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## Low back pain of mechanical origin: randomised comparison of chiropractic and hospital outpatient treatment

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### Abstract

**Objective**—To compare chiropractic and hospital outpatient treatment for managing low back pain of mechanical origin.

**Design**—Randomised controlled trial. Allocation to chiropractic or hospital management by minimisation to establish groups for analysis of results according to initial referral clinic, length of current episode, history, and severity of back pain. Patients were followed up for up to two years.

**Setting**—Chiropractic and hospital outpatient clinics in 11 centres.

**Patients**—741 Patients aged 18-65 who had no contraindications to manipulation and who had not been treated within the past month.

**Interventions**—Treatment at the discretion of the chiropractors, who used chiropractic manipulation in most patients, or of the hospital staff, who most commonly used Maitland mobilisation or manipulation, or both.

**Main outcome measures**—Changes in the score on the Oswestry pain disability questionnaire and in the results of tests of straight leg raising and lumbar flexion.

**Results**—Chiropractic treatment was more effective than hospital outpatient management, mainly for patients with chronic or severe back pain. A benefit of about 7% points on the Oswestry scale was seen at two years. The benefit of chiropractic treatment became more evident throughout the follow up period. Secondary outcome measures also showed that chiropractic was more beneficial.

**Conclusions**—For patients with low back pain in whom manipulation is not contraindicated chiropractic almost certainly confers worthwhile, long term benefit in comparison with hospital outpatient management. The benefit is seen mainly in those with chronic or severe pain. Introducing chiropractic into NHS practice should be considered.

### Introduction

The high incidence of back pain, its chronic and recurrent nature in many patients, and its contribution as a main cause of absence from work are well known. No general consensus exists about the most effective

treatment. Largely anecdotally, patients and therapists often claim great improvements after manipulative treatment by alternative practitioners, including chiropractors. A recent report from the board of science and education of the BMA considered that manipulative treatment of back pain by lay practitioners may provide "a safe and helpful service," thus strengthening the Cochrane committee's recommendation that randomised trials of treatment for back pain should include an evaluation of heterodox methods.<sup>1</sup>

A comparison of chiropractic with conventional hospital outpatient management of low back pain could take one of two main forms. Firstly, it could be a "pragmatic" trial, which would test what happens in day to day practice and in which details of the type, frequency, and duration of treatment would be at the discretion of the chiropractor or hospital team.<sup>2</sup> The disadvantage of a pragmatic trial is that if a clear difference is found between the treatments it may not be possible to identify the components of the more successful treatment that were responsible. Secondly, it could be a "fastidious" trial, which would compare chiropractic manipulation with a particular form of non-manipulative physiotherapy.<sup>3</sup> Though this type of trial may be more likely to identify specific components of treatment that are effective, there would be a high chance of not including the effective components because of the many techniques used to treat back pain.<sup>4</sup> In addition, its results might have only limited applicability.

We adopted a pragmatic approach for two main reasons: firstly, because of the probable difficulty of securing agreement about standard forms of treatment, particularly in hospital, and consequently the small number of patients who could be recruited into a fastidious trial and, secondly, because the effectiveness of treatment in day to day practice, whether chiropractic or in hospital, is of most immediate interest to patients as well as doctors and therapists.

### Patients and methods

#### CENTRES AND CLINICS

The study was based on the methods of a feasibility study.<sup>5</sup> Each centre consisted of a chiropractic clinic

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and a hospital clinic. After the feasibility study had been completed 11 centres with hospital and chiropractic clinics within a reasonable distance of one another agreed to take part in this trial.

TABLE 1—Reasons for ineligibility for or exclusion from trial in patients with back pain presenting to hospital or chiropractor in two centres. Figures are numbers (percentages)

	Initially attended:	
	Hospital (n=751)	Chiropractor (n=543)
<b>Ineligibility:</b>		
Outside age range	67 (9)	17 (3)
Nerve root affected	168 (22)	124 (23)
Spinal abnormality	22 (3)	24 (4)
Recent treatment	53 (7)	52 (10)
Free of pain	99 (13)	6 (1)
Other*	207 (28)	81 (15)
<b>Total</b>	<b>616 (82)</b>	<b>304 (56)</b>
<b>Exclusion:</b>		
Unwilling, no time	16 (2)	62 (11)
Wanted chiropractic treatment		87 (16)
Wanted hospital treatment	9 (1)	
Other	2 (0.3)	23 (4)
<b>Total</b>	<b>27 (4)</b>	<b>172 (32)</b>

\*Includes other diseases, psychosocial difficulties, previous surgery, and litigation pending.  
†Includes previously unsuccessful treatment in hospital.

PATIENTS

The main criterion for eligibility was that patients should have no contraindication to manipulation as almost all the patients treated by chiropractic would receive manipulation and it was important to avoid damage by manipulation. Thus patients were excluded if there was evidence that a nerve root was affected, though restricted straight leg raising on its own was not a reason for exclusion; major structural abnormalities were visible on radiography; or osteopenia or an infectious cause was suspected and for various other reasons, including social conditions and pending litigation. Only patients aged 18 to 65 who had not been treated within the past month and who had not attended the same referral clinic within the past two years were recruited.

Two of the 11 centres kept a record of all patients presenting with back pain. Table 1 summarises the reasons for ineligibility or exclusion in these two centres, confirming the general finding of the feasibility study in one of the other centres that contraindications were commoner among patients presenting initially to hospital while considerations of convenience—for example, to avoid waiting and delay in starting treatment—were commoner among patients initially presenting to the chiropractors. Among 135 eligible patients referred to hospital 108 (80%) entered the trial, compared with 67 of 239 (28%) referred to chiropractors. In all, 175 (47%) of those eligible in these two centres entered. Figure 1 summarises the recruitment, investigation, treatment, and follow up procedures in eligible patients.

All patients underwent radiography of the lumbar spine, the x ray films (whether taken by the chiropractor or in hospital) being reported on by a hospital radiologist. Permission was then sought from general practitioners for each patient's participation in order to comply with the General Medical Council's advisory guidelines about collaboration with heterodox practitioners. Two general practitioners in one centre said that they did not want any of their patients included. Permission was also withheld for five patients under other general practitioners. The General Medical Council also advised that the medically qualified members of the hospital teams should satisfy themselves about the competence of the chiropractors. This was done through discussions during the early stages of the trial.

