Spinal manipulation and mobilisation for back and neck pain: a blinded review

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Abstract

Objective—To assess the efficacy of spinal manipulation for patients with back or neck pain.

Design—Computer aided search for published papers and blinded assessment of the methods of the studies.

Subjects—35 randomised clinical trials comparing spinal manipulation with other treatments.

Main outcome measures—Score for quality of methods (based on four main categories: study population, interventions, measurement of effect, and data presentation and analysis) and main conclusion of author(s) with regard to spinal manipulation.

Results—No trial scored 60 or more points (maximum score 100) suggesting that most were of poor quality. Eighteen studies (51%) showed favourable results for manipulation. In addition, five studies (14%) reported positive results in one or more subgroups. Of the four studies with 50-60 points, one reported that manipulation was better, two reported that manipulation was better in only a subgroup, and one reported that manipulation was no better or worse than reference treatment. Eight trials attempted to compare manipulation with some placebo, with inconsistent results.

Conclusions—Although some results are promising, the efficacy of manipulation has not been convincingly shown. Further trials are needed, but much more attention should be paid to the methods of study.

Introduction

About 80% of people in Western countries will experience back pain at some time during their lives.[1,2] Fortunately, the disease is usually self limiting. Most patients recover from an attack of back pain within six weeks, irrespective of the type of treatment given, although the recurrence rate is high.[2,3] Despite the common occurrence of back pain its management remains controversial. A wide variety of therapeutic possibilities exists, but no single treatment seems to be superior to others.[4] Spinal manipulation or mobilisation are widely used for treating back pain, and their efficacy has been studied in randomised clinical trials.[5] The similarities and differences between the several manipulative techniques available are not always clear. However, there seems to be agreement that manipulation involves a high velocity thrust to a joint beyond its restricted range of movement. Mobilisation uses low velocity passive movements within or at the limit of joint range.[6] Throughout this article we will use manipulation to cover both manipulation and mobilisation.

The rationale given for manipulation in the management of back and neck pain ranges from reduction of a bulging disk, correction of the internal displacement of disc fragments, and freeing of adhesions around a prolapsed disc or facet joints to inhibition of transmission of nociceptive impulses.[7,8] Whether manipulation is effective can be evaluated only in randomised clinical trials, but the outcome of such trials may be biased by flaws in the methods of the study. We present a critical review of the available randomised clinical trials of spinal manipulation for back and neck pain. Strong emphasis will be put on the methods of the studies included.

Methods

A MEDLINE literature search was carried out for the period 1966-90 (keywords: backache, musculoskeletal diseases, joint diseases, manipulation, osteopathy, chiropractic, evaluation studies, outcome and process assessment). In addition, the references given in relevant publications were further examined. Abstracts and unpublished studies were not selected. Studies had to meet the following criteria: the (experimental) treatment regimen included manipulation of the spine (additional interventions were allowed); the subjects had back or neck pain; the study was a randomised clinical trial.

All trials were scored according to the criteria listed in table I. The criteria are based on generally accepted principles of intervention research.[9,10] The criteria were developed by Ter Riet *et al*[11] and have been modified for this study. Each criterion is given a weight and the maximum score was set at 100 points for each study. All publications were blinded for author(s), journal, and outcome by one of us (BWK). Subsequently, the methodological quality of the studies was assessed by two blinded reviewers (WJJA, GJMGH) independently. In a subsequent meeting they (still blinded) tried to reach consensus on each criterion they disagreed about. When disagreement persisted a third blinded reviewer (LMB) made the decision. The assessments resulted in a hierarchical list in which higher scores indicate studies with better methods. The outcome of the studies will be discussed in relation to their method scores.

A study was determined to be positive if the authors concluded (in their abstract or conclusions, or both) that manipulation was more effective than the refer-

TABLE I—*Criteria for assessing methods of randomised clinical trials of manipulation for back and neck pain*

Criterion*		Weighting
Study population		30
A Homogeneity	2	
B Comparability of relevant baseline characteristics	5	
C Randomisation procedure adequate	4	
D Drop outs described for each study group separately	3	
E <20% Loss to follow up	2	
<10% Loss to follow up	2	
F >50 Subjects in the smallest group	6	
>100 Subjects in the smallest group	6	
Interventions		30
G Interventions included in protocol and described	10	
H Pragmatic study	5	
I Cointerventions avoided	5	
J Placebo controlled	5	
K Mentioning good qualification of manipulative therapist	5	
Effect		30
L Patients blinded	5	
M Outcome measures relevant	10	
N Blinded outcome assessments	10	
O Follow up period adequate	5	
Data presentation and analysis		10
P Intention to treat analysis	5	
Q Frequencies of most important outcomes presented for each treatment group	5	

*Further details given in appendix.

