A total of 201 patients with neck or back pain of 2–12 weeks duration were allocated at random between usual GP care and an additional three sessions of osteopathic spinal manipulation. The primary outcome measure was the Extended Aberdeen Spine Pain Scale (EASPS). Secondary measures included SF-12, EuroQol and Short-form McGill Pain Questionnaire. Health care costs were estimated from the records of referring GPs.

Results. Outcomes improved more in the osteopathy group than the usual care group. At 2 months, this improvement was significantly greater in EASPS [95% confidence interval (CI) 0.7–9.8] and SF-12 mental score (95% CI 2.7–10.7). At 6 months, this difference was no longer significant for EASPS (95% CI −1.5 to 10.4), but remained significant for SF-12 mental score (95% CI 1.0–9.9). Mean health care costs attributed to spinal pain were significantly greater by £65 in the osteopathy group (95% CI £32–£155). Though osteopathy also cost £22 more in mean total health care cost, this was not significant (95% CI −£159 to £142).

Conclusion. A primary care osteopathy clinic improved short-term physical and longer term psychological outcomes, at little extra cost. Rigorous multicentre studies are now needed to assess the generalizability of this approach.

Keywords. Back pain, economic evaluation, neck pain, randomized controlled trial, spinal manipulation.

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Introduction

Spinal pain is very common in the general population, and a common cause of disability and work loss, resulting in 150 million working days lost in 1993 for low back pain alone.[1,2] It is one of the main reasons for consulting a GP (accounting for 843 consultations per year in a practice population of 10 000 patients[3]) and practitioners of complementary medicine, particularly osteopaths and chiropractors.[4]

British and American low back pain management guidelines[2,5,6] have recommended early referral for spinal manipulation for persistent mechanical low back pain, in order to reduce the proportion of patients developing chronic pain lasting longer than 12 weeks. A recent update of the systematic reviews[7] has reported moderate evidence of efficacy from poor quality trials. There was evidence of short-term pain relief following manipulation compared with some types of placebo therapy. Most pragmatic trials comparing manipulation with other non-surgical therapies have also reported a benefit, but the quality of trials was poor. Indeed, the highest quality trial reported a negative result. Because of these inconsistent findings, it was not possible to judge whether manipulation was effective.[7] Dutch management guidelines[8] have reflected this by asserting that the British guidelines go beyond what can be concluded from the evidence. Therefore, more pragmatic trials based in primary care have been recommended.

Although similar guidelines have not been developed for neck pain, an argument can be made that the same management principles apply.[9] Systematic reviews have been cautious about the effect of spinal manipulation for acute and subacute neck pain, because there is insufficient evidence from a small number of studies.[10] More pragmatic trials are needed.

Most studies do not examine the spine as a whole but concentrate on the lower back or to a lesser extent the neck, ignoring the thoracic spine or upper back. Physical therapies such as osteopathy, on the other hand, treat the spine as a 'functional unit'.[11,12] Recently, we have developed a set of outcome measures suitable for the whole spine,[13] allowing all regions of the spine to be included in the same study.

Treatments such as spinal manipulation should not just be effective, but should also make efficient use of health service resources.[14] The low back pain management guidelines[2] recommended that prompt referral for manipulation should be funded by diverting resources away from inappropriate secondary care referrals. The cost-effectiveness of this approach has not been demonstrated. A systematic review found that the economic aspects of low back pain have received little attention, and neck pain even less attention.[15] Therefore, more high quality economic evaluations have been recommended.

Spinal manipulation is being increasingly provided in primary care.[16] Since 1996, a GP who is also a qualified osteopath (NHW) has run an osteopathy clinic in Llanfairfechan health centre on the North Wales coast.[17] To examine the benefits and costs of this service, we conducted a pragmatic randomized controlled trial. We treated patients referred from neighbouring practices with acute and subacute pain from all regions of the spine, and compared this with usual care from their GPs.

Methods

Recruitment

This trial was conducted in North West Wales with local research ethics committee approval, between September 1997 and March 2001. The target population was patients between 16 and 65 years old, presenting to 14 general practices [excluding Llanfairfechan health centre (LlHC), where the osteopath (NHW) was a principal] with mechanical pain in the neck or upper or lower back of 2–12 weeks duration, either the first episode or a recurrence. We excluded patients likely to have serious spinal pathology suggested by 'red flag' symptoms[2], and those with features of nerve root pain, previous spinal surgery or major psychological disorder. Eligible patients were identified by their GPs, who obtained informed consent and forwarded referral forms direct to the trial office at LlHC, run by the practice manager under the direction of an experienced trialist (IR).

