



Randomised Osteopathic Manipulation Study (ROManS) - Measuring the Efficacy and Cost Effectiveness of Osteopathic Treatment in Primary Care

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INTRODUCTION

Spinal pain is extremely 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 general practitioner (GP), accounting for 843 consultations per year in a practice population of 10,000 patients³ 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 twelve weeks. A recent update of the systematic reviews has reported moderate evidence of efficacy, from poor quality trials. There was evidence of short-term pain relief following manipulation compared with some type 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 an overall negative result, and because of these inconsistent findings it was not possible to judge whether manipulation was a more effective treatment⁷. Dutch management guidelines⁸ 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 sub-acute 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, a set of outcome measures suitable for the whole spine has been developed,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 be an efficient use of health service resources.¹⁴ The low back pain management guidelines² 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, with even less attention to neck pain interventions.¹⁵ Therefore more economic evaluations have been recommended.

Spinal manipulation is being increasingly provided in primary care.¹⁶ Since 1996 an osteopathy clinic run by a GP, who is also a qualified osteopath, has been based in Llanfairfechan health centre on the North Wales coast.¹⁷ In order to examine the costs and benefits of this osteopathic service, a pragmatic randomised controlled trial was conducted, treating patients referred from neighbouring practices with acute and sub-acute pain from all regions of the spine, compared with usual care from their GP.

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 with mechanical neck, upper or lower back pain of two to twelve weeks duration, whether the first episode or a recurrence. Patients likely to have serious spinal pathology because of "red flag" symptoms² were excluded, as were those with features of nerve root pain, previous spinal surgery and major psychological disorder. Eligible patients were identified by their GP, who obtained informed consent and forwarded a referral form to the study centre.

Randomisation

The unit of randomisation was the patient. The randomisation procedure followed best statistical practice by being kept secure from all clinicians. Using information from the referral form the sample was stratified according to symptom location (neck, thoracic, low back, or combination), the referring GPs' perception of symptom severity (mild, moderate, or severe) and whether the first episode of pain or a recurrence.

The interventions

All patients in the trial continued to receive treatment from their GPs, who were asked not to practice any type of spinal manipulation themselves during the study period. 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 (NW), at intervals of one to two weeks. Treatment consisted of osteopathic spinal manipulation, but also exercises and occasionally injection of tender ligaments or trigger points.

Outcome measurement

A series of generic and condition specific outcome measures were sent by postal questionnaire on entry to the study prior to randomisation, after two months when treatment in the intervention group was complete, and finally after six months. Non-responders received up to three reminders at two weekly intervals. Two condition specific measures were used, the Extended Aberdeen Spine Pain Scale [EASPS], which was the primary outcome measure,¹³ and the Short-form McGill Pain Questionnaire [SMPQ].¹⁸ Two generic measures were used, the SF-12 health profile¹⁹ and the EuroQol EQ-5D index of health utility.²⁰ Activity data were collected from practice records for the six months preceding and the six months during the trial. This included primary care consultations, investigations, prescribing and outpatient referrals. Unit costs were obtained from national sources,^{21,22} and finance officers of local provider units. 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

Two hundred patients were needed to give a power of 80% for detecting a change in standardised difference of 0.4 in the Extended Aberdeen Spine Pain Scale (which has a range of 0-100) with a significance level of 5%.

Data analysis

Descriptive statistics were used to assess baseline comparability of the two trial arms. Analysis was by simple intention to treat comparisons of the groups as randomised. Both hypothesis testing and confidence intervals for comparisons between the groups were used, using independent t tests of the change scores of the outcome measures.

Economic Evaluation

Economic evaluation took the form of a cost effectiveness analysis of osteopathy plus usual general practice care as compared with usual GP care alone. The study took an NHS perspective. Health service utilisation for back pain and for back pain plus all other reasons was recorded from GP records over the six-month study period and for the six months prior to the beginning of the study.

We present mean service contact frequencies and costs for the six-month period prior to the start of the study, followed by mean service contact frequencies and costs for the six-month

study period for back pain problems and all other reasons; and for back pain related contacts alone. Statistical tests of significance of difference in mean costs are presented, confirmed using the bootstrap method.