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ence treatment. Sometimes the authors reported favourable outcomes for manipulation in only a subgroup of the study population. In a negative study the authors reported no differences between the study treatments or better results with the reference treatment. Short term outcome refers to effect measurements during or just after the intervention period. Long term outcome refers to outcome measurements at least three months after randomisation.

Results

Thirty eight trials met the inclusion criteria. Three trials were found to be reported twice and the publication with the lowest method score in each case was excluded.[7 12 13] Table II gives the remaining 35 trials in a hierarchical order according to their methodological score. Thirty trials were in patients with back pain and five in those with neck pain. Initially the two blinded reviewers disagreed over the criterion in 276 (20%) of the 1400 instances. Usually this seemed to be due to errors in reading. After their consensus meeting disagreement was reduced to four instances, for which the third blinded reviewer made the final decision.

No trial scored 60 or more points, and only four studies (three of back pain, one of neck pain) scored more than 50 points, suggesting a general poor quality. The most prevalent methodological problems were the proper description of drop outs, the small size of the study population, the lack of a placebo group, the blinding of patients, and the blinded measurements of effect. In 18 trials (51%) the authors reported better results for manipulation than the reference treatment (for example, short wave diathermy, massage, exercises, analgesics, or placebo treatment). In addition, five other trials reported better results in only a subgroup of the study population. In 11 studies manipulation seemed to be no more effective than the reference treatment.

Considering the four trials with methodological scores of 50-60 points, one reported positive results and one negative results, and two studies reported better results in only a subgroup of the study population. Considering the nine trials with method scores of 40-50 points two reported positive results, six negative, and one better results in only a subgroup. Only 14 studies measured the effect at least three months after randomisation, only four of which reported long term positive effects of manipulation.

The figure presents the relation between the method score and the outcome of the study. Included are the 18 positive studies and the 11 negative studies. The five trials reporting positive results of manipulation in only a subgroup were omitted because the labelling as positive or negative would be ambiguous for these. One study in which the author did not draw a conclusion was also omitted. Only three of the 18 positive studies (17%) scored 40 points or more. In contrast, seven of the 11 negative studies (64%) scored 40 points or more. In general the negative studies seemed to have higher method scores.

Table III presents the comparison of manipulation with other conservative treatments and gives the main characteristics of the forms of manipulation included in the trials. Manipulation was given alone or in combination with other treatments. The reference

TABLE II—*Randomised trials on the efficacy of manipulation for back pain and neck pain in order of methods score*