Randomization

The unit of randomization was the patient. Still under the direction of IR, the practice manager at LlHC used random number tables kept secure from all participants. Using information from the referral form, she stratified the sample by symptom location (neck, upper back, lower back or combination), the referring GPs' perception of symptom severity (mild, moderate or severe) and whether the pain was a first episode or a recurrence. A data monitoring committee comprising CW, IR and an independent physiotherapist assessed whether marginal patients fitted the inclusion criteria.

The intervention

All patients in the trial continued to receive treatment as usual from their GPs, including advice about rest, activity and work, prescription of analgesics and non-steroidal anti-inflammatory drugs (NSAIDs), and referral to secondary care, physiotherapists or complementary therapists. We asked participating GPs not to perform any type of spinal manipulation themselves. The control group did not receive any additional intervention. The intervention group was referred to the osteopathic clinic based in Llanfairfechan health centre. They received three or four sessions of treatment from a GP who was also a registered osteopath (NHW), at intervals of 1–2 weeks. The treatment package consisted mainly of osteopathic spinal manipulation, but also advice about keeping active, exercising regularly and avoiding excessive rest. Occasionally, if symptoms persisted despite osteopathy, tender ligaments or peripheral joints were injected with corticosteroid and local anaesthetic.

Outcome measurement

We sent generic and condition-specific outcome measures to patients by post before randomization, after

2 months when treatment in the intervention group was complete, and finally after 6 months. They returned completed questionnaires to the trial office in LlHC. Non-responders received up to three reminders at intervals of 2 weeks. The primary outcome measure was the Extended Aberdeen Spine Pain Scale (EASPS), a set of condition-specific measures for spinal pain and disability, validated for all regions of the spine.[13] Secondary outcome measures included the Short-form McGill Pain Questionnaire (SMPQ)[18] and two generic measures, the SF-12 health profile[19] and the EuroQol (EQ-5D) index of health utility.[20]

Costs

We collected data on health care use from practice records for the 6 months preceding and the 6 months following randomization. This included primary care consultations, investigations, prescribing and referrals. To assess costs from a National Health Service (NHS) perspective, we estimated unit costs for the year 1999–2000 in pounds sterling, from national sources[21,22] and information provided by finance officers of local provider units. It is difficult to decide which costs are attributable to a spinal problem, as patients commonly present with related co-morbidity. Therefore, we collected total costs as well as spine-related costs.

As the principal researcher was also the provider of the osteopathic service, an independent statistician (RH) performed an audit of the data collection process, under the auspices of the all Wales primary care research network (CAPRICORN), in anticipation of the research governance framework for Wales.

Sample size

In the pilot study, we used patient perceptions whether their pain had changed to estimate the minimal clinically important difference of the EASPS as six points. As the SD is 15 points, we needed 200 patients to give a power of 80% for detecting a change of six points (equivalent to a standardized difference of 0.4) in the EASPS with a significance level of 5%.

Data analysis

Analysis was by intention to treat, i.e. by comparing the groups as randomized. We derived confidence intervals (CIs) for differences between the groups from two-sample *t*-tests of changes in the outcome measures.

The cost data were skewed, as a small number of patients made extensive use of health care services. To analyse these cost data, we therefore used the 'bootstrap' technique[23] by applying the program S-Plus 2000 (Mathsoft Inc., Seattle, WA) for 1000 replications. Given the variety of different outcome measures employed, we used cost-consequences analysis, and estimated all the identifiable incremental costs and consequences (health outcomes) without aggregation.[24] Cost-effectiveness and cost-utility analysis will be the subject of a subsequent publication.

Results

Recruitment rate

Fourteen practices with 54 GPs enrolled in the study. However, only 20 GPs referred more than one patient to the trial, at the rate of 1.9 referrals per 1000 registered patients per year. In total, 201 patients were recruited.

Representativeness of sample

These 20 GPs had a total practice population of 32 000. Recruitment lasted 43 months for the earliest recruited practices and 22 months for the last. Thus the population were available for recruitment over 97 000 patient years. From UK GP morbidity statistics, 84 patients consult with spinal pain per 1000 registered patients per year.[3] From a previous audit in the Llanfairfechan practice, ~25% of these fulfil the trial entry criteria, so that 21 per 1000 registered patients per year would be eligible. From this, we estimate that the total potential eligible population for the trial was ~2000 (Fig. 1).