The purpose of the trial was explained to eligible patients by the nurse coordinator in each centre, who pointed out that participation would mean an equal chance of being treated by chiropractic or conventional hospital methods, the decision being made at random. Patients were also given a written explanation and told that if they were allocated for treatment at the clinic they had not originally attended they would be free at any stage to return to the original clinic. All patients signed a consent form, and the study was approved by the ethical committees of the 11 centres.

The fees of patients receiving chiropractic treatment were paid by grants from funding agencies regardless of whether these patients had originally attended chiropractic or hospital clinics. The number of patients recruited in each centre ranged from 14 to 198.

General practitioners in three centres had direct access to physiotherapy departments for all or part of the trial, accounting for the higher proportion of patients with short episodes of pain compared with that in the feasibility study.<sup>1</sup>

OUTCOME

The patients' progress was measured with the Oswestry back pain questionnaire,<sup>2</sup> which gives scores for 10 sections—for example, intensity of pain, difficulty with lifting, walking, and travelling. The result is

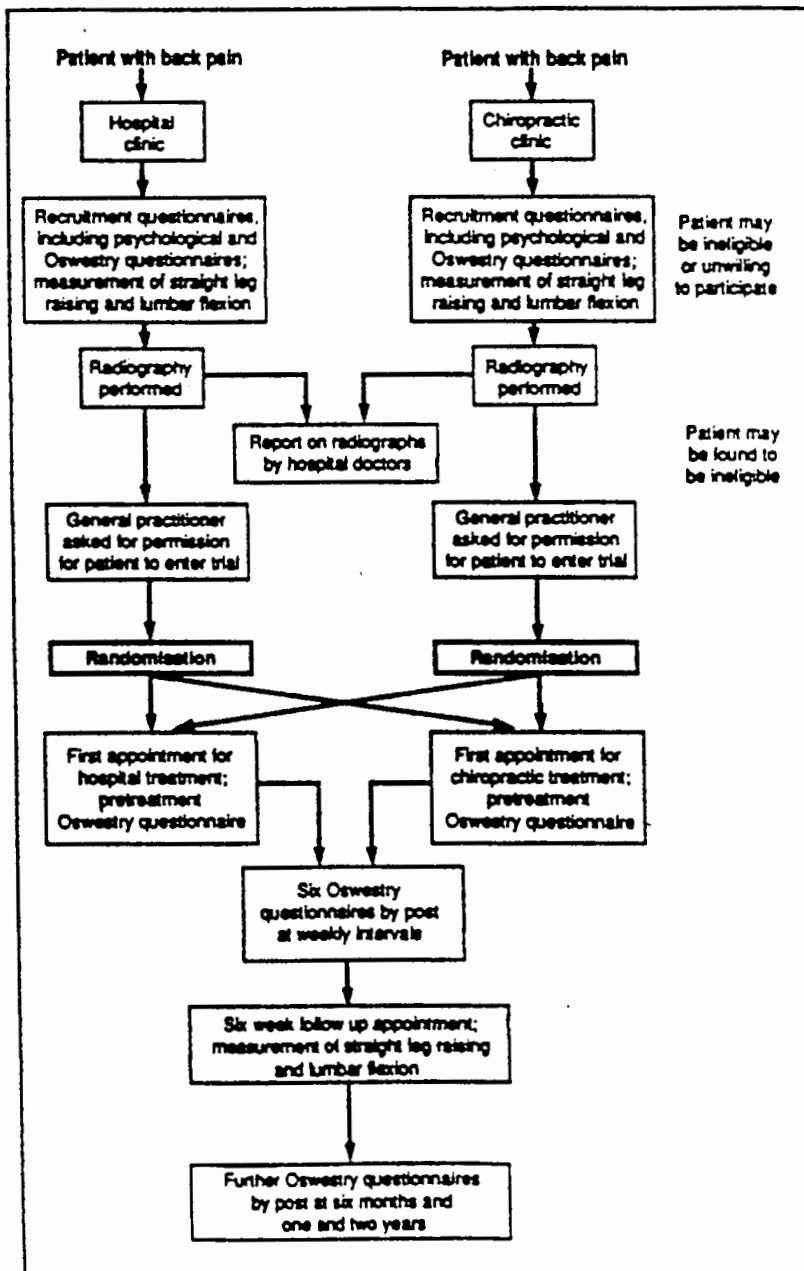


FIG 1—Recruitment and follow up procedures

on all items). Each patient completed the questionnaire at recruitment and shortly before starting treatment. Further questionnaires were then sent by post with prepaid reply envelopes at weekly intervals for six weeks, at six months, and at one and two years after entry. Subsidiary measures of outcome included assessing straight leg raising with a goniometer<sup>2</sup> and lumbar flexion<sup>3</sup>; both were measured at entry and at six weeks by the coordinating nurse, the readings made at entry being unavailable to her at the six week follow up appointment. The results reported here include the responses to follow up questionnaires and other measures completed by the end of September 1989, when all patients had been followed up for six months, fewer patients having completed one and two year follow up questionnaires.

At entry patients also completed psychological questionnaires dealing with depressive symptoms, somatic awareness, and inappropriate symptoms.<sup>4</sup>

#### TREATMENT

Each patient's treatment was at the discretion of the chiropractor or hospital team. Based on the pattern of chiropractic treatments in the feasibility study and in discussion with a representative of the British Chiropractic Association the chiropractors were allowed to give a maximum of 10 treatments, which were intended to be concentrated within the first three months but could be spread over a year if considered necessary.

#### STATISTICS

We recruited as many patients as the available funding allowed. We estimated from the feasibility study that about 2000 patients would be needed to detect a difference between the two approaches of 2% points on the Oswestry scale (at the 5% level, with 90% power)—for example, a decrease in Oswestry score from 30% to 25% in one group compared with a decrease from 30% to 23% in the other—and that differences of 2.5%, 3.0%, 4.0% and 5.0% points would require about 1200, 850, 500, and 300 patients respectively. Table II gives examples of the implications of a range of differences in mean Oswestry scores.

Patients were randomly allocated to treatment, and the method of minimisation<sup>5</sup> was used within each centre to establish groups for analysis of results according to initial referral clinic, length of current episode (more or less than a month), presence or

had shown that the length of the current episode, in particular, clearly distinguished two groups of patients, those with a short current episode improving much more rapidly (regardless of treatment) than those with longer episodes.<sup>1</sup>

The interval between recruitment and the start of treatment varied slightly among the four referral and treatment clinic groups. To allow for any changes before the start of treatment the results were based on changes in Oswestry scores, and this also allowed for the small differences in pretreatment scores between the hospital and chiropractic groups (see table III).