A cost effectiveness analysis is used to assess dominance of the intervention service relative to the control service. Average cost effectiveness ratios and incremental cost effectiveness ratios (ICERs) are then calculated for total service use.

The cost data was likely to be skewed, as a small number of participants were likely to have extremely high use of health care services. To examine the variance in this cost data the "bootstrap" technique was used²³ using the programme S-Plus for 1,000 replications.

Sensitivity analysis was conducted in the form of recalculation of cost-effectiveness ratios and ICERs based on costs of health service utilisation for back pain alone. The paper concludes by raising a number of questions as to the potential usefulness of cost effectiveness acceptability and affordability curves in advising health Authorities or Local health Boards in Wales as to whether or not osteopathy services should be funded in primary care.

RESULTS

Recruitment rate

Fourteen practices representing 54 GPs were enrolled throughout the study, but four practices (with 13 GPs) only recruited one patient each. Furthermore only twenty GPs referred more than one patient to the trial, at the rate of 1.9 referrals per thousand registered patients per year, which compares favourably with recruitment rates from other trials for spinal pain.²⁴ In total 201 patients were recruited.

Representativeness of sample

The share of the practice populations seen by these twenty GPs was 32,000. Recruitment lasted 43 months for the earliest recruited practices and 22 months for the last. The population available for recruitment amounted to 96,800 patient years. From national UK GP morbidity statistics 84.3 patients consult with spinal pain per thousand registered patients.³ From a previous audit in the Llanfairfechan practice 25% of these would be expected to fulfil the trial entry criteria, so that 21.1 per thousand registered patients per year would be eligible. Taking the figure for the population available for recruitment, the total potential eligible population for the trial was 2,040 (see Figure 1).

Baseline comparability

There was no marked difference between osteopathy and usual GP care groups in terms of socio-demographic characteristics, mean outcome measure scores, or treatment activity and health service cost over the previous six months (see Tables 1 & 2).

A two-tailed student t-test revealed that there was no statistically significant difference in mean costs of service utilisation between the intervention and control groups for the six month period prior to the beginning of the study for either back pain related contacts alone ($p=0.76$), or for contacts for all reasons ($p=0.29$) (see Tables 3 & 4).

There was an imbalance of nineteen in the randomisation between the number of subjects in the control and treatment groups. This was not surprising given that there were twenty four strata and fourteen referring practices. The imbalance was not large enough to affect the power of the trial. There were two randomisation errors, one with a symptom duration of fifty weeks and another with nerve root pain, who were excluded by the data monitoring committee (see Figure 1).

Two month questionnaire results

At two 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 mental score of the SF-12 (95% CI 2.7, 10.7). Similar but smaller differences in improvements were seen in the SMPQ and EQ-5D (see Table 5).

Six month questionnaire results

At six months most outcome measures had continued to improve in both groups. For the EASPS, the difference in change scores between the groups was no longer significant (95% CI -1.5, 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 (see Table 6).

Health service activity and costs

Over the six-month study period total health service activity was similar between the two groups (see table 7). Health service activity attributable to spinal pain was similar in both groups, apart from osteopathic treatment and one inpatient admission in the osteopathic treatment group. Health service costs attributable to spinal pain were almost twice as large in the osteopathic treatment group (see Table 8), with a mean difference in cost of £65,

which was statistically significant ($p=0.03$) (95% CI £6, £124). Bootstrap results were very similar (95% CI £33, £155). Although total health service costs were slightly higher in the osteopathic treatment group (see Table 8), with a mean difference in cost of £22, there was no statistically significant difference ($p=0.817$) (95% CI -£205, £162).

Bootstrap results were very similar (95% CI -£159, £142) (See Table 9). There was however a statistically significant difference in mean cost for back-pain only related health service utilisation between intervention and control groups for the six-month study period (See Table 10).

COST EFFECTIVENESS ANALYSIS

Cost effectiveness analysis for all costs

The analysis in this section is based on total costs of service utilisation (for back pain and other reasons) (see Table 9).