Baseline comparability

There was no marked difference between osteopathy and usual GP care groups in terms of socio-demographic characteristics, baseline outcome scores, or treatment activity and health service cost over the previous 6 months (Table 1). There was an imbalance of 19 between the number of subjects in the control and treatment groups. This was not surprising given that there were 24 strata and 14 referring practices. The imbalance was not large enough to affect the power of the trial. There were two randomization errors, one with a symptom duration of 50 weeks and another with nerve root pain, who were excluded by the data monitoring committee (Fig. 1). Seven patients in the osteopathy group also received corticosteroid injections, one into the subacromial space and six into tender sacroiliac ligaments. No adverse events were reported in either treatment group.

Two month questionnaire results

At 2 months, all outcome measures had improved in both groups; the osteopathic treatment group by more than the usual care group. This improvement was significantly greater in the primary outcome measure the EASPS (95% CI 0.7–9.8) and the SF-12 mental score (95% CI 2.7–10.7). Similar but non-significant differences were seen in the SMPQ and EQ-5D (Table 2).

Six month questionnaire results

At 6 months, most outcome measures had continued to improve in both groups, but the osteopathy group showed stagnation in the SF-12 mental score and the EQ-5D. For the EASPS, the difference in change scores between the

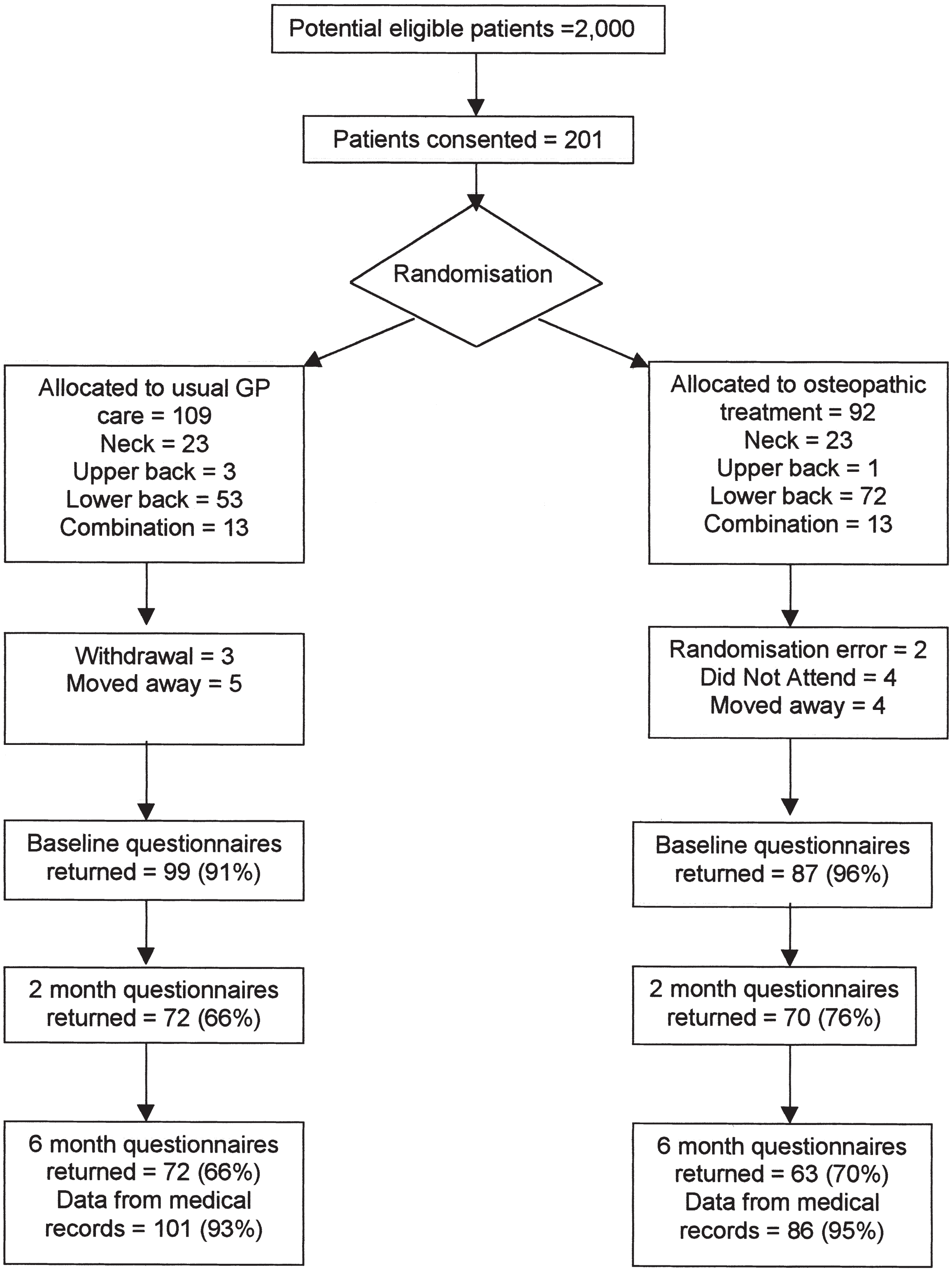

FIGURE 1 *Trial Profile flow chart*

groups was no longer significant (95% CI −1.5 to 10.4). The improvement in the osteopathy group remained significantly greater for the mental score of the SF-12 (95% CI 1.0–9.9). The small difference in improvement persisted in the SMPQ scores, but not the EQ-5D score (Table 3).

Health service activity and costs

Over the study period of 6 months, the two groups made similar use of primary care and out-patient care apart from osteopathy treatment (Table 4). In the usual care group, however, there were more in-patient admissions

TABLE 1 *Mean scores of all outcome measures and health service costs at baseline (SD)*[a]

Outcome measure	Usual care	Osteopathy
EASPS (0–100)		
All patients recruited	38.6 (15.2) n = 97	38.4 (14.1) n = 87
Neck pain only	33.4 (15.8) n = 22	42.1 (16.9) n = 23
Low back pain only	39.8 (14.1) n = 63	38.1 (13.0) n = 49
All other groups	42.0 (18.4) n = 12	33.7 (11.8) n = 15