TABLE III—Characteristics of patients according to randomised treatment group. Figures are numbers (percentages) unless otherwise stated

	Hospital group (n=357)	Chiropractic group (n=384)
Mean (SD) age (years)	38.5 (10.8)	38.9 (11.2)
Men	190 (53)	190 (49)
Women	167 (47)	194 (51)
Social class*:		
I and II	113 (34)	123 (34)
III	163 (49)	180 (50)
IV and V	52 (16)	50 (14)
Armed forces	6 (2)	7 (2)
Self employed	47 (13)	42 (11)
Initially attended:		
Hospital clinic	194 (54)	189 (49)
Chiropractic clinic	163 (46)	195 (51)
Back pain:		
With history	271 (76)	288 (75)
With current episode > 1 month	214 (60)	226 (59)
With Oswestry score > 40*	70 (20)	78 (20)
Previously treated (any method)	296 (83)	326 (85)
Previously using drugs†	192 (54)	212 (55)
Mean Oswestry score at recruitment (SD)	30.1 (13.8)	30.6 (13.7)
Mean pretreatment Oswestry score (SD)	28.5 (14.1)	29.8 (14.2)

\*Details not known in 47 patients.

†Mainly analgesics and anti-inflammatory drugs

The negative sign for changes in Oswestry scores in figures 2 and 3 means a fall—that is an improvement in these scores (between pretreatment and follow up)—reflecting the well known tendency for back pain to improve spontaneously as well as any treatment effects. (Similar figures for results according to referral clinic, length of current episode, and past history are available on request.)

TABLE II—Examples of interpretation of differences or changes in Oswestry scores\*

	Difference % points
No pain compared with mild pain; or Moderate pain compared with fairly severe pain; or Able to lift only light weights compared with not able to lift anything; or Able to sit for one hour compared with only half an hour	2%
No pain compared with moderate pain; or Moderate pain compared with very severe pain; or Able to lift light to medium weights compared with unable to lift anything; or Able to sit for up to one hour compared with less than 10 minutes	4%
Mild pain, ability to lift heavy weights without extra pain, and ability to sit for up to one hour compared with moderate pain, ability to lift heavy weights only if conveniently positioned, and unable to sit for more than half an hour	6%
Mild pain, ability to lift light to medium weights, and ability to sit for up to one hour compared with fairly severe pain, unable to lift anything, and able to sit for up to half an hour	10%

\*Scores for sections on lifting, sitting, and pain intensity account for most of the total Oswestry scores. The examples assume no differences in other items.

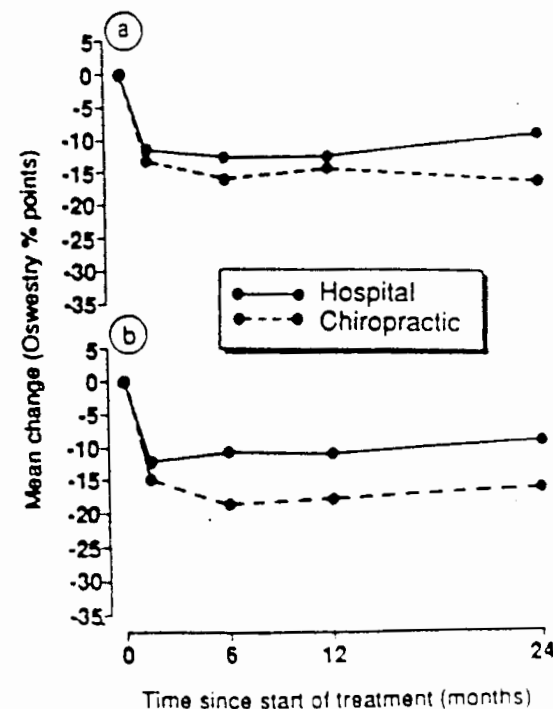


FIG 2—Mean changes in Oswestry scores: a=for all patients, b=for all patients who had been followed up for two years

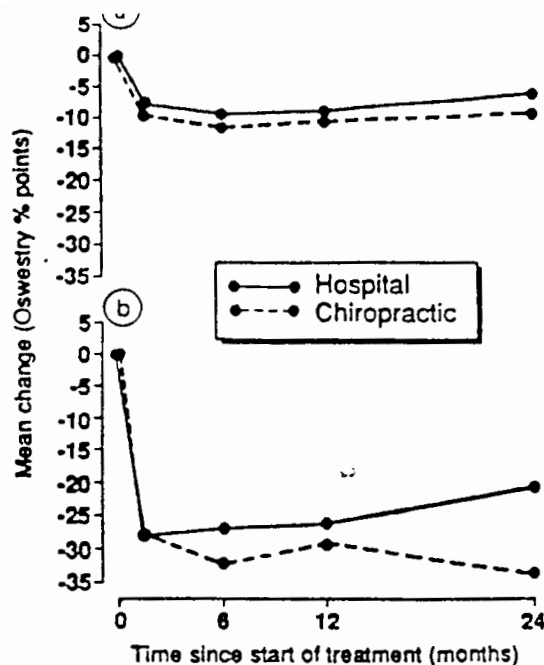


FIG 3—Mean changes in Oswestry score: a=for all patients with recruitment score  $\leq 40\%$  points, b=for all patients with recruitment score  $> 40\%$  points

The results were analysed by intention to treat (subject to availability of data on follow up and at entry for individual patients). Differences between the mean changes in the two groups were tested by unpaired *t* tests.  $\chi^2$  Tests were used to detect any significant differences between the two treatment groups—for example, in the proportion of patients off work. Missing data account for slightly differing numbers in the text and tables.

### Results

Patients were recruited during March 1986 to March 1989. In all, 781 patients were recruited from the 11 participating centres. Of these, 24 (13 from hospitals, and 11 from chiropractic clinics) were later found to be ineligible and 16 (eight, eight) withdrew from the study almost immediately so that 741 started treatment (384 receiving chiropractic and 357 hospital treatment). Table III summarises the characteristics of the patients in the two treatment groups.