Cost effectiveness analysis provides a method of comparing alternative treatments in which the costs and consequences of the treatments vary. Costs included direct costs of all primary and secondary health care services used by participants in the intervention and control arms of the Romans study. (No indirect or intangible costs were included.) Effectiveness was measured in terms of the primary clinical endpoint, Extended Aberdeen Spine Pain Scale.

Incremental Cost-Effectiveness Analysis

Incremental Cost-Effectiveness Analysis enable analysis of additional costs and consequences associated with different treatments. The incremental cost-effectiveness ratio is obtained by dividing the cost differences ($C2 - C1$) by the effectiveness differences ($E2 - E1$).

Where:

C1 = Mean cost of treatment of participants in control arm

C2 = Mean cost of treatment of participants in intervention arm

E1 = Mean point score change on Extended Aberdeen Spine Pain Scale of participants in control arm

E2 = Mean point score change on Extended Aberdeen Spine Pain Scale of participants in intervention arm

The incremental cost-effectiveness ratio tells us the change in costs and effectiveness of moving from/extending osteopathy services in primary care (intervention treatment) as compared with usual GP care (control treatment).

Assessment of Dominance

Figure 2 shows a framework used in Laupacis et al.²⁵ which allows us to plot the relationship between the intervention and control treatments in the Romans study on a plane. We can assess whether the intervention treatment is:

1. Dominant (accept intervention treatment) $C2 - C1 < 0, E2 - E1 > 0$
2. Dominant (reject intervention treatment) $C2 - C1 > 0, E2 - E1 < 0$
3. Trade-off (need to assess relative size of difference in costs to difference in effectiveness) $C2 - C1 > 0, E2 - E1 > 0$
4. Trade -off (need to asses relative size of difference in costs to difference in effectiveness) $C2 - C1 < 0, E2 - E1 < 0$

In the Romans study the intervention service is both more costly and more effective than the control service, placing it in the north-east trade off quadrant of the above diagram.

COST EFFECTIVENESS RATIOS

This section is based on service utilisation for back pain and all other reasons for the trial period 0-6 months.

Where:

C1 = Mean cost of all services utilised by patients in the control group

C2 = Mean cost of all services utilised by patients in the intervention group

E1 = Mean Extended Aberdeen Spine Pain Scale score change for the control group

E2 = Mean Extended Aberdeen Spine Pain Scale score change for the intervention group

C1= 307.31

C2= 328.81

E1=10.4

E2=14.9

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Intervention group	C2/E2	=	£328.81/14.9	=	£22.07
Control group	C1/E1	=	£307.31/10.4	=	£29.55

Interpretation

This calculation shows that to achieve a one point change on the Extended Aberdeen Spine Pain Scale score costs £22.07 for the intervention group and £29.55 for the control group.

These average cost effectiveness ratios show the cost per unit of benefit of the new treatment independent of other treatments.

INCREMENTAL COST EFFECTIVENESS RATIO (ICER)

The incremental cost effectiveness ratio is obtained by dividing the cost difference (C2-C1) by the outcome difference (E2-E1) for the two treatments

$$C2-C1/E2-E1 = £21.50/4.5 = £4.78$$

Interpretation

The figure £4.78 may be interpreted as the cost per unit of increase on the Extended Aberdeen Spine Pain Scale of switching from the control treatment to the intervention treatment. The ICER indicates relative cost effectiveness compared with any other existing treatment options. In itself this is of little help unless it were possible to rank the intervention treatment against a range of other possible treatment options. In such a scenario it would be possible to rank or prioritise treatment options with the lowest ICER above those with a higher ICER.

SENSITIVITY ANALYSIS

Reassessment of dominance using costs associated with back pain only rather than costs of all health service contacts (back pain and other reasons) still results in a trade-off outcome.