SF-12 physical score (0–100)	35.0 (8.3) n = 97	36.1 (7.8) n = 82
SF-12 mental score (0–100)	44.2 (11.5) n = 97	43.0 (10.5) n = 82
EQ-5D score (0–1.0)	0.50 (0.32) n = 96	0.56 (0.26) n = 82
EQ-5D thermometer (0–100)	61.3 (20.7) n = 93	58.9 (21.0) n = 81
SMPQ total score (0–45)	13.2 (8.3) n = 98	13.6 (7.4) n = 86
SMPQ VAS (0–100)	46.3 (22.4) n = 97	46.9 (19.6) n = 86
SMPQ 0–5 scale	2.3 (1.0) n = 98	2.2 (0.9) n = 86
Health service costs for the 6 months preceding the trial		
Mean total health service costs	£290 (£918) n = 101	£257 (£430) n = 86
Mean spinal pain costs	£58 (£74) n = 101	£47 (£62) n = 86

[a] No significant differences in outcome measure or health service costs between usual care and osteopathy groups at baseline.
EASPS = Extended Aberdeen Spine Pain Scales; SMPQ = Short-form McGill Pain Questionnaire; VAS = visual analogue scale; EQ-5D = EuroQol EQ-5D.

for all reasons, but fewer admissions attributed to spinal pain. The unit cost for in-patient care was very much higher than any other cost. Hence, small differences in in-patient activity had large effects on cost, so that costs directly attributed to spinal pain were twice as large in the osteopathy group as in the usual care group (Table 4).

The mean difference of £65 in all health care costs attributed to spinal pain was statistically significant, with a bootstrapped 95% CI[23] from £32 to £155. However, the mean difference in total health care costs of £22 was not statistically significant, with a bootstrapped 95% CI[23] from −£159 to £142.

Discussion

We recruited only 10% of potentially eligible patients to this trial. This underlines the difficulty of recruiting patients from primary care. Even so, the recruitment rate compared favourably with other trials for spinal pain.[25]

That said, patients presenting to their GP with subacute spinal pain reported greater improvement in short-term physical and longer term psychological outcomes if treated in a primary care-based osteopathy clinic in addition to usual GP care. The relative improvement in the primary outcome measure (EASPS) at 2 months was statistically significant but small, equivalent to a quarter of the difference in mean baseline scores between those with mild and those with severe symptoms. The relative improvement at 6 months was not statistically significant, because the difference narrowed as the control group continued to improve, and the sample size was lower because of non-returned questionnaires.