Follow up Oswestry questionnaires were returned by 90% patients at six weeks, by 84% at six months (86% treated by chiropractors, 81% in hospital), by 79% at a year (83% chiropractors, 74% hospital) and by 72% at two years (76% chiropractors, 69% hospital). Because non-response was more common among patients treated in hospital than by chiropractors and randomisation had by chance resulted in a few more patients being allocated to chiropractors (see above) there were usually more patients treated by chiropractors than in hospitals in the analyses. There were no obvious systematic differences in the characteristics of non-responders treated by chiropractors or in hospital.

Table IV summarises the treatments received in the chiropractic and hospital clinics. Not all hospitals had access to hydrotherapy, but otherwise there were no appreciable differences in treatment patterns among hospitals. Virtually all the patients treated by chiropractors received chiropractic manipulation such as high velocity, low amplitude manipulation at some stage. Patients treated by chiropractors received about 44% more treatments than those treated in hospital. At six weeks 79% of hospital patients had completed

treatment compared with 27% of patients treated by chiropractic. Almost all patients had completed treatment by 12 weeks in the hospital group and by 30 weeks in the chiropractic group (97%). The chiropractors generally treated all patients over a similar period whereas the hospital therapists treated patients with long episodes of back pain who were never free of symptoms for longer periods than those with short episodes.

Of the 741 patients who started treatment, 29 changed their treatment centre (22 within the first six weeks). Sixty patients did not complete their course of treatment and 77 did not attend for six week follow up with the nurse coordinator. Altogether 608 completed the trial to six weeks without missing any treatments or the six week questionnaire, changing treatment centre, or missing follow up appointments.

Table V gives the differences in the changes in Oswestry scores between the two treatment groups. Figure 2a, which is based on all data for all patients, shows that the change for those treated by chiropractic was consistently greater than that for those treated in hospital. At two years the patients treated by chiropractic had improved by 7% more than those treated in hospital ( $p=0.01$ ). When the analysis was confined to patients all of whom had been followed up for two years and who had complete data at six weeks, six months, one year, and two years the general pattern was similar (fig 2b) but the differences at six months and a year were greater. Among patients who originally attended hospital there was no difference between chiropractic and hospital treatment until two years after entry, when the patients treated by the chiropractors had improved more than those treated in hospital (table V). For patients who originally attended a chiropractor the chiropractic treatment was more effective throughout the follow up period. When the results were confined to patients with complete follow up data for two years, however, the patients in both referral groups who were treated by chiropractic tended to show greater improvement throughout the follow up.

The results were also analysed according to length of the current episode of pain. In both groups those treated by chiropractors improved more than those treated in hospital, the benefit possibly being seen somewhat earlier in those with a long current episode (table V). There was no difference between the two treatments in those with no history of back pain, but chiropractic treatment was more effective than hospital treatment in those with a history. Figure 3 shows that those with Oswestry scores  $> 40\%$  at entry responded better to chiropractic treatment (by 13% at two years) than those with scores  $\leq 40\%$ .

Between follow up at one and two years 17% (18/107) of those initially treated by chiropractors had further chiropractic treatment and 24% (22/92) of those initially treated in hospital had further hospital treatment.

TABLE IV—Numbers (percentages) of patients receiving specified treatments\* and mean numbers of treatment sessions

	Treated in hospital (n=339)	Treated by chiropractor (n=378)
Maitland mobilisation or manipulation, or both	243 (72)	6 (2)
Cyrax manipulation	42 (12)	
Chiropractic manipulation		375 (99)
Traction	36 (25)	1 (2)
Corset	13 (4)	1 (2)
Exercises	102 (30)	33 (9)
No (SD) of treatment visits:		
In six weeks†	5.6 (3.7)	6.9 (2.1)
Total†	6.3 (4.8)	9.1 (3.6)

\* Many patients, especially those treated in hospital, received more than one type of treatment. Data on 24 patients were incomplete. Other treatments not shown above included short wave diathermy and hydrotherapy.  
†  $p < 0.0001$

TABLE IV—Differences (95% confidence intervals) in changes in Oswestry score (mean score hospital group minus mean score for chiropractic group)†

	Six weeks	Six months	One year	Two years
All patients	1.69 (-0.74 to 4.12) H=309, C=357	3.31* (0.51 to 6.11) H=282, C=325	2.09 (-1.13 to 5.31) H=207, C=247	7.16** (-1.86 to 12.45) H=90, C=104
All patients with results at two years	2.92 (-2.27 to 8.11) H=83, C=97	7.89** (2.35 to 13.42) H=83, C=97	6.59** (1.79 to 11.40) H=83, C=97	7.45** (2.08 to 12.82) H=83, C=97
Hospital referrals:				
All results	-0.25 (-3.68 to 3.19) H=172, C=168	-0.32 (-4.41 to 3.78) H=149, C=154	-0.94 (-5.88 to 3.99) H=110, C=110	5.74 (-1.12 to 12.61) H=56, C=54
With results at two years	-0.49 (-6.97 to 5.99) H=52, C=51	3.95 (-3.04 to 10.93) H=52, C=51	4.84 (-1.69 to 11.37) H=52, C=51	5.98 (-1.08 to 13.05) H=52, C=51
Chiropractic referrals:				
All results	3.37* (0.01 to 6.73) H=137, C=189	6.75*** (2.92 to 10.58) H=133, C=171	4.87** (0.80 to 8.94) H=97, C=137	7.82 (-0.62 to 16.27) H=34, C=50
With results at two years	6.49 (-1.94 to 14.92) H=31, C=46	12.35** (2.75 to 21.94) H=31, C=46	8.17* (0.85 to 15.48) H=31, C=46	8.71* (0.15 to 17.27) H=31, C=46
Duration of current episode:				
≤1 month	0.09 (-3.98 to 4.15) H=126, C=150	4.32 (-0.31 to 8.95) H=116, C=138	2.21 (-3.06 to 7.48) H=86, C=97	9.32* (0.07 to 18.56) H=39, C=40
>1 month	2.61 (-0.10 to 5.33) H=183, C=207	2.35 (-0.86 to 5.56) H=166, C=187	2.39 (-1.41 to 6.19) H=121, C=150	6.60* (0.76 to 12.44) H=51, C=64
History:				
Yes	2.04 (-0.80 to 4.88) H=242, C=270	3.11 (-0.15 to 6.37) H=220, C=245	2.99 (-0.83 to 6.80) H=162, C=184	8.31** (2.24 to 14.38) H=75, C=73
No	0.51 (-4.13 to 5.14) H=67, C=87	4.04 (-1.37 to 9.46) H=62, C=80	-0.99 (-6.88 to 4.91) H=45, C=63	1.42 (-10.12 to 12.95) H=15, C=31
Oswestry score at entry:				
≤40%	1.73 (-0.28 to 3.74) H=251, C=284	2.39* (0.05 to 4.73) H=226, C=256	1.76 (-1.13 to 4.65) H=163, C=194	3.19 (-1.52 to 7.90) H=71, C=74
>40%	-0.14 (-7.35 to 7.07) H=58, C=73	5.59 (-2.79 to 13.97) H=56, C=69	3.15 (-5.57 to 11.86) H=44, C=53	13.13* (0.24 to 26.01) H=19, C=30

\*p<0.05, \*\*p<0.01, \*\*\*p<0.001.