Study	Methods criteria: A (2)	B (5)	C (4)	D (3)	E (4)	F (12)	G (10)	H (5)	I (5)	J (5)	K (5)	L (5)	M (10)	N (10)	O (5)	P (5)	Q (5)	Total score (100)	Indication*	Conclusion†
Back pain trials:																				
MacDonald, Bell[14]	1	4		3	4		10	5	5		5		6		3	5	5	56	Acute plus chronic low back pain	Positive (only in patients with pain of 2-4 weeks' duration not those with <2 weeks or >4 weeks)
Hadler *et al*[15]	1	3			4		10	5	5		5	3	4		3	5	5	53	Acute low back pain	Positive (only in patients with pain of 2-4 weeks' duration not those with <2 weeks)
Ongley *et al*[16]	2	4	2		4		5	5				5	4	4	5	5	5	50	Chronic low back pain	Positive
Bergquist-Ullman, Larsson[17]	2	1	2		4	6	10	5		5	5	2	2		5			49	Acute low back pain	Positive compared with placebo Negative compared with back school
Meade *et al*[18]		4	4		2	12		5			5		6		5		5	48	Acute plus chronic low back pain	Positive
Gibson *et al*[19]	2	3		3	4			5	5	5	5		4	2	3		5	46	(Sub)acute low back pain	Negative
Sims-Williams *et al*[20]	1	2			4		5	5	5		5		6	2	5		5	45	Acute plus chronic low back pain	Negative
Helliwell, Cunliffe[21]	1	3		3	4		5	5	5				2	2	3	5	5	43	Acute low back pain	Negative
Doran, Newell[22]	1				2	12		5			5	3	4	2	3		5	42	Acute plus chronic low back pain	Negative
Mathews *et al*[23]		2	0	3	2	12	5	5					2		5		5	41	Acute back pain	Positive (only in patients in whom straight leg raising was limited)
Evans *et al*[24]			2		2		5	5	5		5		6	2	3		5	40	Chronic low back pain	Positive
Glover *et al*[25]		3	4	3	4		5		5	5			2		3	5		39	Acute back pain	Negative
Coxhead *et al*[26]	1	1			2	12		5					4		3	5	5	38	Sciatic symptoms	Positive
Waagen *et al*[27]	1	2					5	5	5		5	5	4	2	3			37	Chronic low back pain	Positive
Hoehler *et al*[28]		1			4			5		5		3	4		3	5	5	35	Acute plus chronic low back pain	Positive
Sims-Williams *et al*[29]	1				4		5	5			5		8	2	5			35	Acute plus chronic low back pain	Positive
Zylbergold, Piper[30]		2		3	4			5					6		3	5	5	33	Not mentioned	Negative
Postacchini *et al*[31]		2			2			5	5	5	5		4		5			33	Acute plus chronic low back pain	Positive (only in patients with acute back pain not those with chronic pain)
Rasmussen[32]	1	1			4			5	5				4		3	5	5	33	Acute low back pain	Positive
Farrell, Twomey[33]	2	4			2			5	5				6		3		5	32	Acute low back pain	Positive
Nwuga[34]	2	3					10	5	5				2	2	3			32	Acute low back pain (prolapsed disc)	Positive
Waterworth, Hunter[35]	2	3		3	4			5	5				6		3			31	Acute low back pain	Negative
Arkuszewski[36]		1	2		4			5					4		5	5	5	31	Acute plus chronic low back pain	Positive
Buerger[37]	1						10	5	5		5		2		3			31	Not mentioned	Positive
Tobis, Hoehler[38]							5	5	5		5	3	4		3			30	Not mentioned	Positive
Bronfort[39]	1	2			2			5			5	3	2		5		5	30	Acute plus chronic low back pain	No conclusion
Kinalski *et al*[40]					4	6			5				4				5	24	Not mentioned	Positive
Godfrey *et al*[41]	1	1			2			5					8	2	3			22	Acute low back pain	Negative
Siehl *et al*[42]	1	1						5	5		5				5			22	Not mentioned	Positive (only in patients with no nerve root compression not those with compression)
Rupert *et al*[43]	1	1								5	5	3	2		3			20	Acute plus chronic low back pain	Positive
Neck pain trials:																				
Sloop *et al*[44]	2	1	2		4		5			5	5	5	4	4	3	5	5	50	Chronic neck pain	Negative
Nordemar, Thörner[45]	1	3		3	4		5	5	5				4		3	5	5	43	Acute neck pain	Negative
Brodin[46]		1	4		2		5	5	5		5		4		3		5	39	Acute plus chronic neck pain	Positive
Howe, Newcombe[47]		3	2				5	5					4	2	3		5	29	Acute plus chronic neck pain	Positive
Mealy *et al*[48]	1	2	4		2			5					4		3		5	26	Acute neck pain (whiplash)	Positive

*The labels acute and chronic are according to the authors of study. Classification might vary between the studies.
†Conclusion of the author(s) of the study. Positive conclusion=manipulation better than the control treatment; negative conclusion=manipulation worse than or equally effective as control treatment.

treatments were mainly physiotherapeutic interventions (shortwave diathermy, massage, exercises) and drugs (analgesics). Thirty one trials compared manipulation with other conservative treatments. Of these, 15 (48%) reported positive results in patients with both acute and chronic back and neck pain.

Of the three studies with method scores of 50-60 points one reported negative results, and two studies reported positive results in only a subgroup. Among the eight studies with method scores of 40-50 points there were five reported negative results, two positive, and one positive results in only a subgroup.

Table IV presents the eight trials comparing manipulation with placebo. In most studies the placebo

TABLE III—*Details of trials comparing manipulation with other conservative treatments*