However, the relative improvement in the SF-12 mental score was significant at both 2 and 6 months, and equivalent to three-quarters of the difference in mean baseline scores between those with mild and those with severe symptoms. The other outcome measures were known to be less responsive, and a larger sample would be needed to detect any significant change.

There is already evidence of the efficacy of spinal manipulation from explanatory trials, which are designed to equalize the placebo effect between experimental and control groups. In contrast, pragmatic trials like this seek to maximize the placebo effect of each intervention, rather than separate them from the intrinsic effects of each. Therefore, there are many possible explanations for the psychological benefits of osteopathy in this trial. These could reflect biases, for example in the form of increased patient contact between osteopathy patients and therapist, of awareness among osteopathy patients that their therapist was also the principal researcher resulting in more favourable responses, or even of 'resentful demoralization' in control patients. Fortunately, similar response rates in osteopathy and control patients (Fig. 1) provide reassurance that that the last two potential biases have not occurred.

Alternatively, the psychological benefits may have been due to reduction in distressing symptoms, improvement in patients' understanding of spinal pain or other genuine differences in the size of the placebo effect between the two treatments. Psychosocial factors are important in the development of disability and the transition to chronic pain states,[26] and can be identified and possibly modified by psychological interventions.[27] According to the biopsychosocial model of illness, all treatments including osteopathy comprise physical, psychological and social components.

Mean costs attributed to spinal pain were significantly greater by £65 in osteopathy patients. This is very similar to the cost of osteopathy treatment itself. However, the corresponding increase of £22 in total health care costs for osteopathy patients was not significant. This might be because the sample size was calculated on the basis of the condition-specific outcome measure rather than costs, and there was insufficient power to detect a significant difference.

The trial involved a single practitioner in a single location. This reduces the generalizability of the

TABLE 2 *Improvement in mean scores of all outcome measures at 2 months*

Outcome measures	Usual care Mean change in score (SD)	Osteopathy Mean change in score (SD)	Difference between mean change scores	95% CI	*P*-value
EASPS	8.6 (14.2) *n* = 67	13.9 (12.8) *n* = 69	5.3	0.7 to 9.8	0.02
SF-12 physical score	4.1 (8.6) *n* = 68	5.4 (8.9) *n* = 65	1.3	−1.7 to 4.3	0.39
SF-12 mental score	1.2 (12.0) *n* = 68	7.9 (11.2) *n* = 65	6.7	2.7 to 10.7	0.001
SMPQ total score	2.1 (7.0) *n* = 67	4.6 (8.0) *n* = 70	2.5	−0.1 to 5.0	0.06
SMPQ sensory subscale	1.6 (5.9) *n* = 67	3.5 (6.3) *n* = 70	1.8	−0.2 to 3.9	0.08
SMPQ affective subscale	0.5 (2.0) *n* = 67	1.1 (2.6) *n* = 70	0.6	−0.2 to 1.4	0.12
SMPQ VAS	6.8 (23.4) *n* = 68	14.4 (24.7) *n* = 70	7.6	−0.5 to 15.8	0.07
SMPQ 0–5 scale	0.4 (1.2) *n* = 68	0.7 (1.2) *n* = 70	0.3	−0.1 to 0.7	0.17
EQ-5D score	0.06 (0.29) *n* = 65	0.11 (0.28) *n* = 66	0.06	−0.04 to 0.15	0.26
EQ-5D thermometer	4.8 (20.9) *n* = 64	10.6 (22.6) *n* = 64	5.8	−1.8 to 13.5	0.13

EASPS = Extended Aberdeen Spine Pain Scales; SMPQ = Short-form McGill Pain Questionnaire; VAS = visual analogue scale; EQ-5D = EuroQol EQ-5D.