†H=Number of patients in hospital group. C=number of patients in chiropractic group

TABLE VI—Mean change at six weeks (number of patients) for straight leg raising and lumbar flexion, and percentages of patients recording other events according to treatment group

	Treated in hospital	Treated by chiropractor	Difference between two groups (95% confidence interval)
Straight leg raising (°):			
Right leg	5.0 (291)	7.1 (325)	2.1 (0.0 to 4.1)*
Left leg	5.3 (288)	5.8 (323)	0.5 (-1.6 to 2.6)
Lumbar flexion (cm)	0.62 (302)	0.85 (344)	0.23 (-0.04 to 0.50)
Treatment at 6 weeks:			
Satisfied or very satisfied	81 (253/311)	91 (329/361)	9.7 (4.5 to 14.9)**
Partially or complete relieved	77 (245/317)	87 (312/360)	9.4 (3.6 to 15.2)**
Any further treatment between 1 and 2 years	41 (38/92)	36 (39/107)	-4.9 (-18.5 to 8.7)
Using drugs:			
At 6 months	35 (99/285)	33 (109/331)	-1.8 (-9.3 to 5.7)
At 1 year	29 (62/212)	30 (75/251)	0.7 (-7.6 to 9.0)
At 2 years	36 (33/92)	30 (32/107)	-6.0 (-19.1 to 7.1)
Pain at 1 year:			
Pain free for "several months"	59 (81/137)	64 (112/176)	4.5 (-6.4 to 15.4)
Further equally severe episode	25 (33/131)	24 (42/172)	-0.8 (-10.6 to 9.0)
Experiencing pain daily	37 (73/198)	31 (71/232)	-6.3 (-15.3 to 2.7)
Oswestry score as high as or higher than before treatment:			
At 6 months	26 (72/274)	17 (53/321)	-9.8 (-16.4 to -3.2)**
Up to 1 year	34 (67/195)	24 (57/238)	-10.5 (-19.1 to -1.9)*
Up to 2 years	45 (37/83)	28 (27/97)	-16.8 (-30.7 to -2.9)*

\*p<0.05, \*\*p<0.005.

†Including treatment in general practice.

‡Mainly analgesics and anti-inflammatory drugs.

Thus the tendency for the changes in the Oswestry score to remain in favour of chiropractic during the second year was probably not due to a disproportionate reinforcement from further chiropractic treatment during this period.

In only one centre was hospital treatment possibly more effective than chiropractic, by 3% and 1% on the Oswestry scale at six months and two years respectively. This centre recruited many patients, mostly through open access arrangements, and omitting its results increased the apparent effectiveness of chiropractic treatment in the 10 other centres. Two centres showed little if any difference between chiropractic and hospital treatment, and in eight chiropractic was more effective. No clear relation was found between the number of treatments and extent of improvement for either chiropractic or hospital treatment.

Table VI shows that the change in straight leg raising and lumbar flexion was greater in those treated by chiropractic than those treated in hospital and that for nearly all other subsidiary measures patients treated by chiropractors did better than those treated in hospital. The smaller proportions of patients treated in hospital than by chiropractic who were satisfied with their treatment or relieved by it may well account for the somewhat greater loss to follow up in the hospital group. Because treatment for those allocated to chiro-

practic lasted longer than that for those allocated to hospital effects on time off work during the first year were difficult to assess. Between one and two years the frequency and duration of absence from work were less in those treated by chiropractic. Of those with jobs, 21% (18/84) of patients given chiropractic had time off work because of back pain compared with 35% (26/74) of hospital patients (p=0.055).

#### ECONOMIC IMPLICATIONS

The potential economic, resource, and policy implications of our results are extensive. The average cost of chiropractic investigation and treatment at 1988-9 prices was £165 per patient compared with £111 for hospital treatment. Some 300 000 patients are referred to hospital for back pain each year,<sup>11</sup> of whom about 72 000 would be expected to have no contraindications to manipulation.<sup>12</sup> If all these patients were referred for chiropractic instead of hospital treatment the annual cost would be about £4m. Our results suggest that there might be a reduction of some 290 000 days in sickness absence during two years, saving about £13m in output and £2.9m in social security payments. As it was not clear, however, that the improvement in those treated by chiropractic was related to the number of treatments the cost of essential chiropractic treatment might be substantially less than £4m. The possibility that patients treated in hospital would need more treatment during the second year than those treated by chiropractic (see above and table VI) also has to be borne in mind. There is, therefore, economic support for use of chiropractic in low back pain, though the obvious clinical improvement in pain and disability attributable to chiropractic treatment is in itself an adequate reason for considering the use of chiropractic.

#### Discussion

Though many randomised controlled trials of treatments for back pain have been carried out, there have so far been no clear indications in favour of any particular method. The place of manipulation in back pain has been reviewed by Jayson,<sup>13</sup> who concluded that any minor benefits seemed to be confined to those with acute pain of recent onset, that there was no evidence that manipulation helped those with severe or chronic back problems, and that it did not reduce long

term complications or prevent recurrences. For chiropractic our findings suggest otherwise. The difficulties of clinical trials in low back pain have been discussed.<sup>14</sup> Our trial had the combined advantages of considerably larger numbers and a longer follow up period than other trials comparing orthodox treatments or, less often, orthodox and alternative treatments.