Study	Manipulation (No of patients)	Comparison treatment (No of patients)	Methods score	Results*
Back pain:				
MacDonald, Bell[14]	(i) Osteopathic (49)	(ii) Exercises and advice on posture (46)	56	All patients: no significant different recovery rates between treatment groups. In subgroup with current attack duration of 2-4 weeks: % of patients recovered after one week; (i) 46%; (ii) 17%.
Hadler *et al*[15]	(i) Rotational (26)	(ii) Spinal mobilisation (28)	53	All patients: similar response rates according to Roland Morris questionnaire. In subgroup with current attack duration of 2-4 weeks: better results in manipulation group (i) after one week.
Bergquist-Ullman, Larsson[17]	(i) Cyriax, Kaltenborn, Lewitt, Janda (72)	(ii) Back school (70)	49	Mean No of days until recovery: (i) 15·8; (ii) 14·8.
Meade *et al*[18]	(i) Chiropractic (384)	(ii) Physiotherapy (357)†	48	Difference in change in Oswestry questionnaire (mean score group (ii) minus mean score group (i) after 6 weeks, 6 months, 1 year, and 2 years: 1·69, 3·31, 2·09, 7·16, respectively. Manipulation significantly better after 6 months and 2 years.
Gibson *et al*[19]	(i) Osteopathic (41)	(ii) Short wave diathermy (34)	46	% Of patients free of pain after 4 and 12 weeks: (i) 28%, 42%; (ii) 28%, 37%.
Helliwell, Cunliffe[21]	(i) Cyriax (6)	(ii) Analgesics (8)	43	Combined symptom score (SD) (maximal severity=28) after 1 and 4 weeks: (i) 2·6(2·6), 3·8(3·3); (ii)6·17(7·2), 2·2(2·5). No significant differences.
Doran, Newell[22]	(i) At discretion of manipulator (116)	(ii) Physiotherapy (114), (iii) analgesics (113), (iv) corset (109)	42	% Of patients better after 6 and 12 weeks: (i) 65%, 74%; (ii) 67%, 65%; (iii) 58%, 76%; (iv) 77%, 83%.
Mathews *et al*[23]	(i) Cyriax (165)	(ii) Infrared heat (126)	41	% Of patients recovered after 2 weeks: In subgroup (n=58) without limitation in straight leg raising: (i) 62%; (ii) 70%. In subgroup (n=233) with limitation in straight leg raising: (i) 80%; (ii) 67%. Manipulation gave significant beneficial effect in subgroup with limited straight leg raising.
Evans *et al*[24]	(i) Rotational (15)	(ii) Analgesics (17)	40	No of patients assessing treatment as effective after 3 weeks: (i) 9; (ii) 3. Significant.
Coxhead *et al*[26]	(i) Maitland (155)	(ii) Exercises or corset or traction (137)	38	No of patients reporting to feel better compared with baseline after 4 weeks and 4 months: (i) 127, 100; (ii) 100, 81. No significant difference.
Waagen *et al*[27]	(i) Chiropractic (9)	(ii) Massage and sham manipulation (10)	37	Improvement on visual analogue scale (10 cm) after 2 weeks: (i) 2·3; (ii) 0·6. Manipulation significantly better.
Hoehler *et al*[28]	(i) Rotational (56)	(ii) Massage (39)	35	No of patients reporting moderate to severe pain at discharge (variable) and 3 weeks after discharge: (i) 17, 21; (ii) 29, 48. Manipulation significantly better after first treatment. No differences at discharge and 3 weeks later.
Zylbergold, Piper[30]	(i) Rotational (8)	(ii) Heat and exercises (10)	33	Improvement (SD) on 5 point pain scale: (i) −1·5(0·1); (ii) −1·0(0·85). No significant differences but results indicate slight advantage for manipulation.
Postacchini *et al*[31]	(i) Chiropractic (87)	(ii) Physiotherapy (78), (iii) drugs (81), (iv) bedrest (29), (v) back school (50)	33	Mean improvement on combined pain, disability, and spinal mobility score (5-32) after 3 weeks, 2 months, and 6 months. In subgroup with acute pain: (i) 7·5, 9·7, 12·3; (ii) 5·0, 8·4, 10·2; (iii) 3·0, 10·7, 14·0; (iv) 5·4, 7·5, 7·3. Manipulation significantly better (short term) only in subgroup with acute pain only after 3 weeks. In subgroup with chronic pain: (i) 2·2, 2·6, 4·3; (ii) 3·9, 4·2, 6·0; (iii) 2·6, 2·2, 4·0; (v) 0·5, 4·6, 8·9. Manipulation not better in subgroup with chronic pain.