Recalculation of cost effectiveness ratios using costs associated with back pain alone results as follows:

Intervention group	C2/E2	=	£128.93/14.9	=	£8.65
Control group	C1/E1	=	£63.83/10.4	=	£6.14

Recalculation of the ICER using costs associated with back pain only results in the following figures:

$$C2-C1/E2-E1 = £65.10/4.5 = £14.47$$

Interpretation

Based on health service utilisation costs associated with back pain alone, the cost of switching from the control treatment to the intervention treatment has increased to £14.47 per additional one point improvement on the Extended Aberdeen Spine Pain Scale.

QUESTIONS FOR DISCUSSION AT HESG

1. To what extent does it matter that there was no statistically significant difference at six months in the primary clinical endpoint in the study, the Extended Aberdeen Spine Pain Scale, which was used as the measure of effectiveness in the cost effectiveness analysis? Should we/could we use the 2 month results which were statistically significant?
2. Sensitivity analysis showed that the ICER based on health service utilisation costs of back pain alone was higher than the ICER based on health service utilisation costs for all reasons. The Romans study was a pragmatic randomised controlled trial conducted in primary care. Is it therefore appropriate to accept the lower ICER?
3. What would be an appropriate shadow price or ceiling ratio for the treatment of back pain in primary care?
4. Can the use of acceptability curves or affordability curves help in interpreting our findings with a view to advising health authorities or local health boards in Wales as to the future funding of osteopathy in primary care? ^{27, 28, 29}

REFERENCES

- 1 Cote P, Cassidy D, Carroll L (1998). The Saskatchewan health and back pain survey. The prevalence of neck pain and related disability in Saskatchewan adults. *Spine* 1998;23:1689-1698.
- 2 *Clinical Standards Advisory Group [CSAG]. Back pain. London: HMSO, 1994.*
- 3 McCormick A, Fleming D, Charlton J. Morbidity statistics from general practice: fourth national study 1991-1992. *London: HMSO, 1995.*
- 4 Thomas KJ, Carr J, Westlake L, Williams BT (1991). Use of non-orthodox and conventional health care in Great Britain. *BMJ* 1991;302:207-210.
- 5 Wadell G, Feder G, McIntosh A, Lewis M, Hutchinson A. *Low back pain evidence review.* London: Royal College of General Practitioners, 1996.
- 6 *Agency for Health Care Policy and Research [AHCPR]. Acute low back problems in adults. Clinical Practice Guideline 14. US Department of Health and Human Services, Rockville, Maryland, 1994.*
- 7 vanTulder MW, Wadell G. *Conservative treatment of acute and sub-acute low back pain.* In: *Neck and back pain: the scientific evidence of causes, diagnosis and treatment.* Eds. Nachemson A, Jonsson E. Philadelphia: Lippincott Williams & Wilkins, 2000.
- 8 Faas A, Chavannes AW, Koes BW, et al (1996). NHG-standaard lage-rugpijn. *Huisarts Wet* 1996;39:18-31.
- 9 Williams N, Hoving J. *Neck pain.* In *Oxford textbook of primary medical care.* Eds. Jones R, Britten N, Culpepper L, et al. Oxford: OUP(in press).
- 10 Harms-Ringdahl K, Nachemson A. *Acute and sub-acute neck pain: non-surgical treatment.* In: *Neck and back pain: the scientific evidence of causes, diagnosis and treatment.* Eds. Nachemson A, Jonsson E. Philadelphia: Lippincott Williams & Wilkins, 2000.
- 11 Greenman PE. *Principles of manual medicine, 2nd edition.* Baltimore MA: Williams and Wilkins, 1996.
- 12 Williams N. Managing back pain in general practice – is osteopathy the new paradigm? *BJGP* 1997;47:653-655.
- 13 Williams N, Wilkinson C, Russell I. Extending the Aberdeen back pain scale to include the whole spine: a set of outcome measures for the neck, upper and lower back. *Pain* 2001;94:261-74.
- 14 Cochrane AL. Effectiveness and efficiency: random reflections on health services. *London: Nuffield Provincial Hospitals Trust, 1972.*
- 15 Goossens M, Evers M. *Cost-effectiveness of treatment for neck and low back pain.* In: *Neck and Back Pain: The Scientific Evidence of Causes, Diagnosis and*