We studied only patients who had no contraindications to manipulation. Although this group represents a substantial proportion of all patients with back pain, the findings cannot be automatically applied to all patients with back pain. With this proviso the results leave little doubt that chiropractic is more effective than conventional hospital outpatient treatment. The confidence intervals for the differences in Oswestry scores were wide, but the degree of improvement recorded for many of the secondary outcome measures (table VI) suggests that chiropractic has appreciable benefit. The effects of chiropractic seem to be long term, as there was no consistent evidence of a return to pretreatment Oswestry scores during the two years of follow up, whereas those treated in hospital may have begun to deteriorate after six months or a year. Chiropractic was particularly effective in those with fairly intractable pain—that is, those with a history and severe pain. Although we have discussed the results in terms of differences at the various follow up intervals, the full effects of treatment are better thought of as an integrated benefit throughout the two year follow up period, represented by the area between the curves for the two treatments. The greater proportions of patients treated by chiropractic who were satisfied and relieved at six weeks, when 90% of patients had provided follow up data, strengthens the likelihood that the differences in Oswestry scores and other variables later on, when fewer patients have provided data, were true differences.

The results from the secondary outcome measures (table VI) suggest that the advantage of chiropractic starts soon after treatment begins. The reason for the much larger advantage later on is not obvious. Part of the explanation could be that hospital treatment is effective in the short term but not the longer term, perhaps because it is not given for as long as chiropractic. The undoubted difficulties under which some of the participating physiotherapy departments were working during the trial almost certainly meant that they were unable to give all the specific treatment they would have wished to all patients.

A central question is the extent to which the results could be due to biases and placebo effects. Patients were deliberately sent follow up Oswestry questionnaires at home to minimise any chance that their answers might be affected by actual or perceived influence by their therapist. Ideally, straight leg raising and lumbar flexion should have been measured by an assessor who was blind to the treatment allocation. The nurse coordinators, however, did not have the initial results available at the time of the follow up measurements at six weeks. In addition nearly all the other subsidiary measures suggested greater improvement among those treated by chiropractic.

The consequences of biased outcome measures or of a placebo effect associated with chiropractic would almost certainly have been more evident when treatment was still in progress or just afterwards. In fact, the main difference between hospital and chiropractic treatment was seen from six months or a year onwards, well after treatment and contact with therapists had ended.

The fact that chiropractic treatment tended to be more effective in those initially presenting to the chiropractors than in those presenting to hospital raises the possibility that the self assessment by the patients who presented to chiropractors may have been

influenced by their expectation that chiropractic would be effective. The results in all patients who had been followed up for two years, however, indicate a similar effect of chiropractic in both referral groups (table V). There were several differences between the two referral groups that may have influenced response to treatment (these will be reported in detail elsewhere). For example, a significantly higher proportion of patients initially attending the chiropractors had had previous episodes of back pain. Those initially attending chiropractors had also waited much less time for appointments for the current episode and scored significantly less on questionnaires for depressive and inappropriate symptoms and for somatic awareness than the patients initially attending hospital. In addition, the analyses among the (non-clinic) subgroups prespecified in the minimisation procedure were balanced for referral clinic, there being similar proportions initially presenting to chiropractors and to hospital in each of the randomised treatment groups. Yet the tendency for chiropractic to be more effective was not universal—for example, the absence of clear benefit in those with no previous history of back pain. Finally, the self exclusion of many patients who initially presented to the chiropractors probably resulted in only a few of these patients who might automatically have assessed themselves as better after chiropractic or worse after hospital treatment being included. In summary, it is unlikely that the benefits of chiropractic are the result of biased outcome assessments or of a placebo effect.

Centres where chiropractic was more effective at six weeks and six months and those where there was less difference between the two treatments at that stage contributed to the results to about the same extent at a year and two years. The sustained effect of chiropractic was therefore probably not due to a disproportionate contribution from individual centres where there was an obvious early benefit from chiropractic.

In the absence of any clear relation between the number of treatment sessions and outcome, specific components of chiropractic responsible for its effectiveness have to be considered. An obvious possibility is the use of high velocity, low amplitude manipulation in virtually all the patients treated by chiropractic. Another is that chiropractic was given for a longer period than hospital treatment. Whatever the explanation for the difference between the two approaches, however, this pragmatic comparison of two types of treatment used in day to day practice shows that patients treated by chiropractors were not only no worse off than those treated in hospital but almost certainly fared considerably better and that they maintained their improvement for at least two years.

If our results are more widely applicable the practical implications are far reaching. Consideration should be given to recognising appropriately trained and experienced chiropractors and to providing chiropractic within the NHS, either in hospitals or by purchasing chiropractic treatment in existing clinics. Further trials to identify the specific component(s) responsible for the effectiveness of chiropractic should be undertaken. Whether the results of this trial can also be applied to other heterodox regimens of manipulation is an open question.

We thank the nurse coordinators, medical staff, physiotherapists, and chiropractors in the 11 centres for their work, and Mr Alan Breen of the British Chiropractic Association for his help. The centres were in Harrow, Taunton, Plymouth, Bournemouth and Poole, Oswestry, Chertsey, Liverpool, Chelmsford, Birmingham, Exeter, and Leeds. Without the assistance of many staff members in each the trial could not have been completed. The study was supported by the Medical Research Council, the National Back Pain Association, the European Chiropractors Union, and the King Edward's Hospital Fund for London.

## Randomised comparison of chiropractic and hospital outpatient management for low back pain: results from extended follow up

T W Meade, Sandra Dyer, Wendy Browne, A O Frank

### Abstract

**Objective**—To compare the effectiveness over three years of chiropractic and hospital outpatient management for low back pain.

**Design**—Randomised allocation of patients to chiropractic or hospital outpatient management.

**Setting**—Chiropractic clinics and hospital outpatient departments within reasonable travelling distance of each other in 11 centres.

**Subjects**—741 men and women aged 18-64 years with low back pain in whom manipulation was not contraindicated.

**Outcome measures**—Change in total Oswestry questionnaire score and in score for pain and patient satisfaction with allocated treatment.

**Results**—According to total Oswestry scores improvement in all patients at three years was about 29% more in those treated by chiropractors than in those treated by the hospitals. The beneficial effect of chiropractic on pain was particularly clear. Those treated by chiropractors had more further treatments for back pain after the completion of trial treatment. Among both those initially referred from chiropractors and from hospitals more rated chiropractic helpful at three years than hospital management.

**Conclusions**—At three years the results confirm the findings of an earlier report that when chiropractic or hospital therapists treat patients with low back pain as they would in day to day practice those treated by chiropractic derive more benefit and long term satisfaction than those treated by hospitals.