TABLE 3 *Improvement in mean scores of all outcome measures at 6 months*

Outcome measures	Usual care Mean change in score (SD)	Osteopathy Mean change in score (SD)	Difference between mean change scores	95% CI	*P*-value
EASPS	10.4 (18.0) *n* = 68	14.9 (16.1) *n* = 62	4.4	−1.5 to 10.4	0.14
SF-12 physical score	5.5 (9.4) *n* = 64	7.4 (10.3) *n* = 57	1.9	−1.6 to 5.4	0.29
SF-12 mental score	1.4 (11.3) *n* = 64	6.8 (13.6) *n* = 57	5.5	1.0 to 9.9	0.02
SMPQ total score	3.7 (8.1) *n* = 69	6.6 (8.8) *n* = 61	2.9	−0.05 to 5.8	0.05
SMPQ sensory subscale	3.0 (6.6) *n* = 69	4.8 (6.8) *n* = 61	1.8	−0.55 to 4.1	0.13
SMPQ affective subscale	0.7 (2.7) *n* = 69	1.8 (2.8) *n* = 61	1.1	−0.1 to 2.1	0.03
SMPQ VAS	10.1 (24.1) *n* = 68	15.7 (27.3) *n* = 61	5.5	−3.4 to 14.4	0.22
SMPQ 0–5 scale	0.6 (1.1) *n* = 69	0.9 (1.1) *n* = 62	0.3	−0.06 to 0.7	0.10
EQ-5D score	0.10 (0.28) *n* = 66	0.10 (0.30) *n* = 57	0	−0.1 to 0.1	0.95
EQ-5D thermometer	5.1 (20.7) *n* = 65	10.2 (24.9) *n* = 58	5.1	−3.1 to 13.2	0.22

EASPS = Extended Aberdeen Spine Pain Scales; SMPQ = Short-form McGill Pain Questionnaire; VAS = visual analogue scale; EQ-5D = EuroQol EQ-5D.

Table 4 *Frequency of health service activity and costs for the 6 months study period*

Health care activity	Usual care Mean (SD) $n = 101$	Mean cost per contact	Osteopathy Mean (SD) $n = 86$	Mean cost per contact
All GP contacts	3.26 (2.69)	£15.03	3.16 (2.81)	£15.58
GP contacts for spinal pain	1.75 (2.22)	£14.74	1.49 (2.00)	£15.45
All PHCT contacts	0.61 (1.51)	£8.80	0.66 (1.12)	£8.80
Other PHCT contacts for spinal pain	0.02 (0.14)	£8.80	0.02 (0.15)	£8.80
All investigations	0.67 (1.10)	£29.76	0.50 (0.84)	£26.53
Spine radiographs	0.10 (0.33)	£44.10	0.06 (0.24)	£30.20
All prescriptions	5.11 (7.41)	£12.63	5.28 (8.62)	£11.60
Analgesic/NSAID prescriptions	1.30 (2.17)	£7.92	1.21 (1.9)	£6.61
All consultant contacts	0.28 (0.62)	£113.79	0.26 (0.49)	£97.55
Consultant contacts for spinal pain	0.09 (0.38)	£110.89	0.06 (0.24)	£74.32
All A&E contacts	0.05 (0.22)	£89.00	0.03 (0.18)	£89.00
A&E contacts for spinal pain	0	£0	0.01 (0.11)	£89.00
All in-patient/daycare episodes	0.10 (0.39)	£1188.67	0.05 (0.21)	£2272.80
In-patient/daycase episodes for spinal pain	0	£0	0.01 (0.11)	£2202.21
All physiotherapy contacts	0.81 (1.96)	£18.00	0.38 (1.76)	£18.00
Physiotherapy contacts for spinal pain	0.73 (1.96)	£18.00	0.36 (1.73)	£18.00
All aids and appliances	0.01 (1.20)	£12.05	0.01 (0.16)	£1.50
Aids and appliances for spinal pain	0.01 (1.20)	£12.05	0.01 (0.16)	£1.50
Osteopathy contacts	N/A	N/A	2.97 (1.30)	£19.73
Health care costs				
Mean total costs[a]	£307 (£687)	£328 (£564)		
Mean costs for spinal pain[a]	£64 (£90)	£129 (£283)		

PHCT = Primary Health Care Team; NSAID = non-steroidal anti-inflammatory drug; A&E = Accident and Emergency Department.
[a] The difference of £22 in mean total health care costs is not significant: the bootstrapped 95% CI extends fom −£159 to £142. In contrast, the difference of £65 in mean health care costs for spinal pain is significant: the bootstrapped 95% CI extends from £32 to £155.

findings. However, the trial was examining an innovative clinic, where the osteopath was also a general medical practitioner. It would have been difficult to recruit other centres with similar clinics. It is nevertheless important to evaluate such innovations early in their development.

Osteopathic spinal manipulation is increasingly provided in primary care, but only occasionally by a member of the primary health care team. In this trial, provision of such a service yielded extra benefits at little extra cost. However, further research is needed to test whether this result can be generalized to more common forms of osteopathy provision, such as osteopaths working on primary care premises.

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