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- Treatment*. Eds. NACHEMSON A, JONSSON E. Philadelphia: Lippincott Williams & Wilkins, 2000.
- 16 Wearn AM, Greenfield SM (1998). Access to complementary medicine in general practice: survey in one UK health authority. *J Royal Soc Med* 1998; 91:465-470.
- 17 Williams N. A primary care musculoskeletal clinic: clinical and financial audit of twelve months activity. *J Orthop Med* 2000;22:48-51.
- 18 Melzack R. The short-form McGill Pain Questionnaire. *Pain* 1997;30:191-197.
- 19 Ware JE, Kosinski M, Keller SD. A 12-item Short-Form health survey, construction of scales and preliminary tests of reliability and validity. *Medical Care* 1996;34:220-233.
- 20 EuroQol Group. EuroQol: a new facility for the measurement of health related quality of life. *Health Policy* 1991;16:199-208.
- 21 *British National Formulary [BNF] 37*: BMA, Royal Pharmaceutical Society of Great Britain, 1999.
- 22 Netten A, Curtis L. *Unit costs of health and social care 2000*. PSSRU, University of Kent at Canterbury, 2000.
- 24 S-Plus 2000 (Computer programme) Mathsoft Inc, Seattle, WA.
- 25 Laupacis A, Feeny D, Detsky A, Tugwell P. How attractive does a new technology have to be to warrant adoption and utilisation? Tentative guidelines for using clinical and economic evaluations. *Canadian Medical Association Journal* 1992; 146: 473-481.
- 26 Willan A & O'Brien B. Confidence Intervals for cost-effectiveness ratios: An application of Fieller's theorem. *Health Economics* 1996; 5:297-305.
- 27 Pedram Sendi P, Briggs AH. Affordability and cost-effectiveness: decision-making on the cost-effectiveness plane. *Health Economics* 2001; 10: 675-680.
- 28 van Hout BA, Al MJ, Gordon GS, Ruttun FF. Costs, effects and C/E ratios alongside a clinical trial. *Health Economics* 1994; 3: 309-319.
- 29 Briggs AH. A Bayesian Approach to stochastic cost-effectiveness analysis. *Health Economics* 1999; 8: 257-262.