### Introduction

In 1990 we reported greater improvement in patients with low back pain treated by chiropractic compared with those receiving hospital outpatient management.<sup>1</sup> The trial was "pragmatic" in allowing the therapists to treat patients as they would in day to day practice. At the time of our first report not all patients had been in the trial for more than six months. This paper presents the full results up to three years for all patients for whom follow up information from Oswestry questionnaires and for other outcomes was available for analysis. We also present data on pain from the questionnaire, which is by definition the main complaint prompting referral or self referral.

### Methods

Methods were fully described in our first report.<sup>1</sup> Patients initially referred or presenting either to a chiropractic clinic or in hospital were randomly allocated to be treated either by chiropractic or in hospital. A total of 741 patients started treatment. Progress was measured with the Oswestry question-

naire on back pain, which gives scores for 10 sections—for example, intensity of pain and difficulty with lifting, walking, and travelling. The result is expressed on a scale ranging from 0 (no pain or difficulties) to 100 (highest score for pain and greatest difficulty on all items). For an individual item, such as pain, scores range from 0 to 10. The main outcome measures are the changes in Oswestry score from before treatment to each follow up. At one, two, and three years patients were also asked about further treatment since the completion of their trial treatment or since the previous annual questionnaire. At the three year follow up patients were asked whether they thought their allocated trial treatment had helped their back pain.

In the random allocation of treatment minimisation was used within each centre to establish groups for the analysis of results according to initial referral clinic, length of current episode (more or less than a month), presence or absence of a history of back pain, and an Oswestry score at entry of  $\geq 40$  or  $\leq 40$ %.

Results were analysed on an intention to treat basis (subject to the availability of data at follow up as well as at entry for individual patients). Differences between mean changes were tested by unpaired *t* tests, and  $\chi^2$  tests were used to test for differences in proportions between the two treatment groups.

### Results

Follow up Oswestry questionnaires were returned by a consistently higher proportion of patients allocated to chiropractic than to hospital treatment. At six weeks, for example, they were returned by 95% and 89% of chiropractic and hospital patients, respectively and at three years by 77% and 70%.

Mean (SD) scores before treatment were 29.3 (14.2) and 28.5 (14.1) in the chiropractic and hospital treatment groups, respectively. Table 1 shows the differences between the mean changes in total Oswestry scores according to randomly allocated treatment group. The difference at each follow up is the mean change for the chiropractic group minus the mean change for the hospital group. Positive differences

TABLE 1—Differences (95% confidence intervals) between mean changes in Oswestry scores\*

Time of follow up	Difference	No. of patients undergoing chiropractic	No. of patients undergoing hospital treatment
Six weeks	1.69 (-0.74 to 4.12)	187	179
Six months	2.31 (-0.53 to 6.11)	125	142
One year	2.04 (-0.71 to 4.79)	114	165
Two years	3.02 (0.08 to 5.96)	285	231
Three years	3.18 (0.16 to 6.20)	290	216

\*Positive differences indicate greater improvement in patients treated with chiropractic.

\*P < 0.02, \*P < 0.05

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therefore reflect more improvement (due to a greater change in score) in those treated by chiropractic than in hospital (negative differences the reverse). The 3.18 percentage point difference at three years in table I represents a 29% greater improvement in patients treated with chiropractic compared with hospital treatment, the absolute improvement in the two groups at this time being 14.1 and 10.9 percentage points, respectively. As in the first report those with short current episodes, a history of back pain, and initially high Oswestry scores tended to derive most benefit from chiropractic. Those referred by chiropractors consistently derived more benefit from chiropractic than those referred by hospitals.

Table II shows changes between the scores on pain intensity before treatment and the corresponding scores at the various follow up intervals. All these changes were positive—that is, indicated improvement—but were all significantly greater in those treated by chiropractic, including the changes early on—that is, at six weeks and six months, when the proportions returning questionnaires were high. As with the results based on the full Oswestry score the improvement due to chiropractic was greatest in those initially referred by chiropractors, although there was also a non-significant improvement (ranging from 9% at six months to 34% at three years) due to chiropractic at each follow up interval in those referred by hospitals.

Other scores for individual items on the Oswestry index to show significant improvement attributable to chiropractic were ability to sit for more than a short time and sleeping ( $P=0.004$  and  $0.03$ , respectively, at three years), though the differences were not as consistent as for pain. Other scores (personal care, lifting, walking, standing, sex life, social life, and travelling) also nearly all improved more in the patients treated with chiropractic, though most of the differences were small compared with the differences for pain.

Higher proportions of patients allocated to chiropractic sought further treatment (of any kind) for back pain after completion of trial treatment than those managed in hospital. For example, between one and

TABLE II—Changes in scores from section on pain intensity in Oswestry questionnaire between score before treatment and score at follow up intervals according to method of treatment and difference between changes

Interval and method of treatment	No of patients	Mean change in score	Difference (SE) between changes	P value
Six weeks:				
Chiropractic	357	0.99		
Hospital	309	0.71	0.28 (0.08)	0.006
Six months:				
Chiropractic	324	1.05		
Hospital	282	0.67	0.36 (0.10)	0.0002
One year:				
Chiropractic	314	0.94		
Hospital	265	0.73	0.21 (0.10)	0.03
Two years:				
Chiropractic	285	0.98		
Hospital	250	0.63	0.35 (0.11)	0.001
Three years:				
Chiropractic	290	0.90		
Hospital	236	0.56	0.34 (0.11)	0.004

TABLE III—Number/percentage of patients at three year follow up who considered allocated trial treatment had helped their back pain

	Hospital treatment		Chiropractic treatment	
	Help	No help	Help	No help
Hospital	71 (60.2)	47 (39.8)	103 (79.2)	27 (20.8)
Chiropractic	76 (65.5)	40 (34.5)	127 (84.7)	23 (15.3)

For hospital referrals,  $\chi^2=10.7$ ,  $P=0.001$   
 For chiropractic referrals,  $\chi^2=13.3$ ,  $P<0.0001$

### Key messages

- Back pain often remits spontaneously
- Effective treatments for non-remitting episodes need to be more clearly identified
- Chiropractic seems to be more effective than hospital management, possibly because more treatments are spread over longer time periods
- A growing number of NHS purchasers are making complementary treatments, including chiropractic, available
- Further trials to identify the effective components of chiropractic are needed

two years after trial entry 122/292 (42%) patients treated with chiropractic compared with 80/258 (31%) of hospital treated patients did so ( $\chi^2=6.8$ ,  $P=0.01$ ).