Rasmussen[32]	(i) Rotational (12)	(ii) Short wave diathermy (12)	33	No (%) of patients totally restored after 14 days: (i) 11 (92%); (ii) 3 (25%). Manipulation significantly superior.
Farrell, Twomey[33]	(i) Stoddard, Maitland (24)	(ii) Short wave diathermy and exercises (24)	32	Manipulation group was symptom free in significantly less days. (Data in graphs).
Nwuga[34]	(i) Rotational (26)	(ii) Short wave diathermy and exercises (25)	32	Improvement in spinal flexion and straight leg raising after 6 weeks: (i) 34°, 39°; (ii) 13°, 4°. Manipulation significantly better than comparison treatment.
Waterworth, Hunter[35]	(i) At discretion of physiotherapist (38)	(ii) Short wave diathermy, ultrasound, and exercise (34) (iii) Non-steroidal antiinflammatory drugs (36)	31	Mean change in pain intensity on 4 point scale after 4 and 12 days: (i) −1·1, −1·7; (ii) −0·9, −1·6; (iii) −0·9, −1·7. No significant differences in pain and mobility.
Arkuszewski[36]	(i) Lewit (50)	(ii) Bedrest, analgesics, and massage (50)	31	Pain severity (SD) on 4 point scale (0-3) immediately after treatment and after 6 months; (i) 0·6(0·5), 0·7(0·6); (ii) 1·0(0·4), 1·0(0·5). Improvement was significantly greater in manipulation group.
Buerger[37]	(i) Rotational (-)	(ii) Massage and sham treatment (-)	31	% Of patients who feel better after last treatment and 5 days later: (i) 83%, 52%; (ii) 67%, 66%. Manipulation significantly superior only immediately after last treatment.
Tobis, Hoehler[38]	(i) Rotational (-)	(ii) Massage (-)	30	Manipulation significantly better result in pain relief immediately after treatment. After 5 days no significant differences (data in graphs).
Bronfort[39]	(i) Chiropractic (10)	(ii) Medical treatment (for example, drugs) (9)	30	% Of patients improved after 1, 3, and 6 months; (i) 70%, 70%, 80%; (ii) 55%; 66%, 66%. Author gives no conclusion because of small sample size.
Kinalski *et al*[40]	(i) Janda, Lewitt (61)	(ii) Physiotherapy (50)	24	% Of patients with good result (low pain grade) after treatment: (i) 84%, (ii) 78%.
Godfrey *et al*[41]	(i) Rotational manipulation (44)	(ii) Massage and electrical stimulation (37)	22	% Of patients with moderate or marked improvement in general symptoms on a 5 point scale after 2 weeks: (i) 77%; (ii) 70%. Five other indexes also showed no significant differences.
Sichl *et al*[42]	(i) Osteopathic (21)	(ii) Conservative treatment (7), (iii) Surgery (19)	22	% Of patients showing electromyographic and clinical improvement after 6 and 12 months; (i) 14%; (ii) 0%; (iii) 47%.
Rupert *et al*[43]	(i) Chiropractic (-)	(ii) Drugs and bed rest (-), (iii) Home care instructions (-)	20	Improvement on pain visual analogue scale during treatment: group (i) more pain reduction than groups (ii) and (iii). Data in graphs.
Neck pain:				
Sloop *at al*[44]	(i) Cyriax, Maigne, Maitland (21)	(ii) Diazepam (18)	50	% Of patients reporting that the treatment helped after 3 weeks; (i) 57%; (ii) 28%. No significant difference.
Nordemar, Thörner[45]	(i) Mobilisation therapy (10)	(ii) Transcutaneous nerve stimulation (10), (iii) neck collar (10)	43	Mean (SD) on pain visual analogue scale after 1 and 6 weeks: (i) 18(25), 0; (ii) 17(19), 0; (iii) 34(45), 0. No significant difference.
Brodin[46]	(i) Stoddard (23)	(ii) analgesics (23), (iii) analgesics and mock manual therapy (17)	39	% Of patients reporting no pain one week after final treatment: (i) 48%; (ii) 22%; (iii) 12%. Manipulation significantly better.
Howe, Newcombe[47]	(i) Bourdillon (26)	(ii) Analgesics (26)	29	% Of patients improved (pain measurement) immediately and 1 and 3 weeks after treatment: (i) 68%, 74%, 76%; (ii) 6%, 60%, 58%. Manipulation significantly better only immediately after treatment.
Mealy *et al*[48]	(i) Maitland (31)	(ii) Rest and cervical collar (30)	26	Mean (SE) pain visual analogue scale 4 and 8 weeks after treatment: (i) 2·85(0·57), 1·69(0·43); (ii) 5·08(0·48), 3·94(0·58). Manipulation significantly better.