Figure 1: Trial profile flow chart

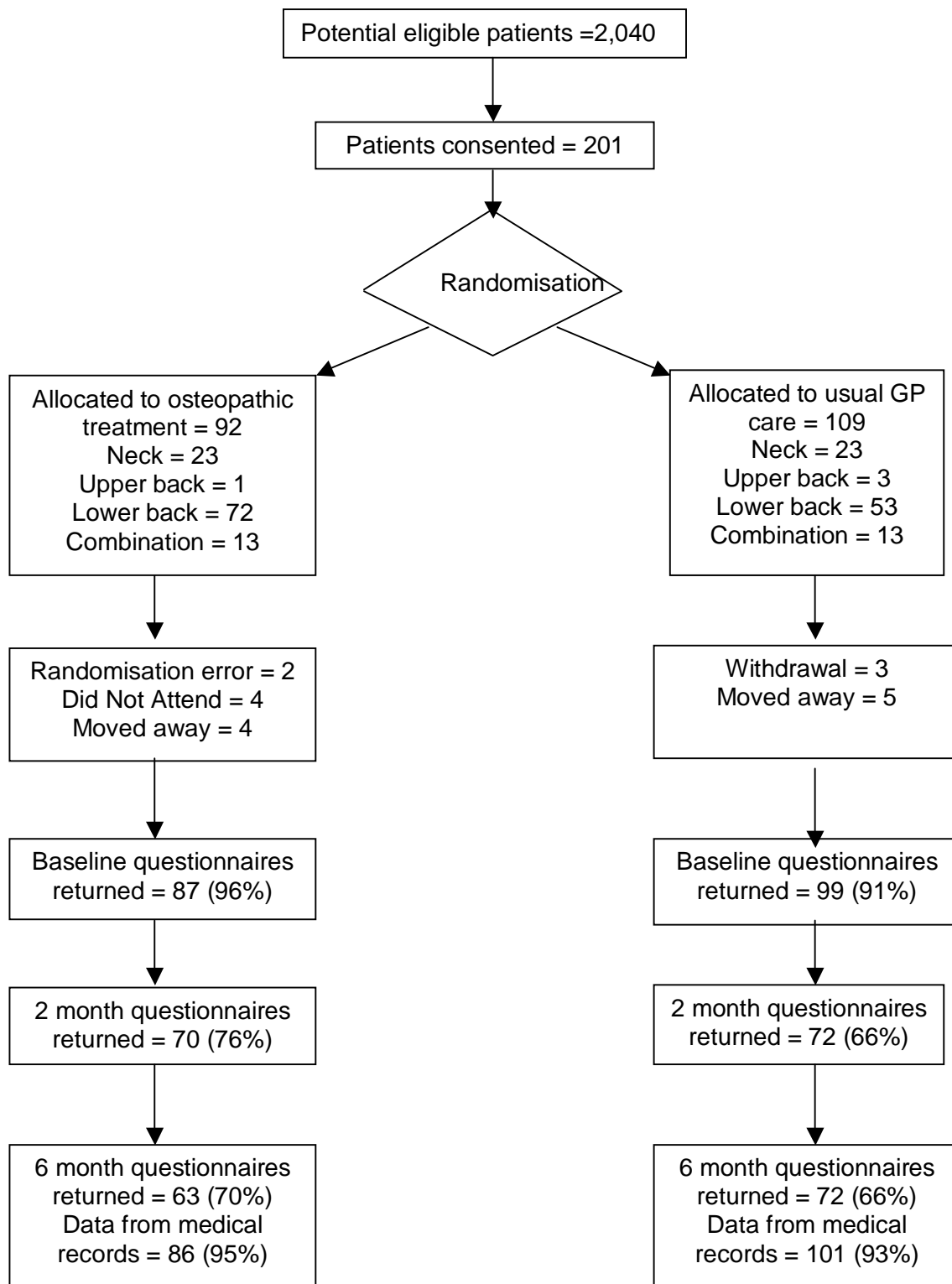
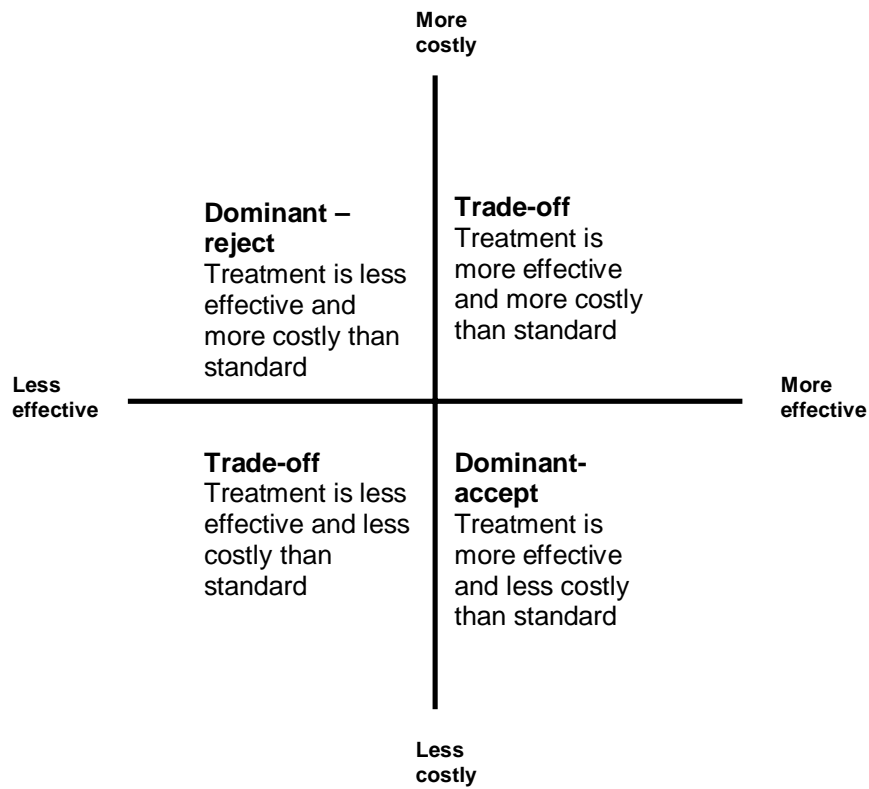