Table III shows the proportions of patients at three years who thought their allocated trial treatment had helped their back pain. Among those initially referred by hospitals as well as among those initially referred by chiropractors higher proportions treated by chiropractic considered that treatment had helped compared with those treated in hospital.

### Discussion

The results at six weeks and six months shown in table I are identical with those in our first report, as all patients had then been followed up for six months. The findings at one year are similar as many patients had also been followed up then. The considerably larger numbers of patients with data now available at two and three years show smaller benefits at these intervals than previously, though these still significantly favour chiropractic. The substantial benefit of chiropractic on intensity of pain is evident early on and then persists. The consistently larger proportions lost to follow up throughout the trial in those treated in hospital than in those treated by chiropractic suggests greater satisfaction with chiropractic. This conclusion is supported (table III) by the higher proportions in each referral group considering chiropractic helpful by comparison with hospital treatment.

The main criticism of the trial after our first report centred on its "pragmatic" nature, particularly the larger number of chiropractic than hospital treatments and the longer period over which the chiropractic treatments were spread and which were deliberately allowed. These considerations and any consequences of the higher proportions of patients allocated to chiropractic who received further treatment in the later stages of follow up, however, do not apply to the results at six weeks and only apply to a limited extent at six months, when the proportions followed up were high and extra treatment had either not occurred at all or was not yet extensive. Benefits attributable to chiropractic were already evident (especially on pain, table II) at these shorter intervals.

We believe there is now more support for the need for "fastidious" trials focusing on specific components of management and on their feasibility. Meanwhile, the results of our trial show that chiropractic has a valuable part to play in the management of low back pain.

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Taunton, Plymouth, Bournemouth and Poole, Oswestry, Chertsey, Liverpool, Chelmsford, Birmingham, Exeter, and Leeds. Without the assistance of many staff members in each the trial could not have been completed.

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Conflict of interest: None.

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## Using decision analysis to compare policies for antenatal screening for Down's syndrome

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### Abstract

**Objective**—To compare different screening policies for Down's syndrome across a broad range of outcomes, using decision analysis, with particular reference to the role of maternal serum testing.

**Design**—A decision tree was used to combine data from local sources and the medical literature to predict the likely frequency of several outcomes. Sensitivity analyses were used to test the robustness of the conclusions drawn.

**Setting**—Oxfordshire Health Authority.

**Main outcome measures**—Live births with and without Down's syndrome; miscarriages with Down's syndrome; cases of Down's syndrome detected antenatally; amniocenteses performed (and associated miscarriages); direct NHS screening costs; number of women offered screening.

**Results**—Screening policies for Down's syndrome that include serum testing can produce better population outcomes than programmes that do not. Each option for screening for Down's syndrome that we considered had significant drawbacks. In Oxfordshire, offering serum testing to women of all ages would prevent the birth of approximately one more baby with Down's syndrome per year than would a policy of screening for women aged 30 years or more. The cost of preventing this one extra Down's birth would be one or two normal babies lost after amniocentesis, 4500 blood tests for young women (with the associated anxiety and counselling), approximately 200 false positive serum test results and amniocenteses (with the associated anxiety and distress), and £90 000 for the extra tests, counselling, and amniocenteses. Opinions are divided as to which policy is the better option for the population.

**Conclusions**—Decision analysis is a useful tool for determining the likely consequences of different policy options across a broad range of outcomes. This focuses debate and decision making on outcomes of care, which in turn makes it clear that the choice of screening programme for Down's syndrome depends on the relative importance ascribed to the different outcomes. If individuals' values vary widely it may be impossible to find one screening policy that meets the needs of all pregnant women.

### Introduction

Maternal serum concentrations of various analytes including  $\alpha$  fetoprotein, oestrogen, and human chorionic gonadotrophin can be used to estimate the probability of a fetus having Down's syndrome. Waid and colleagues have predicted and subsequently shown that information derived from measurements of various combinations of such analytes, when interpreted in the knowledge of a woman's age and the

gestational age of the fetus, allows a more accurate estimation of the risk of a fetus being affected with Down's syndrome than does risk estimation based on maternal age alone.<sup>1</sup> This has raised the possibility of introducing biochemical testing as a screening test for Down's syndrome for some or all pregnant women. However, there is no consensus among health authorities in Britain as to whether biochemical screening for Down's syndrome should be offered and if so to which groups of pregnant women.<sup>2</sup> The main issues that have been the topics of professional and public debate are the ethics of prenatal screening; the performance of biochemical screening tests; the choice of test; the relative costs, both personal and monetary; whether centres which introduced biochemical screening early have done the right thing; and the importance of counselling.<sup>3</sup>

The consequences of screening for Down's syndrome are various. They may include changes in the number of Down's syndrome babies detected, the number of Down's syndrome babies born, the number of unaffected babies born, the number of pregnancies lost by miscarriage, the amount of anxiety generated, and the direct and indirect financial costs of the programme to the NHS, other agencies, and pregnant women and their families. Most published contributions to the debate have provided information about only one or two measures of outcome such as detection rate<sup>4</sup> or psychological costs.<sup>5,6</sup> Others have used summary measures such as overall cost or saving per Down's syndrome case detected.<sup>7</sup> However, a decision to implement a particular screening programme should be based on as full an assessment of as many as possible of the relevant outcomes of a screening programme. In 1993, in the absence of clear regional or national guidance, Oxfordshire health authority had not decided whether to purchase a serum screening programme. In that same year about a third of pregnant women over 35 years in Oxfordshire chose to pay around £50 each to have biochemical tests for Down's syndrome performed privately; this choice was available only to those who could afford to pay. This was widely regarded as unsatisfactory. A decision was required about the NHS provision of serum screening for Down's syndrome for the women of Oxfordshire. The district health authority sought a screening option that was as effective or better at detecting Down's syndrome than current practice, addressed the controversy surrounding stress and the screening of younger women, and was cost neutral or cheaper in direct NHS costs than current practice.

We wanted to use the large amount of national and local data that is available about biochemical screening for Down's syndrome to quantify as many as possible of the likely consequences of different screening options for the population of Oxfordshire. We used the technique of decision analysis, which is a well

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