*Results of the most important outcome measure according to the author(s) of the study. When not explicitly stated presentation of pain or a global measure of improvement. Significant means $p<0.05$. †Including Cyriax and Maitland manipulation. (-) Number not stated.

TABLE IV—*Details of trials comparing manipulation with placebo*

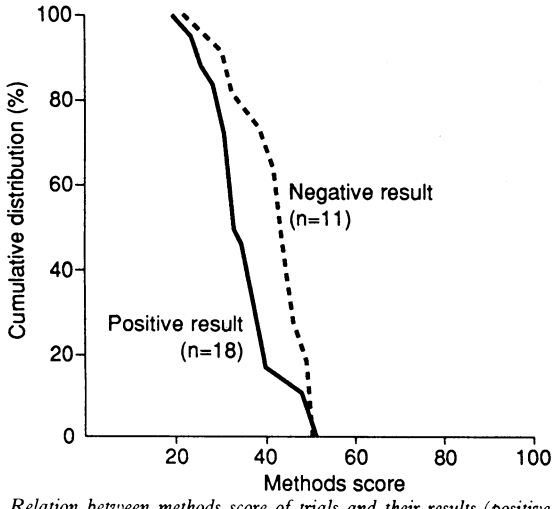
Study	Manipulation (No of patients)	Placebo (No of patients)	Methods score	Results*
Ongley *et al*[10]	(i) Bourdillon (40)	(ii) Non-forceful manipulation (41)	50	Mean (SE) pain on visual analogue scale after 1, 3, and 6 months: (i) 2·1(0·2), 1·8(0·2), 1·5(0·2); (ii) 3·1(0·3), 2·9(0·3), 3·1(0·3). All differences significant
Bergquist, Larsson[17]	(i) Cyriax, Kaltenborn, Lewitt, Janda (72)	(ii) Short wave diathermy at lowest intensity (75)	49	Mean No of days until recovery: (i) 15·8; (ii) 28·7. Difference significant.
Gibson *et al*[19]	(i) Osteopathic (41)	(ii) Detuned short wave diathermy (34)	46	% Of patients free of pain after 4 and 12 weeks: (i) 28%, 42%; (ii) 27%, 44%.
Sims-Williams *et al*[20]	(i) Maitland (48)	(ii) Microwave at lowest setting (46)	45	No of patients improved after 4 and 12 weeks: (i) 29, 28; (ii) 25, 27. Not significantly different. Also no evidence that manipulation produced any long term (one year) benefit.
Glover *et al*[25]	(i) Rotational (43)	(ii) Detuned short wave diathermy (41)	39	Mean pain relief (%) on visual analogue scale immediately after treatment and after 3 and 7 days: (i) 34%, 50%, 75%; (ii) 22%, 56%, 80%. Apart from slight immediate improvement after treatment no benefit from manipulation.
Sims-Williams *et al*[29]	(i) Maitland (47)	(ii) Microwave at lowest setting (47)	35	No of patients improved after 4 and 12 weeks: (i) 39, 26; (ii) 32, 22. After 4 weeks the differences were of borderline significance. After 12 weeks the differences disappeared.
Postacchini *et al*[31]	(i) Chiropractic (87)	(ii) Antioedema gel (73)	33	Mean improvement on combined pain, disability, spinal mobility score (5-35) after 3 weeks, 2 months, and 6 months. In subgroup with acute pain: (i) 7·5, 9·7, 12·3; (ii) 1·8, 7·3, 11·0. In subgroup with chronic pain: (i) 2·2, 2·6, 4·3; (ii) 0·7, 1·2, 2·0. Manipulation was significantly better only in subgroup with acute pain after 3 weeks.
Rupert *et al*[43]	(i) Chiropractic (-)	(ii) Sham manipulation, massage (-)	20	Improvement on pain visual analogue scale during treatment: more pain reduction in group receiving manipulation (data in graphs).

*Results of the most important outcome measure according to the author(s) of the study. When not explicitly stated presentation of pain or a global measure of improvement. Significant means $p<0.05$.
(-) Number not stated.

consisted of detuned shortwave diathermy. Four (50%) studies reported positive results, one positive results in only a subgroup, and three negative results. The study populations included patients with both acute and chronic conditions. Sims-Williams *et al* in two studies with comparable designs, report positive results of manipulation (compared with microwave at lowest setting) for patients in general practice but not for hospital patients.[20 29] Long term effects were found only in study by Ongley *et al*.[10] In their study, however, manipulation was only one part of a treatment regimen which also included injections and exercises and the effect of manipulation could not be isolated.