Figure 2: Cost-effectiveness plane ²⁶



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Table 1: Mean scores of all outcome measures and health service costs at baseline (SD)^b

Outcome measure^a	Usual care (control group)	Osteopathy (intervention group)
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 six 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 Key: EASPS -Extended Aberdeen Spine Pain Scales; SF-12 - SF-12; SMPQ - Short-form McGill Pain Questionnaire; VAS - Visual Analogue Scale; EQ-5D - EuroQol EQ-5D.

^b No significant differences in outcome measure or health service costs between usual care and osteopathy groups at baseline.

Table 2: Frequency of contacts for 6 months prior to study period (means and SD)

Control group contacts (n=101)		Service	Intervention group contacts (n=86)	
Mean	SD		Mean	SD
3.60	2.84	All GP contacts	3.45	2.62
1.89	1.79	GP contacts for back pain	1.60	1.49
1.71	1.90	GP contacts for non-back pain	1.84	2.33
0.39	0.85	All Primary Health Care Team (PHCT) contacts	0.37	0.78
0.03	0.22	PHCT contacts for back pain	0.05	0.21
0.36	0.83	PHCT contacts for non-back pain	0.32	0.74
0.60	1.11	All tests	0.61	0.89
0.15	0.36	Tests directly for back pain	0.10	0.31
0.46	1.07	Tests for non-back pain	0.50	0.83
5.38	8.12	Total number of prescriptions	5.36	8.32
1.41	1.91	Prescriptions for back pain	1.40	2.08
3.97	6.96	Prescriptions for non-back pain	3.97	7.48
0.25	0.61	All consultant contacts	0.18	0.45
0.04	0.20	Consultant contacts for back pain	0.03	0.18
0.21	0.52	Consultant contacts for non-back pain	0.15	0.39
0.07	0.29	All A&E contacts	0.03	0.18
0.02	0.14	A&E contacts directly for back pain	0.03	0.18
0.05	0.26	A&E contacts for non-back pain	0	0
0.08	0.39	All inpatient/day patient episodes	0.08	0.28
0.01	0.10	Inpatient/day patient episodes directly for back pain	0.01	0.11
0.07	0.38	Inpatient/day patient episodes for non back pain	0.07	0.26
0.07	0.26	All NHS Practitioner contacts	0.05	0.21
0.04	0.20	NHS practitioner contacts for back pain	0.02	0.15
0.03	0.17	NHS practitioner contacts for non-back pain	0.02	0.15
0.01	0.10	Aids and Appliances	0	0
0.01	0.10	Private referrals	0.02	0.15
n/a	n/a	Osteopathy contacts	n/a	n/a

Table 3: Mean cost of service utilisation for back pain and other reasons for 6 months pre-trial period

Group	Mean	Standard deviation
Intervention	£257.17	£430.41
Control	£290.24	£918.49

Table 4: Mean back pain only costs for 6-month pre-trial period

Group	Mean	Standard deviation
Intervention	£47.29	£61.91
Control	£58.00	£74.01

Table 5: Improvement in mean scores of all outcome measures at two months

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

^a Key: EASPS Extended Aberdeen Spine Pain Scales
 SF-12 SF-12
 SMPQ Short-form McGill Pain Questionnaire
 VAS Visual Analogue Scale
 EQ-5D EuroQol EQ-5D

Table 6: Improvement in mean scores of all outcome measures at six months

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

^a Key: EASPS Extended Aberdeen Spine Pain Scales
 SF-12 SF-12
 SMPQ Short-form McGill Pain Questionnaire
 VAS Visual Analogue Scale
 EQ-5D EuroQol EQ-5D