Discussion

The value of a review of the literature depends on the success in obtaining the results of all studies that have been conducted on the subject at issue. Such studies are subject to bias caused by the outcomes of published and unpublished studies differing (publication bias). There are indications that, especially, small clinical trials with positive results are more likely to be published.[49] Although we put much effort into obtaining all the available published randomised clinical trials, we may have missed both published and unpublished trials, the results of which might differ from those of the trials we have presented. No register of trials that are or will be carried out exists in this subject. Thus it is unknown whether there are trials that have not been published because of negative results. We did not find any completed unpublished studies, although our search was not primarily focused to trace them.



Relation between methods score of trials and their results (positive results shows manipulation is better than reference treatment, negative result shows manipulation is no better or worse than reference treatment)

Although there were many randomised clinical trials of manipulation, most showed major methodological flaws. The criteria that we used to assess methods are based on the requirements for high quality of intervention research in this subject. Although the standard of 100 points is probably difficult to reach in this area of research, it was disappointing to find that most trials scored less than 50 points. In future studies more attention should be given to the description of drop outs, the size of the study population, the use of placebo groups, and blinded measurements of effect. It seems difficult to develop a placebo manipulation treatment that has no specific effect and is trusted by the patients. Some authors supplied high doses of diazepam to patients, thus making the patients amnesic for the procedure and unaware of the treatment given.[16 44] Other authors include non-therapeutic massage[43] or massage in combination with sham adjustments[27] to simulate the effect of laying on of hands. These efforts can be criticised on the grounds that they might have some therapeutic effects. Detuned shortwave diathermy seems to be a placebo therapy which patients can trust and which has no specific effects, but this has little similarity to manipulation.

ANALYSIS OF TRIALS

The other published reviews of the efficacy of manipulation have summarised only seven to 17 of the 35 randomised clinical trials we included in our analysis. Greenland *et al*,[50] Brunarski,[51] and Di Fabio[52] stated that adequate randomised clinical trials are still needed for a valid assessment of the efficacy of manipulation. Ottenbacher and Di Fabio conducted a quantitative meta-analysis in which the results from nine trials were pooled statistically and concluded that there is only limited empirical support for the efficacy of manipulation.[6] We chose not to pool statistically the results of the available trials, mainly because we do not like the idea of pooling data from studies of high and low methodological quality. This decision was supported by our finding that the trials which reported positive results of manipulation more often had relatively low method scores. We did not pool the results of the subgroup of trials with a relatively high method score as we did not think that the patient characteristics and treatments used in these trials showed enough similarity to permit pooling of their data.

The methods used in our review are similar to those we used in a review on physiotherapy exercises.[53] The

only difference is that in this review on manipulation we gave five points if the article indicated that the manipulative treatment had been carried out by a qualified or experienced manipulative therapist, or both. These five points were withdrawn from the 17 points that could be earned for the size of the study population, which left 12 points for this criterion. The weighting attached to the criteria remains arbitrarily chosen. For example, description of an adequate randomisation procedure was given low weight (four points) because all the studies included were randomised clinical trials and thus satisfied our demand of random allocation of the participants. Studies could, however, earn points with a proper description of an adequate randomisation procedure. The assessment of trials by blinded reviewers was not difficult, and after a consensus meeting the inter-observer agreement was almost perfect.

Most trials reported only short term effects. The studies that do include a long term follow up mostly show no positive results. Many studies, especially the ones with relatively higher methods scores (>40 points) report negative results, even when compared with placebo. The negative results might be caused partly by relatively small study populations, which make it difficult to detect treatment differences between manipulation and reference treatments.[54] Thus the information in the figure must be interpreted with caution as the labelling of studies as negative might be influenced by the lower power of small trials. The results of all the trials presented indicate that manipulation is not consistently better than other therapies. Manipulation may be effective in only certain subgroups of patients with back and neck pain. The findings of Sims-Williams *et al* seem to support this suggestion.[20,29] Furthermore, five trials reported better results for manipulation in only subgroups. It is still unclear, however, which subgroup(s) benefit most from manipulation. Positive and negative results are reported for patients with both acute and chronic back and neck pain. In two studies with relatively high method scores favourable results of manipulation were found for a subgroup of patients with low back pain of two to four weeks' duration.[14,15] Although the findings from subgroup analyses should be interpreted cautiously,[58] this seems to be an interesting finding for further research.

In the meantime we conclude that, although there are some promising results, so far the efficacy of manipulation has not been convincingly shown. Any further research should pay more attention to the methodological quality of the study design.

Appendix

Details of criteria listed in table I. Each criterion must be applied independently of the other criteria.

A Description of inclusion and exclusion criteria (1 point). Restriction to a homogeneous study population (1 point).

B Comparability for duration of complaints, value of outcome measures, age, recurrences, and radiating complaints (1 point each).

C Randomisation procedure described (2 points). Randomisation procedure which excludes bias—for example, sealed envelopes—(2 points).

D Information about which group patients withdrew from and reason for withdrawal.

E Loss to follow up: all randomised patients minus the number of patients at main point of measurement of the main outcome measure, divided by all randomised patients, multiplied by 100.

F Smallest group immediately after randomisation.

G Manipulative treatment explicitly described (5 points). All reference treatments explicitly described (5 points).

H Comparison with an established treatment.

I Other physical treatments or medical interventions are avoided in the design of the study (except analgesics; advice on posture; or use at home of heat, rest, or a routine exercise scheme).

J Comparison with placebo.

K Mentioning of qualified education or experience of the manipulative therapist(s), or both.

L Placebo controlled study: attempt at blinding (3 points), blinding evaluated and fully successful (2 points).
Pragmatic study: patients fully naive (3 points) or time restriction (no manipulative treatment for at least one year) (2 points); naiveness evaluated and fully successful (2 points).

M Use (measured and reported) of pain, global measurement of improvement, functional status (activities of daily living), spinal mobility, use of drugs and medical services (2 points each).

N Each blinded measurement mentioned under point M earns 2 points.

O Outcome of measures assessed during or just after treatment (3 points). Outcome of measures assessed six months or longer (2 points).

P When loss to follow up is less than 10%: analyses on all randomised patients for main outcome measures, and on the most important points of measurement minus missing values, irrespective of non-compliance and cointerventions. When loss to follow up is greater than 10%: intention to treat as well as an alternative analysis that accounts for missing values.

Q For main outcome measures, and at main times of measurement. In the case of (semi)continuous variables; presentation of the mean or median with standard error or centiles.

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Dynamics of spread of HIV-I infection in a rural district of Uganda

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Abstract

***Objective*—To define the geographical distribution of HIV infection and the community characteristics associated with HIV prevalence in a rural population of Uganda.**

***Design*—Seroprevalence survey and interviews of the population aged 13 years and older in 21 randomly selected clusters.**

***Setting*—Rural population of Rakai district, south west Uganda.**

***Subjects*—1292 adults, of whom 594 men and 698 women gave a blood sample and answered the questionnaire.**

***Main outcome measures*—HIV status determined by ELISA and western blotting in relation to community characteristics.**

***Results*—The weighted seroprevalence of HIV for the district was 12·6% with prevalence by cluster varying from 1·2% to 52·8%. Seroprevalence was highest in main road trading centres (men 26%, women 47%), intermediate in rural trading villages on secondary roads (men 22%, women 29%), and lowest in rural agricultural villages (men 8%, women 9%). For both men and women, multiple regression showed a strong negative association between cluster seroprevalence and the proportion of the population employed in agriculture ($\beta = -0{\cdot}677$ for men, $-0{\cdot}807$ for women). Among women, cluster seroprevalence increased with a higher proportion of the population reporting multiple sex partners ($\beta = 0{\cdot}814$), external travel ($\beta = 0{\cdot}579$), and injections ($\beta = 0{\cdot}483$).**

***Conclusions*—Community characteristics, particularly the proportion of the population in agriculture, are associated with HIV prevalence and can be used for targeting interventions. The seroprevalences of HIV suggest spread of infection from main road trading centres, through intermediate trading villages, to rural agricultural villages.**

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Introduction

Despite reports of high rates of HIV infection from clinical and urban settings in Africa[1-6] data on rural populations are still scarce. Limited information suggests that HIV infection is spreading rapidly outside urban centres in some east and central African countries.[7,8] As about 70% of the sub-Saharan African population does not live in cities, it is critical to understand the dynamics of the HIV epidemic in rural areas. Trading villages along main roads represent one obvious reservoir of infection outside the main urban areas; their importance as focuses of infection, related in part to commercial sex between local women and long distance truck drivers, has been reported in Uganda.[9,10] However, the spread of HIV from these centres and the distribution of infection within agricultural areas have not been adequately defined. We attempted to define the spread of HIV in Rakai district, south western Uganda, where a random sample of residents have been enrolled in a longitudinal cohort study of HIV-I transmission and prevention.

Subjects and methods

SAMPLING

Rakai district has a population of 350 000, is about two hours by road from Kampala, and borders on northern Tanzania. Although Rakai is primarily rural, it is traversed by major roads that carry traffic from Tanzania, Rwanda, Kenya, and Lake Victoria (figure). The district contains 780 level one resistance committees, which are the smallest administrative units in