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Table 7: Frequency of all service utilisation (for back pain and other) over the study period 0-6 months

Control group contacts (n=101)		Service	Intervention group contacts (n=86)	
Mean	SD		Mean	SD
3.26	2.69	All GP contacts	3.16	2.81
1.75	2.22	GP contacts for back pain	1.49	2.00
1.50	1.84	GP contacts for non-back pain	1.67	2.27
0.61	1.51	All Primary Health Care Team (PHCT) contacts	0.66	1.12
0.02	0.14	PHCT contacts for back pain	0.02	0.15
0.59	1.51	PHCT contacts for non-back pain	0.64	1.11
0.67	1.10	All tests	0.50	0.84
0.10	0.33	Tests directly for back pain	0.06	0.24
0.57	1.02	Tests for non-back pain	0.44	0.73
5.11	7.41	Total number of prescriptions	5.28	8.62
1.30	2.17	Prescriptions for back pain	1.21	1.90
3.81	6.05	Prescriptions for non-back pain	4.07	7.91
0.28	0.62	All consultant contacts	0.31	0.54
0.08	0.27	Consultant contacts for back pain	0.07	0.26
0.20	0.49	Consultant contacts for non-back pain	0.24	0.48
0.07	0.29	All A&E contacts	0.03	0.18
0	0	A&E contacts directly for back pain	0.01	0.11
0.07	0.29	A&E contacts for non-back pain	0.02	0.15
0.10	0.39	All inpatient/day patient episodes	0.05	0.21
0	0	Inpatient/day patient episodes directly for back pain	0.01	0.11
0.10	0.39	Inpatient/day patient episodes for non back pain	0.03	0.18
0.23	0.42	All NHS Practitioner contacts	0.14	0.35
0.17	0.38	NHS practitioner contacts for back pain	0.10	0.31
0.06	0.24	NHS practitioner contacts for non-back pain	0.04	0.19
0.04	0.20	Aids and Appliances	0.04	0.19
0.01	0.10	Private referrals	0.01	0.11
n/a	n/a	Osteopathy contacts	2.92	1.29

Table 8: Frequency of health service activity and costs for the six months study period

Health care activity^a	Usual care Mean (SD) n=101	Osteopathy Mean (SD) n=86
All GP contacts	3.26 (2.69)	3.16 (2.81)
GP contacts for spinal pain	1.75 (2.22)	1.49 (2.00)
Other PHCT contacts for spinal pain	0.02 (0.14)	0.02 (0.15)
Spine radiographs	0.1 (0.33)	0.06 (0.24)
Analgesic/NSAID prescriptions	1.3 (2.17)	1.21 (1.9)
Consultant contacts for spinal pain	0.08 (0.27)	0.07 (0.26)
A&E contacts for spinal pain	0	0.01 (0.11)
Days admitted as inpatient for spinal pain	0	0.01 (0.11)
Physiotherapy contacts for spinal pain	0.17 (0.38)	0.10 (0.31)
Aids and Appliances	0.04 (0.20)	0.04 (0.19)
Private referrals for spinal pain	0.01 (0.1)	0.01 (0.11)
Osteopathy contacts	0	2.92 (1.29)
Health care costs		
Mean total health care costs 95% CI (-£159, £142) ^b	£307 (£687)	£328 (£564)
Mean health care costs for spinal pain 95% CI (£32, £155) ^b	£64 (£90)	£129 (£283)

^a Key: GP General Practitioner
 PHCT Primary Health Care Team
 NSAID Non-Steroidal Anti-inflammatory Drugs
 A&E Accident and Emergency Department
 95% CI 95% Confidence Interval

^b No significant difference in health care costs except for spinal pain.

Table 9: T-test and bootstrap results using all service costs for the six months study period

Test	95% confidence interval	standard error
t-test	-204.93 to 161.96	92.99
bootstrap	-158.53 to 142.20	93.22

Table 10: T-test and bootstrap results using back pain costs only for the six months study period

Test	95% confidence interval	standard error
t-test	-123.86 to -6.34	29.78
bootstrap	-155.27 to -32.47	30.80